Advisory Panel on Communication and Dissemination Research

April 21, 2017
8:00 AM to 5:00 PM ET
Welcome and Introduction

Lauren McCormack, PhD, MSPH
Communication and Dissemination Research Panel Chair

Danny van Leeuwen, MPH, RN, CPHQ
Communication and Dissemination Research Panel Co-Chair

Michelle Henton, MA
Program Associate, Clinical Effectiveness and Decision Science, Patient-Centered Outcomes Research Institute
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 or by emailing advisorypanels@pcori.org
• Visit www.pcori.org/events for more information
• Chair Statement on COI and Confidentiality
Agenda

8:00 AM – Welcome, Review of Agenda, and Fall Meeting Recap
8:45 AM – PCORI Updates
9:15 AM – Update on Framework for CDR
10:15 AM – BREAK
10:45 AM – Review of CDR portfolio – Presentations by Awardees
12:00 PM – LUNCH
1:00 PM – Communicating Uncertainty of Evidence – Panel discussion
2:15 PM – BREAK
2:30 PM – Continuation of CDR portfolio discussion – What’s missing in CDR?
3:30 PM – Dissemination and Translation of Research
4:30 PM – Wrap-up and Next Steps
5:00 PM – Adjourn
Introductions

• Name
• Employer / Organization
• Quick highlight about your work that is CDR related
Review of Fall 2016 Panel

CDR program update
- Changes to broad PFA – including hybrid designs
- Involvement in targeted PFAs (tPFAs)

Communication and dissemination channels – Reaching people at the center of care
- Presentations from four speakers

Terms and definitions commonly used in CDR
- Lack of consensus on terms; terms are not interchangeable

Dissemination Opportunities at PCORI
- Joint session with the PEAP

Framework discussion
- Discussed next steps of revised framework
CDR Program and PCORI Updates

Bill Lawrence, MD
Associate Director, Clinical Effectiveness and Decision Science, Patient-Centered Outcomes Research Institute

Jean Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer
Patient-Centered Outcomes Research Institute
Program Update

New to the team:
Amanda Barbeau, Program Associate

Merging within Science:
Clinical Effectiveness and Decision Science (CEDS) includes the following programs
• Assessment of Prevention, Diagnosis, and Treatment Options
• Communication and Dissemination Research
• Improving Methods for Conducting PCOR

Healthcare Delivery and Disparities Research (HDDR) includes the following programs:
• Addressing Disparities
• Improving Healthcare Systems

This merge does not change the five national priorities and their respective funding announcements
Program Update

CDR Broad PFA announcement: Cycle 1 2017 and Cycle 3 2017

PCORI seeks to fund projects that address critical knowledge gaps in the communication and dissemination process—both the communication and dissemination of research results to patients, their caregivers, and clinicians, and the communication between patients, caregivers, and clinicians—in the service of enabling patients and caregivers to make the best-possible decisions in choosing among available options for care and treatment.

**Funds Available:** $8 million

**Maximum Project Budget (Total Direct Costs):** $1.5 million

**Maximum Research Project Period:** Three years

The CDR PFA for Cycle 1 2017 can be found on the PCOR website under Funding Opportunities

Cycle 3 2017 will open October 3
Program Update

Inclusion of CDR priority research question in two targeted PFAs (tPFA) for Cycle 3 2016

• Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain
  o What is the comparative effectiveness of different patient- and provider-facing interventions that facilitate improved knowledge, communication, and shared decision making about the relative harms and benefits of opioids and alternative treatments on prevention of unsafe prescribing and improved patient outcomes?

• Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers
  o Advance Care Planning: What is the comparative effectiveness of different patient and caregiver-directed, clinician-directed, and combination approaches to facilitating advance care planning conversations between adult patients living with advanced illnesses, their caregivers, and clinicians on patient-centered and other outcomes over time?
  o Community-Based Models of Palliative Care: What is the comparative effectiveness of different established models of palliative care in community settings on improving patient-centered and other outcomes among adult patients with advanced illnesses and their caregivers?
Program Update

Involvement in professional meetings:

• PCORI’s Second Annual Meeting – Changing the Conversation about Health Research – November 17-19, 2016
  o Breakout Session: Golden Years and Easing Fears: Complex Medical Decision Making among Older Adults

• Society for Medical Decision Making 38th Annual North American Meeting – October 23 – October 26, Vancouver, BC

PCORI Updates
Update on Framework for Communication and Dissemination Research

Lauren McCormack, PhD, MSPH
Communication and Dissemination Research Panel Chair

Bridget Gaglio, PhD, MPH
Senior Program Officer, Clinical Effectiveness and Decision Science, Patient-Centered Outcomes Research Institute
Purpose of the Article

• Introduce the framework and explain how it was generated
• Describe the framework’s key concepts and constructs while defining terminology
  – To reduce confusion about the field itself
  – To highlight the goals of the PCORI CDR funding mechanism
• Provide examples for how the framework could be used to guide future research, contribute to CER, and help stakeholders in the process make decisions about care
Contents of the Article

- Introduction – context of the PCORI CDR portfolio
- Methods – original literature review supplemented by updated review, advisory panel collaboration process
- Results
  - Framework visual
  - Communication & dissemination strategies
  - Outcomes
- CDR funding mechanism
- Application of the framework in the future
Next Steps and Discussion

Overall content

- Better integration of the framework into the text of the paper

Making the article more accessible in terms of reading level

- We are trying to find a happy medium in that we want all of PCORI’s audience to understand the paper but at the same time not be out of bounds with the expectations of the scientific journal

Name of the framework

Any additional feedback
Break
10:15 AM to 10:45 AM
Review of Communication and Dissemination Research Portfolio – Presentations by Awardees

Rachel Thompson, PhD, BPsySc – Dartmouth College
*The Comparative Effectiveness of Patient- and Provider-Directed Strategies for Increasing Shared Decision –Making in Reproductive Health Care*

Peter Schwartz, MD, PhD – Indiana University
*Describing the Comparative Effectiveness of Colorectal Cancer Screening Tests: The Impact of Quantitative Information*

Rebecca Smith-Bindman, BS, MD – University of California San Francisco
*UCSF CT Radiation Dose Registry to Ensure a Patient-Centered Approach for Imaging*
Research reported in this presentation was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CDR-1403-12221).

The views in this presentation are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.
Right For Me Team

Scientists, patient partners, and other stakeholders meaningfully engaged in all stages of the research
Objective

To assess the comparative effectiveness of patient- and provider-targeted interventions for facilitating shared decision-making about contraceptive methods
Video + Prompt Card

• Patient-targeted

• Two components:
  • brief video
  • small prompt card

• Delivered in the clinic immediately before the health care visit
Video + Prompt Card

Try asking these questions today
What are my options?
What are the possible pros and cons of those options?
How likely are each of those pros and cons to happen to me?

Trate de hacer estas preguntas hoy
¿Qué opciones tengo?
¿Cuáles son las posibles ventajas y desventajas de esas opciones?
¿Qué probabilidades tengo yo de tener esas ventajas o desventajas?
Decision Aids + Training

• Provider-targeted
• Three components:
  • encounter decision aids
  • brief training video
  • written guidance
• Training video and written guidance provided prior to decision aid use
• Decision aids to be used with patients
## Decision Aids + Training

### Types of Birth Control Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Effective Duration</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Contraceptives</td>
<td>Pills, patches, implants, injections</td>
<td>1 week - 1 year</td>
<td>Side effects, usage instructions</td>
</tr>
<tr>
<td>Intrauterine Device (IUD)</td>
<td>Small device placed in the uterus</td>
<td>3-10 years</td>
<td>Pregnancy protection, long-term use</td>
</tr>
<tr>
<td>Condoms</td>
<td>Rubber sheath on the penis</td>
<td>1 use</td>
<td>Protection against sexually transmitted infections</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>Rubber dome placed on the cervix</td>
<td>1 use</td>
<td>Proper fit and usage instructions</td>
</tr>
<tr>
<td>Vaginal Ring</td>
<td>Small plastic ring inserted into the vagina</td>
<td>1 week</td>
<td>Side effects, usage instructions</td>
</tr>
</tbody>
</table>

### Other Contraception Options

- Emergency Contraception
- Spacers
- Breastfeeding

### Training Video

![Training Video](image)

**Explain it**

Decision Aids
Design + Setting

2x2 factorial cluster randomised controlled trial with four arms:

(1) video + prompt card
(2) decision aids + training
(3) video + prompt card and decision aids + training
(4) usual care

16 primary care and/or reproductive health care clinics in the Northeast United States
Participants

People who:

• have completed a health care visit
• were assigned female sex at birth
• are aged 15 to 49 years
• are able to read and write English or Spanish
• have not previously participated in the study
Primary outcome is shared decision-making about contraceptive methods in the health care visit.

Secondary outcomes include contraceptive utilization, adherence, decision regret, unintended pregnancy.

Data collected by three patient surveys:
- immediately after the health care visit
- four weeks after the health care visit
- six months after the health care visit
Progress

- Recruitment complete
- 3,335 eligible participants enrolled

Video + Prompt Card  
$n = 875$

Decision Aids + Training  
$n = 671$

Video + Prompt Card & Decision Aids + Training  
$n = 945$

Usual Care  
$n = 844$

- Follow-up data collection in progress
- Interviews with clinic staff in progress
- Project completion by December 2017
Lessons Learned

• Genuine engagement of patients and stakeholders requires time, resources, and new ways of working (but is worth it!)

• Partnering with ‘real world’ clinics enhances the ecological validity of findings but necessitates support and oversight from research team

• Significant interest in the topic of shared decision-making among multiple stakeholder groups provides ideal conditions for dissemination and implementation of findings
Learn More

www.rightforme.org

@rightformestudy

rightforme@dartmouth.edu

rachel.thompson@dartmouth.edu
Describing the Comparative Effectiveness of Colorectal Cancer Screening Tests: The Impact of Quantitative Information

PCORI Communication and Dissemination Research Advisory Panel Meeting
April 21, 2017

Peter H. Schwartz MD, PhD
Indiana University Center for Bioethics
Indiana University School of Medicine
Philosophy Department, IUPUI
Colorectal cancer

- Second largest cancer killer in United States
- Screening recommended for all people 50-75 years old.
- Uptake approximately 65%
- Goal of increasing uptake to 80% by 2018
- Widespread lack of understanding and informed decision making by eligible individuals.
Colorectal cancer screening

American Cancer Society, United States Preventive Services Task Force, and others approve multiple screening tests:

- Colonoscopy performed every 10 years
- Flexible sigmoidoscopy every 5 years *
- CT colonography ("virtual colonoscopy") every 5 years *
- Stool DNA test (e.g. Cologuard) every 1 or 3 years *
- Stool blood test (e.g. Fecal Immunochemical Test (FIT)) every 1 year *

* positive findings require follow-up with colonoscopy
Pros and Cons of Tests

- Colonoscopy: Most sensitive and specific, but most invasive, uncomfortable prep, expensive, and risks of its own.

- Stool blood test (FIT): Noninvasive and done at home, but can miss polyps and cancers, must be done annually, and may need follow-up colonoscopy.
Patient Decision Making

• Two decisions to make:
  ➢ Whether to be screened: follow recommendation or not
  ➢ Which test to undergo: preference-sensitive

• Seven decision aids tested in randomized trials (see Cochrane Review, Stacey et al. 2014).

• Three decision aids led to increased uptake.
Designing Decision Aids

• How to educate patients about the benefits of screening, potential harms of screening, tradeoffs among the tests?

• International Patient Decisions Aids Standards (IPDAS) (2006, 2012) recommend that decision aids regarding screening tests disclose quantitative information (natural frequencies, icon charts) regarding:
  ➢ Baseline risk
  ➢ Absolute risk reduction
  ➢ Probability of false positives and negatives
  ➢ Probability of other negative outcomes

• Similar recommendations by National Quality Forum (2016)
Presenting Quantitative Information

• Rationale: Informed choices, ethics
• Concerns:
  ➢ Widespread innumeracy
  ➢ Heuristics, biases, gist
• No studies that compared a decision aid that includes quantitative information of the sort recommended by IPDAS and others to a decision aid that is similar but does not have such quantitative information.
• Pilot research
• Patient advisory board
Our study

Aim #1: To compare screening intention, screening behavior, and perceptions of patients eligible for CRC screening who view a decision aid (DA) that includes quantitative information versus a DA without such data.

Aim #2: To determine whether numeracy moderates the effect of quantitative information

- Randomized, controlled trial of 720 patients drawn from primary-care clinics in Indianapolis, IN
- Pre- and Post-intervention questionnaire (T0, T1)
- Six-month follow up interview and check of electronic health record (T2)
- Completed enrollment in Nov. 2016
Our study

Aim #3: To develop recommendations through the use of public deliberation regarding how comparative effectiveness data should be provided to patients considering CRC screening.

- Public deliberation exercise conducted over four days involving a diverse sample of 32 individuals from Central Indiana
- General description of this method and rationale for our project
- To be held: May 6-7 and May 20-21, 2017
What led me to this area of work?

- MD, PhD in Philosophy (University of Pennsylvania, 1999)
- Practicing general internal medicine
- Patient responses to quantitative information about preventive measures (e.g. prostate cancer screening)
- Ethics debate:
  - Carl Schneider (1999), *The Practice of Autonomy*
  - Onora O’Neill (2002), *Autonomy and Trust in Bioethics*
- Why decision aids are especially important
- Why colorectal cancer screening
Gaps in CDR research

• Comparing decision aids
• Danger of assuming that more extensive or complex decision aids are better
• Other features of decision aids: e.g. values clarification
• Personalized medicine
Acknowledgments

• Primary mentors/ collaborators: Eric Meslin, Greg Sachs, Tom Imperiale, Susan Perkins, Susan Rawl
• Research team: Karen Schmidt, Paul Muriello, Sandy Althouse, Stan Taylor, Wendy Forrest
• Additional collaborators: Brian Zikmund-Fisher, Tony and Dena Cox, Michael Burgess, Kieran O’Doherty
• Funding:
  ➢ Richard M. Fairbanks Foundation,
  ➢ American Cancer Society – Cancer Control Career Development Award for Primary Care Physicians,
  ➢ Indiana University Health Values Program,
  ➢ Patient Centered Outcomes Research Institute.
UCSF CT Radiation Dose Registry

to Ensure a Patient-Centered Approach for Imaging

CDR Advisory Panel Presentation

Rebecca Smith-Bindman, MD
Professor, Radiology and Biomedical Imaging,
Epidemiology and Biostatistics
Philip R. Lee Institute for Health Policy
Director of the Radiology Outcomes Research Lab
The University of California San Francisco
The use of CT has risen dramatically last 20 years

Radiation doses for CT are higher than widely reported, and in the range where they will cause cancer in small but significant number of patients

Doses are highly variable across institutions, and higher than needed

While higher dose can lead to more detailed images, there is no evidence that these lead to more accurate diagnosis

Variation in dose reflects practice preferences, not evidence

Systematic strategies are needed to standardize practice

Why Are Doses so Variable?

- No comprehensive standards or guidelines for CT – few agreed upon definitions.
- No organization responsible for reporting dose data
- Technologists receive no consistent education
- Doses should be as low as reasonably achievable – ALARA - but there are few guidelines for what is reasonable or achievable
- In the absence of explicit guidelines, practice variation introduces unnecessary harm from excessive radiation
UCDOSE
University of Calif. Dose Optimization and Standardization Endeavor

- Collaboration across 5 UC Medical Centers
- Medical physicists, radiologists, technologists, biostatisticians
- Primary goals were to create a collaborative working group, pool data, use these data to describe and improve practice.
- We were able to successfully collect CT data from across the 5 institutions, pool radiation dose data, use these data to create standards, and optimize doses across campuses
Develop, implement and disseminate strategies to standardize and optimize the doses used for CT across a large number of institutions to improve patient safety. Basically to scale-up our UCDOSE work

- Collect detailed data from diverse institutions
- Use data to assess practice
- Develop metrics that would be useful in community setting
- Create benchmarks (what is the right dose)
- Develop and test interventions to improve dose
- To study organizational factors associated with optimizing dose
- Work with a large number of diverse stakeholders
Engage leaders from diverse institutions

Work out the logistics of collecting and assembling a large amount of data from diverse institutions, given different rules, regulations and frameworks (US and non-US)

Obtain IRB approvals (and modifications) 25 organizations

Since our goal was to improve practice, we needed to engage not only a site champion, but others from the institution who could implement changes (technologists, physicists, radiologists)

We wanted to understand facility specific environments and this meant surveying many individuals
Out goal was to reach diverse institutions and therefore we looked beyond academic institutions.

While finding interested institutions was not difficult, bringing them onto the project was logistically very difficult— from setting up mechanisms to transfers data, to getting approval (i.e. who had to sign off on project, etc).

Getting IRB approval was difficult, in part because of the number of institutions, and their lack of experience, and partly because our project fell in the grey area between quality improvement and research. 

*Example:* was asking technologists about their CT experience research? was asking administrators about processes research?

The data we have collected are far less ‘clean’ than we had anticipated.
Collaborating Institutions > 120

- UCSF
- UC Davis
- UC Irving
- UC San Diego
- Health Partners Institute
- University of Duisburg-Essen
- Oxford University Hospitals NHS
- University Hospital of Basel
- Maastricht University Med Center
- St. Luke's Hospital, Tokyo
- Assuta Health, Israel
- Center for Diagnostic Imaging
- San Francisco Veterans Affairs
- City of Hope
- Henry Ford Health System
- St. Joseph Health System
- Mount Sinai School of Medicine
- Miami Children's Hospital
- Emory Health System
- University of Virginia
- Children's Mercy Hospitals
- Huntsville Hospital System
- Olive View - UCLA
- Einstein Healthcare Network
- Community Health Network
- Maricopa Integrated Health
- East Texas Health Centers
Overview of Some of Our Successes

- We created a CT dose registry where data flow daily on 4,000 CTs.
- We have collected nearly 4 million CT scans and are in the process of writing up the results describing these data and analysis.
- Many individuals have been surveyed at each institution: we have learned about factors that are associated with CT quality.
- Each of the facilities received detailed audit feedback on their doses and we are trying to understand the impact on dose.
- We convened in-person meetings which were well attended and we hope will enhance the impact of our intervention.
What Accounts For Variation in Dose

- We have looked at the variation in doses within specific categories, such as suspected pulmonary embolism.
- Variation by patient characteristics – such as body circumference is a relatively small contributor to differences.
- Variation by manufacturer and machine make and model is real, but also relatively small.
- Variation by how machines are used, the specific settings, is highly associated with country and is very strongly associated with dose.
Results preliminary, but the following are associated with dose:

- Reporting measurements of unit performance in comparison with peers is most important factor.
- Doing any patient safety activities improves dose.
- Using standardized processes that make it easy to optimize dose.
- Organizing people into teams focused on improving dose.
- Setting specific goals for improving radiation dose.

We have assessed the association between institutional factors and improvement but this is the biggest gap.
The PCORI funded project has ended

We are using the small amount of funding to analyze the data

The project turned out to be far more logistically complex than anticipated – it’s hard to change practice in the community

I wish we had more time and resources to continue the analyses as there is a lot more to learn from the data

The research area will continue through a RCT funded by NIH
Lunch
12:00 PM to 1:00 PM
Communicating Uncertainty about Evidence

Danny van Leeuwen, MPH, RN, CPHQ

Communication and Dissemination Research Panel Co-Chair
Communicating Uncertainty of Evidence

• What challenges have you experienced in your life or your work when speaking, hearing, writing, or thinking about the uncertainty of evidence?

• How do those challenges affect decisions you, your patients, or members of your health team make?

• How do those decisions affect the relationships between you and your patients or members of your health team?

• What research might mitigate any of those challenges?
Break
2:15 PM to 2:30 PM
Continuation of Review of Communication and Dissemination Research Portfolio – What’s Missing in Communication and Dissemination Research?

Bridget Gaglio, PhD, MPH
Senior Program Officer, Clinical Effectiveness and Decision Science, Patient-Centered Outcomes Research Institute

Lauren McCormack, PhD, MSPH
Communication and Dissemination Research Panel Chair
CDR Program to date

Cycles – Cycle 1, 2017 is the 12th release

• Funds available – Up to $8 million per cycle; up to $1.5 million in direct costs
• The majority of our projects are 36 months in duration

AS OF CYCLE 1, 2016

• 45 awards $84,832,634 funds committed
• DFRRs submitted as of 1 March, 2017 = 2
High level overview of the CDR portfolio

Studies funded by area of emphasis

<table>
<thead>
<tr>
<th>Communication</th>
<th>Dissemination</th>
<th>Explaining Uncertainty</th>
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<tr>
<td>EU</td>
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Studies funded by health topic

<table>
<thead>
<tr>
<th>Main Health Topic</th>
<th>#</th>
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<tbody>
<tr>
<td>Cancer</td>
<td>9</td>
</tr>
<tr>
<td>Self-management chronic conditions</td>
<td>6</td>
</tr>
<tr>
<td>Mental health</td>
<td>5</td>
</tr>
<tr>
<td>Contraception/Reproductive Health</td>
<td>3</td>
</tr>
<tr>
<td>COPD / Asthma</td>
<td>3</td>
</tr>
<tr>
<td>Chronic kidney disease/ ESRD</td>
<td>2</td>
</tr>
<tr>
<td>Rare genetic disorders</td>
<td>2</td>
</tr>
<tr>
<td>Ventricular assist device</td>
<td>2</td>
</tr>
<tr>
<td>Surgical treatment</td>
<td>2</td>
</tr>
<tr>
<td>Opioids</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
</tr>
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</table>
CDR Portfolio -- gaps/priorities

- Laboratory versus real world studies (clinical or community based study)?
- What communication strategies (e.g., tailoring or targeting) or dissemination strategies/channels (paper, electronic, in person) are least studied?
- How important is it to look at the interactive or synergistic effect of communication & dissemination (e.g., tailoring plus electronic vs. targeting and in-person)
- To what extent should there be emphasis placed on risk communication including the presentation of quantitative information?
- Other issues, trends to consider: How important are values clarification, personalized on medicine, clinical practice variation, ethics, how should decision aids be designed?
- What outcomes are critical to study? What intervening variables (e.g., trust) should be prioritized when looking at the impact of strategies?
CDR Portfolio -- gaps/priorities

• Should the focus be on provider communication given differences in clinical practice? Should all studies have a patient and a provider component?
• Should the evidence be graded (high/med/low quality) when communicating uncertainty to patients/providers? Should certain methods be required when looking at evidence or guidelines based care? How should guidelines be used in CDR studies?
• Should we be focusing more on high-risk, underserved populations? Other populations?
• Focus on certain fields/topics (e.g., cancer, mental health)? Are certain policy level issues higher priority (like Know Your Dose.ucsf.edu)?
• How can we increase the quality of the research being done? How can we ensure that studies are implemented as proposed and completed successfully?
Dissemination and Translation of Research – Update from PCORI’s Dissemination & Implementation program and Translation Center

Joanna Siegel, SM, ScD
Director, Dissemination and Implementation, Patient-Centered Outcomes Research Institute
The D&I Program is charged with heightening awareness of the results of PCORI-funded research, and with advancing efforts to put these findings into practice to improve healthcare delivery and health outcomes.
Today

- Updates on our D&I Award Program
- Public Reporting Activities Updates
PCORI Dissemination and Implementation Awards (Limited Competition)

<table>
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<tr>
<th>Key Information</th>
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<tbody>
<tr>
<td><strong>Full Announcement:</strong> Dissemination and Implementation of PCORI-funded Patient-Centered Outcomes Research Results</td>
<td><strong>Purpose:</strong> Offer PCORI awardee teams an opportunity to propose <em>investigator-initiated</em> strategies for disseminating and implementing their research results.</td>
</tr>
<tr>
<td><strong>Eligibility:</strong> Current Awardee; draft final research report submitted</td>
<td><strong>Funding Level:</strong> $350,000 total direct costs. Greater budget levels may be considered with appropriate justification.</td>
</tr>
<tr>
<td><strong>Letters of Intent:</strong> Competitive</td>
<td><strong>Project Period:</strong> 2 years. Longer projects may be considered with appropriate justification.</td>
</tr>
<tr>
<td><strong>First Awards Announced:</strong> Dec 2016</td>
<td><strong>Funding Cycles Per Year:</strong> 3</td>
</tr>
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</table>
D&I Awards are designed to give PCORI awardee teams an opportunity to:

- Propose **investigator-initiated** strategies for disseminating and implementing findings from their PCORI-funded studies
- Undertake the **next step(s)** for making their research results more useful, actionable, and accessible to targeted end users
- Promote and facilitate the **effective and timely** use of research evidence in the real world
Important Considerations for D&I Projects

We fund projects that:

• disseminate/implement PCORI findings that have real potential to affect healthcare and health outcomes in the short or long term.

• disseminate/implement PCORI findings through active approaches to appropriate target populations.

• draw upon principles of effective implementation, as described in established dissemination and implementation models and frameworks.

• actively engage those required to accomplish the project successfully (patients, providers, representatives of the host delivery system, or others who are critical to the success of the proposed project).

• evaluate the success of the dissemination and implementation strategy.
Supported D&I Project Approaches

– **Develop and demonstrate approaches** for incorporating PCORI research results in specific decision-making settings.

– **Adapt** the content, format, or vehicle for delivering PCORI findings for different populations and/or across different settings.

– Take programs and products found effective to scale in diverse settings and populations.

– **De-implement** or reduce the use of interventions that are not evidence based, have been prematurely adopted, or are harmful or wasteful.
Activities we do not fund

We do not fund projects that propose to:

• **develop or validate a new tool** or system for patients or clinicians *unless* it has the primary purpose of disseminating or implementing evidence in the proposed project.

• translate or adapt a finding **without** actively disseminating or implementing it.

• focus on a **passive dissemination plan** (publications or presentations to heterogeneous audiences).

• focus on conducting **new research**. Activities to **evaluate** success of D&I efforts are not considered “new research” and are acceptable/required.

• disseminate/implement findings not associated with a PCORI-funded **comparative-effectiveness or methods study**.

*Note:* Applicants must submit the Draft final research report from their original PCORI study before the D&I award application deadline.
New Collaborations

- Projects involving collaboration to disseminate the results of eligible studies.
- Must involve the partnership of two or more PCORI-funded investigators partnering to disseminate the collective results of two or more eligible studies on a single/closely related condition, population, decision dilemma, or evidence gap.
- Use of Greater Than Budget/Time Request is encouraged for collaborative projects.
- Must have demonstrated support from PI of each PCORI study being disseminated.
To date

• 2 Projects Awarded December 2016
• 3 Projects Awarded March 2017

Next awards

– August 2017
– September 2017
Preventing Venous Thromboembolism (VTE) in Hospitalized Patients

**Original PCORI Study** tested a patient education intervention to prevent VTE in hospitalized patients.

- Real-time EMR alert notified a health educator immediately when a patient missed a dose of VTE prophylaxis.
- Health educator provided one-on-one, face-to-face education about risks of VTE and potential benefit from prophylaxis.

**PCORI Study Findings**

- The intervention led to a 57% reduction in non-administration (missed doses and refusals) of VTE prophylaxis across intervention floors ($p < .001$).

**PCORI Study Findings**

- AHRQ has called VTE prevention the number one strategy to improve patient safety in hospitals.
- Proper administration of VTE prophylaxis is associated with reduction in VTE risk.
- Omitting even a single dose of VTE prophylaxis is associated with an event.

_Elliott Haut, MD, Johns Hopkins University Baltimore, MD_

Dissemination & Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products, awarded December 2016
Preventing Venous Thromboembolism in Hospitalized Patients

Dissemination & Implementation Project: Preventing VTE: Engaging Patients to Reduce Preventable Harm from Missed/Refused Doses of VTE Prophylaxis

Aims
- Implement intervention in
  - all floors of a large teaching hospital (Johns Hopkins)
  - a medium-sized, community, non-teaching hospital (Howard County General)
- Examine effect of VTE prophylaxis for inpatients at both hospitals

If successful, this D&I project will result in
- Improved quality of patient-nurse communication about VTE and VTE prophylaxis.
- More informed patient decisions regarding the choice to take VTE prophylaxis.
- Decreased VTE events; decreased mortality and morbidity (heart attack, stroke, organ damage) associated with VTE events

Evaluation Plan
- Measuring rates of missed doses, patient refusal, and VTE events
- Will capture VTE rates in hospital and 30 days post-discharge through diagnosed VTE in 2 hospital EDs, readmissions, 38 outpatient clinics, and other sources.
Using Causal Inference Methods to Compare Treatment Strategies

Original PCORI Study tested use of advanced causal inference methods (G-methods) to compare dynamic treatment strategies over time using observational data sets.

• To see if these methods can be used when RCT data are not available.
• Investigators validated these methods by comparing results from analysis using Medicare claims data versus RCTs.

PCORI Study Findings

• Using causal inference methods, investigators were able to approximate RCT results both in terms of magnitude and direction of risk estimates.

To compare changing treatments using the plethora of existing data...new analytic approaches are necessary.

Conventional (traditional) statistical approaches are not well-equipped to deal with changing treatments and can provide inaccurate or spurious results.

Yi Zhang, PhD,
Medical Tech. and Practice Patterns Institute
Bethesda, MD

Dissemination & Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products, awarded December 2016
Dissemination & Implementation Project: Enhancing Dissemination and Implementation of Causal Inference Methods through Partnerships with a Large Health System

Aims

• Demonstrate use of advanced causal inference methods in 11 funded studies currently conducting CER using observational data. Studies funded by AHRQ, PCORI, NIH, VA, industry.

• Provide hands-on training in appropriate applications of these methods

• Communicate experience to trialists, methodologists, others in partnership with study teams.

If successful, this D&I project will result in

• Improved ability to use observational data to compare changing treatment strategies – particularly important when clinical trials are not feasible.

Evaluation Plan:

• Adoption and effective use of the methods within each partner site
**Advance Planning for Home Services for Seniors**

**Original PCORI Study** developed and tested a web-based tool (PlanYourLifespan) to educate seniors on health crises that often occur with age and connect them to home-based resources that can provide support.

**PCORI Study Findings**

Use of PlanYourLifespan led to improvements in

- Planning behavior scores (primary outcome; $p < 0.01$)
- Home services knowledge ($p < 0.01$)

Satisfaction scores were significantly higher for PlanYourLifespan users than for the control group.

- People with unmet health and home-based needs face increased rates of hospitalizations, re-hospitalizations, morbidities, and institutionalization.

*Lee Lindquist, MD, MPH, MBA, Northwestern University at Chicago, Chicago, IL*

*Dissemination & Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products, awarded March 2017*
Advance Planning Support to Keep Seniors in the Home

**Dissemination & Implementation Project:** Leveraging Patient Partner/Stakeholder Engagement to Implement PCOR - PlanYourLifespan.org

**Aims**
- Implement PlanYourLifespan through diverse community organizations: FirstVitals (Hawaii) and Pastors4PCOR (Chicago) using train-the-trainer approach.
- Training to be led by original study patient partners. New trainees will train 3-5 additional community members who will promote access in their communities.

**If successful, this D&I project will result in**
- Increased use of this popular tool
- Validation of this training approach for extending reach of PlanYourLifespan.

**Evaluation Plan:**
- Training outcomes including satisfaction with training, knowledge gained, trainings held, use of PlanYourLifespan
- Patient outcomes: impact on anxiety, stress, self-efficacy, planning behavior
- Investigators are pursuing research funding to test impact on other outcomes.
Original PCORI Study evaluated the feasibility, effectiveness, and satisfaction associated with telehealth care visits for patients with Parkinson Disease.

PCORI Study Findings

• Telehealth visits successfully delivered: 98% of study patients had 1 or more video house calls.

• Intervention group spent less time on appointments and more time interacting with a doctor (p<0.01).

• No significant differences in quality of life, quality of care, or caregiver strain for intervention group versus control.

• 95% of patients were “satisfied” or “very satisfied” with the care, convenience, comfort, and overall quality of the video house calls.

• Telehealth is growing rapidly; has the potential to improve access to care and reduce health care costs.

• Over 40% of Medicare beneficiaries with Parkinson Disease do not receive care from a neurologist within four years of diagnosis, increasing their risk for morbidity, loss of independence, and death.

Earl “Ray” Dorsey, MD, MBA
University of Rochester
Rochester, NY

Dissemination & Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products, awarded March 2017
A Virtual Care Model for Parkinson Disease Specialty Care

**Dissemination & Implementation Project:** Dissemination and implementation of a virtual care model for Parkinson disease and other chronic conditions

**Aims**

- Refine and expand the telehealth intervention to include multidisciplinary care and address comorbid conditions (anxiety, depression, dementia).
- Implement the revised model into a funded statewide telemedicine program that will provide care to 500+ individuals with Parkinson Disease.

**If successful, this D&I project will**

- Increase access to multidisciplinary care for individuals with Parkinson Disease.
- Assess effectiveness of telehealth program as a viable option for providing care for people with restricted access to in-person health care.

**Evaluation Plan:**

- In addition to patients reached, sites providing the service, and other measures of program implementation, will examine clinical outcomes, quality of life, caregiver burden, and other patient-centered outcomes.
Targeting Interventions to Prevent Diabetes to Patients at Higher Risk

Original PCORI Study assessed heterogeneity of treatment effect in clinical trials. Researchers analyzed individual patient data from 32 studies including the 2002 Diabetes Prevention Program Study.

PCORI Study Findings

- Baseline risk for developing diabetes varies dramatically. Some patients had a 1-2% risk of developing diabetes within 3 years; the risk was 90% for others.
- Low-risk patients showed little benefit from interventions (metformin; lifestyle modification) in the Diabetes Prevention Program Study.
- High-risk patients showed significant benefit from these interventions.

- Pre-diabetes affects approximately 86 million people in the US.
- For every patient screened for diabetes who’s identified as being diabetic, screening also identifies 3 patients with pre-diabetes.
- The main interventions for pre-diabetes are pharmacotherapy with metformin and an intensive lifestyle program.

David Kent, MD
Tufts Medical Center Inc.
Boston, MA

Dissemination & Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products, awarded March 2017
Dissemination & Implementation Project: Improving Diabetes Prevention with Benefit-Based Tailored Treatment: Disseminating Patient-Centered Estimates of Benefit

Aims

• Adapt and incorporate the prediction model based on the Diabetes Prevention Program Study into an EHR-based risk-prediction tool that clinicians can access at the point of care

• Partner with American Medical Group Association (AMGA) to launch the EHR tool in 50 clinic sites within two AMGA-member health care provider organizations.

If successful, this D&I project will:

• Help clinicians triage costly and potentially burdensome preventive interventions to patients with prediabetes based on their risk for developing diabetes, improving the appropriateness of care at all levels.

Evaluation Plan:

• Will assess use of the EHR-based tool, the rate clinicians preferentially refer prediabetic patients at high risk to Diabetes Prevention Program interventions, and patients’ acceptance/adherence to their prescribed interventions.
Meeting PCORI’s Public Reporting Mandate
Mandated Public Reporting of PCORI Research Findings

PCORI’s authorizing language and the processes adopted by the Board outline approach for releasing findings.

- Post to pcori.org within 90 days of PCORI’s acceptance of the draft final research report following peer review:
  - 500-word public abstract
  - 500-word professional abstract
- Link to results tables in ClinicalTrials.gov
- Summary of peer review process; reviewer comments
- Ancillary information: COIs, investigator identification

Assures full transparency in reporting results from all PCORI studies
Public and Professional Abstracts for Primary Research Results

• Templates for these abstracts completed December 2016.
  – Cognitive testing included patients/consumers, clinicians, and other PCORI stakeholders.

• Translation Center is preparing drafts of abstracts for the first submitted research findings.

• Abstracts will be finalized when peer review is complete.
Public Release of PCORI Research Findings

Public and Professional Results Abstracts

- Total DFRRs submitted to PCORI: 58
- DFRRs in peer review: 54
- FRRs accepted (peer review complete): 1
- Projects with abstracts posted: 0
- Projects with all products: 0
Posting Primary Study Results to PCORI.ORG

WHAT WAS THE RESEARCH ABOUT?
Researchers studied whether children who have been in the hospital with serious infections do better when they go home with antibiotics by mouth or by IV.

WHAT DID THE RESEARCH TEAM LEARN?
Both ways of delivering antibiotics work about the same at treating infection. Some children who had antibiotics by IV had problems with the IV equipment or the medicine. These children were more likely to come back to the emergency room or stay in the hospital again because of those problems. Children who took antibiotics by mouth had fewer problems than those who got antibiotics by IV.

HOW CAN THESE RESULTS HELP PEOPLE MAKE BETTER CHOICES?
When children have serious appendicitis, pneumonia, or bone infections, their families and doctors can use this information to decide which way to give antibiotics after the children leave the hospital.

If your child is in the hospital for serious appendicitis, pneumonia, or bone infections, talk with your doctor about treatment plans for when your child goes home. You may have a choice of antibiotics by mouth or IV.

WHO WAS IN THE STUDY?
Researchers looked at health records for more than 6,500 children and teens between the ages of 2 months and 18 years.

WHAT DID THE RESEARCH TEAM DO?
The researchers looked at the health records for children who had been in the hospital for serious appendicitis, pneumonia, or bone infections. The team looked at whether children got antibiotics by mouth or by IV. The team compared how often children’s infections got better and how often children had to go back to the hospital because of other problems.

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WHAT WERE THE LIMITS OF THE STUDY?
There are many types of oral and IV antibiotics. Not all hospitals use the same antibiotics to treat infections. Some antibiotics might work better than others. In the future, researchers could compare different types of antibiotics to see if one works better than others. They could find out how long children need to take antibiotics.

Patients might not have gone back to the hospital where they were treated the first time. Researchers may have missed health problems if children went back to a different hospital.

There are many types of oral and IV antibiotics. Not all hospitals use the same antibiotics to treat infections. Some antibiotics might work better than others. In the future, researchers could compare different types of antibiotics to see if one works better than others.
Other products in process

For Primary Findings:
• Downloadable versions of public abstract
• Spanish and audio versions of public abstract
• Summary of peer review comments
  – High-level summary of peer review comments on PCORI’s primary research results pages

For Pilot projects:
• Public and Technical versions

For Ongoing Research:
• Revised summaries of ongoing PCORI research on the website
Revising the Project Summaries

Improving consistency, comprehensibility, and accuracy of ongoing project summaries

**Project Summary**
- What is the research about?
- Who can this research help?
- What is the research doing?
- Research methods at a glance

- First revised summary posted last week -- Teaching CPR to Families of Heart Patients Before They Leave the Hospital; Benjamin Abella
Questions?
Wrap-up and Next Steps
Thank You!