

Advisory Panel on Improving Healthcare Systems

November 9th- 10th, 2015

8:30 a.m. – 5:00 p.m. EST (9th)

8:00 a.m. – 12:30 p.m. EST (10th)



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome & Introductions

Steven Clauser, PhD, MPA

Director, Improving Healthcare Systems

Housekeeping

- Today's webinar is open to the public and is being recorded.
- Members of the public are invited to listen to this teleconference and view the webinar.
- Anyone may submit a comment through the webinar chat function, although no public comment period is scheduled.
- Visit www.pcori.org/events for more information.
- Chair Statement on COI and Confidentiality



Panel Leadership

- Doris Lotz, MD, MPH
 - IHS Advisory Panel Chair
- Michael Dueñas, OD
 - IHS Advisory Panel Co-Chair
 - *Unable to attend this meeting*



Advisory Panel Members

- **Jim Bellows, PhD, MPH**
Managing Director, Care Management Institute, Kaiser Permanente
- **Mary Blegen, RN, MA, PhD, FAAN**
Professor Emerita, University of CA San Francisco
- **David Bruhn, PharmD, MBA**
Director, Respiratory, North America Medical Affairs, GlaxoSmithKline
- **Daniel Cherkin, MS, PhD**
Director, Bastyr University Research Institute Senior Scientific Investigator, Group Health Research Institute
- **Bonnie Clipper, DNP, RN, MA, MBA, FACHE, CENP^{*}**
Vice President, Patient Care Services and Chief Nursing Officer, Medical Center of the Rockies
- **Elizabeth Cox, MD, PhD**
Associate Professor, Departments of Pediatrics and Population Health Sciences, University of Wisconsin-Madison
- **Timothy Daaleman, DO, MPH**
Professor and Vice Chair, Family Medicine, University of North Carolina at Chapel Hill School of Medicine
- **Lisa Freeman**
Independent Patient Safety Advocate and Consultant
- **John Galdo, PharmD, BCPS**
Assistant Professor, Samford University School of Pharmacy
- **Ravi Govila, MD**
Vice President, Medical Management and PPO, Blue Cross Blue Shield of Michigan
- **Eve Kerr, MD, MPH**
Director, Ann Arbor Center for Clinical Management Research
- **Joan Leon, BA**
Consultant, World Institute on Disability and the Center for Independent Living
- **John Martin, MPH**
Senior Director, Research Operations, Premier Inc.
- **Carolyn Petersen, MS, MBI**
Senior Editor, MayoClinic.org
- **Susan Salahshor, MPAS, PA-C**
Physician Assistant, Liver Transplant, Mayo Clinic in Florida
- **Anne Sales, RN, PhD^{*}**
Professor, School of Nursing, University of Michigan
- **Jamie Sullivan, MPH**
Director of Public Policy, COPD Foundation
- **Leonard Weather Jr., MD, RPH**
Director, Omni Fertility and Laser Institute



The Improving Healthcare Systems Program Staff



Steven Clauser, PhD, MPA
Director



Penny Mohr, MA
Sr. Program Officer



Beth Kosiak, PhD
Program Officer



Neeraj Arora, PhD
Sr. Program Officer



Els Houtsmuller, PhD
Sr. Program Officer



Michelle
Johnston-Fleece, MPH
Engagement Officer



Carly Parry, PhD, MSW
Sr. Program Officer



Lauren Azar, MHA
Sr. Program Associate



Alex Hartzman, MPH, MPA
Program Associate



Andrea Hewitt, MPH
Program Associate



Hannah Kampmeyer
Senior Admin Assistant



Jasmine Turner
Program Assistant

Gyasi Moscou-Jackson, PhD
Program Officer



Vivian Nguyen
Intern

Today's Agenda & Meeting Objectives

- **Day 1:**

- IHS Program & PCORI Updates/Discussion
- PCORI Topic Generation and Portfolio Evaluation Processes
- Strategic Vision Updates and Discussion
- Review Results of Pre-Meeting Prioritization and Objectives of Afternoon Break-Out Sessions
- Topic Refinement Breakout Session
 - *Compare the effectiveness of multicomponent management interventions for individuals with dementia*
 - *Compare the effectiveness of different care coordination strategies designed to transition patients from skilled nursing facilities back into the community*

- **Day 2:**

- Topic Refinement Breakout Session
 - *Compare the effectiveness of alternative features to address antimicrobial resistance in hospitals*
 - *Compare the effectiveness of different screening and brief interventions approaches to reduce hazardous drinking among adolescents who abuse alcohol*
- Review Results of Re-Prioritization and Recap of the Meeting



IHS Program & PCORI Updates

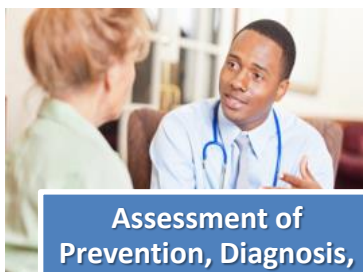
Steven Clauser, PhD, MPA

Director, Improving Healthcare Systems

Overview of PCORI and IHS

PCORI's MISSION

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from **research guided by patients, caregivers and the broader health care community.**



IHS Goal Statement

To support studies of the comparative effectiveness of alternative features of healthcare systems that will **provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders, regarding which features of systems lead to better patient-centered outcomes.**



Improving Healthcare Systems (IHS) Program

- IHS supported studies aim to facilitate the delivery of care that is accessible, safe, effective, patient-centered, timely, efficient, equitable, and/or coordinated and ultimately improve patient-centered outcomes.
- Alternative features of healthcare systems evaluated in CER studies supported by IHS may include, but are not limited to:
 - Technology applications
 - Patient and provider incentives
 - *only non-financial provider incentives are of interest*
 - Organizational models and policies within and across healthcare systems
 - Personnel
 - *Studies that focus solely on community health workers and peer navigators are not of interest*
- Responsive studies must have high potential for sustained impact and replication within and across healthcare systems



IHS Studies Comparing Interventions by System Level

System Level	Examples of Comparisons in the IHS Portfolio
Individual Patient	Compares the use of an electronic asthma medication tracker to standard primary care (no tracker) for children with asthma and their parents and caregivers to improve quality of life, among other patient-centered outcomes.
Family and Social Supports	Compares the use of advance planning tools for access to community-based and in-home services for the frail elderly and their caregivers to an electronic educational intervention of available services and programs. Measures understanding and knowledge outcomes.
Provider/Team	Compares nursing home staff team-based training and palliative care delivery using an adapted NQF protocol to a standard nursing home palliative care protocol to improve EOL outcomes, such as pain, shortness of breath, in-hospital deaths, hospitalizations, and presence of advance directive
Organization and/or Practice Setting	Compares elements of patient-centered medical home (e.g., addition of a PCP in the context of regularly scheduled dialysis sessions and health promoters to help support patients and their caregivers) to traditional team-based specialty care for end-stage renal disease patients to improve utilization, quality of life and caregiver burden outcomes.
Local Community Environment	Compares an ED-to-home community health worker that links patients with community-based social-support (e.g., home-delivered meals) and medical follow-up, to care transition programs using written and verbal discharge instructions alone to improve utilization and quality of life outcomes.



The IHS Portfolio Overview

- 71 Projects; ~\$250 million funding; 25 States including D.C.

Funding Mechanism	N of Projects	Total Funding as of 5/13/15
Broad	64	\$137 million
Pragmatic	4	\$54 million
Targeted	3	\$59 million
Total	71	\$250 million

- **Broad:** Both small (\$1.5M, 3 year) and large (\$5M, 5 year) investigator-initiated studies; 2 cycles per year; competitive LOIs
- **Pragmatic:** \$10M, 5 year head-to-head comparisons in large, representative study populations and settings; PCORI, IOM, and AHRQ CER priorities; 2 cycles per year
- **Targeted:** Largest and require greatest specificity; range from \$5M - \$30M; often collaborations with other organizations; ad hoc funding



AP
Priorities



Our Funded Studies Database

- <http://www.pcori.org/research-results>

Tips: Enter search terms to search the title, researchers, and abstracts. You may also filter by the categories listed below. Select desired terms from the drop-down lists and then click the GO button to view the results.

Displaying 1 - 50 of 64 [Download the filtered data as an .xls](#)

Search our awards

Primary Condition/Disease

State

PCORI Research Priority Area

Award Type: Research

Award Type: Program

[GO](#) [RESET](#)

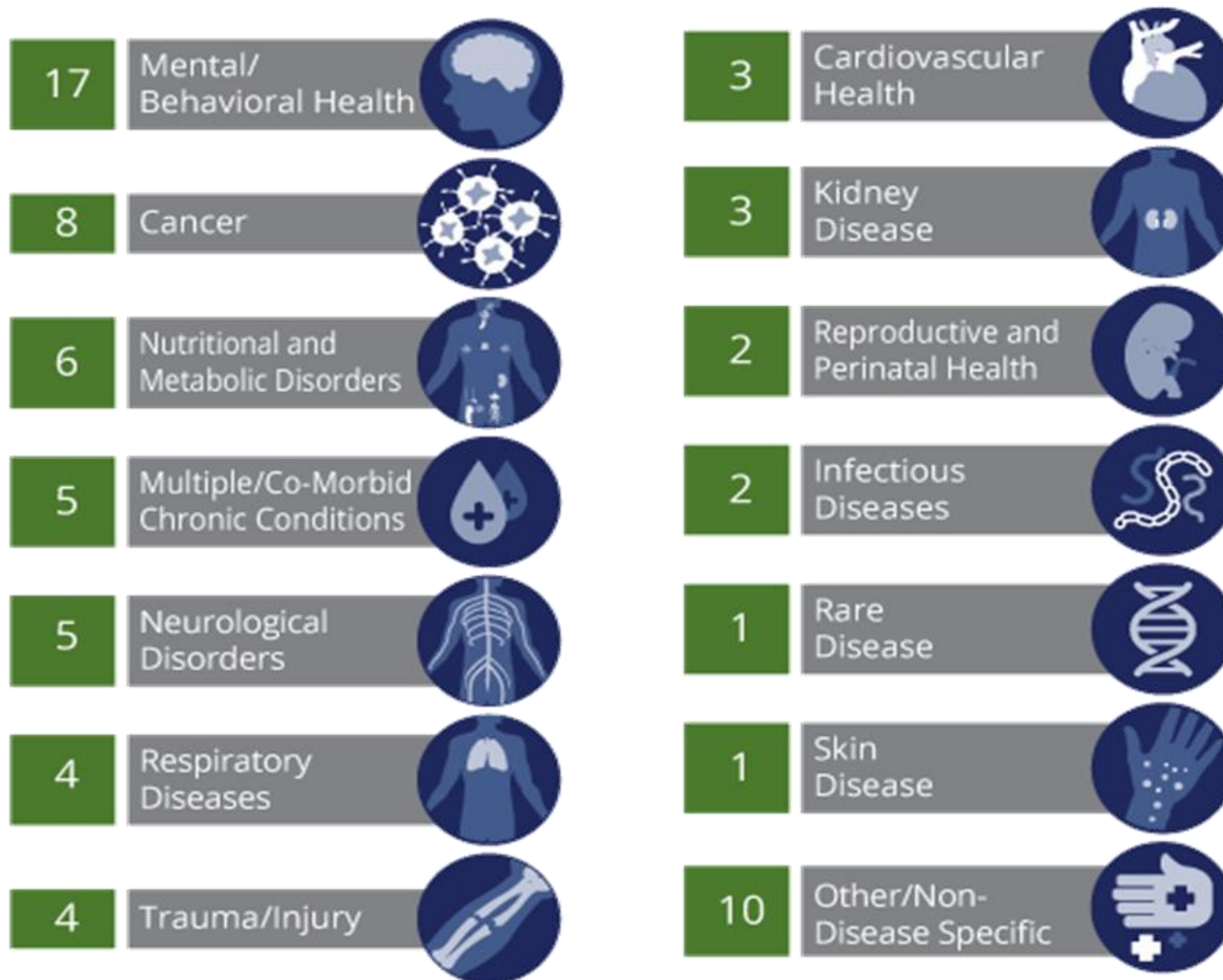
<u>Year Awarded</u>	<u>Project Title</u>	<u>Organization</u>	<u>State</u>
2015	Comparative Effectiveness of State Psychotropic Oversight Systems for Children in Foster Care	Rutgers The State University of New Jersey, New Brunswick	New Jersey
2015	Simplifying Survivorship Care Planning: Comparing the Efficacy and Patient-Centeredness of Three Care Delivery Models	Johns Hopkins University	Maryland
2015	Integrating Online Weight Management with Primary Care Support: Patient-Centered Strategies for Addressing Overweight and Obesity in Primary Care	Brigham and Women's Hospital	Massachusetts
2015	Putting Patients at the Center of Kidney Care Transitions	Duke University	North Carolina

All public abstracts for PCORI-funded studies are available on our website and accessible through a searchable database (shown left)



IHS Portfolio Overview – Cycle I through Spring 2015

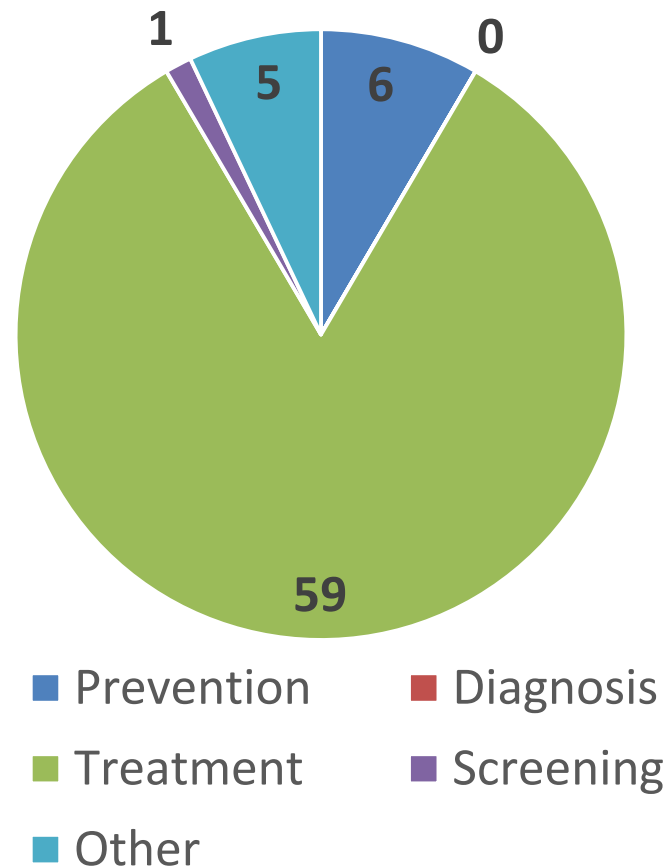
71 PROJECTS



IHS Portfolio Overview – Cycle I through Spring 2015

Care Continuum	# projects	\$
Prevention	6	\$51,243,799
Screening	1	\$2,000,582
Diagnosis	0	\$0
Treatment	59	\$173,366,889
Other	5	\$22,909,836

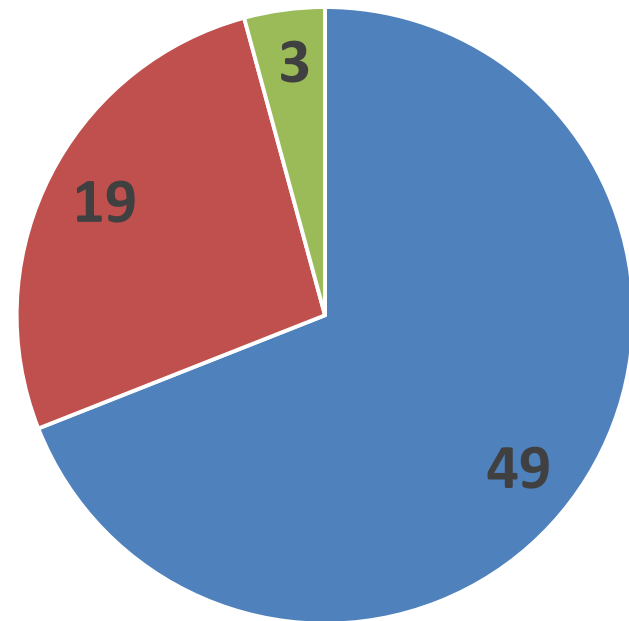
CARE CONTINUUM



IHS Portfolio Overview – Cycle I through Spring 2015

STUDY DESIGN

Study Design	# projects	\$
RCT	49	\$192,171,105
Observational	19	\$52,005,614
Secondary Data	3	\$5,344,388



■ RCT ■ Observational ■ Secondary Data Analysis



The IHS Portfolio – Pragmatic Clinical Studies

IHS has funded 4 studies in 3 cycles thus far:

1. **“Integrating Behavioral Health and Primary Care”** – PI: Benjamin Littenberg, MD at University of Vermont and State Agricultural College
2. **“Early Supported Discharge for Improving Functional Outcomes After Stroke”** – PI: Pamela Duncan, PhD, PT at Wake Forest University
3. **“A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer”** – PI: Scott Ramsey, MD, PhD at Fred Hutchinson Cancer Research Center
4. **“Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture”** – PI: Christopher Sciamanna, MD at Penn State U Hershey Medical Center

Improving Healthcare Systems Priority Topics Included in Most Recent PFA

Topic	Date Prioritized
Integration of Mental Health and Primary Care	April 2013
Perinatal Care	April 2013
Discharge from the NICU	January 2015
Prevention of Dental Caries	January 2015
Chronic nonspecific, musculoskeletal pain	May 2014
Pharmacy Integration	January 2015
Suicide Prevention	January 2015
Rehab for Traumatic Brain Injuries	January 2015



The IHS Portfolio – Targeted Funding

- Targeted funding initiatives are the most resource intensive
 - Require greatest specificity
 - Take most time for development
 - Expert workgroups
 - Iterative review with Board Subcommittee
 - Review and approval by the Board of Governors

Funded Targeted Topics	Total Funding Allocated
STRIDE / Falls Injury Prevention (Administered by NIA)	\$30 million
Effectiveness of Transitional Care* (Project ACHIEVE)	\$15 million
Managing Anti-Viral Therapy for Hepatitis C infected persons who inject drugs	\$14 million

Targeted Topics Under Development	Total Funding Allocated
Multiple Sclerosis	\$10 million
Palliative Care*	2016 expert workgroup



* Topics prioritized by the IHS Advisory Panel
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Treatment of Multiple Sclerosis PCORI Funding Announcement (PFA)

- Published October 12, 2015
 - Letter of Intent Due November 12, 2015 at 5:00 p.m.
 - \$3-\$10 million per application depending on research question
 - Study duration 3-5 years

Seeking studies that compare two or more alternatives for the treatment of multiple sclerosis, with a focus on the effects of therapies on the symptoms experienced by patients with MS and on quality of life and functional status. Comparisons of the effects of disease-modifying therapies (DMTs) and DMT-based strategies, of non-DMT therapies aimed at specific symptoms, and of telerehabilitation versus conventional direct care, on functional status, fatigue, and quality of life are of interest.

- More information available at <http://www.pcori.org/funding-opportunities/announcement/treatment-multiple-sclerosis-cycle-3-2015>

Other Ongoing IHS Initiatives - PCORNet

- Natural Experiments Network
 - Collaborative Initiative with Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)/ National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). A multi-center network intended to:
 - 1) Test the comparative health impact of naturally occurring interventions; and
 - 2) Improve the methods and research infrastructure for natural experiments for clinical comparative effectiveness in public health
 - Will fund up to three additional research projects; Limited to PCORnet Clinical Data Research Networks (CDRNs) that have applied to CDC Funding Opportunity Announcement (FOA) RFA-DP-15-001.
- Systems Initiative
 - Under development
 - January 2016 expected release



Other Updates

- **New Chief Science officer starting January 2016**

Evelyn P. Whitlock, MD, MPH

- Currently the Senior Investigator and Senior Director, Evidence-Based Medicine Research, at the Center for Health Research at Kaiser Permanente Northwest
- Ongoing conversations to ensure alignment with IHS program
- Onboarding to include information about the Advisory Panel's contributions to our work

- **PCORI Inaugural Annual Meeting**

- October 6-8, 2015
- More information available at <http://www.pcori.org/blog/pcoris-inaugural-annual-meeting-milestone-research-done-differently>



The Inaugural PCORI Annual Meeting

- Sessions highlighting IHS projects or sponsored by the IHS program:
 - Team-Based Approaches to Improving Care for the Whole Person
 - The Value of Interdisciplinary Teams in Mental Health Research
 - Patient-Centered Approaches to the Management of Symptoms and Side Effects in Cancer Care
 - Community Health Workers and Patient Navigators: Bridging the Gap Between Health Systems and Patients to Improve Care
 - Patient-Centered Approaches to Optimizing the Delivery of Palliative Care
 - Pragmatic Clinical Studies Summit
 - Transitional Care Evidence to Action Network (TC-E2AN) Summit



The Transitional Care Evidence to Action Network (TC-E2AN) Summit

- Network of 15 Transitional Care Awardee Teams
 - PCORI has made a \$52M investment in research (across the broad, pragmatic and targeted portfolios) studying care transitions across 14 states.
 - Goal of the TC-E2AN is to facilitate engagement among awardees and cross-learning between projects, to promote collaboration among awardees to enhance in-progress work, engage key stakeholders and end-users, and facilitate exchanges between awardees and key stakeholders/end-users.
- In-person summit meeting on Oct. 6 held in conjunction with Annual Meeting
 - Refined goals of the network, developed workgroups and objectives, and identified goals for 2016 focus topics and activities
 - Key next step is to form affinity groups on the following topics:
 - Transitional Care Measurement
 - Knowledge Transfer and Sustainability Activities
 - Research Design and Process



Questions and Discussion



PCORI Topic Generation and Portfolio Evaluation Processes

Kelly Dunham, MPP, Program Manager, Research Portfolio Development
Rachel Witsaman, MPH, PMP, Senior Program Associate, Evaluation & Analysis

An Overview of Portfolio and Topic Analysis at PCORI

Rachel Witsaman, MPH, PMP

Senior Program Associate, Evaluation & Analysis

November 9, 2015

Strategic Portfolio Analysis Team



Lori Frank



Mary Jon
Barrineau



Heather Edwards



Lauren Fayish



Ninma Fearon



Vadim Gershteyn



Mary Kay Margolis



Rachel Witsaman

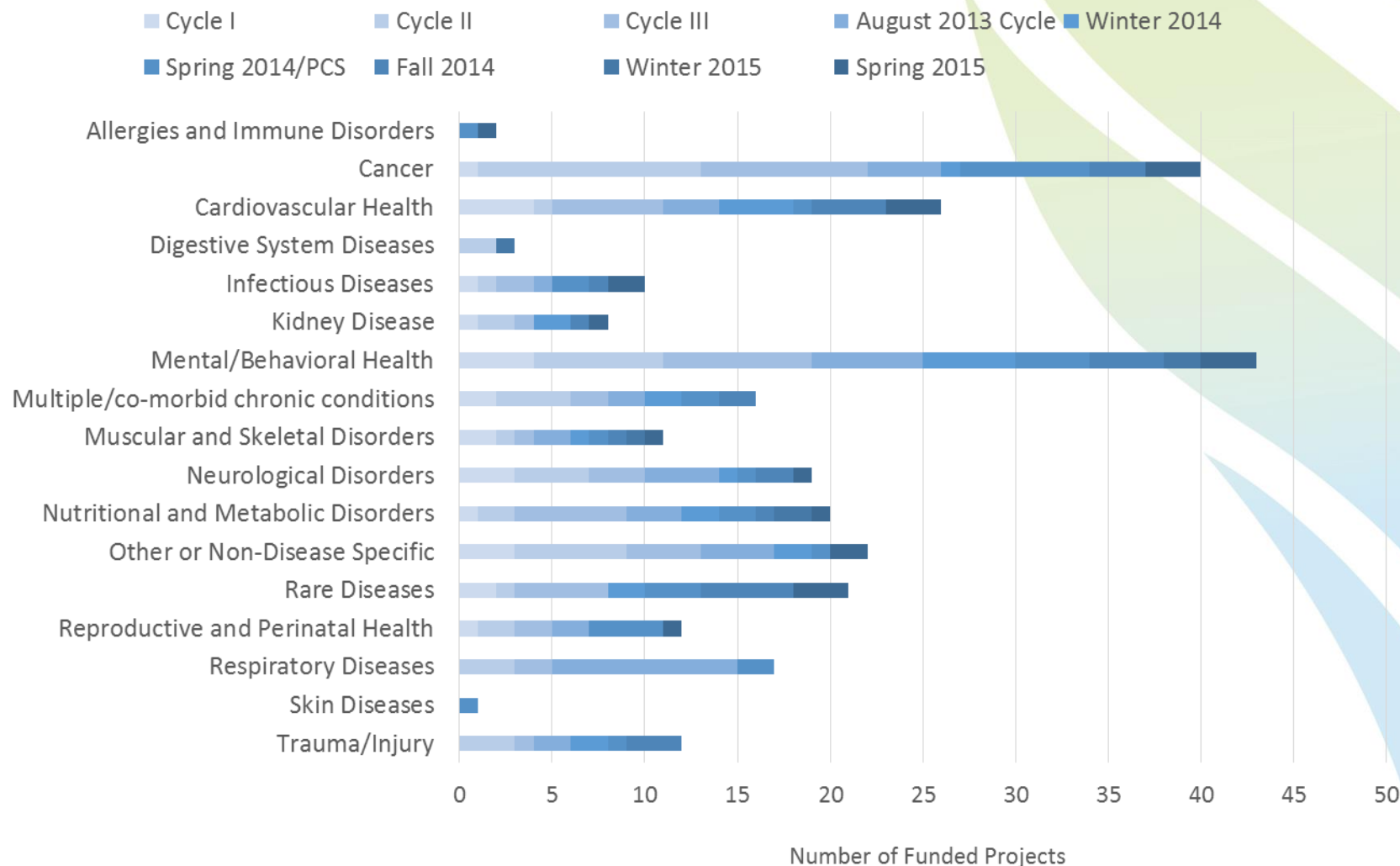
Portfolio Analysis

- The SPA team at PCORI performs analyses on our funded portfolio to assist Science staff with understanding how knowledge gaps are being filled and to help identify promising areas for future funding.
- We have coded the individual projects within the funded portfolio data for:
 - Cycles
 - Program
 - PI characteristics
 - Executed contract
 - Primary disease/condition
 - Study design
 - Populations
 - Ad hoc coding
- SPA produces a Portfolio Briefing Book using the coded portfolio data
 - Consists of standardized descriptive reports about our portfolio.
 - Serves as a communication tool to support strategic decision making.
- We also support ad hoc analyses requested by programmatic staff

Portfolio Analysis

Funded Projects by Disease/Condition and Cycle (N=283)*

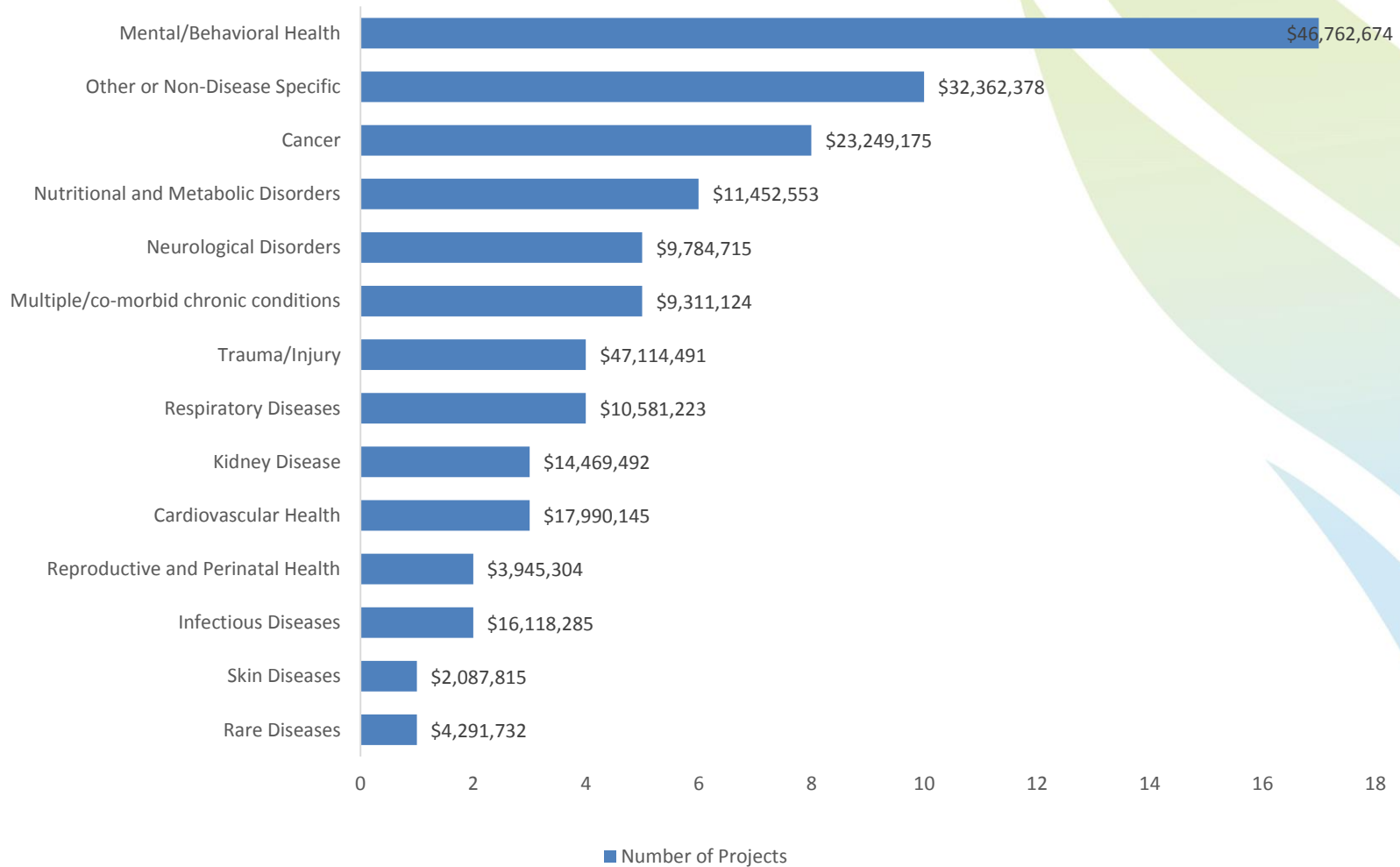
Cycle I through Spring 2015



*does not include projects in Improving Methods for Conducting Patient-Centered Outcomes Research

Top Disease/Condition Categories in IHS (N=71)*

Cycle I through Spring 2015



New Taxonomy Development

- PCORI and researchers from The Ohio State University collaborated to develop a comprehensive taxonomy of project attributes
- Ohio State researchers and PCORI staff developed the taxonomy by:
 - performing a data-driven analysis of PCORI's unique portfolio
 - synthesizing existing health sciences research terminology including Medical Subject Headings (MeSH) and Unified Medical Language System (UMLS).
- The taxonomy was applied to our funded portfolio of projects
 - As projects are added in subsequent funding cycles, project information is also coded using the taxonomy
 - Ensures consistent and comprehensive portfolio data are available for reporting and analysis.

STUDY



Taxonomy description – structure*

- Disease/condition
- Study population
- Intervention type
- Comparators
- Approach
- Care continuum
- Outcomes
- Study design
- Care setting
- Research setting
- IOM100 & AHRQ Research Priorities
- Stakeholder engagement
- Dissemination activities
- Products/tools
- Translational continuum

*Each Theme includes Subthemes of varying complexity

Topic Capture, Coding, and Analysis

Topic Capture and Research Prioritization



Suggest a Patient-Centered Research Question

The Patient-Centered Outcomes Research Institute (PCORI) welcomes suggestions for comparative effectiveness research questions that will result in practical information to help patients and other stakeholders make informed decisions about their health care and health outcomes. PCORI invites you to submit a research question.

PCORI is interested in questions that compare the effectiveness of two or more strategies for prevention, screening, diagnosis, treatment, or management of a condition; compare alternative system-level approaches; or compare factors that may affect patients' adherence to treatments. In addition, we also are interested in questions that would help address disparities in health care, improve the communication of research findings, or advance methods for patient-centered outcomes research. For more information about the type of research PCORI funds, please see [PCORI's National Priorities for Research](#).

Example Question: People with chronic obstructive pulmonary disease (COPD) need information on the safest and most effective way to quit smoking. How does a traditional education program on how to quit compare to a guided maintenance therapy program with nicotine replacement? ([Read more about this project](#))

Topics submitted to PCORI will be posted word for word, so please make sure you do not include any personally identifiable information or sensitive information that you would not like to publicly display on the PCORI website.

Suggesting a research question is the [first step in a six-step process to identify specific research topics for funding](#). We will carefully consider each question and determine which ones we will fund with input from patients and other stakeholders. To see what PCORI has already funded, please visit our [Funding Awards](#) page.

After submitting your research question, we will assign it a topic ID that will allow you to track the status of your question through our research prioritization process. All submissions are reviewed by PCORI staff and grouped together with similar topics by their disease/condition, population addressed, or other descriptive information. PCORI staff will determine if the research question is already addressed in an existing PCORI funding announcement and/or if the research question has been answered, in whole or in part, by PCORI. If this is the case, the research question will not move any further in the PCORI research prioritization process. Some submissions will be ineligible for further consideration because they are not within the scope of the research that PCORI funds, which is patient-centered comparative effectiveness research. Research questions that are eligible for further consideration will continue on through the [research prioritization process](#).

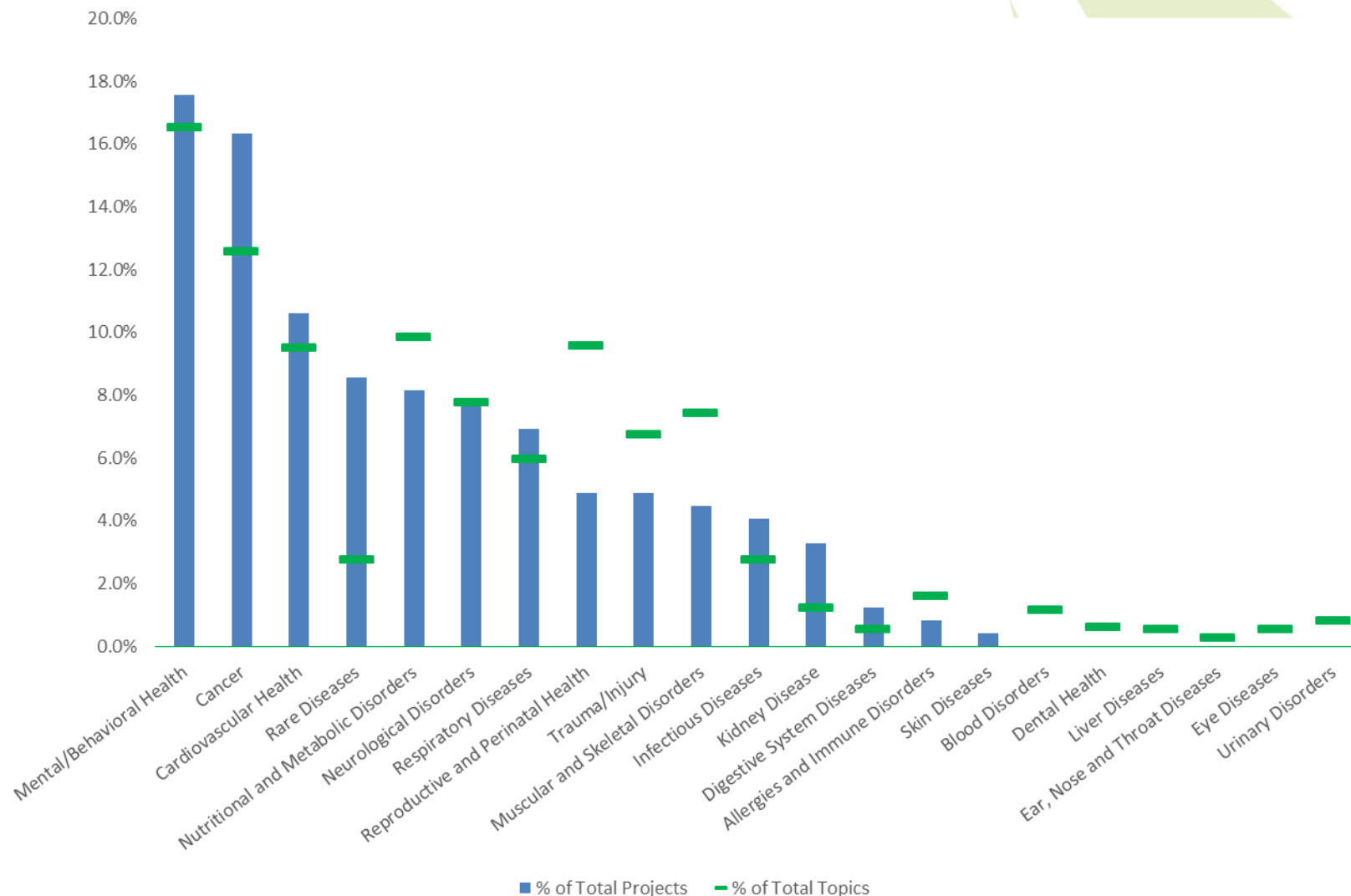
Is your research question related to a specific disease or condition? (Select the best option.)

- ☐ Cancer
- ☐ Cardiovascular Health
- ☐ Diabetes/Endocrine Diseases
- ☐ Mental Health
- ☐ Pain
- ☐ Rare disease
- ☐ Other (please specify)

What is your research question?*

- Topics are submitted to PCORI from the general public and stakeholder organizations
- Submitted topics enter a database and are coded using a code set aligned to major thematic areas of the portfolio taxonomy
- We analyze topics to determine the
 - type and number of topics we receive
 - types of stakeholders who submit the ideas
- Staff may also request extraction of topics to determine whether there are:
 - Gap areas that align with stakeholder interests
 - Stakeholder interest in topics that build on existing projects within the portfolio

Submitted Topics (N=1439) v Funded Projects (N=245) by Disease/Condition*



Topic Prioritization and Refinement at PCORI: An Overview of the Topic Prioritization Pathway

Kelly Dunham, MPP

Program Manager, Research Portfolio Development

November 9, 2015

Our Broad and Complex Mandate

“The purpose of the Institute is to **assist patients, clinicians, purchasers, and policy-makers in making informed health decisions** by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed **through research and evidence synthesis...**”

The Institute shall **identify national priorities** for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), **gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care**, the potential for new evidence to improve patient health, well-being, and the quality of care...



How We Select Research Topics: Approach One

- **Investigator-Initiated Approach**
 - Aligned with our national priorities
 - Topic identified by research team in funding application
 - PCORI's first funding stream
 - 321 studies in progress; \$554M awarded to-date

Assessment of
Prevention, Diagnosis,
and Treatment Options

Communication and
Dissemination Research

Improving Health
Systems

Addressing Disparities

Accelerating Patient-
Centered Outcomes
Research and
Methodological
Research

How We Select Research Topics: Approach Two

- **Patient- and Other Stakeholder- Initiated Approach**
 - Designed primarily for targeted PCORI Funding Announcements (PFAs)
 - Also utilized for priority topics in Pragmatic Clinical Studies PFAs
 - Allows us to focus dedicated resources on high-priority topics
 - Topics submitted to PCORI directly from patients and other stakeholders via website, engagement initiatives or similar efforts
 - Approximately 2,000 topics submitted to-date
 - Informed by portfolio analysis
 - Refined through topic prioritization pathway

Topic Prioritization Pathway



Pathway to a Funding Announcement

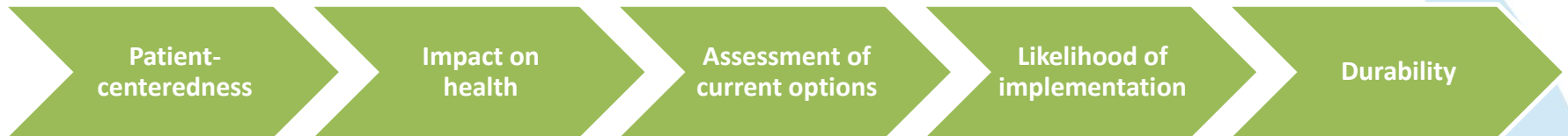


Topic Refinement: Dementia

- **Topic nomination:** Compare the effectiveness of alternative detection and management strategies (e.g., pharmacologic treatment, social/family support, combined pharmacologic and social/family support) for dementia in community-dwelling individuals and their caregivers
- **Sources:** Institute of Medicine, Society of General Internal Medicine



- **IHS topic refinement:** What is the comparative effectiveness of multicomponent management interventions for community-dwelling individuals with dementia in reducing caregiver burden and improving patient health-related quality of life?



PCORI Tier 3 Review Criteria

Topic Prioritization at PCORI to Date

- Since 2013, **136 topics** have entered the prioritization pathway across 20 distinct therapeutic areas
- **78 topics** are under active consideration
- Pathway and topic status available on our website

Approved for Refinement

Palliative Care: Comparative effectiveness of different models of delivering palliative care at the end of life.

[*\(Approved for Refinement\)*](#)

Reviewed by Advisory Panels

Care Coordination and Management: Compare the effectiveness of usual care with care management (designed to optimize care coordination and continuity) on patient-centered outcomes among patients with chronic or progressive conditions, disability, cancer, or other potentially life-changing illnesses.

[View the topic brief](#)

[*\(Reviewed by Advisory Panels\)*](#)

Care Coordination and Management: Compare the effectiveness of care from a non-physician patient-centered medical home with usual care on care quality and patient-centered outcomes.

[View the topic brief](#)

[*\(Reviewed by Advisory Panels\)*](#)

Targeted Funding Announcements

- **12 topics** have resulted in targeted PFAs:
 - New Oral Anticoagulants (NOACs)
 - Multiple Sclerosis
 - Major Depressive Disorders
 - Chronic Pain—Long Term Opioid Therapy
 - Coronary Artery Disease (Optimal Aspirin Dose) ✓ Funded
 - Hypertension ✓
 - Hepatitis C ✓
 - Care Transitions ✓
 - Uterine Fibroids ✓
 - Severe Asthma in African Americans ✓
 - Obesity in Diverse Populations ✓
 - Falls in the Elderly ✓

✓ notes funded awards.

Pragmatic Clinical Studies Priority Topics

- **29 topics** have been listed as PCORI Priority Topics in the Pragmatic Clinical Studies PFA
- **6 topics** have been funded:
 - Bipolar Disorder
 - Cancer—Particle Beam Therapy
 - Cancer—Pulmonary Nodules
 - Crohn's Disease
 - Hip Fracture
 - Mental Health and Primary Care

Caregiver Engagement and Support

- Compare the effectiveness of strategies that incorporate involvement and/or support of patients and their families or other caregivers in care for patients with chronic mental illness (e.g., bipolar disorder, major depression, anxiety disorders, schizophrenia). Studies comparing different delivery system designs and measuring patient and caregiver outcomes (e.g., health-related quality of life, symptom relief, caregiver stress) are of particular interest.

Mental Health and Primary Care

- Compare the effectiveness of different sustainable and scalable models for integrating mental and behavioral health services into primary care provided by large and small practice organizations. These studies should account for contextual effects of different payment methods (e.g., fee-for-service, capitation, and accountable care organizations).

Thank You

Kelly Dunham, MPP

Program Manager, Research Portfolio Development



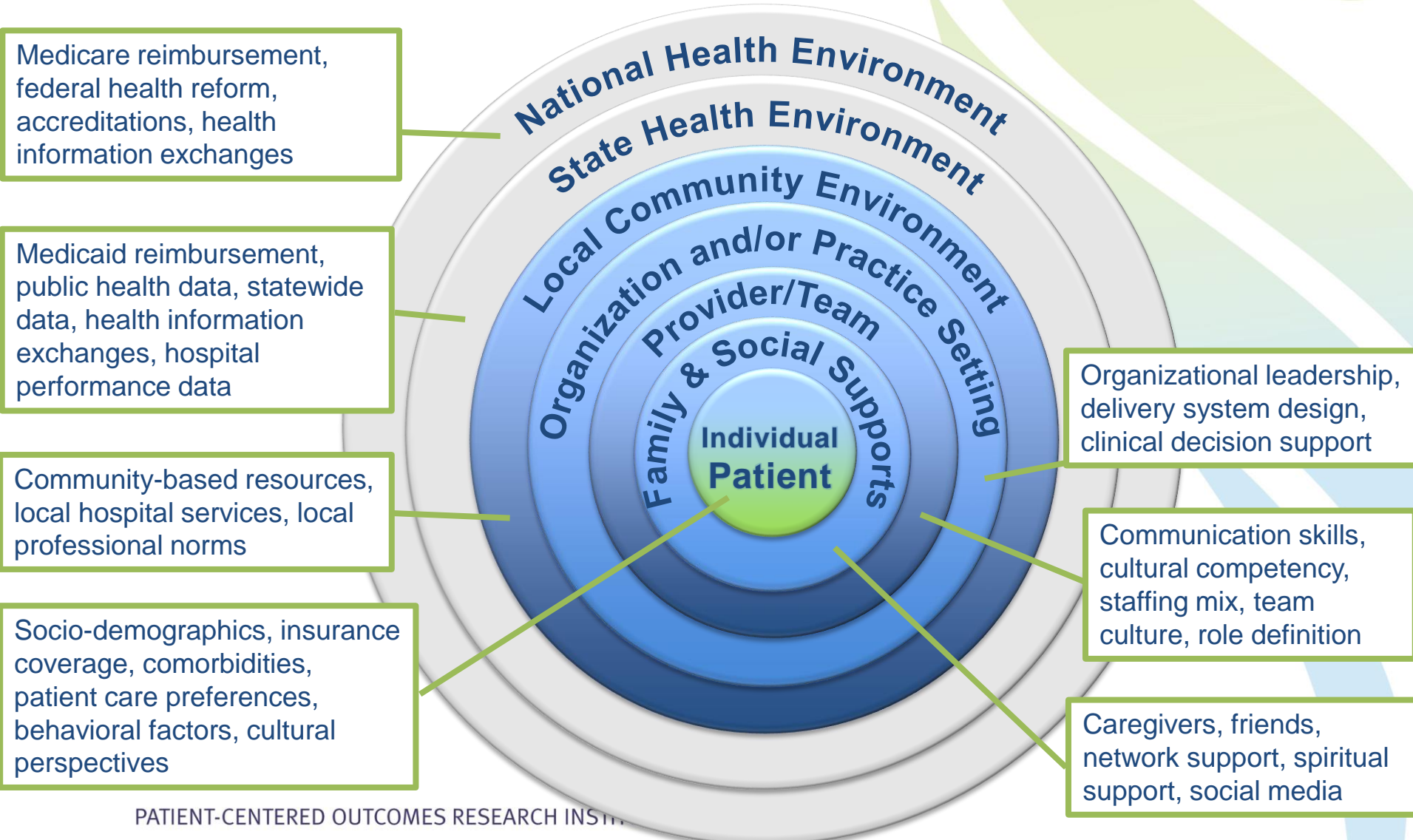
IHS Program Strategy Updates and Discussion

Neeraj Arora, MS, PhD

Senior Program Officer, IHS

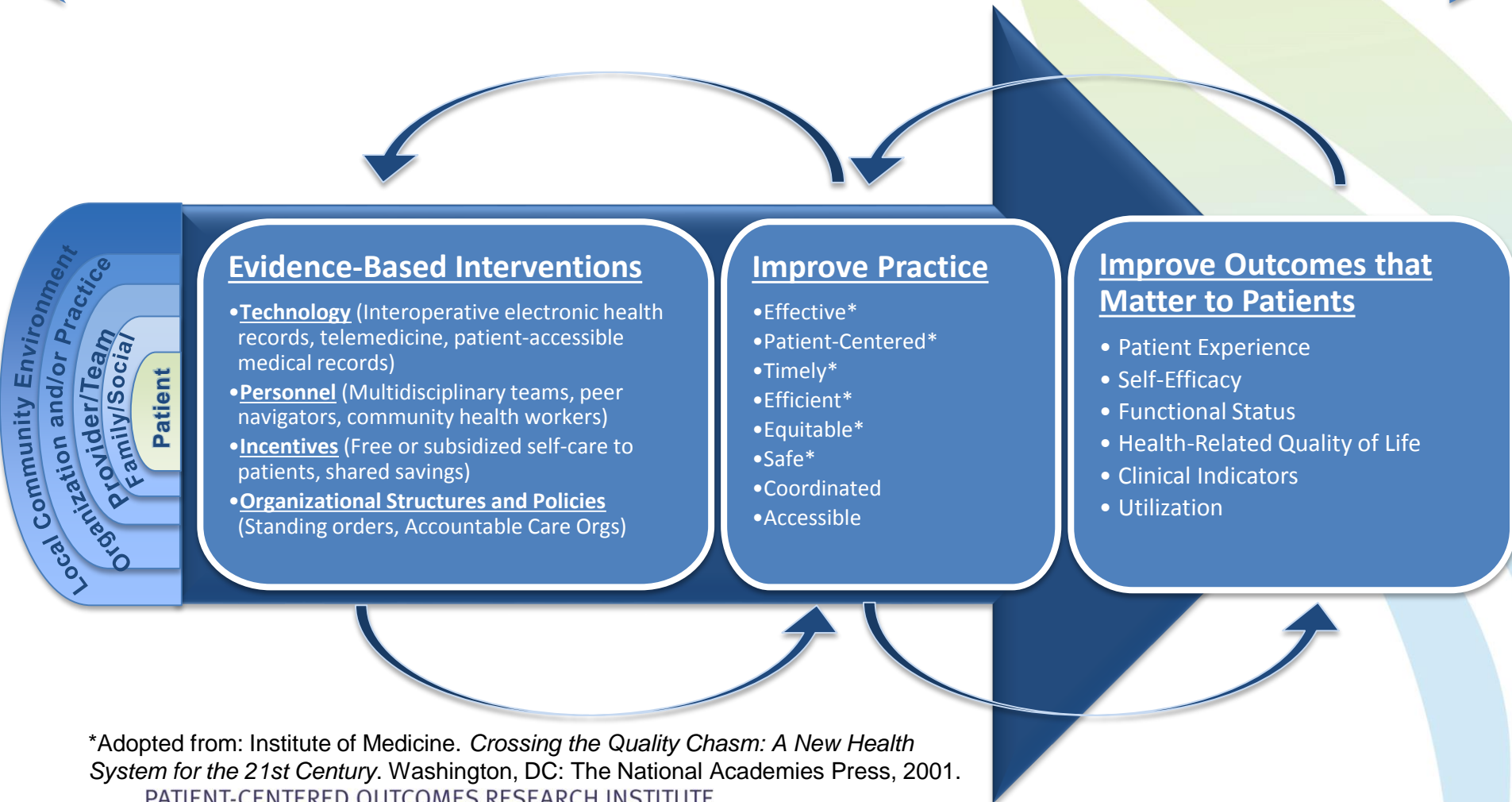
The Healthcare System

Figure adapted from: Taplin, SH; Clauser, S., et al. (2012). Introduction: Understanding and Influencing Multilevel Factors across the Cancer Care Continuum. *Journal of the National Cancer Institute*, 44, 2-10.



IHS Strategic Framework

Patient and Stakeholder Engagement Throughout



*Adopted from: Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: The National Academies Press, 2001.

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Recap of Last Meeting

- Reviewed diagram of healthcare system levels and the existing IHS strategic framework
 - Feedback generally positive and some general editing input
 - Need to incorporate patients more
 - Needs to be clearer regarding what we do, our portfolio, and strategy for the future
- Agreed this is a fluid document
 - Aiming for a realistic structure for evaluating our work that encompasses the most critical aspects of our research and accounts for critical issues facing patients and other stakeholders in the real world

Progress to Date

- **Strategic Planning Retreat – September 2015**
 - Pre-meeting 1:1 structured interviews of all IHS staff
 - Facilitated discussion based on review of:
 - Internal Considerations
 - Portfolio Strengths and Opportunities
 - Developed a five year vision focused on:
 - Impact
 - Visibility
 - Support

Key Discussion Points: Internal Strengths

- **Effectiveness Supports**
 - Strong IHS leader and strong/collaborative team
 - IHS reaches out to, and collaborates with other parts of the organization
 - IHS is good at initiating processes and implementing infrastructure
 - PCORI is a dynamic organization that has freedom to be innovative

Key Points: Portfolio Strengths & Opportunities

- **Portfolio Strengths**

- Uniquely engaging patients, caregivers, other stakeholders
- Breadth and diversity of the portfolio across the healthcare system
- A few strong areas of concentration (e.g., care transitions)
- Research that looks at multiple levels of the system
- Research that can be operationalized in real world settings and has high impact potential

- **Portfolio Opportunities**

- Missing a focus on healthcare system fragmentation as a meta-category to consider/evaluate gaps

Key Discussion Points: Impact Opportunities

- Improve Communication (internally and externally) about:
 - The IHS program, existing portfolio, and research priorities to a variety of audiences;
 - Increased rigor in systems research; and
 - The value of systems research;
- Improve Engagement through:
 - Stronger collaborations across funding agencies and other critical organizations, both public and private
 - A systematic process and criteria for linking and grouping the portfolio;

Our Five Year Vision

Impact

- Improvements in healthcare systems have resulted from PCORI IHS research

Visibility

- There is common awareness and recognition of PCORI and IHS among key stakeholder groups

Support

- Foundational supports, including Congressional renewal and leadership support are in place

Next Steps

- Hope to work with patient and caregiver panelists to provide input on the story and journey
 - *Goal is to relate the patient journey to the system to the research to the improvements, and the outcomes*
- Success in Patient-Centered Healthcare will look like:
 - *The system works for the patient and caregiver;*
 - *They don't need to be experts to navigate it;*
 - *And healthcare will simply be an interruption, not a full time occupation (for the patient and/or caregiver)*



Discussion

Review Results of Pre-Meeting Prioritization and Objectives of Afternoon Break-Out Sessions

Lauren Azar, Senior Program Associate, IHS

Summary of Overall Importance and Ranking

“Prioritize the 4 topics from 1 – 4 with 1 being the highest priority and 4 being lowest priority for PCORI to pursue.”

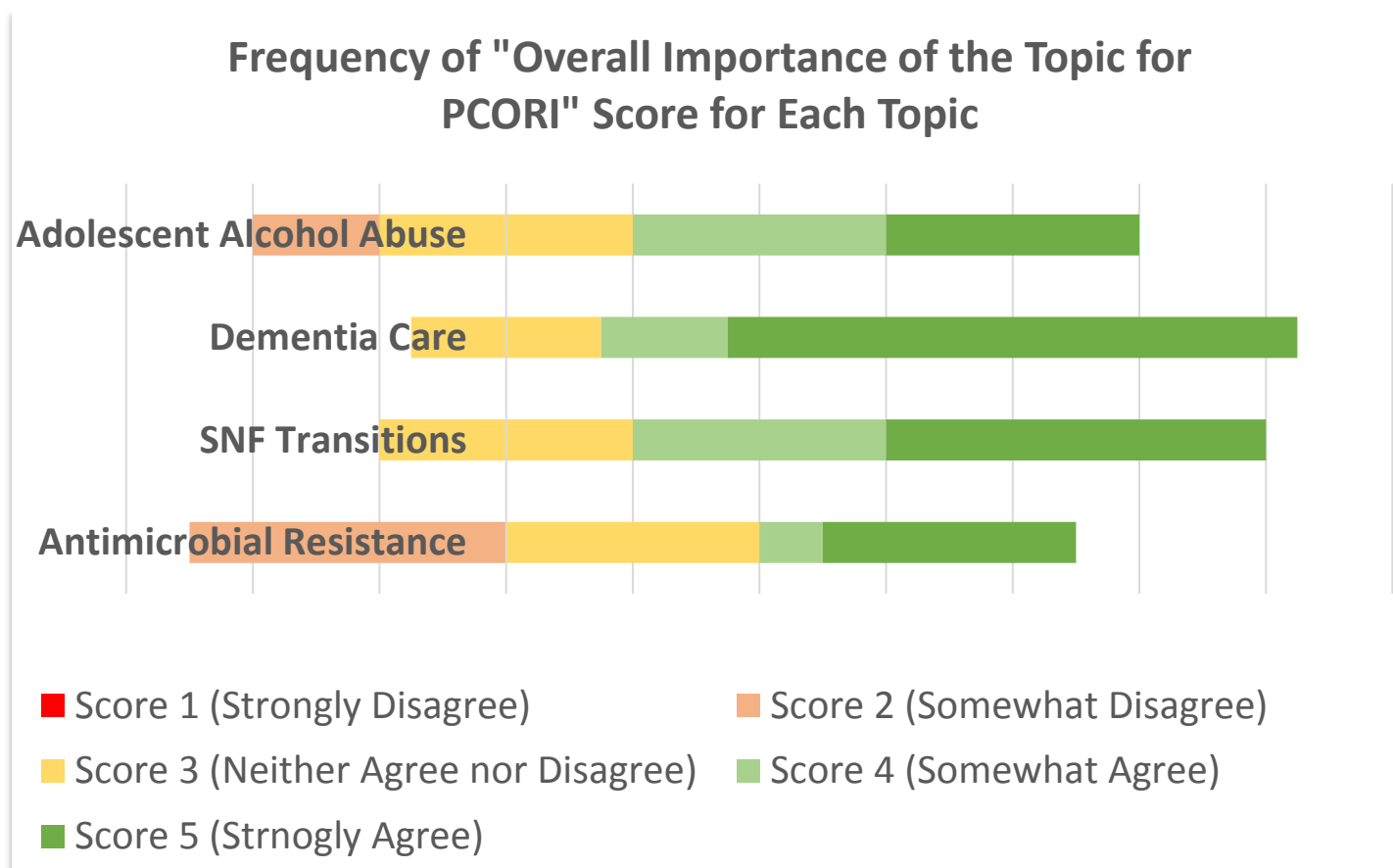
Topic	Score*	Overall Rank
Improving Quality of Life for Individuals with Dementia	39	1
Interventions to Address Antimicrobial Drug Resistance	36	2
Prevention and Treatment of Adolescents with Alcohol Abuse Issues	35	3
Discharge from Short-Term Skilled Nursing Facility	30	4

*Score is a weighted calculation. Items ranked first are valued higher than the following ranks, the score is the sum of all weighted rank counts.



Frequency of Scores for “Overall Importance”

Score each topic from (1 – Strongly Disagree) to (5 – Strongly Agree) in response to the “Overall Importance: Research on this topic is well-suited for CER and PCORI funding overall.”



Dementia Management Scores

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	0 0.0%	0 0.0%	0 0.0%	2 14.3%	12 85.7%	14
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	0 0.0%	1 7.1%	0 0.0%	6 42.9%	7 50.0%	14
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	0 0.0%	0 0.0%	2 14.3%	4 28.6%	8 57.1%	14
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	0 0.0%	1 7.1%	2 14.3%	4 28.6%	7 50.0%	14
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	0 0.0%	0 0.0%	3 21.4%	4 28.6%	7 50.0%	14
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	0 0.0%	0 0.0%	3 21.4%	2 14.3%	9 64.3%	14



Skilled Nursing Facility (SNF) Transitions

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	0 0.0%	0 0.0%	0 0.0%	5 35.7%	9 64.3%	14
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	0 0.0%	0 0.0%	1 7.1%	8 57.1%	5 35.7%	14
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	0 0.0%	0 0.0%	3 21.4%	5 35.7%	6 42.9%	14
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	0 0.0%	0 0.0%	1 7.1%	6 42.9%	7 50.0%	14
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	1 7.1%	0 0.0%	1 7.1%	7 50.0%	5 35.7%	14
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	0 0.0%	0 0.0%	4 28.6%	4 28.6%	6 42.9%	14



Adolescent Alcohol Abuse Scores

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	0 0.0%	0 0.0%	6 42.9%	5 35.7%	3 21.4%	14
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	0 0.0%	1 7.1%	4 28.6%	3 21.4%	6 42.9%	14
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	1 7.1%	2 14.3%	3 21.4%	2 14.3%	6 42.9%	14
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	1 7.1%	1 7.1%	5 35.7%	3 21.4%	4 28.6%	14
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	0 0.0%	4 28.6%	2 14.3%	8 57.1%	0 0.0%	14
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	0 0.0%	2 14.3%	4 28.6%	4 28.6%	4 28.6%	14



Antimicrobial Resistance Scores

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	2 14.3%	5 35.7%	2 14.3%	4 28.6%	1 7.1%	14
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	0 0.0%	3 21.4%	2 14.3%	3 21.4%	6 42.9%	14
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	1 7.1%	3 21.4%	2 14.3%	5 35.7%	3 21.4%	14
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	1 7.1%	1 7.1%	1 7.1%	6 42.9%	5 35.7%	14
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	0 0.0%	2 14.3%	3 21.4%	7 50.0%	2 14.3%	14
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	0 0.0%	5 35.7%	4 28.6%	1 7.1%	4 28.6%	14



Conclusion / Discussion

- Dementia Management topic highest ranked and scored across all criteria
- SNF Transitions considered high in terms of overall importance of the topic, but not ranked highly as compared to the other topics
- Antimicrobial drug resistance considered a high priority when ranked in comparison with other topics, but not consistently scored on criteria and especially low in terms of patient-centeredness
- Adolescent alcohol abuse ranked third both when compared to other topics and in terms of overall importance of the topic

Keep these issues in mind when discussing topics in break-out groups. Be clear about opportunities and issues for each topic when reporting back to the group.



Objectives of Breakout Sessions & Formulating CER Questions

Lauren Azar, MHA

Senior Program Officer, Improving Healthcare Systems

Break-Out Session Format

- Today's Topics:
 - 1) Compare the effectiveness of multicomponent management interventions for individuals with dementia
 - 2) Compare the effectiveness of different care coordination strategies designed to transition patients from skilled nursing facilities back into the community
- Tomorrow's Topics:
 - 1) Compare the effectiveness of alternative interventions to address antimicrobial resistance in hospitals
 - 2) Compare the effectiveness of different screening and brief interventions approaches to reduce hazardous drinking among adolescents who abuse alcohol

Sequence of Events:

1. Topic presentation to full panel based on topic brief
2. Disburse to assigned break-out group
 - Three break-out groups organized by stakeholder (see assignments)
 - Facilitators and note takers assigned; Will need to identify the report back presenter
 - Reference hand-outs: Topic briefs, sample CER questions, guides
3. Note taker will help presenter put together report back slides
4. Panel will reconvene; 3 presenters report back for each of their groups; followed by discussion facilitated by PCORI staff



Break-Out Session Objectives

- Recommend whether the topic is well suited for PCORI to fund
 - Consider the prioritization criteria, and where the topic might be weak
- Consider what specific populations/subpopulations would be important to study
- Recommend what interventions should be compared or tested
- Identify specific CER questions and rank them
 - Hand-outs with example CER questions provided
- List key stakeholder groups we should involve in the topic development process moving forward



How to Write a Research Question



PEOPLE: the group of people to be studied

OPTIONS: the choices or options that should be compared

OUTCOMES: what good and bad things a patient can expect from each option to help them make a decision



What Research Questions are Within PCORI's Mandate?

- PCORI funds studies that compare the benefits and harms of two or more approaches to care.
- Cost-effectiveness: PCORI will consider the measurement of factors that may differentially affect patients' adherence to the alternatives such as out-of-pocket costs, but it cannot fund studies related to cost-effectiveness or the costs of treatments or interventions.
- Disease processes and causes: PCORI cannot fund studies that focus on risk factors, origins, or mechanisms of disease.



Collaborative Break-Out Discussion

- Focus: Provide targeted input without scientific jargon
- Participate: Encourage exchange of ideas among diverse perspectives
- Be respectful: Disagree with ideas, not people
- Ask for help when you need it: PCORI staff will be present at each break-out session



Questions / Discussion



Lunch Break

12:00 p.m. – 12:45 p.m. EST



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Topic Presentation:

Comparative Effectiveness of Multicomponent Management Interventions for Community-Dwelling Individuals with Dementia

Timothy P. Daaleman, DO, MPH

Department of Family Medicine

University of North Carolina at Chapel Hill

Multicomponent Management Interventions

- Purpose: To determine the comparative effectiveness of multicomponent management interventions in reducing caregiver burden and maintaining patient health-related quality of life among community-dwelling individuals with dementia.

Multicomponent Management Interventions

- Introduction to the Topic
- Patient-Centeredness and Impact/Burden of the Condition
- Evidence Gaps and Ongoing Research
- Potential Research Questions
- PCORI Funding on this Topic

Introduction to the Topic

- Dementia is a terminal condition marked by progressive cognitive impairment that leads to decreased physical functioning, worsening health status, and increased caregiver dependency
- Growing attention to dementia due its prevalence and associated financial and societal costs
- Strategies to Mediate Effects:
 - Single intervention (e.g., clinical drug trial)
 - Multicomponent interventions that include two or more strategies (e.g., pharmaceutical, behavioral)

Introduction to the Topic

- **Domains of Interest:**

- While multiple single and multicomponent interventions have demonstrated ***efficacy*** that are specific to patient-centered outcomes, PCORI's areas of interest focus attention on the following approaches:
 - Medication management
 - Community-based services providing social/family support
 - Patient and caregiver education, such as behavior/symptom management
 - Care management

- **Current Evidence Base:**

- More targeted research is needed to understand what combination of strategies work best for specific populations and at identified points in the dementia trajectory, from first diagnosis to the end-of-life

Patient-Centeredness and Impact/Burden

Impact/Burden:

- Impact: 5.3 million people in the US are affected by Alzheimer's disease, the most common form of dementia; currently the sixth leading cause of death in the US
- Patients: Dementia cannot currently be prevented, cured, nor slowed, however several interventions can help maintain patients' quality of life
- Family/Caregivers: Strategies that help family members in managing dementia for loved ones can reduce caregiver burden by improving quality of life and social support

Ongoing Research and Evidence Gaps

- Ongoing Clinical Trials (ClinicalTrials.Gov):
 - One pragmatic pre-post study to assess quality of care for newly diagnosed patients with Alzheimer's disease
 - Three RCT studies that examines various evidence-based management interventions practices for patients with dementia
 - One pragmatic RCT to study effectiveness of online videoconferencing counseling service for families and caregivers
- 6 review of meta-analyses showed:
 - Interventions are not tailored to patient and caregiver needs
 - No study has clarified which components, employed individually vs. combined are important to which patients, and at which points in disease trajectory
 - No study has identified which components are most effective at reducing caregiver burden
 - Did not identify outcomes that are important to caregivers and patients
 - Lack of knowledge regarding facilitators and barriers needed for implementation

Potential Research Questions

- **Do multicomponent interventions provide a differential advantage over single component interventions in maintaining quality of life for community-dwelling patients with dementia and reducing caregiver burden?**
- **What is the comparative effectiveness of two or more multicomponent interventions, that incorporate different approaches to dementia care, in reducing caregiver burden and maintaining quality of life for caregivers and individuals with dementia?**
 - What elements of dementia care strategies are essential and necessary to a multicomponent dementia care model? How can fidelity to these components be prioritized, sequenced, and sustained?
 - What adaptations to dementia care strategies are most effective for specific patient populations, such as racial/ethnic minorities, in maintaining quality of life for individuals with dementia and reducing caregiver burden?
 - What adaptations to dementia care strategies are most effective at identified points in the dementia trajectory, from first diagnosis to the end-of-life, in maintaining quality of life for individuals with dementia and reducing caregiver burden?

PCORI Funding on this Topic

- **PCORI has funded 8 studies** specific to dementia or Alzheimer's disease care
 - One study (IHS) examines the effect of a team-based approach on health service utilization and patient outcomes
 - 2 studies include vulnerable population subgroups in dementia care (i.e., rural setting and Hispanics)
 - 5 studies focus on decision aids/support, patient/caregiver-provider communication that include goals of care, incorporation of caregiver and other key stakeholders perspectives, and effective technological intervention to reduce caregiver burden

Topic Presentation:

Different Care Coordination Strategies to Move Chronically Ill Older Adults from Short-term Skilled Nursing Facility Stays back into the Community

Mary Blegen

Care Coordination Strategies

- Purpose: Comparative effectiveness of different care coordination strategies designed to move chronically ill older adults from post-acute, short-term skilled nursing facility (SNF) stays back into the community in terms of reducing patient hospital readmissions and care giver burden, and improving patient well-being.

Care Coordination Strategies

- Introduction to the Topic
- Patient-Centeredness and Impact/Burden of the Condition
- Evidence Gaps and Ongoing Research
- Potential Research Questions
- PCORI Funding on this Topic

Introduction to the Topic

- Older adults entering SNFs today are often chronically ill with multiple comorbid conditions, some degree of cognitive impairment, and limited capacity to perform activities of daily living.
 - Vulnerable to medical complications that results in re-hospitalizations, worsening symptoms, adverse effects from medications, failed follow-up testing, and excess ED visits
- Transition of care from SNF is challenging for these complex patients
 - Limited coordination between providers and care settings and insufficient supports available to the patient and caregiver in the home

Introduction to the Topic

- **Who Provides this Care:**

- Providers include:

- Nurses, Primary care providers, specialists, physical therapists, caregivers, pharmacists and home health providers

- **Evidence Base to Date:**

- Effectiveness and efficacy data on various transitional care strategies exists, more work is needed to understand
 - Relative benefits and harms of such approaches
 - Applicability to transitions from SNF
 - Identify practices that promote safety and positive health outcomes for patient, families, and caregivers

Patient-Centeredness and Impact/Burden

Impact/Burden:

- Population Aging → greater proportion of individuals likely to be diagnosed with multiple comorbid conditions
- Patients → Growing desire to age in the comfort of one's own home and community as independently as possible
- Family/caregivers → Suffer profound physical and emotional consequences (e.g. caregiver burden, loss of wages, lowered quality of life, depression and stress)

Ongoing Research and Evidence Gaps

- Review of 43 reports of care intervention:
 - Primarily focuses on hospital transitions with potential to support aging in place initiatives and SNF transition
- Three successful evidence-based hospital-to-home transition programs have components that could be applied to SNF:
 - Project BOOST: Family meeting one week prior to discharge to ensure agreement of goals of care; involves transmitting discharge summary to community-based providers who are responsible for post-discharge
 - Transitional Care Model (TCM): transitional care nurse provides continuity of care management throughout the process
 - Project RED: Provides medication management and reconciliation with a patient-centered approach

Ongoing Research and Evidence Gaps

- Need for more research on care coordination strategies and outcomes beyond 30 days
- More research on care coordination activities that promote discharge of SNF patients that facilitates successful aging-in place, and improvements in quality of life and symptom relief
- Studies did **not** identify a single or bundle of interventions that reliably reduce risk for 30 day re-hospitalization
- Limited information on incorporation and efficacy of home health providers in the transition of care
- Research on the role of caregivers in care coordination for transitions between SNFs and the community
 - Identification of how to better support caregivers is lacking

Potential Research Questions

- What is the relative effectiveness of different transitional care models (e.g., Project RED, TCM, BOOST) in avoiding re-hospitalizations and supporting long-term (i.e., longer than 30 days), patient-centered outcomes after discharge from SNFs?
- What combinations or bundles of care coordination services (e.g., coaching, medication education and reconciliation, predischARGE planning with family, care coordinators) can reduce re-hospitalizations and other acute care utilization for individuals that have transitioned from a SNF back to the community?
 - How do discrete components of these service bundles compare to one another in improving patient-centered outcomes such as reduced symptom burden and improved health-related quality of life?

Potential Research Questions

- What is the comparative effectiveness of different care strategies for involving caregivers in the care transition and care coordination process for individuals moving from SNFs into the community?
 - Which strategies are most effective in terms of reducing caregiver burden during and after the transition?
- What is the relative effectiveness of different combinations of community resources and types of providers (e.g., ADRCs, home health providers) for supporting the population of older adults transitioning from SNFs into the community?
 - Are such community resources and combinations of resources effective in ensuring positive outcomes beyond the immediate transition period, extending their utility into the longer term health and safety of these individuals?

Potential Research Questions

- Which components can be incorporated into the Patient Centered Healthcare Home organizations to successfully transition chronically ill older adults from SNFs back into their community homes?

PCORI Funding on this Topic

- **PCORI has 16 studies** funded in care transitions:
 - 1 is specifically aimed at patients in rural-setting
 - 5 are disease-specific care transition interventions
 - 10 are studies of decision aids, patient/caregiver-provider communication or other decision-making aides that include goals of care, informed consent for high-intensity treatments, and other important stakeholder engagement and aspects of decision-making for patients and families during transitions of care
 - **ALL** 16 studies look at transitions from hospital to community and not from SNFs

Breakout Session

1:05 p.m. – 2:45 p.m. EST



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Report Back & Discussion

Topics: Dementia Management and Skilled Nursing Facility (SNF Transitions)

2:45 – 4:30 p.m. EST

Facilitated by: Carly Parry, PhD, MSW, MA, Senior Program Officer



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Topic: Dementia Management Break-Out Discussion

Stakeholder Group: Patients, Caregivers, and Patient Advocates

November 9, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Focus: Is this topic well suited for PCORI to fund?

- Does this topic address all prioritization criteria? Where is it weak?
- **Patient Centered?:** Yes— must be sure that studies cover the various stages of dementia and not create narrow recommendations of best practices that do not show concern over the differences in individuals with dementia. Ensuring that outcomes examined are centered around quality of life measurements, rather than readmissions and other clinical outcomes.
- **Impact of Health on Populations:** High impact. Increasing numbers of aging population indicates that there will be more affected with dementia, and this issue is relevant to a significantly large population.
Assessment of Current Options: There are quite a bit of resources out there for caregivers currently; head-to-head comparisons of these current options are important in identifying current system level approaches that are relevant.
- **Likelihood of Implementation and Practice:** Yes, a lot of relevant stakeholders such as patients; families and caregivers; clinicians are interested in issues of dementia management. LTC institution must be rebuilt in order to improve dementia management, an issue area where there is concern if PCORI can actually contribute to.
- **Durability of Information:** This information will help inform future implementation efforts, research, adaptations, and will be relevant for a long time as the population continues to age.

Populations/subpopulations: What specific group(s) of people should be studied?

- Specifically caregivers and patients (across the spectrum and in different stages of dementia)

Interventions/comparators: What choices or options should be compared?

- Existing resources out there can provide additional efficacy data on current interventions in dementia management
- Include additional multicomponent interventions (e.g. physical therapists, home nursing, and other home and health care services)
 - Interventions vary by location and services provide; must be sure that studies do not exclude specific interventions and are broad enough to include various multicomponent interventions

Potential Research Questions

1. What adaptive tailoring approaches to dementia and care management are most effective across the trajectory of disease progression in promoting quality of life and reducing burden for caregivers and individuals with dementia?
 1. Must start from the time of diagnosis, and able to change according to the dynamic disease trajectory
2. How do we evaluate the which needs are most important to patients, families and caregivers. What is the system not providing today, so that the system can have some genuine direction on what needs to be studied and developed. Can we look at existing programs and compare outcomes? Compare existing programs, with focus on caregiver and patient needs, and on the ways decisions and needs change overtime.
3. Which different combinations of component work best for subgroups, including different stages of disease progression?
 1. Current domains are acceptable, but should specify that they include home and health care aids and are not limited to interventions (e.g. medication management, social/family support, patient and caregiver education, case management, and counseling.)

Key Stakeholders for Follow-Up

- Include academic researchers
- Encompassing patients with no caregivers
- Including others outside of the community
 - Other subgroups (various ethnic groups, non-English speaking, immigrants, and etc.)

Topic: Dementia Management Break-Out Discussion

Stakeholder Group: Researchers / Clinicians

November 9, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Focus: Is this topic well suited for PCORI to fund?

- The evidence gap is unclear
- There is ongoing research funded by PCORI and other funders that needs to be explored to ensure this is complementary, not duplicative
 - Concerned whether this topic is ready for additional funding and whether we would duplicate other projects in the PCORI portfolio
 - It is unclear where PCORI could specifically contribute
- Not sure whether the focus should be on site of care vs. population vs. caregiving (formal and informal)
- Overall, the evidence-base is not clear

Populations/subpopulations: What specific group(s) of people should be studied?

- Currently, there's a lack of focus on younger populations (a potential opportunity for PCORI)
- It is unclear whether the patient and caregiver should be considered separately or as a dyad
- There is clear opportunity for interventions to support the caregiver specifically
 - The caregiver could play the tailoring role for the intervention
 - It is unclear whether formal and/or informal caregivers should be considered
- The patient population would include early onset patients because this is focused on community-dwelling settings
- This could potentially be part of a larger initiative to support caregivers, rather than focusing specifically on caregivers for persons with dementia

Interventions/comparators: What choices or options should be compared?

- The comparison should be formulated based on “what” interventions and “how” they are delivered
 - Specific for healthcare systems research
 - E.g., formal vs. informal caregivers, or one setting vs. another
- It is not clear where the gaps are and specifically where PCORI could make a unique contribution

Potential Research Questions

- No specific research questions were identified because it is not clear what the patient issue is that can be solved by a system intervention
- Consider a broader topic on caregiver issues specifically

Key Stakeholders for Follow-Up

- Potential partnership with the Alzheimer's association
- Work directly with patients/caregivers who are dealing with this issue
- Meet with continuing care retirement communities (CCRCs) and other similar organizations to learn what they are doing well
 - The Villages in Cambridge, MA
- J.A. Hartford Foundation and other funders

Topic: Dementia Management Break-Out Discussion

Stakeholder Group: Payers, Administrators and Other Industry

November 9, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Focus: Is this topic well suited for PCORI to fund?

- It is unclear whether effective dementia care programs exist
 - Not sure this is ready for comparative effectiveness research (CER)
- There is a considerable amount of ongoing research in this area already, so PCORI's role is unclear
- It is also unclear whether research on this topic should focus on a healthcare intervention or a social intervention

Populations/subpopulations: What specific group(s) of people should be studied?

- Early, middle and late stage disease represent substantially different patient groups likely with different goals of care and in need of very different interventions
 - This would need to be clarified if the topic is pursued
- Patient and caregiver issues should be untangled where possible

Interventions/comparators: What choices or options should be compared?

- Specific interventions/comparators were not identified
- Comparators must be derived from the evidence base, which is unclear at this point

Potential Research Questions

- What evidence-based programs work best for which subgroups of patients and caregivers, including patients at different stages of disease progression?
- What components of multicomponent interventions are most essential in promoting quality of life and maintaining function for dementia patients?

Key Stakeholders for Follow-Up

- Patients and caregivers dealing with dementia
- CMS and other payers
- Social service agencies

Topic: SNF Transitions Break-Out Discussion

Stakeholder Group: Patients, Caregivers, and Patient Advocates

November 9, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Focus: Is this topic well suited for PCORI to fund?

- Does this topic address all prioritization criteria? Where is it weak?
- **Patient Centered?:** Yes— two components have to be considered, such as the patient and caregivers, which are sometimes in tension with one another
- **Impact of Health on Populations:** High impact with an aging population and growing sentiment to aging in place
- **Assessment of Current Options:** Current funded projects via CMS examining transition from SNF back to the community
- **Likelihood of Implementation and Practice:** Relevant stakeholders have a high stake in facilitating the smooth transition from SNF to the community
- **Durability of Information:** This information will help inform future implementation efforts, research, adaptations, and will be relevant for a long time as the population continues to age.

Populations/subpopulations: What specific group(s) of people should be studied?

- Include not just older adults, but all that rely on SNF care

Interventions/comparators: What choices or options should be compared?

- Various care coordination strategies that involve home and health aids and other providers as well

Potential Research Questions

1. What is the relative effectiveness of different combinations of community resources and types of providers (e.g. ADRCs, home health providers) for supporting the population of **assisting people** transitioning from SNFs into the community? Are such community resources and combinations of resources effective in ensuring positive outcomes beyond the immediate transition period, extending their utility into the longer term health and safety individuals?
 - No longer limiting population to older adults
2. What combinations or bundles of care coordination services can reduce rehospitalizations and other acute care utilization for individuals that have transitioned from a SNF back to the community? How do discrete components of these service bundles compare to one another in improving patient-centered outcomes and **caregiver needs and abilities** such as reduced symptom burden and improve health-related quality of life?
3. What is the comparative effectiveness of different care strategies for involving caregivers in the care transition and care coordination process for individuals moving from SNFs into the community?

Key Stakeholders for Follow-Up

- Professional associations: Nursing home associations, AARP, other aging organizations
- Centers for Medicare and Medicaid Services
- Gerontologists
- County management

Topic: SNF Transitions Break-Out Discussion

Stakeholder Group: Researchers / Clinicians

November 9, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Focus: Is this topic well suited for PCORI to fund?

- This topic is well suited for PCORI to fund, but the topic needs to be reframed to focus on the patient issue that can be addressed by a system intervention.
- There is currently a lack of defined responsibility for these patients (which provider has responsibility for seeing these patients to home?)
- PCORI has funded a lot on care transitions in terms of discharge from the hospital, but there is clearly opportunity for patients transitioning from SNFs to home
 - Focus on patient-centered outcomes, such as quality of life, functional status, etc.

Populations/subpopulations: What specific group(s) of people should be studied?

- Chronically ill older adults with short-term stays in SNF
- There is currently a lack of defined responsibility for these patients (which provider?)
- Different patients will need different trajectories – Need to focus on what works best for whom

Interventions/comparators: What choices or options should be compared?

- Discharge planning (should initiate upon admission)
- The current evidence-base is highly focused on transitions from hospitals, but it is translatable.
 - The issue is there are varying regulations (e.g., medication disbursement) in SNF's as compared to hospitals
- Compare models implemented at the hospital site (the hospital is responsible for the entire transition) vs. those implemented specifically in SNFs

Potential Research Questions

- What is the comparative effectiveness of the hospital managing the entire transition of patients vs. those initiated at the SNF level
 - Consider attribution

Key Stakeholders for Follow-Up

- CMS – Reimbursement, CMMI demonstration projects (e.g., CCTP)
- SNF Administrators and clinical staff
- Physical Therapy, home health, pharmacists, other clinicians

Topic: SNF Transitions Break-Out Discussion

Stakeholder Group: Payers, Administrators and Other Industry

November 9, 2015



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Focus: Is this topic well suited for PCORI to fund?

- Transition issue is far more present in post-acute setting than acute setting (much higher readmit rate), however it is not clear that the research needs to be redone in this setting
- SNFs may be too narrow, broader look at post-acute settings may be more appropriate
- Point of Consideration: The incentive structure in SNFs is currently very different from acute settings – per diem payments, differing quality metrics (or lack thereof), etc.

Populations/subpopulations: What specific group(s) of people should be studied?

- Specific considerations based on insurance status
 - Consider healthcare coverage as a proxy for resources
 - Socioeconomic status (SES) may determine 'readmission' profile, stratify by SES, payer type
- Support needs after discharge – high need as a separate population from low need

Interventions/comparators: What choices or options should be compared?

- Choices to be compared could be based on current studies in hospital-to-home studies
 - Why is post-acute world so different from acute settings in terms of quality standards, measures, staffing, outcomes?
 - May need to look by setting capabilities and model reliance on these capabilities (e.g. TCM may be highly appropriate as discharging entity is external staff)
- Incentive structure is at least as important as staffing/model comparators here

Potential Research Questions

- What is the comparative effectiveness of different incentive structures and alternative payment models for SNFs and other post-acute settings in terms of improving quality of life, functionality, utilization, etc.?

Key Stakeholders for Follow-Up

- Payers (private, public, other relevant units of government which may not be a payer in other areas)
- Hospitals
- Patients, advocates, family members
- Long-term care facilities

Recap of the Day

Doris Lotz, MD, MPH

Next Steps & Closing Remarks

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems



Adjourn

Thank you for your participation!

**Our meeting tomorrow will begin
at 8:00 am EST**

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Advisory Panel on Improving Healthcare Systems

November 10, 2015

8:00 a.m. – 12:30 p.m. EST



Housekeeping

- Today's webinar is open to the public and is being recorded.
- Members of the public are invited to listen to this teleconference and view the webinar.
- Anyone may submit a comment through the webinar chat function, although no public comment period is scheduled.
- Visit www.pcori.org/events for more information.
- Statement on COI and Confidentiality



Today's Agenda & Meeting Objectives

- **Day 2:**
 - Topic Refinement Breakout Session
 - *Compare the effectiveness of alternative features to address antimicrobial resistance in hospitals*
 - *Compare the effectiveness of different screening and brief interventions approaches to reduce hazardous drinking among adolescents who abuse alcohol*
 - Re-Prioritization and Next Steps
 - Boxed Lunches



Topic Presentation:

Alternative Interventions to Address Antimicrobial Resistance in Hospitals

Jim Bellows



Alternative Interventions to Antimicrobial Resistance

- Purpose: Comparative effectiveness of alternative interventions to address antimicrobial resistance in hospitals, including informatics technology, point-of-care prescribing and patient-outcome monitoring, or use of educational materials, and reminder systems, in improving hospital lengths of stay and mortality.



Alternative Interventions to Antimicrobial Resistance

- Introduction to the Topic
- Patient-Centeredness and Impact/Burden of the Condition
- Evidence Gaps and Ongoing Research
- Potential Research Questions
- PCORI Funding on this Topic



Introduction to the Topic

- **Definition:** Antimicrobial drug resistance defined as microbes (bacteria, viruses, fungi, and parasites) evolving to survive in the presence of drugs that previously killed or limited the growth of the microbe
- Amount of resistance is expected, but more strains of bacteria have become resistant to more antibiotics
 - Treatment choices become limited, less effective, and more expensive
 - Common life-saving medical procedures such as transplants, surgery, or chemotherapy are rendered impossible as a result of drug resistant microbes



Patient-Centeredness and Impact/Burden

Patient-Centeredness:

- Clinicians and public health professionals: Antimicrobial resistance is a threat to many treatments and procedures
- Patients: Research interventions to address antimicrobial resistance is relevant to patient outcomes, in the forms of:
 - Patient health status
 - e.g. delay in administration of effective therapy, toxicity level of therapy, activity level at discharge
 - Health care utilization
 - e.g. length of stay, readmissions, health care costs
 - Loss of functional time, ability to work, and excess mortality



Patient-Centeredness and Impact/Burden

Impact/Burden:

- At least 2 million people acquire and 23,000 people die from antibiotic-resistant infections each year in the US
- \$20 billion in excess direct healthcare costs and \$35 billion in lost productivity (e.g., lost wages, extended hospital stays, and premature deaths)
- Global public health threat that crosses international borders



Ongoing Research and Evidence Gaps

- Five major systematic reviews of the effectiveness of antimicrobial stewardship programs (ASPs) has been evaluated
- 6 ongoing studies (ClinicalTrials.Gov): 2 focused on drug dosing or drug timing; 2 focused on improving lab tests for ASPs; and 2 that are observational studies or RCTS focused on structural ASP interventions
- New Research is Needed:
 - More published studies using rigorous scientific methods (RCTs)
 - ASP programs that tailors therapy to individualized patients
 - Studies to estimate likely impact of change in prescribing microbial outcomes
 - Longer-duration studies on ASPs, given that current studies are one year or less
 - Head-to-head studies of different types of ASPs
 - More studies on the implementation, sustainability, scalability or specific components of interventions that are effective



PCORI Funding on this Topic

- **PCORI has 9 studies** funded in antimicrobial or antibiotics effectiveness
 - 4 are studies that examine the effectiveness of specific clinical antibiotic interventions
 - 5 studies look at informatics technology, point-of-care prescribing and patient-outcome monitoring, or use of educational materials, and support in decision-making, in improving hospital lengths of stay and mortality
 - None of the studies are funded via IHS



Potential Research Questions

What is the comparative effectiveness of...

- different combinations of interventions, including “restrictive” versus “persuasive”?
- ASPs combined with infection control practices, such as hand hygiene and isolation, compared with infection control alone?
- different types of clinical decision support programs?
- implementing ASPs tailored to individualized patient needs compared to uniform therapy guidelines?

What are the challenges, resource and workflow considerations for ASP implementation in specific inpatient settings, e.g ED?

- What is the relative impact of different approaches to mitigating these barriers?



Some Discussion Questions

Likelihood of Implementation

- What are the gaps in sustainable implementation of ASPs?
 - Lack of knowledge? Motivation? Something else?
 - Which gaps could CER address?
- Will results about approaches to mitigating challenges (resources, workflow, etc.) be generalizable?

Durability

- Will evolution of computerized clinical decision support affect applicability of current approaches? How soon?



Topic Presentation:

Intervention Models to Reduce Hazardous Drinking Among Adolescents who Abuse Alcohol

Lisa Freeman



Models of Screening for Alcohol Abuse

- Purpose: Comparative effectiveness of different screening and brief interventions (BIs) approaches (e.g., school-based versus primary care-based education and motivational interviewing) to reduce hazardous drinking among adolescents who abuse alcohol.



Models of Screening for Alcohol Abuse

- Introduction to the Topic
- Patient-Centeredness and Impact/Burden of the Condition
- Evidence Gaps and Ongoing Research
- Potential Research Questions
- PCORI Funding on this Topic



Introduction to the Topic

- **Definitions:**

- Alcohol abuse is the pattern of drinking that causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.
- Binge drinking: “Consuming five or more drinks (men) or four or more drinks (women), in a about two hours”

- **Significance:**

- Youth abuses alcohol more frequently than tobacco or other drugs
- Early initiation of alcohol abuse is a risk factor for:
 - Alcohol/substance abuse and dependency later in life
 - Physical, emotional, and social consequences
 - Increased morbidity and mortality among young people
 - Lasting effects on brain structure and function that adversely affect development for adolescents



Patient-Centeredness and Impact/Burden

Patient-Centeredness:

- Given potential physical, psychological, and social and legal consequences of alcohol abuse makes this topic inherently patient-centered as it impacts:
 - Adolescents, families, loved ones and community

Impact/Burden:

- Over 10 million adolescents drink alcohol each year in the US
- 2013- 14.2% of adolescents (ages 12-20) reported binge drinking; estimated 2.8% had alcohol use disorder; 20.8% of high schools students participated in heavy episodic drinking in a 30 day-period
- Alcohol abuse among youth is responsible for more than 4,300 deaths linked to 189,000 ED visits annually



Ongoing Research and Evidence Gaps

- **Ongoing Research:**

- Meta-analyses review identified 200 studies examining effects of BIs on alcohol use and abuse; only 24 of these studies focused on adolescents (ages of 11-18)
- Less than half of studies were done outside of the U.S.
- Only 4 studies focused on non-whites

- **Evidence Gaps:**

- Different BI approaches have not been tested head-to-head
- Few RCTs had a follow-up period longer than 12 months; long-term effects of interventions unknown
- Further research needed regarding which optimal settings, personnel, session frequency, and delivery modality for better screening and treatment interventions for alcohol abuse
- Effect of different approaches to screening and BI on different subpopulations



Potential Research Questions

- What is the comparative effectiveness of screening and BIs of a universal/general adolescent population and a targeted approach focused on at-risk youth (i.e. with comorbidities such as other substance use or mental health disorders)?
- What is the comparative effectiveness of screening and BIs in different settings (primary care settings, schools, sexual health clinics, adolescent mental health services)?
- What is the comparative effectiveness of using different personnel to screen and deliver BIs, i.e., medical doctors, nurses, other outpatient clinicians, mental health professionals, school-based practitioners?
- What is the comparative effectiveness of on-site face-to-face, on-site computer-delivered, and remote electronically delivered BI for different subgroups of adolescents?



PCORI Funding on this Topic

- PCORI has no studies funded related to adolescent alcohol abuse as of November 2015



Breakout Sessions

8:30 a.m. – 10:10 a.m. EST



Report Back & Discussion of Topics: Antimicrobial Resistance and Adolescent Alcohol Abuse

10:10 – 11:40 a.m. EST

Facilitated by: Alex Hartzman, Program Associate



Topic: Antimicrobial Resistance Break-Out Discussion

Stakeholder Group: Patients, Caregivers, and Patient Advocates

November 10, 2015



PCORI Focus: Is this topic well suited for PCORI to fund?

- Does this topic address all prioritization criteria? Where is it weak?
- **Patient Centered?:** Focusing antimicrobial resistance in hospital-settings only may narrow the patient-centered focus— must look outside to other settings and different social contexts as well (i.e. role of food industry in the US).
 - Readjust CER question so that resistance in hospitals is the end-result, and instead the work is directed towards improving the track for patients (via education materials, more consumer choice focus)
- **Impact of Health on Populations:** High impact.
- **Assessment of Current Options:** Existing applications available via mobile technology does allow individuals to compare hospital infection ratings.
- **Likelihood of Implementation and Practice:** This CER question may be better tailored for the other teams in PCORI besides IHS
- **Durability of Information:** Extremely durable as more microbes become resistant to drugs and antibiotics



Populations/subpopulations: What specific group(s) of people should be studied?

- Use of antimicrobial resistance in the context of dental work



Interventions/comparators: What choices or options should be compared?

- Different modalities of patient and provider education
- Comparing patients (utilizing patient and provider education) vs. those who do not
- Look at common current practices



Potential Research Questions

- Focus on improving antibiotic prescribing/use first, as that will influence the antibiotic resistance issue.



Key Stakeholders for Follow-Up

- APIC (Association for Professionals in Infection Control and Epidemiology) (CDC/CMS partnership)
- Professional associations (i.e. family care, primary care, AFP, AHA)
- Consumer choice groups
- FDA (device safety data)
 - Center for Device Regulation, Radiation Health Research (CDRRHR)



Topic: Antimicrobial Resistance Break-Out Discussion

Stakeholder Group: Researchers / Clinicians

November 10, 2015



PCORI Focus: Is this topic well suited for PCORI to fund?

- This is a patient-centered issue (patients don't want to contract an infection in the hospital)
- There is high potential for impact on the health of individuals and populations
- There is great opportunity to engage patients to address this issue
- The only question is whether the evidence base is developed enough for CER



Populations/subpopulations: What specific group(s) of people should be studied?

- No specific populations identified
 - Opportunity to learn from pediatrics, VA, and other existing toolkits



Interventions/comparators: What choices or options should be compared?

- Compare different appropriate antimicrobial prescribing practices in hospitals
- Consider alignment with Choosing Wisely
 - To compare community prescribing practices
- Consider redirecting the hospital focus on Hospital Acquired Infections
 - There is some evidence-base around bundles/toolkits, but we would need to revise the topic brief/ lit review to include this body of evidence
 - Nonetheless, this research space may be saturated



Potential Research Questions

- What is the comparative effectiveness of different appropriate antimicrobial prescribing practices in hospitals.
- What is the comparative effectiveness of implementation of ASPs, such as toolkits/bundles, tailored to individualized patient needs compared to uniform therapy guidelines.
 - Different implementation strategies of the same bundles could also be a focus



Key Stakeholders for Follow-Up

- Infectious Disease Society of America
- Society of Hospital Medicine
- CDC – Toolkit
- AHRQ – Toolkit
- CMS – Hospital Compare
- RWJ Foundation
- PCORnet – systems
- ASHP
- American Academy
- ABIM Foundation
- Leapfrog Group
- Veterans Administration



Topic: Antimicrobial Resistance Break-Out Discussion

Stakeholder Group: Payers, Administrators, and Other Industry

November 10, 2015



PCORI Focus: Is this topic well suited for PCORI to fund?

- Major problem in US healthcare – BUT do not feel it is ready to tackle in its current formulation
- Morbidity and mortality are patient-centered outcomes; more near-term outcomes are uncertain to the group
- Likelihood of implementation in practice seems very low (at least of what is currently known), especially in hospitals. New knowledge isn't the gap.
 - Incentive programs are being put in place by CMS
 - Seems to be a hospital-by-hospital problem that cannot be solved with generalizable research



Populations/subpopulations: What specific group(s) of people should be studied?

- Hospitalized patients



Interventions/comparators: What choices or options should be compared?

- Seems to be a fractal study design with unclear choices – goal is to find good combinations of different approaches



Potential Research Questions

- What is the comparative effectiveness of alternative interventions to address antimicrobial resistance in hospitals, including informatics technology, point-of-care prescribing and patient-outcome monitoring, or use of educational materials, and reminder systems, in improving hospital lengths of stay and mortality?
 - Caveat: still unclear if this topic is appropriate for PCORI
 - Broad study goal: Looking for best practices or combinations of ASP approaches – much activity/research
 - Not completely convinced good practices exist



Key Stakeholders for Follow-Up

- Hospital CEOs, infection control officers, epidemiologists
 - Find actual, crisp clinical questions – implementation issues may be hospital-specific / not generalizable
- CDS developers



Topic: Adolescent Alcohol Abuse Break-Out Discussion

Stakeholder Group: Patients, Caregivers, and Patient Advocates

November 10, 2015



PCORI Focus: Is this topic well suited for PCORI to fund?

- Does this topic address all prioritization criteria? Where is it weak?
- **Patient Centered?:** Yes— focus on approaches to reduce alcohol drinking, and taking out the word “hazardous” from the CER question. Greatest misinformation out there is that researchers are not speaking directly to adolescents-- focus on the alcohol piece and take on a more tailored approach so that the needs of the youth are being directly engaged and addressed in a safe environment. Focus on alcohol abuse as a starting point, as it usually acts as a gateway to other drugs– understanding that alcohol abuse intervention may prevent future dependencies of other drugs even if it is not directly addressed in this CER question.
- **Impact of Health on Populations:** High impact. Increasing numbers of adolescents that abuse alcohol.
- **Assessment of Current Options:**
- **Likelihood of Implementation and Practice:** Strong likelihood of implementation and practice; involves many key stakeholders (schools, counselors, therapists)
- **Durability of Information:**



Populations/subpopulations: What specific group(s) of people should be studied?

- Adolescents with comorbidities, particularly those with mental health conditions and have learning disabilities
- Subgroups that reside in rural areas (e.g. telehealth therapy)



Interventions/comparators: What choices or options should be compared?

- Compare various early screening interventions; head-to-head comparisons to identify different approaches, and under what circumstances are they most effective



Potential Research Questions

1. What is the comparative effectiveness of screening **and community-based and health-based interventions** of a universal/general adolescent population and a targeted approach focused on at-risk youth (i.e. with comorbidities such as other substance use or mental health disorders)? Studies should be sufficiently powered to allow for key adolescent subpopulations, e.g. younger vs older adolescents; who self-identify as heterosexual vs. those who self-identify as LBGTQ.

- Removed the word 'brief'; efficient interventions are not brief and take considerable time
- Combine other CER questions into the first to create a more compelling question
- Further specification of the screening and delivery for specific subpopulations, and various personnel needed

2. What is the comparative effectiveness of on-site face-to-face, on-site computer delivered, and remote electronically delivered **interventions** for different subgroups of adolescents?

- Particularly focus on telehealth screening for those in rural areas

3. What is the comparative effectiveness of using different personnel to screen and deliver interventions i.e. medical doctors, nurses, other outpatient clinicians, mental health professionals, school-based practitioners, **peers, faith-based, and community based practices**? As noted in a recent meta-analysis, many studies fail to report or analyze the backgrounds of the personnel delivering these types of interventions and no studies have compared the effectiveness of different types of personnel.



Key Stakeholders for Follow-Up

- Communities
- Behavioral health professionals
- Inpatient/Outpatient setting
- School resource officers
- Youth clubs
- Community healthcare workers
- Pediatrician groups
- Planned Parenthood and other organizations that provide care for youth
- Alateen (Al-Anon Family Groups)



Topic: Adolescent Alcohol Abuse Break-Out Discussion

Stakeholder Group: Researchers / Clinicians

November 10, 2015



PCORI Focus: Is this topic well suited for PCORI to fund?

- This topic is well-suited for PCORI overall
- This is a major issue and a patient-centered issue
- Sustainability is a key issue - Need to ensure maintenance of the intervention and measure long-term outcomes
- There is great opportunity to engage adolescents, families, and caregivers to shape this research question and especially the outcomes
- Opportunity to potentially partner with NIDA
- Only issue to keep in mind:
 - Likelihood of Implementation is somewhat of a concern because it is unclear whose responsibility this would be (e.g., school system and/or health system screening)



Populations/subpopulations: What specific group(s) of people should be studied?

- The group should include patients covered under the ACA (up to age 26)
 - Significant opportunity with college-age individuals
 - Include minority sub-populations (especially Native American populations)
- This needs to be combined with other substance abuse issues (beyond alcohol abuse)



Interventions/comparators: What choices or options should be compared?

- The intervention must include screening plus an intervention
- Don't limit to alcohol screening, include other drug screening
- The intervention will require tailoring (utilization of a tool to identify the best plan)
 - Intensity of the intervention will need to be tailored - It's not a "one size fits all" issue
- Consider pharmacological agents as part of the interventions/comparators



Potential Research Questions

- Ensure there is sufficient power to identify heterogeneity of treatment effects for specific sub-populations (e.g., Native Americans, low SES)
- Short and Long-term outcomes should be included
- Consider the relationship and modality of the screening personnel (peer, anonymous, professional, remote)

All 4 CER questions had merit, but require tweaking / revision by an expert workgroup:

- What is the comparative effectiveness of screening and BIs of a universal/general adolescent population and a targeted approach focused on at-risk youth (i.e. with comorbidities such as other substance use or mental health disorders)? Studies should be sufficiently powered to allow for key adolescent subpopulations, e.g. younger vs. older adolescents; racial and ethnic minorities, adolescents who self-identify as heterosexual vs. those who self-identify as LGBTQ.
- What is the comparative effectiveness of screening and BIs in different settings (primary care settings, schools, sexual health clinics, adolescent mental health services)? While BIs for adolescent alcohol abuse have been shown to be effective in a variety of settings in a number of separate studies, the comparative effectiveness of different settings has not been established for adolescents and for subgroups of adolescents.
- What is the comparative effectiveness of using different personnel to screen and deliver BIs, i.e., medical doctors, nurses, other outpatient clinicians, mental health professionals, school-based practitioners? As noted in a recent meta-analysis, many studies fail to report or analyze the backgrounds of the personnel delivering these types of interventions and no studies have compared the effectiveness of different types of personnel.
- What is the comparative effectiveness of on-site face-to-face, on-site computer-delivered, and remote electronically delivered BI for different subgroups of adolescents? Face-to-face as well as EBIs have shown positive effects in adolescents. However, no studies have examined these different delivery modes directly, or have evaluated their effects in different subgroups of adolescents (e.g. different age groups, boys vs girls, racial and ethnic minorities).



Key Stakeholders for Follow-Up

- Patients and families affected by this issue should be providing input on the outcomes to ensure that they're truly patient-centered
- Law Enforcement / Legal system
- National Education Association (NEA)
- Universities / National Greek organizations / Sport Organizations
- Guidance Counselors
- School Nurses
- Suicide Prevention Hotline
- Indian Health Service
- Mothers Against Drunk Driving
- Alcoholics Anonymous
- Religious Organizations / Support Groups
- National Institute on Drug Abuse – A potential partnership
- Social Workers
- Alcohol Beverage Standards
- Trauma Organizations
- Payers – Ensure incentives in place to promote screening



Topic: Adolescent Alcohol Abuse Break-Out Discussion

Stakeholder Group: Payers, Administrators, and Other Industry

November 10, 2015

PCORI Focus: Is this topic well suited for PCORI to fund?

- Seems generally well-suited for PCORI to fund
- Setting and responsibility is unclear (i.e., natural environment or a more medicalized approach?)
 - Medical model doesn't seem impactful to date – e.g. low usage of well child visits
- Cross-setting implantation an issue – high-quality school-based clinics are very uncommon, meaning studies with this focus would not be reproducible
- Topic should go beyond alcohol – include narcotics, etc.
- Lack of long-term follow-up both in existing literature and topic as defined
- Different developmental stages are very different populations – studies must define specific, narrow age ranges



Populations/subpopulations: What specific group(s) of people should be studied?

- Different developmental stages need to be specified
- Occasional binge drinkers and/or alcohol use disorders
 - Not sure that experimental drinkers are a worthwhile target population
- Alcohol users vs. other drug users
 - Studies should either be broadly inclusive or smart about how alcohol users may differ from other substance users
- Rural vs. urban



Interventions/comparators: What choices or options should be compared?

- Medical vs. nonmedical approaches
 - School vs. broader community interventions
- Brief vs. sustained follow-up
- Anonymous (computerized) or privacy protected interventions vs. ones which notify or involve family/guardians/caregivers
- Prevention strategies vs. SBIRT



Potential Research Questions

- What is the comparative effectiveness of screening and BIs in different settings (primary care settings, schools, sexual health clinics, adolescent mental health services) or linking settings to reduce problem drinking and subsequent traumatic incidents in adolescents?
 - Secondary outcomes: progression to other substances, sexual outcomes and unintended pregnancies
- What is the comparative effectiveness of screening and BIs of a universal/general adolescent population and a targeted approach focused on at-risk youth (i.e. with comorbidities such as other substance use or mental health disorders) to reduce problem drinking and subsequent traumatic incidents in adolescents?
- What is the comparative effectiveness of brief interventions to more sustained interventions (and who sustains the intervention) to reduce problem drinking and subsequent traumatic incidents in adolescents?



Key Stakeholders for Follow-Up

- Adolescents
- Addiction/use specialists
- Educators, education policymakers
- Community leadership, local public health depts.
- Parents
- Law enforcement community
- Social media entrepreneurs





Reprioritization of all Topics and Break

11:50 a.m. – 12:10 p.m.

Summary of Overall Importance and Ranking

“Prioritize the 4 topics from 1 – 4 with 1 being the highest priority and 4 being lowest priority for PCORI to pursue.”

Topic	Score*	Overall Rank
Prevention and Treatment of Adolescents with Alcohol Abuse Issues	51	1
Improving Quality of Life for Individuals with Dementia	43	2
Discharge from Short-Term Skilled Nursing Facility	39	3
Interventions to Address Antimicrobial Drug Resistance	27	4

*Score is a weighted calculation. Items ranked first are valued higher than the following ranks, the score is the sum of all weighted rank counts.

Adolescent Alcohol Abuse Scores

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	0 0.0%	1 6.3%	1 6.3%	4 25.0%	10 62.5%	16
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	1 6.3%	0 0.0%	4 25.0%	4 25.0%	7 43.8%	16
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	0 0.0%	0 0.0%	5 33.3%	4 26.7%	6 40.0%	15
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	0 0.0%	1 6.7%	1 6.7%	9 60.0%	4 26.7%	15
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	0 0.0%	1 6.7%	2 13.3%	6 40.0%	6 40.0%	15
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	0 0.0%	0 0.0%	3 18.8%	1 6.3%	12 75.0%	16

Dementia Management Scores

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	0 0.0%	1 6.3%	0 0.0%	6 37.5%	9 56.3%	16
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	0 0.0%	2 12.5%	2 12.5%	8 50.0%	4 25.0%	16
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	0 0.0%	2 12.5%	6 37.5%	6 37.5%	2 12.5%	16
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	0 0.0%	2 13.3%	3 20.0%	6 40.0%	4 26.7%	15
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	0 0.0%	1 6.7%	2 13.3%	10 66.7%	2 13.3%	15
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	1 6.3%	1 6.3%	3 18.8%	8 50.0%	3 18.8%	16

Skilled Nursing Facility (SNF) Transitions

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	0 0.0%	0 0.0%	0 0.0%	9 56.3%	7 43.8%	16
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	0 0.0%	1 6.3%	1 6.3%	11 68.8%	3 18.8%	16
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	1 6.7%	2 13.3%	4 26.7%	6 40.0%	2 13.3%	15
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	0 0.0%	2 12.5%	7 43.8%	3 18.8%	4 25.0%	16
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	0 0.0%	1 6.3%	5 31.3%	8 50.0%	2 12.5%	16
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	0 0.0%	2 12.5%	3 18.8%	11 68.8%	0 0.0%	16

Antimicrobial Resistance Scores (n=16)

	1 (Strongly Disagree)	2 (Somewhat Disagree)	3 (Neither Agree nor Disagree)	4 (Somewhat Agree)	5 (Strongly Agree)	Responses
Patient-Centeredness: Patients are likely to think evidence generated from the research question is relevant them and their ability to make more informed decisions about their health care.	3 18.8%	6 37.5%	2 12.5%	4 25.0%	1 6.3%	16
Impact on Health and Populations: Studies of this topic are likely to have a significant impact on the health of populations (in terms of prevalence, mortality, morbidity, individual suffering, and loss of productivity) and are likely to improve healthcare systems issues such as access to care, quality of care, and engagement in care.	1 6.3%	2 12.5%	4 25.0%	7 43.8%	2 12.5%	16
Assessment of Current Options: Research on this topic will address an important gap in the information available to patients and their caregivers, providers, and other key stakeholders.	2 12.5%	9 56.3%	4 25.0%	0 0.0%	1 6.3%	16
Likelihood of Implementation: Results from research on this topic have the potential to lead to meaningful improvement in the quality and efficiency of care.	2 12.5%	4 25.0%	2 12.5%	7 43.8%	1 6.3%	16
Sustainability of Results: New information on this topic is likely to remain current for several years. It is not likely to be rendered obsolete by new technologies or subsequent studies.	3 18.8%	3 18.8%	6 37.5%	3 18.8%	1 6.3%	16
Overall Importance of the Topic for PCORI: Research on this topic is well-suited for CER and PCORI funding overall.	4 25.0%	10 62.5%	1 6.3%	0 0.0%	1 6.3%	16

Concluding Remarks

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems



Adjourn

Thank you for your participation!



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