

Comparative Effectiveness and Patient-Centered Outcomes Research:

Enhancing Uptake and Use by Patients,
Clinicians and Payers

January 26-27, 2017

DAY 1

Welcoming Remarks

Opening Comments

Conference Goals and Objectives

Eileen Cannon

Welcome

- On behalf of the PhRMA Foundation and AMCP, welcome.
- This invitational conference is the second held by the PhRMA Foundation on the topic of CER
 - 2014 Conference: “Curricular Advances for Patient-Center Comparative Effectiveness Research”

The Five Things to Know About the PhRMA Foundation:



50th

In 2016, the PhRMA Foundation celebrated its 50th anniversary, commemorating five decades of support for young scientists.



42

Each year, the PhRMA Foundation gives out 42 individual awards, totaling more than 2,300 awards in the last five decades.



\$3.5 Million

On average, the PhRMA Foundation provides \$3.5 million annually in awards to young scientists – \$83 million through the years. In 2016, \$3 million was provided to award recipients, including 39 new recipients.



8

The PhRMA Foundation's awards support scientists in eight different disciplines, including adherence improvement, clinical pharmacology, health outcomes, informatics, pharmaceuticals, comparative effectiveness research, pharmacology / toxicology and translational medicine and therapeutics.



300

Over the years, the PhRMA Foundation has supported scientists at more than 300 colleges and universities in 49 states, the District of Columbia and Puerto Rico.

Conference Organization

- Organizing committee:
 - Eileen Cannon (PhRMA Foundation)
 - Jean Gagnon (PhRMA Foundation)
 - Joe Vandigo (PhRMA)
 - Glen Schumock (U. Illinois)
 - Simon Pickard (U. Illinois)
 - Beth Devine (U. Washington)
 - Eleanor Perfetto (U. Maryland)
 - Soumi Saha (AMCP)

Welcoming Remarks

Opening Comments

Conference Goals and Objectives

Glen Schumock

Premise for the Conference

- Significant efforts/funding has been directed toward development of methods for CER/PCOR, in CER/PCOR researcher training, and in CER/PCOR studies.
- Today new CER/PCOR evidence is published frequently in major journals and elsewhere.
- Until recently less effort has been directed at the uptake and use of CER/PCOR, and there is a perceived gap here that some previous research has documented.

Conference Aims

1. Provide an overview of the existing landscape on strategies to enhance uptake and use of CER/PCOR by patients, clinicians, and payers.
2. Identify and discuss the needs and gaps in the uptake and use of CER/PCOR evidence by patients, clinicians, and payers.
3. Identify the best methods or approaches to enhance the uptake and use of CER/PCOR evidence by patients, clinicians, and payers.
4. Provide an opportunity for networking among attendees.
5. Develop a consensus document or other enduring material that provides benefit beyond the conference by providing a framework for recommendations and tools for training current and future users of CER-PCOR evidence.

Conference Agenda

1:15 PM – 2:15 PM **Registration**

2:00 PM – 2:05 PM **Welcome Remarks**

Eileen Cannon, President, PhRMA Foundation

2:05 PM – 2:15 PM **Opening Remarks**

Glen Schumock, PharmD, MBA, PhD, University of Illinois at Chicago

2:15 – 2:45 PM **A Look Back: The History of CER Education Programs and The Motivation for PhRMA Foundation Centers of Excellence**

Introduction: Glen Schumock, PharmD, MBA, PhD, University of Illinois at Chicago

Speaker:

- *Michael Murray, PharmD, MPH, Regenstrief Institute, Inc., Purdue University*
-

2:45 PM – 3:30 PM **How Has the Landscape Changed Since the Creation of the PhRMA Foundation Centers of Excellence in CER Education?**

Introduction: Glen Schumock, PharmD, MBA, PhD, University of Illinois at Chicago

Presenters:

- *Lou Garrison, PhD, University of Washington*
 - *Simon Pickard, PhD, University of Illinois at Chicago*
 - *Eleanor Perfetto, PhD, MS National Health Council and University of Maryland*
-

3:30 PM – 3:45 PM **Break**

Conference Agenda

3:45 PM – 4:45 PM CER/PCOR Related Overview and Update on Funding Programs

Introduction: Simon Pickard, PhD, University of Illinois at Chicago

Presenters:

- *Bill Lawrence, MD, MS, Patient-Centered Outcomes Research Institute*
- *Sharon Arnold, PhD, Agency for Healthcare Research and Quality*
- *Josephine Briggs, MD, NIH - National Center for Complementary and Integrative Health*

4:45 PM – 5:45 PM Stakeholder Perspectives: Identifying the Needs and Gaps in the Uptake and Use of CER/PCOR

Introduction: Eleanor Perfetto, PhD, MS, National Health Council and University of Maryland

Moderator: Scott Smith, PhD, Health and Human Services

Panelists:

- *Eleanor Perfetto, PhD, MS, National Health Council and University of Maryland*
- *Caleb Alexander, MD, MS, Johns Hopkins University*
- *Soumi Saha, PharmD, JD, Academy of Managed Care Pharmacy*
- *Murray Ross, PhD, Kaiser Permanente*
- *Julie C. Locklear, PharmD, MBA, EMD Serono*

5:45 PM – 6:30 PM Networking Reception in the Rotunda

6:30 PM – 8:15 PM Dinner and Keynote Address: The Future of CER/PCOR - Navigating Uncertainty

Introduction: Eleanor Perfetto, PhD, MS, National Health Council and University of Maryland

Keynote: Kavita Patel, MD, The Brookings Institution

Conference Agenda

7:30 AM – 8:00 AM	Continental Breakfast
8:00 AM – 9:00 AM	In Action: Dissemination and Uptake of CER/PCOR <i>Introduction: Glen Schumock, PharmD, MBA, PhD, University of Illinois at Chicago</i> <i>Speakers:</i> <ul style="list-style-type: none">- Elaine Morrato, DrPH, MPH, CPH, University of Colorado- Nilay Shah, PhD, Mayo Clinic
9:00 AM – 10:00 AM	Addressing barriers and strategies to enhance the use of CER/PCOR <i>- Moderator: Simon Pickard, PhD, University of Illinois at Chicago</i> A Look at Pre-Conference Survey Results <ul style="list-style-type: none">- Ernest Law, BScPharm, PharmD, University of Illinois at Chicago What We've Learned: Overview of NPC Work on Stakeholder Views and Addressing Barriers to Use <ul style="list-style-type: none">- Jennifer Graff, Pharm D, National Pharmaceutical Council Instructions for Small Group Discussions
10:00 AM – 10:15 AM	Break
10:15 AM – 11:30 AM	A Deeper Dive: Small Group Discussions
11:30 AM – 12:15 PM	Observations: Reports from Small Group Discussions and Overall Consensus <i>Moderator: Simon Pickard, PhD, University of Illinois at Chicago</i>

Conference Agenda

12:15 PM – 1:15 PM **Lunch and Presentation: A Learning Network - Improving the Dissemination of PCOR-Based Clinical Decision Support (with Lunch)**

Introduction: Eleanor Perfetto, PhD, MS, National Health Council and University of Maryland

Remarks: Barry Blumenfeld, MD, MS, RTI International | Division of eHealth, Quality and Analytics (eQUA)

1:15 PM – 2:45 PM **What Is the Future of CER and CER Education? How Will CER Be Integrated Into Practice?**

Introduction: Glen Schumock, PharmD, MBA, PhD, University of Illinois at Chicago

Presenters:

- *Diana Brixner, RPh, PhD, FAMCP, University of Utah & President-Elect, Academy of Managed Care Pharmacy (AMCP)*
- *Bill Galanter, MD, University of Illinois at Chicago*
- *Lou Garrison, PhD, University of Washington & President, International Society of Pharmacoeconomics and Outcomes Research (ISPOR)*

2:45 PM – 3:00 PM **Conference Summary and Next Steps?**

Glen Schumock, University of Illinois at Chicago

3:00 PM **Conference Adjourns**

Conference Materials

- Available at: <http://bit.ly/CERconference>
 - Pre-reading materials are available
 - In the future:
 - Speaker slides
 - Photos
 - Additional materials

History and Overview of Current Landscape on Strategies to Enhance Uptake and Use of CER/PCOR by Patients, Clinicians, and Payers

Part 1: History of CER Education Programs and Motivation for PhRMA Foundation Centers of Excellence

Mick Murray

Motivation for CER Education Program

- March 2009 PhRMA Foundation's Health Outcome Research Committee recommended a Center of Excellence for Comparative Effectiveness Research Education grant program and writing an RFP to develop CER curricula.
- Jean Gagnon and Eileen Cannon formed a workgroup to develop a model graduate education CER curriculum
 - 20 invited clinical effectiveness researchers (academics, health outcome researchers, government program officials, and others)
 - Daniel Mullins and Emily Reese from the University of Maryland conducted a literature review and administered a survey to workshop participants.
 - Cliff Goodman from Lewin was workgroup moderator.

CER Education Workgroup

- December 18, 2009, workgroup participants hear the survey results from Daniel Mullins and Emily Reese, and are provided guidance on curricular design by Robert Beardsley
- The group is divided into subgroups and asked to develop examples of CER curriculums
- After workgroup presentations Cliff Goodman motivates the invitees to develop a consensus CER curriculum
- At the end of the meeting the attendees suggest publishing their proposed considerations for a CER curriculum in a referred journal
- An article entitled “Curricular Considerations for Pharmaceutical Comparative Effectiveness Research” is written by workshop participants and published in *Pharmacoepidemiology and Drug Safety* (2011)

Related Manuscripts

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY (2011)
Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/pds.2100

COMMENTARY

Curricular considerations for pharmaceutical comparative effectiveness research

Michael D. Murray*

Purdue University College of Pharmacy and Regenstrief Institute, Indianapolis, USA

ABSTRACT

In the U.S., pharmacoepidemiology and related health professions can potentially flourish with the congressional appropriation of \$1.1 billion of federal funding for comparative effectiveness research (CER). A direct result of this legislation will be the need for sufficient numbers of trained scientists and decision-makers to address the research and implementation associated with CER. An interdisciplinary expert panel comprised mostly of professionals with pharmaceutical interests was convened to examine the knowledge, skills, and abilities to be considered in the development of a CER curriculum for the health professions focusing predominantly on pharmaceuticals. A limitation of the panel's composition was that it did not represent the breadth of comparative effectiveness research, which additionally includes devices, services, diagnostics, behavioral treatments, and delivery system changes. This bias affects the generalizability of these findings. Notwithstanding, important components of the curriculum identified by the panel included study design considerations and understanding the strengths and limitations of data sources. Important skills and abilities included methods for adjustment of differences in comparator group characteristics to control confounding and bias, data management skills, and clinical skills and insights into the relevance of comparisons. Most of the knowledge, skills, and abilities identified by the panel were consistent with the training of pharmacoepidemiologists. While comparative effectiveness is broader than the pharmaceutical sciences, pharmacoepidemiologists have much to offer academic and professional CER training programs. As such, pharmacoepidemiologists should have a central role in curricular design and provision of the necessary training for needed comparative effectiveness researchers within the realm of pharmaceutical sciences. Copyright © 2011 John Wiley & Sons, Ltd.

KEY WORDS — comparative effectiveness research; curriculum; training

Received 19 August 2010; Revised 9 December 2010; Accepted 13 December 2010

Preliminary Competencies for Comparative Effectiveness Research

Jodi B. Segal, M.D.¹, Wishwa Kapoor, M.D.², Timothy Carey, M.D.³, Pamela H. Mitchell, Ph.D.⁴, Michael D. Murray, PharmD⁵, Kenneth G. Saag, M.D.⁶, Glen Schumock, PharmD⁷, Daniel Jonas, M.D.⁸, Michael Steinman, M.D.⁹, Rosemarie Filart, M.D., M.P.H.¹⁰, Morris Weinberger, Ph.D.¹¹, and Harry Selker, M.D.¹²

Abstract

The Clinical and Translational Science Award (CTSA) Workgroup for Comparative Effectiveness Research (CER) Education, Training, and Workforce Development identified a need to delineate the competencies that practitioners and users of CER for patient-centered outcomes research, should acquire. With input from CTSA representatives and collaborators, we began by describing the workforce. We recognize the workforce that conducts CER and the end users who use CER to improve the health of individuals and communities. We generated a preliminary set of competencies and solicited feedback from the CER representatives at each member site of the CTSA consortium. We distinguished *applied* competencies (i.e., skills needed by individuals who conduct CER) from *foundational* competencies that are needed by the entire CER workforce, including end users of CER. Key competency categories of relevance to both practitioners and users of CER were: (1) asking relevant research questions; (2) recognizing or designing ideal CER studies; (3) executing or using CER studies; (4) using appropriate statistical analyses for CER; and (5) communicating and disseminating CER study results to improve health. Although CER is particularly broad concept, we anticipate that these preliminary, relatively generic competencies will be used in tailoring curricula to individual learners from a variety of programmatic perspectives. Clin Trans Sci 2012; Volume 5: 476–479

Keywords: comparative effectiveness research, competencies, work force

DOI: 10.1111/j.1752-8062.2012.00420.x

476 CTS VOLUME 5 • ISSUE 6

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Centers of Excellence for Comparative Effectiveness Research Education

- The CER Curriculum Initiative and Business Case for a PhRMA Foundation Center of Excellence for Comparative Effectiveness Research Education Program was written and submitted with the CER committee's draft curriculum to the Executive Director and Foundation's Board for approval
- The Board approved the program and a Request for Proposal for CER Education and Training Programs was released on May 23, 2011 with a July 31, 2011 deadline
- A CER Center Advisory Committee, chaired by Eileen Cannon, was formed to review and select awardees on October 10, 2011, October 22, 2012, October 16, 2013, and November 12, 2014
- Two applicants out of seven in 2012 received program awards; two out of five in 2013; one submission out of two in 2014; and one out of six in 2015.

Center Program Objectives

- Support the development of educational and training programs that clearly and efficiently teach students and practitioners how to conduct rigorous, useful, and effective CER.
- Act in a supportive role together with private and public partners to achieve the goal of producing high caliber comparative effectiveness researchers and practitioners who interpret and use research results.
- Furnish the necessary resources that can be used to develop corroborating evidence on the usefulness and value of sound CER.
- Convene public fora and seminars for interested members of the public from the wider university / college community to discuss topical CER issues.

Center Program Objectives

- Promote with other groups the development of a CER Curriculum that offers the appropriate discipline-specific educational skills, research methodology training, and case experience needed to produce highly desirable comparative effectiveness (CE) researchers and practitioners.
- Sponsor lectures and presentations on different programs and venues, e.g., AHRQ, NIH, industry, universities, and others that promote conscientious discussions on important CER topics.
- Work with representatives from government, industry and education to determine the number and types of CER trained experts needed to fill the personnel demands of these societal sectors.
- Make available to interested members of the public, by electronic publication or other easily accessible means, CER educational training tools developed with funding provided by the Foundation.

Reviewers

- Jean Paul Gagnon, PhD
 - Former Senior Director, Public Policy, Sanofi-Aventis
- Jesse A. Berlin, ScD
 - Vice President, Epidemiology, Johnson & Johnson
- Beth Devine, PharmD, MBA, Ph.D.
 - Associate Professor, Pharmaceutical Outcomes Research & Policy Program, University of Washington
- Daniel C. Malone, PhD
 - Professor, Pharmacy Practice and Science, University of Arizona

Reviewers

- C. Daniel Mullins, PhD
 - Professor and Chair, Pharmaceutical Health Services Research Department, University of Maryland
- Michael D. Murray, PharmD, MPH
 - Professor, Purdue University and Regenstrief Institute
- Nancy C. Santanello, MD, MS
 - Former Vice President of Epidemiology, Merck Research Laboratories

Review Criteria

- Qualifications of faculty members and mentors (20%)
- Facilities including experiential learning partners (25%)
- Curriculum/Plan of Study (15%)
- Prior faculty and school or college experience (10%)
- Dissemination strategy (10%)
- Process for internal evaluation (10%)
- Institutional support (10%)

Following AHRQ's review framework, each of the 7 criteria received a score from 1 (best) to 9 (worst).

Centers of Excellence for Comparative Effectiveness Research Education



**THE
UNIVERSITY OF
ILLINOIS
AT
CHICAGO**



Center of Excellence for Comparative Effectiveness Research Education Awardees

2012 –

1. Jodi Segal, MD, MPH, Johns Hopkins University
2. Lou Garrison, AB, PhD, Beth Devine, PharmD, MBA, PhD, and Anirban Basu, MS, PhD, University of Washington

2013 –

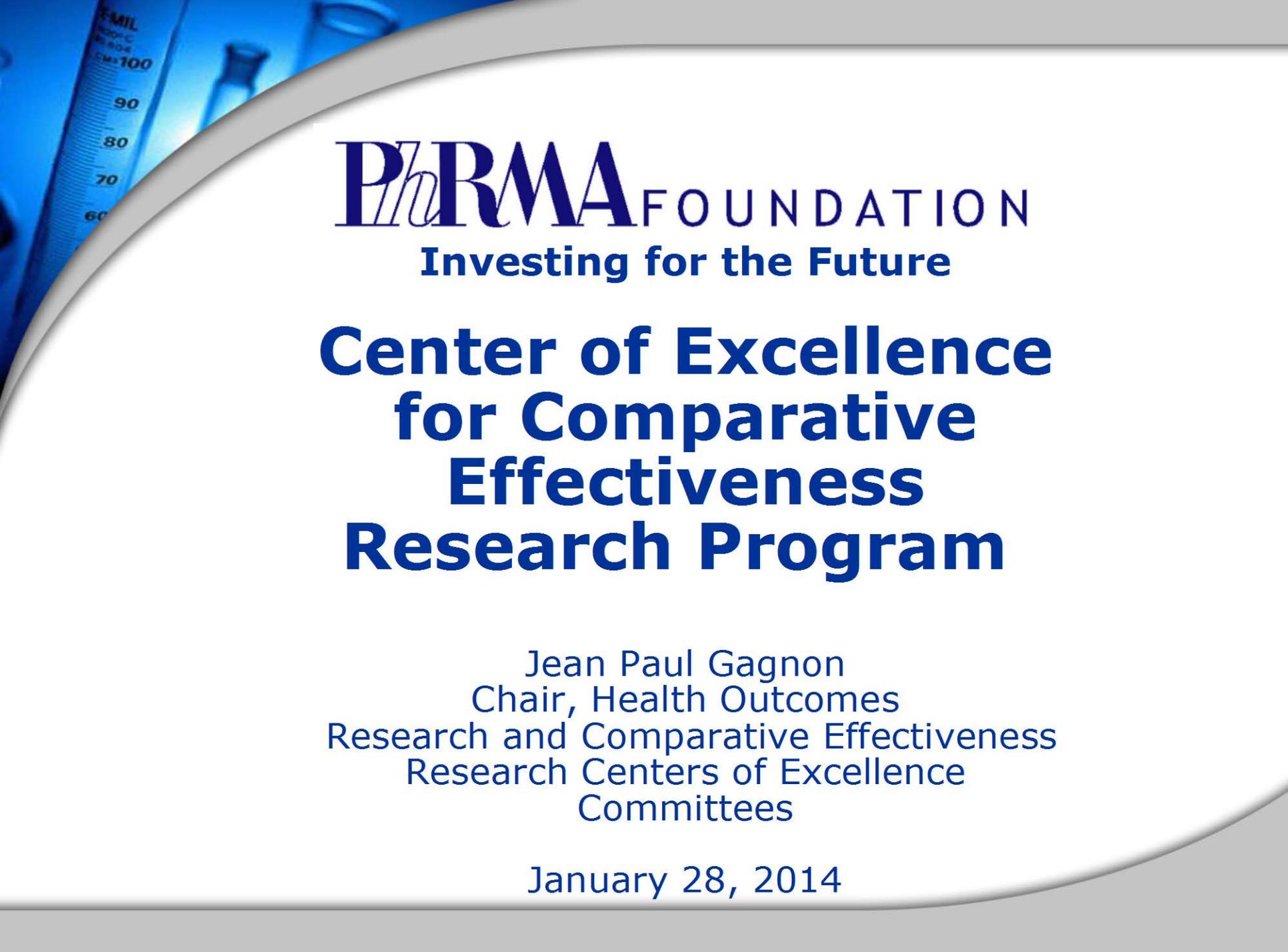
1. Sonia Hernandez-Diaz, MD, DrPH, FISPE, Harvard University
2. Michael G. Spigarelli, MD, PhD and Diana Brixner, RPh, PhD, University of Utah

2014 –

1. Eleanor M. Perfetto, MS, PhD, University of Maryland

2015 –

1. Glen Schumock, PharmD and A. Simon Pickard, PhD, University of Illinois Chicago



PhARMA FOUNDATION
Investing for the Future

**Center of Excellence
for Comparative
Effectiveness
Research Program**

Jean Paul Gagnon
Chair, Health Outcomes
Research and Comparative Effectiveness
Research Centers of Excellence
Committees

January 28, 2014

Previous Conference*

- Held January 28 and 29, 2014
- Objectives: to compare existing competencies, define the scope of CER/PCOR and academic approaches to training, and discuss the need for standardized competencies.
- The five centers reported
- Keynotes by Drs. Gail Wilensky and Mark McClellan.
- CER and PCOR involve team science with breadth of methodologic training and depth in one or more areas of expertise.
- Gaps in training included methods for patient engagement, dissemination and implementation, decision sciences, and use of big data.
- A follow up survey was conducted.

Survey Results*

Participants were asked what was used from the conference (n=43)

	Thinking about	In Development	Implemented	Respondents
New lecture	72.4%	17.2%	10.3%	29
New course	79.2%	16.7%	4.2%	24
New training program	59.1%	31.8%	9.1%	22
New format to course	73.7%	21.0%	5.3%	19
Multidisciplinary teaching of CER/PCOR	53.6%	39.3%	10.7%	28
Improvement to existing offerings	38.9%	44.4%	16.7%	36
New mentored experiences	60.0%	30.0%	13.3%	30

* From Jodi Segal, MD, MPH, May 2014

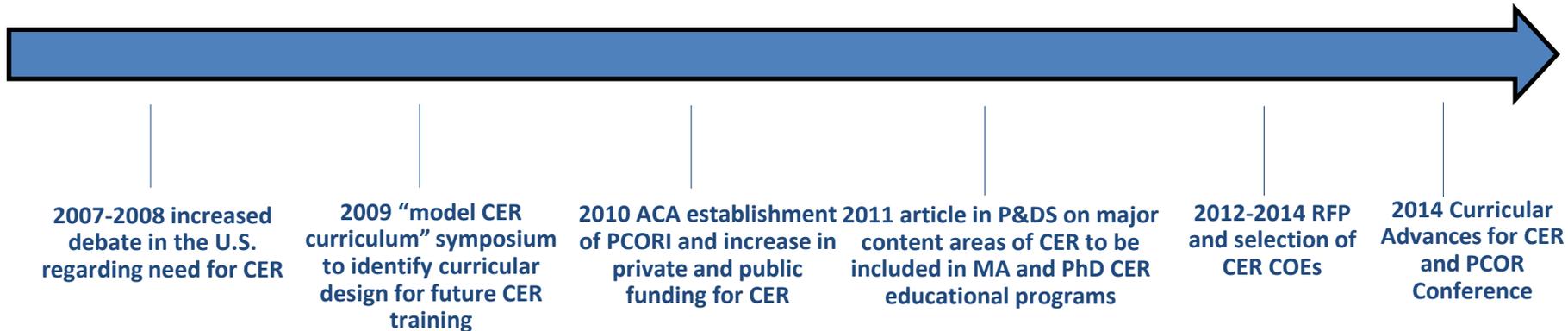


PhRMA Foundation – CER Centers of Excellence Strategic Evaluation

Key Findings

May 13, 2015
avalere.com

Impetus for Establishing Centers of Excellence in CER Education



Based on environmental trends and the CER Curriculum Meeting, the PhRMA Foundation developed a request for proposals (RFP) for establishing Centers of Excellence (COE) in CER education and training, which garnered interest from several leading universities

Findings Show COEs Have Operationalized Objectives, Are Appreciative of PhRMA Foundation Support

Key Findings from Progress Reports and COE Interviews

- 1 COEs appreciate the specific targeting by the PhRMA Foundation for CER curriculum development as this initiative still appears unique in the academic landscape
- 2 Flexibility in crafting a program around individual centers' current offerings contributes to the success and efficient use of resources, as opposed to a one size fits all approach
- 3 COEs employed a variety of approaches, and, as a result, the culmination of all six centers meets (and often exceeds) original objectives outlined in RFP
- 4 COEs with pre-existing and strong foundation in CER were likely to offer the most comprehensive programs
- 5 Though appropriate for initial round of funding, broad objectives outlined in RFP could be narrowed to support COEs in focusing in on targeted areas of student support
- 6 Current CER curriculum and training focuses principally on "producers" of CER; addressing the needs of "users" remains an important gap

Strong Demand Continues Without Sufficient Alternative Support That Targets These Programs

 *“I don’t think CER is just a trend...it has a hugely important niche. We need methodologies that address the limitations of data while capitalizing on their strengths...CER is a methodological way to try to churn the data accumulated in healthcare into meaningful evidence. We need programs in the long-term to accomplish that.”*

 *“I think we can’t possibly keep up with the workforce requirements that we’ll need in this area. Government agencies, patient advocacy groups, industry... all as employers of people who will need to have these kinds of skills. We’re going to have high demand.”*

PhRMA Foundation plays an important and unique role in satisfying the ongoing demand for CER training; the Foundation should consider activities to move forward with the initiative that finely tune current objectives and are targeted towards existing gaps

Future Initiatives To Effectively Meet Identified Needs and Gaps in CER Education and Training (1 of 2)

Key Needs and Gaps	Avalere's Recommendations
<ul style="list-style-type: none">• Greater support for students with CER education and training opportunities	<ul style="list-style-type: none">• Consider targeted fellowships for research, scholarships, and conferences
<ul style="list-style-type: none">• Enhanced collaboration between academic institutions engaged in CER would be beneficial to student academic and professional development, as well as to strengthen the generation and use of CER more widely	<ul style="list-style-type: none">• Organize a follow-on conference on CER curriculum education and training• Propose a bridge grant to support collaboration between academic institutions, with a focus on pairing those with a “researcher” and “user” focus and constituency
<ul style="list-style-type: none">• Lack of academic partnerships with government stakeholders and payers	<ul style="list-style-type: none">• Refine RFP (or other avenues of support) to emphasize innovative partnerships between academic institutions and government stakeholders (e.g., AHRQ, PCORI, CMS) as well as private payers
<ul style="list-style-type: none">• Address growing availability and use of “big data” and subsequent demand for students to obtain and exercise relevant database management and analysis skills for real-world evidence generation	<ul style="list-style-type: none">• Provide targeted funding to academic institutions to support acquisition of databases and develop courses to expose students to such methods

Future Initiatives To Effectively Meet Identified Needs and Gaps in CER Education and Training (1 of 2)

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Future Initiatives To Effectively Meet Identified Needs and Gaps in CER Education and Training (2 of 2)

Key Needs and Gaps	Avalere's Recommendations
<ul style="list-style-type: none">• Current efforts in CER education and training (and general development of the field) are somewhat siloed to certain areas in the U.S.• Limited focus on and outreach to “users” of CER.	<ul style="list-style-type: none">• Support collaboration among regional universities and other partners by way of symposiums/conferences or collaborative CER projects, in order to expand CER capabilities across the country• More curriculum/outreach directed towards "users" of CER to support and also inform the "researchers" regarding applicability and fit for purpose• Dedicate future funding on CER education and training opportunities for healthcare professionals (e.g., physicians, pharmacists)• Engage students outside of program (e.g., pharmacy students) in CER methods and training
<ul style="list-style-type: none">• Demand for CER grows, increasing the need for a robust, diverse, and interconnected CER workforce	<ul style="list-style-type: none">• Expose other relevant stakeholders to CER concepts and methods (e.g., students in undergraduate setting; industry; researchers involved in dissemination science, evaluation, health services research; patient organizations, etc.)

Summary

- The needs for scientists trained to conduct and implement CER continue to grow.
- New elements and methodologies will be needed as it relates to experimental and observational study designs.
- The PhRMA Foundation's Center of Excellence for Comparative Effectiveness Research Education program has been the spearhead of curricular development and training of the future cohort of scientists.
- We will learn more about the next steps for CER training and implementation at this conference.

Next...

- We will hear from several program awardees beginning with Professor Lou Garrison at the University of Washington.

History and Overview of Current Landscape on Strategies to Enhance Uptake and Use of CER/PCOR by Patients, Clinicians, and Payers

Part 2: Experience from Academic Institutions Supported by the PhRMA Foundations Centers of Excellence in CER Education

Beth Devine

Lou Garrison

Simon Pickard

Eleanor Perfetto

Center of Excellence in CER Awardees

2012

1. Beth Devine, PharmD, MBA, PhD, Lou Garrison, AB, PhD, and Anirban Basu, MS, PhD, University of Washington
2. Jodi Segal, MD, MPH, Johns Hopkins University

2013

3. Sonia Hernandez-Diaz, MD, DrPH, FISPE, Harvard University
4. Diana Brixner, RPh, PhD, University of Utah

2014

5. Eleanor M. Perfetto, MS, PhD, University of Maryland

2015

6. Glen Schumock, PharmD and A. Simon Pickard, PhD, University of Illinois Chicago

University of Washington Center of Excellence in Comparative Effectiveness Research

Beth Devine, PhD, PharmD, MBA

Lou Garrison, PhD

Anirban Basu, PhD

UW CER Center of Excellence in CER

- Leverages existing CER expertise and research
 - UW Centers for Comparative and Health System Effectiveness (CHASE) Alliance
 - Public Health, Pharmacy, Medicine and Nursing
- Links capacity and resources across groups to promote greater collaboration and efficiencies in conducting high impact CER
- Partnership institutions
 - Fred Hutchinson Cancer Research Center
 - Group Health Research Institute
 - Veterans Affairs Puget Sound Health Care System
- Involves our stakeholders in real-world settings
- Strengthens partnerships with UW CTSA members in T1 space

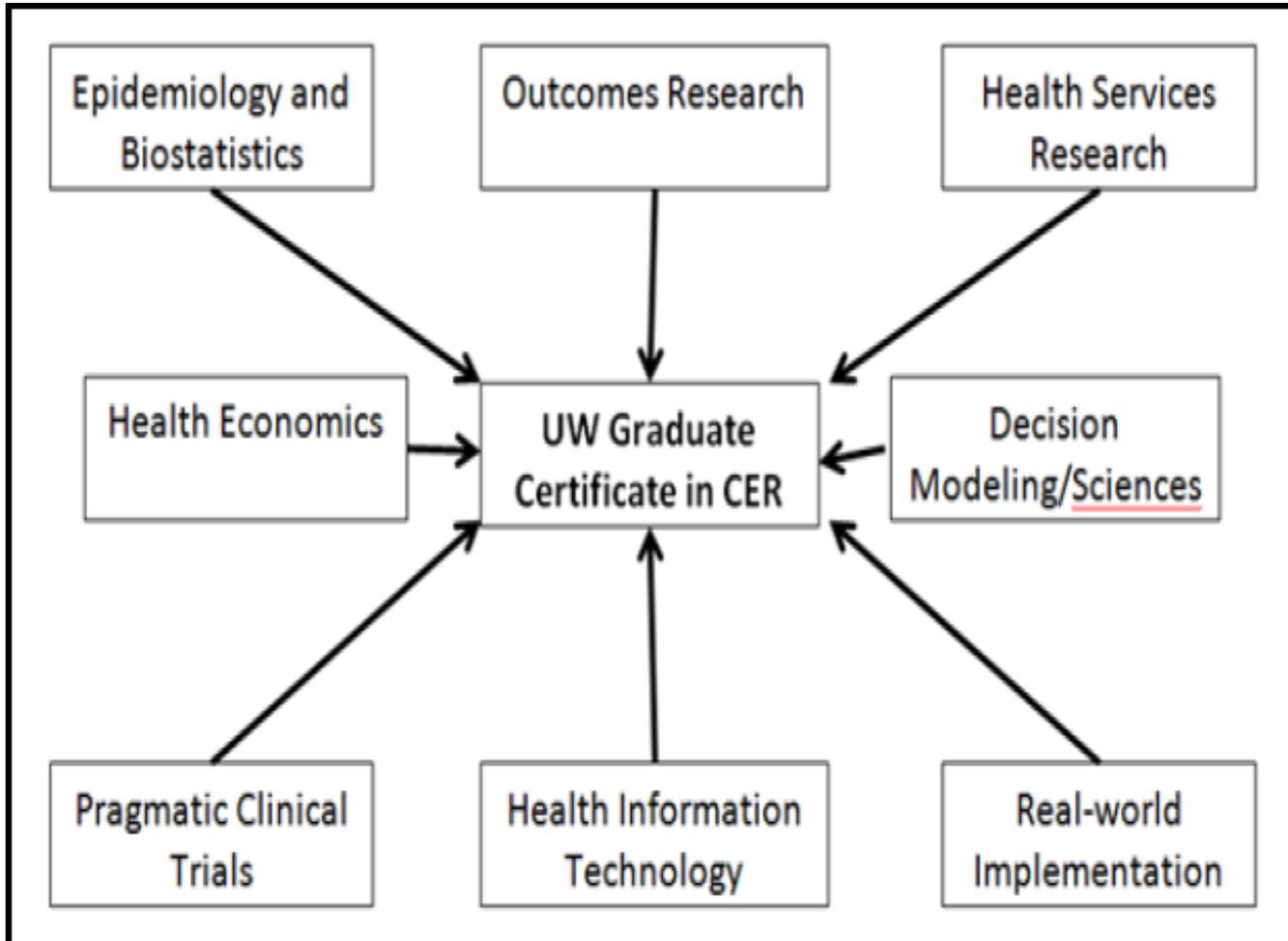
Center Objectives

- Train UW students how to conduct rigorous, useful, and effective CER
- Support private and public partners in training researchers and users of CER
- Develop evidence supporting the usefulness and value of sound CER
- Convene public forums and seminars to discuss CER issues

Center Programs

- **Graduate Certificate in CER (PI: Devine)**
 - Pharmaceutical Outcomes Research & Policy Program
 - Department of Health Services
- **AHRQ T32 funding for Health Services Research (PI: Grembowski)**
 - Pre-doctoral fellows (PhD students)
- **AHRQ K-12 funding for CER/PCOR (PI: Sullivan)**
 - Post-doctoral fellows and junior faculty
 - 2010-2013, 4 scholars
 - 2012-2014, 3 scholars
 - 2014-2019, 10 scholars
- **Patient Centered Outcomes Research Partnership (PCORP) (PI: Kessler)**
 - 2015-2018
 - Investigators from the Washington, Wyoming, Alaska, Montana, Idaho (WWAMI) region (plus South Dakota)
- **AHRQ Evidence-based Practice Center (EPC)**
 - Pacific Northwest EPC (with OHSU and Spectrum Research)

CER Training across 8 Disciplines



Pharmaceutical Outcomes Research & Policy Program, School of Pharmacy
&
The Department of Health Services, School of Public Health

Graduate Certificate in Comparative Effectiveness Research

- Launched in 2011
- Support from the PhRMA Foundation
- Builds on solid, multi-disciplinary doctoral training programs in PORPP and Health Services
- Formally approved by the UW Graduate School and University Board of Regents
- 5 year renewal to UW Graduate School submitted in December 2016



Program Features

Comparative effectiveness research is a growing field that aims to generate evidence to improve health care decisions for patients and providers. It examines the benefits and risks of different medical or healthcare interventions, including drugs and medical technology. The results of these comparison studies are used by clinicians, patients and policy makers to make well informed healthcare decisions and thereby improve patient care.

Learning Objectives

The **Graduate Certificate in CER** provides UW pre-doctoral graduate students with multidisciplinary support and training that will enable them to:

- Use rigorous, state-of-the-art research methods to conduct CER projects,
- Design and execute well-designed CER studies,
- Disseminate the results of CER studies to local, regional and national stakeholders through presentations and publications in the peer reviewed and gray literature,
- Engage a variety of stakeholders (clinicians, payers, patients, caregivers, employers) in discussions about CER,
- Understand, appreciate, and perhaps be involved in policy discussions around implementing the results of CER studies at the local, regional and national levels,

CER Certificate Curriculum

Course Title	PORPP	HSERV
HSERV 523: Advanced Health Services Research Methods, quarter 1	Core	Core
HSERV 524: Advanced Health Services Research Methods, quarter 2	4	Core
HSERV 525: Advanced Health Services Research Methods, quarter 3	4	Core
HSERV 583/ PHARM 534: Economic Evaluation in Health and Medicine	Core	3
HSERV 584/ PHARM 535: Assessing Outcomes in Health and Medicine	Core	3
EPI 541/ HSERV 529/ MEB 511: Introduction to Meta Analysis	3	3
CS&SS 554: Bayesian Statistics for the Social Sciences	4	4
HSERV 585/ PHARM 536: Advanced Methods in CER	3	3
CAPSTONE Project	1	1
TOTAL CREDITS FOR CERTIFICATE	19	17

Big Data and Data Science

- Builds on basic coursework in epidemiology/ pharmacoepidemiology, biostatistics (2 years), medical and pharmaceutical product development and policy, US healthcare system, social determinants of health
- Electives: electives, grant-writing, information technology, clinical trials design, and more

Core Faculty

Leadership Team:

Louis P. Garrison, Jr., PhD, Director, Certificate Program, Professor, Pharmaceutical Outcomes Research & Policy

Beth Devine, PharmD, MBA, PhD, Associate Professor, Pharmaceutical Outcomes Research & Policy

Anirban Basu, PhD, Associate Professor, Health Services

Additional Steering Committee Members:

David Grembowski, PhD, Professor, Health Services

Larry Kessler, ScD, Professor and Chair, Health Services

Sean Sullivan, PhD, Professor, Pharmaceutical Outcomes Research & Policy

David Veenstra, PharmD, PhD, Professor, Pharmaceutical Outcomes Research & Policy

**Plus numerous
additional faculty
and mentors**

Students

Admissions Information

Eligibility Limited to Current UW Graduate Students

Application Deadline: May 23, 2014

One pre-doctoral fellowship will be available and will be awarded to a student in their second or third year upon the following merits of their application: scholarship, number of previous CER projects completed, and number of manuscripts published.

One dissertation fellowship will be awarded to a fourth or fifth year student. Those who qualify will have completed their coursework and are completing dissertation work in CER. This fourth or fifth year student will not be formally enrolled in the CER Certificate; instead they will provide mentorship to the students enrolled in the certificate program.

Students may apply to the Certificate Program regardless of whether they receive support from either fellowship.

Additional application information and the application form is available on the Certificate website.

- Enrollment limited to those currently enrolled in a UW graduate program
- Awarded 3 pre-doctoral and 5 dissertation fellowships
- 3 additional trainees have completed the program
- Seminars: CHASE Alliance WIPS – 137 total; Program in Health Economics and Outcomes Methodology (PHEnOM) – 20 per year

Adding CER Training to the UW PharmD Curriculum

2017 AMCP Foundation Pharmacy & Therapeutic Competition



Print



E-mail

PT & Competition
2017

17th Annual National Student Pharmacist PT Competition

HELD DURING THE AMCP MANAGED CARE & SPECIALTY PHARMACY ANNUAL MEETING
MARCH 27-30, 2017 | DENVER, CO

AMCP Academy of Managed Care Pharmacy®
FOUNDATION

UW local competition held on January 21, 2017

SEATTLE



SEAHAWKS

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Questions?

Thank you!



PhRMA Foundation: CER Center for Excellence in Education

Johns Hopkins University

Jodi Segal, MD, MPH



Academic Home: Health Policy and Management



- **Center for Health Services and Outcomes Research (CHSOR)**
- **Established in 1969**
- **One of oldest in US devoted to interdisciplinary health services research**
- **Director – Albert Wu**
- **Associate Directors– Jodi Segal and Jill Marsteller**
- **Special attention is devoted to vulnerable populations**
 - Children, elderly, uninsured, mentally ill, disabled

Stated Aims

- **Specific Aim 1.** To develop a certificate program in CER. These required and elective courses will also fulfill requirements for a CER track within our existing Masters of Public Health (MPH) degree program
- **Specific Aim 2.** To convert our most relevant CER courses to online courses to allow them to be accessed remotely by learners (2 courses)
- **Specific Aim 3.** To create a series of seminars and lectures that our faculty will disseminate to key stakeholders with interest in CER development and implementation of findings

Certificate in CER

- Students must complete 21 units of coursework
- Letter grades and a 3.0 grade point average required
- Completed within a 3-year period
- In-residence program
- Online program
- Complemented by ongoing seminar series

Certificate Curricula for Comparative Effectiveness Research

[Certificate Requires 21 Credits]

R/E	Course	Credits
R	312.693 Introduction to Comparative Effectiveness Research	3
R	309.712 Assessing Health Status & Patient Outcomes	3
R	340.601 Principles of Epidemiology	5
R	309.631 Population Health Informatics	3
R	Research Ethics Workshops About Responsibilities and Duties of Scientists	Non-credit
E	340.606 Systematic Review and Meta-analysis	5
E	340.728 Advanced Methods for Design and Analysis of Cohort Studies	4
E	221.644 Econometric methods for evaluation of health programs	4
E	340.682 Pharmacoepidemiology Methods	3
E	313.790 Economic Evaluation I	3
E	313.631 Economic Evaluation II	4
E	300.713 Research and Evaluation Methods for Health Policy	4
E	309.600 Evaluating quality improvement and patient safety programs	2

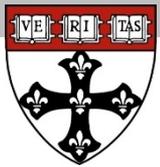
Certificate Curricula for Comparative Effectiveness Research [21 Credits]

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E	340.682 Pharmacoepidemiology Methods	3
E	313.790 Economic Evaluation I	3
E	313.631 Economic Evaluation II	4
E	300.713 Research and Evaluation Methods for Health Policy	4
E	309.600 Evaluating quality improvement and patient safety programs	2

Harvard University

PhRMA Foundation funded CER Educational Centers of Excellence

Sonia Hernandez-Diaz, MD, DrPH, FISPE



History

- **1913** - founding of Harvard School of Public Health
- **1986** - Program in Pharmacoepidemiology
- **1998** - Division of Pharmacoepidemiology and Pharmacoeconomics (DoPE)
- **2010** - Dean's Flagship Initiative in CER
- **2013** - PhRMA Foundation CER Educational Center of Excellence
 - Career Development Program in Core Methods for Patient Centered Outcomes Research
 - Multiple departments and programs; large, interdisciplinary faculty

Objectives

- Advance research in the comparative effectiveness and safety of drugs, vaccines, medical devices and procedures
- Equip scholars with the knowledge and expertise they need to evaluate critical safety and effectiveness issues to improve the health care for patients
- Train a new generation of trainers and leader investigators that will advance the field
- Enhance research and academic capacity on CER
- Specifically, refine education and mentoring program on CER for PhD students and post-docs

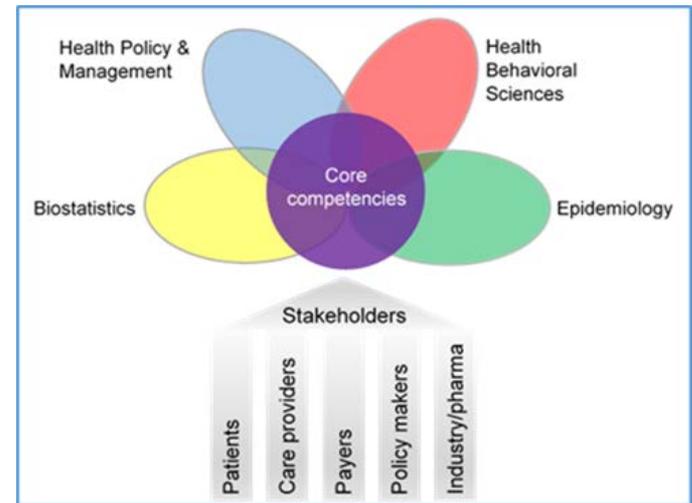
Program

- Offers two advanced degrees:
 - 80-credit ScD/DPH (about 3 students admitted per year)
 - 42.5-credit SM (about 2 students admitted per year)
- and post-doctoral Fellowships
- Most students have prior doctorates in medicine (MD, DMD) or related sciences, including pharmacy (PharmD) and Ph.D. degrees in biostatistics or econometrics; and/or substantial professional experience in a related field

Curriculum

Formal training, methods on evidence

- I. generation, both from clinical trials and observational studies
- II. synthesis of through systematic reviews and decision analyses
- III. interpretation, translation to practice, and communication
- IV. New course: PCOR- Principles and Stakeholder Engagement



- **Supervised research experience**

- **Other experiences**

- Internships in regulatory agencies or pharmaceutical companies, conferences, seminars, teaching

Core Competencies and Course Options

Focus Area	Competencies	Courses Options and Selected Seminars (Courses are 2.5 credits, unless noted.)
Epidemiology	<ul style="list-style-type: none"> ▪ Models for causal inference ▪ Formulation of testable hypothesis ▪ Design of observational studies (case control, cohorts and registries, case only designs) ▪ Advanced analytic methods (propensity score analysis, high dimensional propensity scores, instrumental variables) ▪ Biases: identification in published studies and minimization in research. ▪ Comparative effectiveness methods ▪ Use of large healthcare databases 	<ul style="list-style-type: none"> ▪ EPI289 Models for Causal Inference ▪ EPI207 Advanced Epidemiologic Methods ▪ EPI271 Propensity Score Analysis: Theory & Practice (1.25cr) ▪ EPI208 Introduction to Clinical Epidemiology ▪ EPI242 Seminar in Applied Research in Clinical Epidemiology ▪ EPI221 Pharmacoepidemiology ▪ EPI286 Database Analytics in Pharmacoepidemiology ▪ EPI298 Case-based Seminars on CER and Drug Safety ▪ EPI235 Methods in Health Services Research ▪ EPI233 Research Synthesis & Meta-Analysis ▪ EPI288 Data Mining and Prediction ▪ EPI 253 Effectiveness Research with Longitudinal Healthcare Databases

Core Competencies and Course Options

Focus Area	Competencies	Courses Options and Selected Seminars (Courses are 2.5 credits, unless noted.)
Health Policy & Management Decision Sciences	<ul style="list-style-type: none"> ▪ Decision analysis methods ▪ Cost-effectiveness and cost-benefit analysis ▪ Health services research methods ▪ Healthcare (quality improvement) methods ▪ Program evaluation methods ▪ Measure (patient-centered) health outcomes ▪ Use of health information technology 	<p style="text-align: center;">RDS280 Decision Analysis for Health and Medical Practices</p> <ul style="list-style-type: none"> ▪ RDS285 Decision Analysis Methods ▪ RDS286 Decision Analysis in Clinical Research ▪ RDS288 Methods for Decision Making ▪ RDS282 Cost-Effectiveness and Cost-Benefit Analysis ▪ HPM276 Methods and Application in Health Services Research ▪ HPM516 Health Care: Quality Improvement ▪ HPM543 Quantitative Methods in Program Evaluation ▪ HPM276 Methods and Application in Health Services Research ▪ HPM299 Research with Large Databases ▪ HPM520-01 Community Organizing for Health ▪ HPM530 Measuring Health Outcomes (patient-centered) ▪ HPM519 Health Information Technology & Health Care

Core Competencies and Course Options

Focus Area	Competencies	Courses Options and Selected Seminars (Courses are 2.5 credits, unless noted.)
Social Behavioral Sciences	<ul style="list-style-type: none"> ▪ Qualitative research methods (e.g., focus groups) ▪ Community intervention design, evaluation, and research methods ▪ Social and behavioral research methods ▪ Recognition and mitigation of health disparities ▪ Appraisal of potential of community engagement to identifying health issues and translate findings to reduce health disparities 	<ul style="list-style-type: none"> ▪ SBS288 Qualitative Research Methods in Public Health ▪ SHDH 207 Race, Ethnicity and Health ▪ SHDH231 Community Intervention Research Methods ▪ SHDH245 Social & Behavioral Research Methods ▪ SHDH509 Health Communication in the 21st Century ▪ Harvard Catalyst Seminars
Responsible Conduct Of Research	<p>⌋ Scholars will demonstrate competence in:</p> <ul style="list-style-type: none"> ▪ Protection of human subjects principles ▪ Preparation of an IRB application, development of informed consent procedures ▪ Identification of misconduct in research ▪ Conflict of interest management ▪ Determination of authorship 	<ul style="list-style-type: none"> ▪ ID250 Ethical Basis of the Practice of Public Health ▪ HPM292 Research Ethics (1.25cr) ▪ HPM548 Responsible Conduct of Research (1.25 cr)

Core Competencies and Course Options

Focus Area	Competencies	Courses Options and Selected Seminars (Courses are 2.5 credits, unless noted.)
PCOR Principles & Stakeholder Engagement	<p>⌋ Scholars will demonstrate competence in:</p> <ul style="list-style-type: none"> ▪ PCORI principles for engaging the public in healthcare research ▪ How to define relevant stakeholders ▪ Strategies and methods for involving patients in topic generation for patient-centered CER ▪ Responsible and ethical use of social media ▪ Research dissemination and communication strategies to ensure impact on healthcare delivery 	<ul style="list-style-type: none"> ▪ Patient Centered Outcomes Research Cornerstone Course ▪ ID284 Media and Health Communication: Practical Skills ▪ ID206 Scientific Writing ▪ Stakeholder Advisory Group Seminars: <ul style="list-style-type: none"> - Returning Clinical Trial Results to Patients (Frank) - Involving Patients in the Dissemination of Evidence (Solomon) - Multi-Stakeholder Collaboration (Tunis) - Personalized Medicine: The Big Pharma Perspective (Horwitz) ▪ Harvard Catalyst Seminars

Faculty

- **Program Core Faculty**

- Sonia Hernandez-Diaz, M.D., Dr.P.H.
- Sebastian Schneeweiss, MD, ScD,
- Alexander Walker, MD, DrPH
- John D. Seeger, PharmD, DrPH
- Joshua J. Gagne, PharmD, ScD
- Sengwee (Darren) Toh, PharmD, ScD

- **Program Advising Faculty Includes**

- Miguel Hernan, MD, ScM, DrPH
- Jerry Avorn, M.D.,
- Brian Bateman, M.D., M.P.H.
- Robert Glynn, Ph.D., Sc.D.
- Krista Huybrechts, M.A., Ph.D.
- Sharon-Lise Normand, PhD
- Daniel Solomon, M.D., M.P.H.
- Tyler van der Weele, PhD
- Milton Weinstein, PhD



New Developments

- **Courses**

- More patient-centered research aspects and more training on Big Data Science
- New 2014: *Effectiveness Research With Longitudinal Healthcare Databases*
- New 2016: *Database Analytics in Pharmacoepidemiology*
- New 2016: *Methods in Health Services Research* (focus on CER and PCOR)

- **NEW Core Faculty**

- Dr. Darren Toh, works on comparative effectiveness and patient-centered outcomes research

New Developments

- **Seminars, Symposia and Workshops**
 - 2013: Symposium on statistical, analytical and design methods for CER for therapeutic interventions
 - 2014: Symposium on Comparative Effectiveness Research in Prevention
 - 2014: Development and Safety Management of Cancer Drugs
 - 2014: Symposium on Pharmacoepidemiology and Drug Safety
 - 2015: Patient Oriented Benefit Risk Evaluation in Oncology Symposium
 - 2016: New Data and New Methods in Advancing Patient Care Symposium
 - Monthly seminars on “Patient-Centered Outcomes Seminar Series” (BWH Patient-centered Comparative Effectiveness Research Center), Epidemiology department seminars, Research methods seminars at DoPE, and many other daily seminars at our Institutions

New Developments

- **Leadership**

- Faculty have been reviewers at PCORI, NIH, AHRQ and FDA; Co-authors of methods guidelines for AHRQ, PCORI and Scientific Societies; Co-authors of IOM report on CER; Directors of Patient-centered Comparative Effectiveness Research Center (PCERC); and lecturers on research methods in programs sponsored by government agencies, universities, and other institutions.
- In 2014 Sonia Hernandez-Diaz became **President of the Society for Perinatal and Pediatric Epidemiology** and in 2015 she became **President for the International Society of Pharmacoepidemiology**, where she promoted CER and, in particular, the incorporation of patient-oriented approaches into research planning, translation and implementation. The Society now has a **PCOR Special interest group** and the number of Plenaries and Workshops on CER and PCOR have substantially increased

Graduates supported by PhRMA (2013-2016)

Student	Graduation
Peter Wahl, MLA, MS, DcD	2014
Kim Seo Young, MD, DrPH	2014
Hiraku Kumamaru , MD, MPH, DrPH	2015
Yoon Young Park, MS, ScD	2016
Kazuki Toshida, MD, MS, MPH	2017

Many other students and fellows benefited from the Program

Publications from work as students at HSPH

1. Risk of Guillain-Barré syndrome after meningococcal conjugate vaccination. Velentgas P, Amato AA, Bohn RL, Arnold Chan K, Cochrane T, Funch DP, Dashevsky I, Duddy AL, Gladowski P, Greenberg SA, Kramer JM, McMahonill-Walraven C, Nakasato C, Spettell CM, Syat BL, Wahl PM, Walker AM, Zhang F, Brown JS, Platt R. *Pharmacoepidemiol Drug Saf.* 2012.
2. Health care utilization of patients diagnosed with idiopathic thrombotic thrombocytopenic purpura in a commercially insured population in the United States. Wahl PM, Bohn RL, Terrell DR, George JN, Ewenstein B. *Transfusion.* 2012;52:1614-21.
3. Surveillance for Adverse Events Following Receipt of Pandemic 2009 H1N1 Vaccine in the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) System, 2009-2010. Yih WK, Lee GM, Lieu TA, Ball R, Kulldorff M, Rett M, Wahl PM, McMahonill-Walraven CN, Platt R, Salmon DA. *Am J Epidemiol.* 2012;175(11):1120-8.
4. Validation of a claims-based diagnostic code for Stevens-Johnson syndrome in a commercially insured population. Eisenberg DF, Daniel GW, Jones JK, Goehring EL Jr, Wahl PM, Winters P, Levin J, Bohn RL. *Pharmacoepidemiol Drug Saf.* 2012;21(7):760-764.
5. Early steps in the development of a claims-based targeted healthcare safety monitoring system and application to three empirical examples. Wahl PM, Gagne JJ, Wasser TE, Eisenberg DF, Rodgers JK, Daniel GW, Wilson M, Schneeweiss S, Rassen JA, Patrick AR, Avorn J, Bohn RL. *Drug Saf.* 2012;35(5):407-16.
6. Factors associated with the initiation of proton pump inhibitors in corticosteroid users. Munson JC, Wahl PM, Daniel G, Kimmel SE, Hennessy S. *Pharmacoepidemiol Drug Saf.* 2012;21(4):366-74.
7. Validation of Acute Liver Injury Cases in a Population-Based Cohort Study of Oral Antimicrobial Users. Bui CL, Kaye JA, Castellsague J, Calingaert B, McQuay LJ, Riera-Guardia N, Saltus CW, Quinlan SC, Holick CN, Wahl PM, Suzart K, Rothman KJ, Wallander MA, Perez-Gutthann S. *Curr Drug Saf.* 2013 Oct 9. [Epub ahead of print]
8. Risk of ischemic cerebrovascular and coronary events in adult users of anticonvulsant medications in routine care settings. Patorno E, Glynn RJ, Hernandez-Diaz S, Avorn J, Wahl PM, Bohn RL, Mines D, Liu J, Schneeweiss S. *J Am Heart Assoc.* 2013 Jul 30;2(4):e000208.
9. Effects of disease-modifying antirheumatic drugs on nonvertebral fracture risk in rheumatoid arthritis: a population-based cohort study. Kim SY, Schneeweiss S, Liu J, Solomon DH. *J Bone Miner Res.* 2012 Apr;27(4):789-96.
10. Accuracy of identifying neutropenia diagnoses in outpatient claims data. Kim SY, Solomon DH, Liu J, Chang CL, Daniel GW, Schneeweiss S. *Pharmacoepidemiol Drug Saf.* 2011;20(7):709-13.
11. Oral bisphosphonates and risk of subtrochanteric or diaphyseal femur fractures in a population-based cohort. Kim SY, Schneeweiss S, Katz JN, Levin R, Solomon DH. *J Bone Miner Res.* 2011;26(5):993-1001.
12. Use of administrative claims data for comparative effectiveness research of rheumatoid arthritis treatments. Kim SY, Solomon DH. *Arthritis Res Ther.* 2011;13(5):129.
13. Pharmacotherapy: comparative safety of nonsteroidal anti-inflammatory drugs. Kim SY, Solomon DH. *Nat Rev Cardiol.* 2011;8(4):193-5.
14. Validation of rheumatoid arthritis diagnoses in health care utilization data. Kim SY, Servi A, Polinski JM, Mogun H, Weinblatt ME, Katz JN, Solomon DH. *Arthritis Res Ther.* 2011;13(1):R32.

Publications from work as students at HSPH

15. Risk of osteoporotic fracture in a large population-based cohort of patients with rheumatoid arthritis. Kim SY, Schneeweiss S, Liu J, Daniel GW, Chang CL, Garneau K, Solomon DH. *Arthritis Res Ther.* 2010;12(4):R154.
16. Jalbert JJ, Nguyen LL, Gerhard-Herman MD, Jaff MR, White CJ, Rothman AT, Seeger JD, Kumamaru H, Williams LA, Chen CY, Liu J, Tsai TT, Aronow HD, Johnston JA, Brott TG, Setoguchi S. Outcomes After Carotid Artery Stenting in Medicare Beneficiaries, 2005 to 2009. *JAMA Neurol.* 2015 Jan 12. doi: 10.1001/jamaneurol.2014.3638
17. Kumamaru KK, Kondo T, Kumamaru H, Amanuma M, George E, Rybicki FJ. Repeat coronary computed tomographic angiography in patients with a prior scan excluding significant stenosis. *Circ Cardiovasc Imaging.* 2014 Sep;7(5):788-95.
18. Kumamaru H, Tsugawa Y, Horiguchi H, Kumamaru KK, Hashimoto H, Yasunaga H. Association between hospital case volume and mortality in non-elderly pneumonia patients stratified by severity: a retrospective cohort study. *BMC Health Serv Res.* 2014 Jul 12;14:302.
19. Kumamaru KK, Hunsaker AR, Kumamaru H, George E, Bedayat A, Rybicki FJ. Correlation between early direct communication of positive CT pulmonary angiography findings and improved clinical outcomes. *Chest.* 2013 Nov;144(5):1546-54.
20. Kumamaru H, Judd SE, Curtis JR, Ramachandran R, Hardy NC, Rhodes JD, Safford., MM, Kissela BM, Howard G, Jalbert JJ, Brott TG, Setoguchi S. Validity of Claims-Based Stroke Algorithms in Contemporary Medicare Data: REGARDS Study Linked with Medicare Claims. *Circulation: Cardiovascular Quality and Outcomes* 2014; 7: 611-9
21. Kumamaru H, Jalbert JJ, Nguyen LL, Gerhard-Herman MD, Williams LA, Chen CY, Seeger JD, Liu J, Franklin JM, Setoguchi S. Surgeon Case Volume and 30-day Mortality after Carotid Endarterectomy among Contemporary Medicare Beneficiaries: Before and After National Coverage Decision for Carotid Artery Stenting. *Stroke.* Under review.
22. Kumamaru H, Schneeweiss S, Glynn RJ, Setoguchi S, Gagne JJ. Dimension reduction and shrinkage methods for high dimensional disease risk score in historical data. Under review
23. Kumamaru H, Gagne JJ, Glynn RJ, Setoguchi S, Schneeweiss S. Comparison of high dimensional confounder summary scores in database studies of newly marketed medications. Under review
24. Yoonyoung Park, Jessica Franklin, Sebastian Schneeweiss, Raisa Levin, Stephen Crystal, Tobias Gerhard, Krista F. Huybrechts. Antipsychotics and Mortality: Adjusting for Mortality Risk Scores to Address" Confounding by Terminal Illness. *J Am Geriatr Soc.* 2015;63:516-23.
25. Rough K, Bateman BT, Patorno E, Desai RJ, Park Y, Hernandez-Diaz S, Huybrechts KF. Suppression of Substance Abuse Claims in Medicaid Data and Rates of Diagnoses for Non-Substance Abuse Conditions. *JAMA.* 2016 Mar 15;315(11)
26. Yoshida K, Solomon DH, Kim SC. Importance of active comparator design and new user design in observational studies of drug effects. *Nat Rev Rheumatol* 2015 [in editorial processing]

Publications from work as students at HSPH

27. Hase R, Otsuka Y, Yoshida K, Hosokawa N. Profile of infective endocarditis at a tertiary-care hospital in Japan over a 14-year period: Characteristics, outcome and predictive factors for in-hospital mortality. *Int J Infect Dis* 2015, Jan 7 [Epub ahead of print]
28. Matsue Y, Yoshida K, Hoshino M, Yonetsu T, Suzuki M, Matsumura A, Hashimoto Y, Yoshida M. Clinical Features and Prognosis of Type 2 Myocardial Infarction in Vasospastic Angina. *Am J Med* 2014, Nov 26 [Epub ahead of print; Received editorial coverage]
29. Yoshida K, Radner H, Mjaavatten MD, Greenberg JD, Kavanaugh A, Kishimoto M, Matsui K, Okada M, Reed G, Saeki Y, Tohma S, Kremer J, Solomon DH. Incidence and Predictors of Biological Antirheumatic Drug Discontinuation Attempts among Patients with Rheumatoid Arthritis in Remission: A CORRONA and NinJa Collaborative Cohort Study. *J Rheumatol*. 2015 In press.
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31. Radner H, Yoshida K, Mjaavatten MD, Aletaha D, Frits M, Lu B, Iannaccone C, Shadick N, Weinblatt M, Hmamouchi I, Dougados M, Smolen JS, Solomon DH. Development of a multimorbidity index: Impact on quality of life using a rheumatoid arthritis cohort. *Semin Arthritis Rheum*. 2015;45:167-73
32. Radner H, Yoshida K, Frits M, Iannaccone C, Shadick NA, Weinblatt M, Smolen JS, Solomon DH. The impact of multimorbidity status on treatment response in rheumatoid arthritis patients initiating disease-modifying anti-rheumatic drugs. *Rheumatology (Oxford)*. 2015 Nov;54(11):2076-84
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34. Radner H, Yoshida K, Tedeschi S, Studenic P, Frits M, Iannaccone C, Shadick NA, Weinblatt M, Aletaha D, Smolen JS, Solomon DH. Different Rating of Global Rheumatoid Arthritis (RA) Disease Activity in Multimorbid Patients with RA. *Arthritis Rheumatol*. 2016 Nov 11. doi: 10.1002/art.39988. [Epub ahead of print]
35. Bykov K, Yoshida K, Weisskopf MG, Gagne JJ. Confounding of the association between statins and Parkinson disease: systematic review and meta-analysis. *Pharmacoepidemiol Drug Saf*. 2016. [Epub ahead of print]

Mentored Scholars and Professional Education Program for Comparative Effectiveness Research

University of Utah

Diana Brixner, RPh, PhD

Overall Program Objectives

- Develop new Technology-Oriented Comparative Effectiveness Research (TOCER) training program
- Train a diverse cadre of investigators to conduct and evaluate TOCER studies and publicize research
- Track the effect of scholars' and professionals research activities locally and nationally
- Offering ongoing continuing education modules in physician, nursing and pharmacy professional associations

Specific Objectives

- **Objective 1: Training programs in CER**
 - New courses:
 - Healthcare Data Analytics (New Course)
 - Decision Analysis and Cost-Effectiveness Analysis
 - Methods in Comparative Effectiveness Research
- **Objective 2: Enhance Public/Private Partnerships**
- **Objective 3: Provide resources for data analysis**
 - Developed course on availability and use of secondary data sources for TOCER
- **Objective 4: Convene public forums and seminars to discuss CER issues**
- **Objective 5: Sponsor lectures/presentations on CER topics**
- **Objective 7: Work with representatives from government, industry to train CER workforce**
- **Objective 8: Create public CER educational training tools developed with funding provided by the Foundation**

Scholar Mentorship Program Status

- First cohort of three students are all PhD students in the Pharmacotherapy Department in the College of Pharmacy

Thank You!

lgarrison@uw.edu

Overview of the PhRMA Foundation Centres of Excellence in CER Education

The UIC experience



Presenter: Simon Pickard, PhD



Picture 1: From the 1999 film “The Matrix” where the main character is offered the choice between a red pill and a blue pill. This is symbolic of the choice patients, clinicians, and decision-makers make, and which CER can help inform.

Background

- The sixth (final) center to be funded
- January 2015 – December 2017
- Funding renewed for a second year
- Co-PIs: Glen Schumock, Simon Pickard
- Based in PSOP department
 - Relatively large (12 FTEs) department of its type in a college of pharmacy
 - Many involved in AHRQ's DEcIDE, CERT

Aims

1. Support the development of educational and training that teach students and practitioners how to conduct rigorous, useful and effective CER
2. Work with private/public partners to produce high caliber CE researchers and practitioners who interpret and use CER
3. Furnish resources to develop corroborating evidence on the value of CER
4. Convene public forums/seminars to discuss topical CER issues
5. With other groups, promote the development of a CER curriculum that produces CE researchers and practitioners
6. Sponsor lectures and presentations on different programs and venues that promote discussions on CER topics
7. Work with government, industry and educators to determine personnel demands related to CER
8. Provide accessible CER training tools and resources to the public

Major Accomplishments

- The development of a new, online MS degree in CER.
 - This program was designed for working professionals anywhere in the country
 - Especially clinical researchers and employees in the pharmaceutical industry and health care organizations.
 - In year 1, the curriculum was developed
 - In year 2, the MS degree was approved by the University of Illinois Board of Trustees and the Illinois Board of higher education.
 - Applications now being accepted for Fall 2017



Title	Rubric	Cr
<i>Required Courses (20 Cr)</i>		
Comparative Effectiveness Research	PSOP 516	3
Biostatistics I or Clinical Research Methods I^a	BSTT 400 or HPA 472	4
Introduction to Epidemiology: Principles and Methods^a	EPID 403	3
Pharmacoepidemiology	PSOP 426^d	3
Ethics and Privacy Issues in Comparative Effectiveness Research	PSOP 400	1
Comparative Effectiveness Research Project	PSOP 592	6
	SUBTOTAL	20
<i>Elective Courses (Need 12 Cr, choose among following courses, or as approved by Department. Must take at least 6 credits of 500-level electives not including Independent Study and Department Seminar)</i>		
Principles of Economic Evaluations of Health Care Interventions	PSOP 573	3
Pharmaceutical Policy	PSOP 535	3
Concepts in Drug Development: From Bench to Bedside^b	BPS 508	3
Advanced Decision Analysis Techniques I	PSOP 580	2
Biostatistics II or Clinical Research Methods II^a	BSTT 401 or HPA 473	4
Systematic Reviews and Meta-Analysis	PSOP 484	3
Independent Study	PSOP 596	1-4
Department Seminar^c	PSOP 595	1
	SUBTOTAL	12
Total Credit Hours (Required + Elective)	TOTAL	32

Other Activities

- Convened advisory board
- Initiated workshops to train clinical pharmacists and residents on best practices in CER
- Organized national conference on strategies to enhance uptake of CER/PCOR
- Grant proposals to support conference
- Collaborated with Midwest ISPOR chapter to survey member interest in CER training
- Created web-based CER-related resources for public
- Held weekly public forums and seminars on topical CER issues
- Presented webinars and symposia on CER topics at national and international forums
- Worked with industry to understand the workforce needs related to CER training and education



Patient-Centered Research for Outcomes, Effectiveness and Measurement (PROEM)

A Center of Excellence in Comparative Effectiveness and
Patient-Centered Outcomes Research (CER-PCOR) Training

Eleanor M. Perfetto, PhD, MS, Professor
Department of Pharmaceutical Health Services Research
School of Pharmacy
University of Maryland

PROEM Center of Excellence

- Housed in the UMB School of Pharmacy
- Established in 2014; in its final year
- Objective: Expand CER/PCOR graduate education and training programs
- Focuses on **patient centeredness** with patient engagement as the first step in any CER activity
- Educate on what is CER/PCOR, how to conduct or become more involved, how to interpret/use

PROEM Center of Excellence

- Educational programming on CER/PCOR
 - Degree-related programming
 - CER/PCOR Online Courses
 - Summer Institutes 2015, 2016, planning 2017
 - PCOR Training: A Program for Rare Disease Patient Advocates - Funded by PCORI
 - Collaboration with the PATIENTS Program

Degree-Related Programming

- How to do:
 - PhD/MS concentration in CER-PCOR
 - Six PhD students; 1 MS students (August 2016)
- How to evaluate/use:
 - CER-PCOR for Health Professionals Course – online MS in Health Sciences
 - Fall 2015: 36 students completed
 - Fall 2016: 57 students completed
 - CER-PCOR Mini Course – online MS in Regulatory Science
 - Fall 2015: 23 students completed
 - Fall 2016: 29 students completed
 - Fall 2017: 34 students (starts May 2017)

CER/PCOR Online CE Courses

1. CER Collaborative Certificate Program (CCP)

- 19-hour course on CER methodology
- Initially supported by a contract from the CER Collaborative
- 329 learners registered for the program (2014-2016)
- 221 learners completed the program to date (industry, payer, academia, and consultants)
- <http://pharmacists4knowledge.org/cips/CER>



CER/PCOR Online CE Courses

2. *Engaging in Comparative Effectiveness & Patient-Centered Outcomes Research - Online Module Series*
 - Launched in 2016; 5 CEUs
 - 10 learners completed to date
 - Suggested pre-requisite for CER Collaborative Certificate Program
 - Module topics:
 - Module 1: Fundamentals of CER and PCOR
 - Module 2: Patient & Stakeholder Engagement in Research
 - Module 3: CER-PCOR Research Methodology
 - Module 4: Outcome Measurement

CER-PCOR Summer Institute

- Open to researchers, faculty, graduate students, healthcare professionals, industry researchers, policy makers, and patient advocates
- Conducted in 2015, 2016, planning 2017
 - 2015: 83 registered – Introduction to CER/PCOR Topics
 - 2016: 38 registered – CER/PCOR Advanced Methods
 - 2017: “The Patient Professor”
- Supported by industry grants and registrations

PCOR Training: A Program for Rare Disease Patient Advocates

- PCORI Eugene Washington Engagement Award (\$250,000)
- National Organization for Rare Disorders (NORD)
- Provided rare-disease patient advocates with fundamentals of PCOR, how to participate in PCOR projects
- Delivered at the NORD 2015 Annual Summit
 - Day 1 (half-day session): Over 100 participants
 - Day 2 (full-day session) : 42 participants, only patients/patient advocates
- Participants have reported success in research funding and other collaborations
- Training materials and resources developed available on PCORI website



Thank you !

Break

- Polaris Foyer
- Please return in 15 minutes

History and Overview of Current Landscape on Strategies to Enhance Uptake and Use of CER/PCOR by Patients, Clinicians, and Payers

Part 3: Overview and Update of Funding Programs with Emphasis on CER/PCOR Uptake and Use by Patients, Clinicians, and Payers

Bill Lawrence

David Meyers

Sharon Arnold

Josephine Briggs

PCORI Research Funding and Uptake

William Lawrence, MD, MS

Associate Director

Clinical Effectiveness and Decision Science

January 26, 2017



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI's Mission and Strategic Goals

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

Our Strategic Goals:



Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions



Speed the implementation and use of patient-centered outcomes research evidence



Influence research funded by others to be more patient-centered



We Fund Comparative Clinical Effectiveness Research

- Generates and synthesizes evidence comparing benefits and harms of at least two different methods to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits in real-world populations
- Describes results in subgroups of people
- Helps consumers, clinicians, purchasers, and policy makers make informed decisions that will improve care for individuals and populations
- Informs a specific clinical or policy decision

Note: We do not fund cost-effectiveness research



Authorizing Legislation

“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...**”

... and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services...”

-- from PCORI's authorizing legislation



Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication and Dissemination Research

Addressing Disparities

Accelerating Patient-Centered Outcomes Research and Methodological Research



Funding Mechanisms - Science

- Stakeholder engagement key – in all stages, including dissemination
- Mechanisms – PCORI Funding Announcements (PFAs):
 - Broad awards in each of the five national priorities
 - Help develop the effectiveness data to support uptake
 - Communication and Dissemination Research priority – research on best ways to improve decision making through communication/dissemination of evidence
 - Pragmatic Clinical Studies awards (up to \$10 M direct costs)
 - Targeted PCORI Funding Announcements
 - Cycle 1 2017, 2 PFAs on Management of Back Pain
- *Deadline for Letters of Intent, Cycle 1 2017 – Feb. 14 2017*



Funding Mechanisms - Engagement

- Limited Competition – Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products in Real World Settings
 - Limited to PCORI-funded research projects
- Engagement Award: Knowledge, Training and Development, and Dissemination Awards
 - Focused on infrastructure and relationships to improve channels of dissemination of research findings



<http://www.pcori.org/funding-opportunities>



Thank You!





U.S. Department of Health and Human Services



Agency for Healthcare Research and Quality

Advancing Excellence in Health Care • www.ahrq.gov

Advancing CER and PCOR Uptake: The Role of Training

Sharon Arnold, Ph.D.
Acting Director

David Meyers, Ph.D.
Chief Medical Officer

PhRMA Foundation 2017 Meeting
January 26, 2017 **Washington, DC**



AHRQ Improves the Safety and Quality of the Health Care Delivery System

Mission

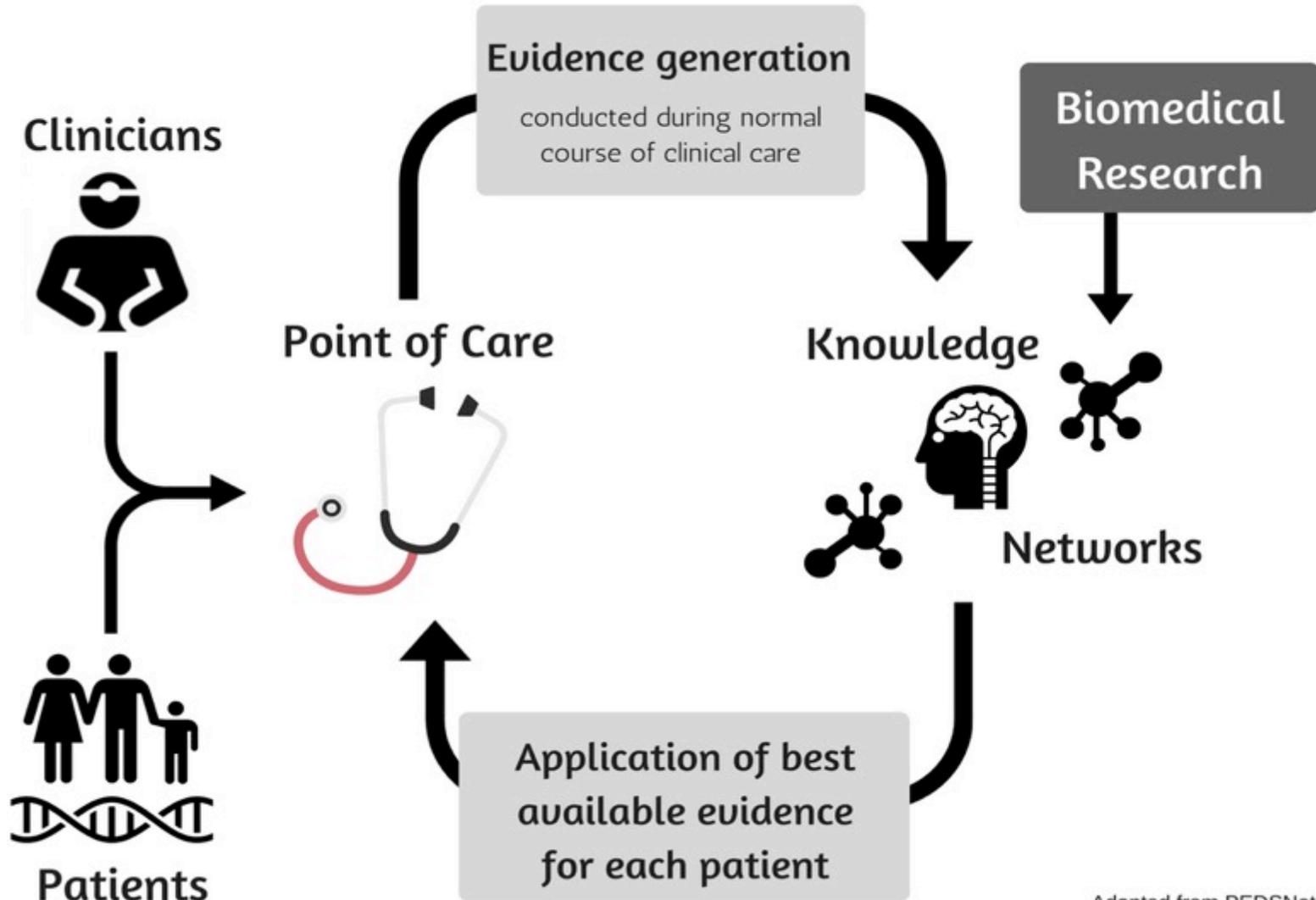
Produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and work within HHS and with other partners to make sure the evidence is understood and used



What AHRQ Does

- **AHRQ invests in research and evidence** to understand how to make health care safer and improve quality
- AHRQ works with frontline clinicians and health care providers, **creating materials to teach and train** them to apply that evidence to improve care
- **AHRQ generates measures and data** used to track and improve performance and evaluate progress of the U.S. health system

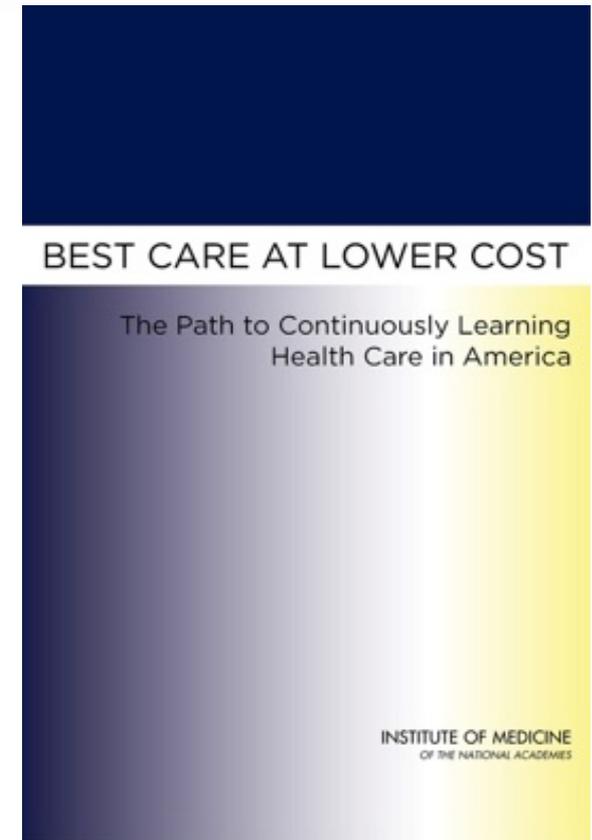
Learning Health System Evidence Implementation and Generation





AHRQ Strategy for a Learning Health System

- Encourage a health system “pull” to transfer knowledge
- Build capacity to generate, adopt, and apply evidence
- Promote data analytics to support population management
- Make evidence available through clinical decision support





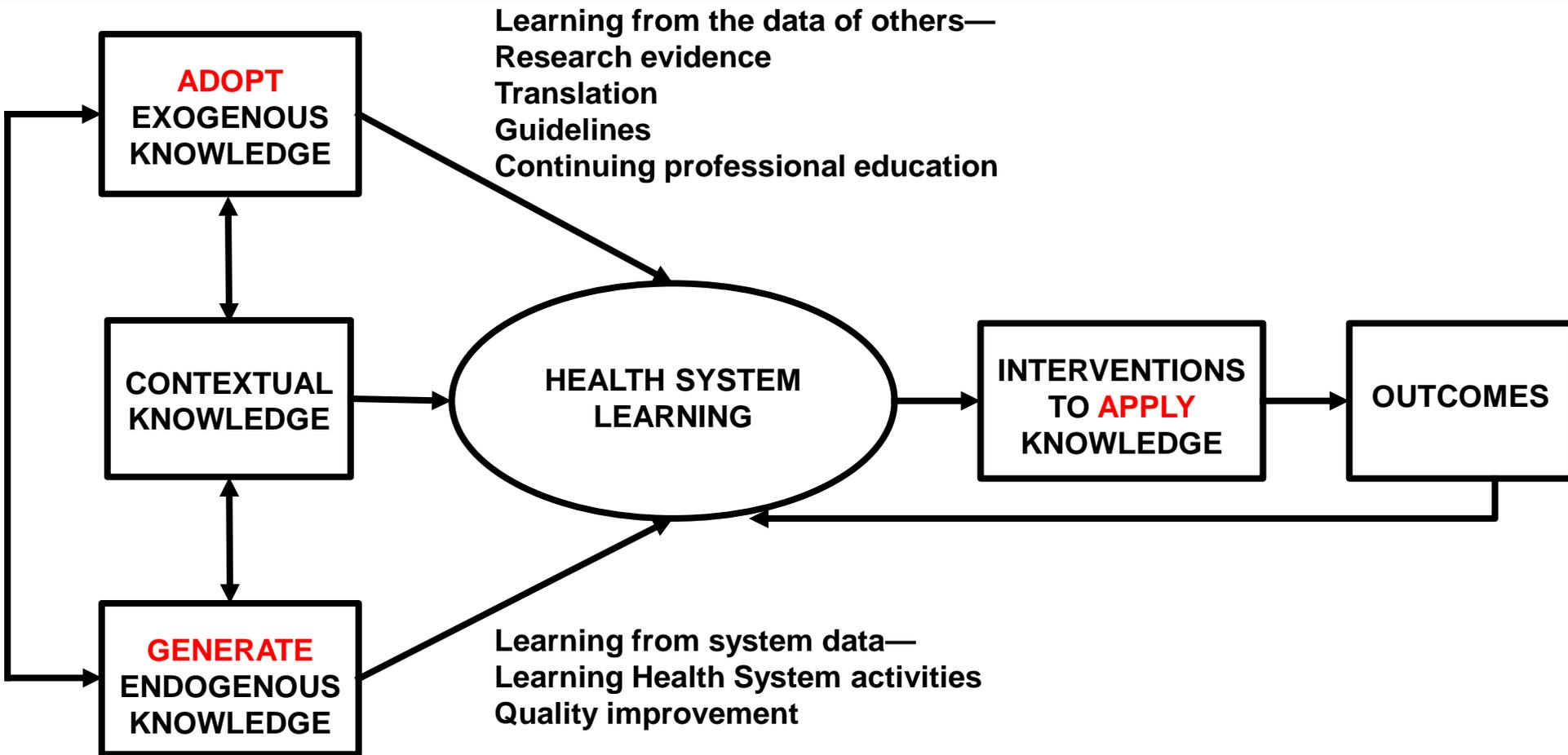
Affordable Care Act Charge to AHRQ

Dissemination, Building Capacity for Research

- AHRQ, in consultation with NIH, shall **broadly disseminate** the research findings that are published by PCORI... and other government research relevant to comparative clinical effectiveness research
- AHRQ shall build capacity for comparative clinical effectiveness research through the **training of researchers**



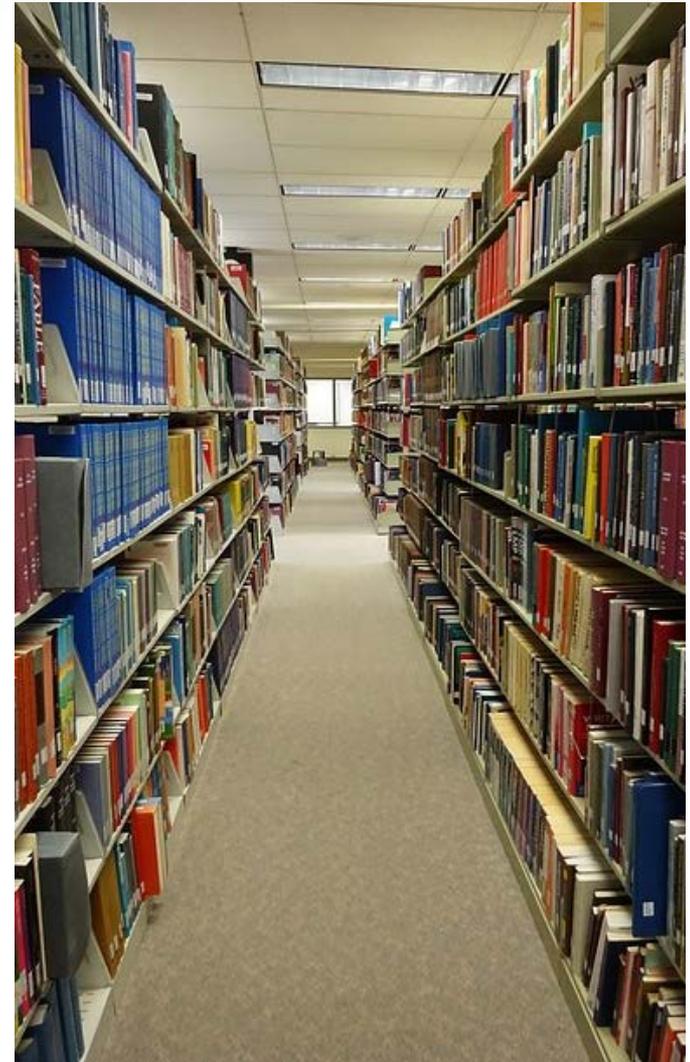
PCOR and Learning Health Systems





Investments in PCOR Dissemination, Training

- Evidence synthesis
 - 27+ systematic evidence reviews since 2010
- Translation and communication
 - Library of PCOR Resources, Eisenberg Center
- Training
 - Funds from PCOR Trust Fund for grants to train researchers





EvidenceNOW Grants

- Grant initiative to support primary care practices' ability to improve heart health for 1 million Americans
- “Personal training” to increase practices' capacity to understand and use evidence
- >1,500 primary care practices
- Focus on ABCS: **A**spirin, **B**lood pressure, **C**holesterol, and **S**moking cessation

Healthy Hearts in the Heartland

(Midwest Cooperative)

HealthyHearts NYC

(New York City Cooperative)

Heart Health Now!

(North Carolina Cooperative)

Healthy Hearts Northwest

(Northwest Cooperative)

Healthy Hearts for Oklahoma

(Oklahoma Cooperative)

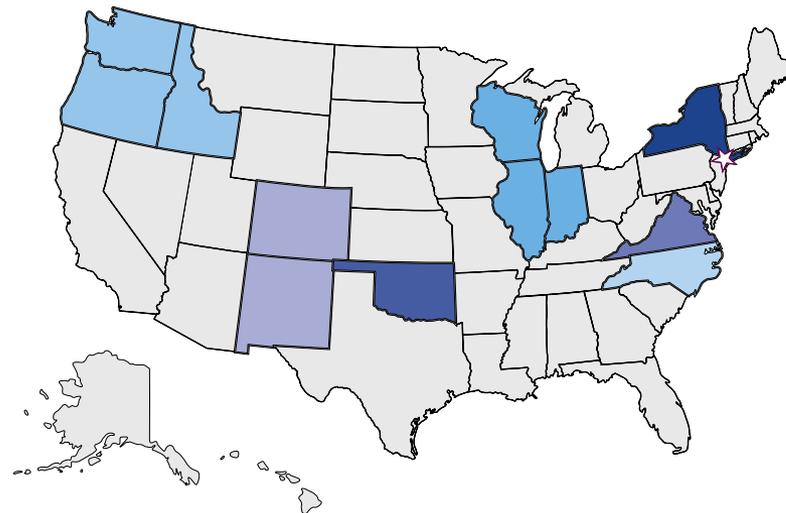
Evidence Now Southwest

(Southwest Cooperative)

Heart of Virginia Healthcare

(Virginia Cooperative)

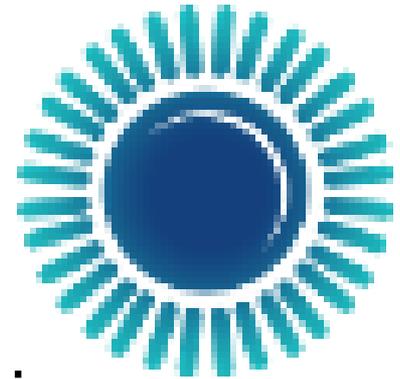
EvidenceNOW
Advancing Heart Health in Primary Care





Clinical Decision Support (CDS) Learning Network

- Accelerate collaborative learning opportunities
- Identify barriers and facilitators to incorporating evidence related to patient-centered outcomes research in CDS
- Monitor use of patient-centered outcomes research evidence in vendor-based and open source CDS tools



www.pcorcds-ln.org



High-Performing Health Systems and Use of PCOR

- Identifying characteristics of health systems that successfully disseminate and apply PCOR evidence
- Five-year study, three sites
 - ▶ **Dartmouth College:** How market and organizational factors influence innovations in biomedical, delivery system, patient engagement
 - ▶ **National Bureau of Economic Research:** How consolidation and integration affects care outcomes
 - ▶ **RAND/Penn State:** Role of incentives, health IT and organizational integration in performance, and evidence dissemination



New Project: PCOR Dissemination and Implementation

- Currently seeking nominations of promising PCOR findings for future D&I activities
- Purpose: to identify promising findings that have the potential for direct impact on patient health outcomes
- Nominated findings must focus on health outcomes of preventive, diagnostic, treatment, or health care delivery approaches; and be published in a peer-reviewed journal





Around the Corner: Training Researchers in Health Systems

- New focus: Learning Health Systems
 - New, evolving approach in which evidence, informatics, incentives, and culture are aligned for continuous improvement and innovation
- K12 Program: Evidence to help LHSs
 - Program seeks PCOR that generates new evidence that LHSs can rapidly implement to improve quality of care and patient outcomes
 - One component of a national multi-pronged approach to training LHS researchers
- Purpose: to prepare newly trained clinician and research scientists



Advancing CER and PCOR Uptake: AHRQ's Role

Thank you!

**Your
questions?**



Clinical Effectiveness
Research
Precise or Pragmatic?
Can We Have it Both?

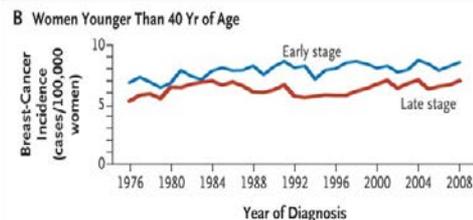
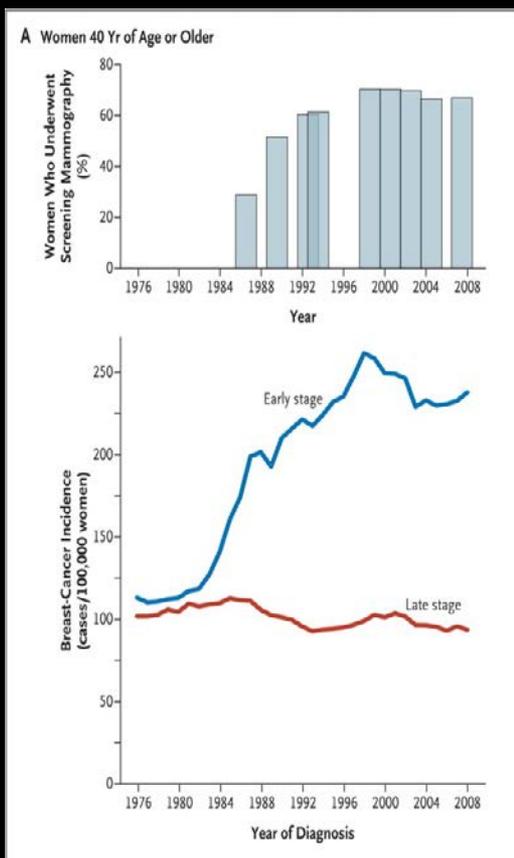
January 26, 2017

PhRMA Foundation

Comparative Effectiveness Conference

The price of imprecision

Use of Screening Mammography and Incidence of Stage-specific Breast Cancer in the United States, 1976-2008



The NEW ENGLAND
JOURNAL of MEDICINE

Bleyer A and Welch HG. Effect of Three Decades of Screening Mammography on Breast-Cancer Incidence. *N Engl J Med* 2012; 367:1998-2005.

Use of Screening Mammography and Incidence of Stage-specific Breast Cancer in the United States, 1976-2008

“Unfortunately, the number of women in the United States who present with distant disease, only 25% of whom survive for 5 years, appears not to have been affected by screening.”

“We estimate that breast cancer was overdiagnosed (i.e. tumors were detected that would never have led to clinical symptoms) in 1.3 million U.S. women in the past 30 years.”

Bleyer A and Welsh HG.
NEJM 2012

NNT

NNH

Screening mammography to prevent breast cancer death

None
ten years

1 in 2 over

Statins for prevention of heart attacks

1 in 104

1 in 100

Source:

The NNT group, Nov. 2015

What is a Pragmatic or Practical Trial?

Practical Clinical Trials

SPECIAL COMMUNICATION

JAMA®

Increasing the Value of Clinical Research
for Decision Making in Clinical and Health Policy

Sean R. Tunis, MD, MSc

Daniel B. Stryer, MD

Carolyn M. Clancy, MD

Decision makers in health care are increasingly interested in using high-quality scientific evidence to support clinical and health policy choices; however, the quality of available scientific evidence is often found to be inad-

- Defined Practical (pragmatic) trials as those in which “the hypothesis and study design are developed specifically to answer the questions faced by decision makers”
- Decision makers include patients, clinicians, payers, policy makers

Decision makers include the
individual

The effectiveness question that matters:

Will it help me?

Special Communication

September 24, 2003

Practical Clinical Trials

Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy

Sean R. Tunis, MD, MSc; Daniel B. Stryer, MD; Carolyn M. Clancy, MD

» [Author Affiliations](#)

JAMA. 2003;290(12):1624-1632. doi:10.1001/jama.290.12.1624

outcomes. The supply of PCTs is limited primarily because the major funders of clinical research, the National Institutes of Health and the medical products industry, do not focus on supporting such trials. Increasing the supply of PCTs will depend on the development of a mechanism to establish

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

This Funding Opportunity Announcement (FOA) is developed as a Common Fund initiative (<http://commonfund.nih.gov>) through the NIH Office of the NIH Director, Office of Strategic Coordination (<https://dpcpsi.nih.gov>). The FOA will be administered on behalf of the NIH by one of the following Institutes, Centers, or Offices:

National Heart, Lung, and Blood Institute (NHLBI)

National Institute on Aging (NIA)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute on Drug Abuse (NIDA)

National Institute of Neurological Disorders and Stroke (NINDS)

National Institute of Nursing Research (NINR)

National Center for Complementary and Integrative Health (NCCIH)

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP)

Division of Program Coordination, Planning and Strategic Initiatives, Office of Strategic Coordination (Common Fund)

Funding Opportunity Title

NIH Health Care Systems Research Collaboratory -
Demonstration Projects for Pragmatic Clinical Trials (UG3/UH3)

Pragmatic vs Explanatory

Broad eligibility

Narrow eligibility

Flexible interventions
instructions

Strict

Typical practitioners
practitioners

Expert

No follow-up visits
follow-up visits

Frequent

Objective clinical outcome
outcomes

Surrogate

Usual compliance
monitoring

Close

Intent-to-treat
protocol

ITT plus per

Thorpe KE et al. CMAJ 2009;180:E47



Browser: http://sites.duke.edu/rethinkingclinicaltrials/ Knowledge Repository Rethinking Clinical Trials®

Rethinking Clinical Trials®

A Living Textbook of Pragmatic Clinical Trials

Welcome to the Living Textbook Topic Chapters Tools for Research

Welcome to the Living Textbook

Welcome to the NIH Collaboratory's Rethinking Clinical Trials Pragmatic Clinical Trials! The Living Textbook is designed to provide you with how to understand, design, conduct, analyze & disseminate pragmatic clinical trials (PCTs).

Topic Chapters



Topic Chapters provide detailed, focused information on various aspects of pragmatic clinical trials and links to resources.

Introduction • Conflict of Interest • Patient-Reported Outcomes • Regulatory Issues • Healthcare Systems • EHR

Tools for Research



Tools for Research encompasses a variety of "toolkits" for conducting different aspects of pragmatic clinical research.

Electronic Phenotyping • Biostatistical Quality • Computer-Adaptive Testing • Outcomes White Papers • Writing for Pragmatic Clinical Trials

Blog



The Living Textbook Blog offers new content available on Rethinking Clinical Trials.

Browser: http://sites.duke.edu/rethinkingclinicaltrials/ Knowledge Repository Tools for Research | Rethinking Clinical Trials®

Rethinking Clinical Trials®

A Living Textbook of Pragmatic Clinical Trials

Welcome to the Living Textbook Topic Chapters Tools for Research Blog Contact Us How to Cite

Tools for Research

This section of the Living Textbook contains a series of tools for conducting pragmatic clinical research, many of them developed by the NIH Collaboratory and our partner organizations. These tools, guidelines, and other resources are also available via the Collaboratory Knowledge Repository. Data of tools are organized by their broad topic area, and include the following:

Electronic Phenotype Definitions & Resources

The Collaboratory Phenotypes, Data Standards, and Data Quality Core is reviewing authoritative sources of electronic phenotype definitions and providing recommendations for the identification and reporting of patient characteristics and clinical conditions. These recommendations and supporting information are intended to promote data standards and help researchers make informed decisions about using electronic health record data for secondary purposes.

Biostatistical Guidance Documents

This biostatistical research tool set includes a series of guidance documents developed by the Collaboratory Biostatistics and Study Design Core. These documents, which focus on detailed aspects of statistical design for conducting pragmatic clinical trials, provide a brief synthesis of current developments, discuss possible future directions, and, where appropriate, make recommendations for application to pragmatic clinical research.

Assessing Data Quality for Healthcare Systems Data Used in Clinical Research

This white paper from the Collaboratory's Phenotypes, Data Standards & Data Quality Core provides guidance, based on the best available evidence and protocol, for assessing data quality in pragmatic clinical trials (PCTs) conducted through the Collaboratory. Topics covered include an overview of data quality issues in clinical research, data quality assessment dimensions (completeness, accuracy, and consistency), and a series of recommendations for assessing data quality.

Computer Adaptive Testing Approach to Patient-Reported Outcomes

This slide presentation illustrates how to use an application programming interface (API) to create a computer adaptive testing (CAT) program that integrates patient-reported outcome (PRO) measures with your institution's electronic health record (EHR) system. With a CAT approach, PRO assessment can cover a wide range of question/responses with increased precision. The authors describe a clinical use case for a mobile health solution.

Patient-Reported Outcomes White Papers

The Collaboratory Patient-Reported Outcomes (PRO) Core and the PCORnet Patient-Reported Outcomes Task Force have developed the following white papers in keeping with their mission to provide and develop strategies, tools, and resources related to the measurement, collection, and analysis of patient-generated health information.

New on the Living Textbook

PCORnet Patient-Reported Outcomes Task Force Review and Comments June 30, 2014

Patient-Reported Outcomes White Paper: Addressing June 30, 2014

In the News: Increase in Use of Patient Health Data June 18, 2014

Search the Living Textbook

NIH News

Apply for sites within or staying within the network

PCORnet News

ADAPTABLE study protocol posted to OSF Preprints 6/18/14

PCORnet focuses on improving capacity to conduct EHR through research network

Categories

- Research Tools
- Clinical Trials
- Cluster Randomized Trials
- Comparative Effectiveness Research
- Search
- Data Sharing
- Electronic Health Records
- Guidance Documents
- Informed Consent
- Learning Health Systems
- Patient-Centered Outcomes Research
- Patient-Reported Outcomes
- Regulatory Issues
- Research Reports
- Research



The NEW ENGLAND JOURNAL

Pers

A New Initiative on Precision Medicine

Francis S. Collins, M.D., Ph.D., and Harold Varmus, M.D.

“**T**onight, I’m launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes — and to give all of us access to the personalized information we need to keep ourselves and our families healthier.”

— President Barack Obama, State of the Union Address, January 20, 2015



Building a Cohort of 1,000,000 Volunteers



CORE VALUES- *All of Us*SM Research Program

- Participation is **open** to interested individuals.
- Reflecting the rich **diversity** of America is essential.
- Participants are **partners** in all phases of the program.
- Participants have **access** to information and data about themselves.
- The program will adhere to the PMI **Privacy and Trust Principles** and the PMI **Data Security Policy Principles and Framework**.
- *All of Us*SM is a catalyst for **progressive research programs and policies**.

Requirements for the Next Generation CER

Built to capture real world information

Built with the participant at the center

Recruitment approach and scale allows
conclusions about the diversity of America

Yes- PRECISE

Yes-
PRAGMATIC

Perspectives: Needs and Gaps in the Uptake and Use of CER/PCOR

Panel Discussion

Scott Smith

Panelists

- Eleanor Perfetto, PhD, MS
National Health Council and University of Maryland
- Caleb Alexander, MD, MS
Johns Hopkins University
- Soumi Saha, PharmD, JD
Academy of Managed Care Pharmacy
- Murray Ross, PhD
Kaiser Permanente
- Julie C. Locklear, PharmD, MBA
EMD Serono

Patient Perspective



Eleanor Perfetto, PhD, MS
National Health Council
University of Maryland School of Pharmacy

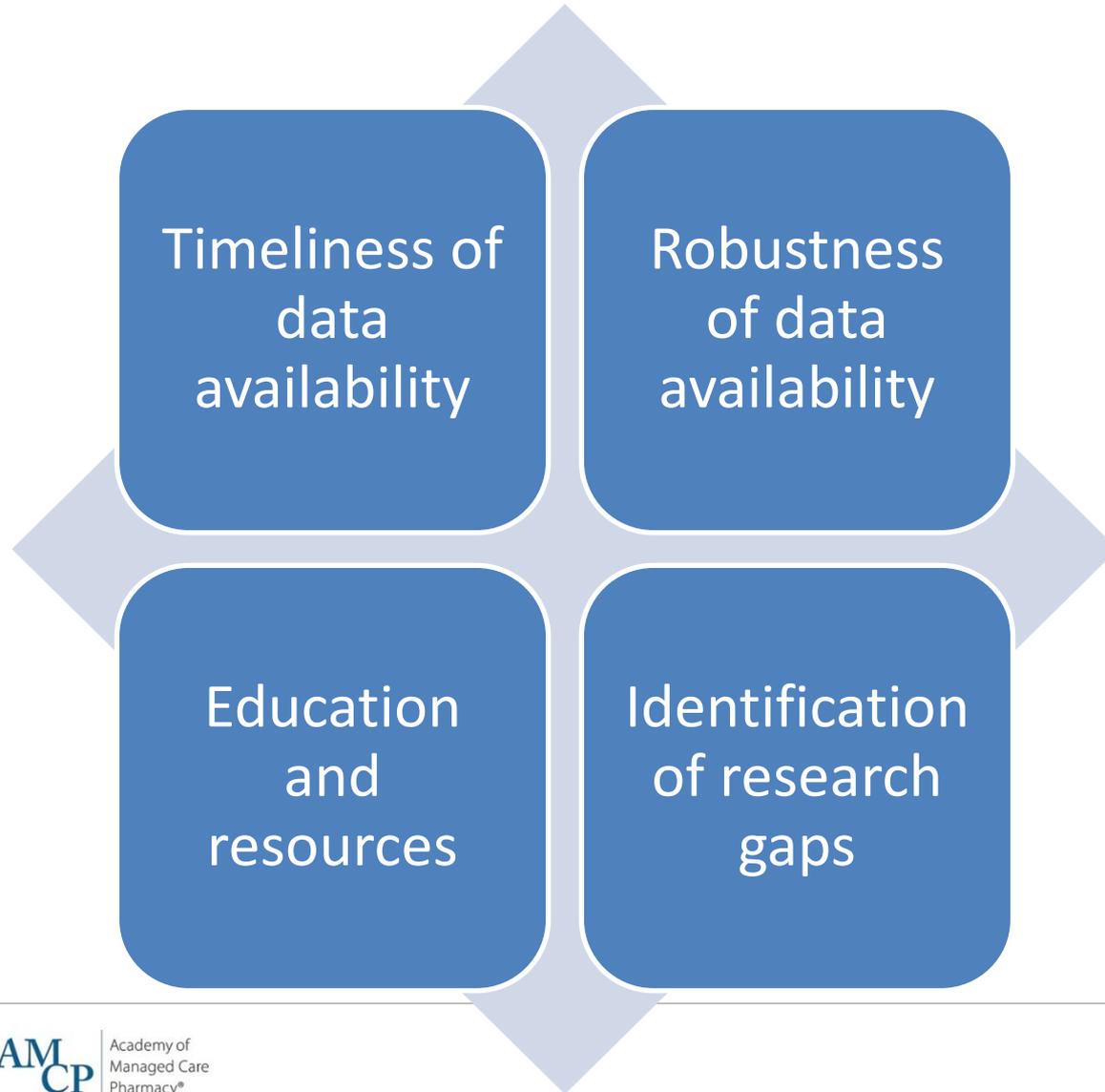
Clinician Perspective



Caleb Alexander, MD

Associate Professor of Epidemiology and Medicine
Johns Hopkins Bloomberg School of Public Health

Payer Perspective



Payer Perspective



Murray N. Ross, PhD

Vice President, Kaiser Foundation Health Plan, Inc.
Director Kaiser Permanente Institute for Health Policy

Clinician Perspective



Julie C. Locklear, PharmD, MBA
Vice President & Head, Health Economics & Outcomes Research
EMD Serono

Instructions for Evening

- Rotunda Ballroom
 - Please take elevators to 8th floor
 - Networking Reception
 - Dinner and Keynote Presentation

The Future of PCOR/CER – Navigating Uncertainty

Keynote Presentation

Kavita Patel