UNIVERSITY of WASHINGTON

DEPARTMENT OF PHARMACY
PHARMACEUTICAL OUTCOMES RESEARCH & POLICY PROGRAM
December 12, 2016

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Dean, Graduate School
Vice-Provost
University of Washington

Sean D. Sullivan, PhD, BScPharm
Dean, School of Pharmacy

Joel Kaufman, MD, MPH
Dean (interim), School of Public Health

Subject: Five Year Report on the Graduate Certificate in Comparative Effectiveness Research
Departments of Pharmacy and Health Services, University of Washington

Dear Dr. Eaton, and Drs. Sullivan and Kaufman:

We are pleased to provide you with the first Five Year Report on the Graduate Certificate in Comparative Effectiveness Research (CER), housed in the Center of Excellence for CER, Departments of Pharmacy and Health Services, University of Washington. Our Report is prepared as a Limited Review, with full concurrence from our School's leadership as noted by Andy Stergachis, Associate Dean for Research and Graduate Programs in his message to Westley Henry dated November 17, 2015.

In the following pages, we outline the activities and accomplishments of our CER Certificate, and describe the meritorious graduate students whom we have been able to support. We are pleased with the achievements of students and faculty involved in the UW Graduate Certificate in CER, and in the CER Center of Excellence. We are confident that this Certificate has enhanced the education of several of our students, and that our reach extends beyond UW. We look forward to continuing the Certificate program in future years.

Please let us know if we can provide additional information.

Best regards,

Beth Devine

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Director, Graduate Certificate in Comparative Effectiveness Research
Graduate Program Coordinator, Department of Pharmacy
Associate Professor, Pharmaceutical Outcomes Research and Policy Program (PORPP)
Adjunct: Health Services; Biomedical Informatics; Surgery

cc.: Andy Stergachis, Associate Dean for Research and Graduate Programs, School of Pharmacy
Anirban Basu, Director, PORPP, Department of Pharmacy
Louis P. Garrison, Emeritus Professor, PORPP, Department of Pharmacy
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Five Year Report to the Graduate School
University of Washington
Graduate Certificate in Comparative Effectiveness Research

December 12, 2016

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UW Graduate Certificate in CER Leadership Team:
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1. CER Certificate Overview

Introduction and Historical Context: Comparative effectiveness research (CER) is the conduct and synthesis of research comparing alternative interventions designed to diagnose, treat and monitor health conditions in real-world settings. The purpose of CER is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers about which interventions are most effective for which patients under specific circumstances.

Although having existed for over 30 years, CER was first called out as a unique discipline in 2006, with work conducted by the Institute of Medicine (now National Academy of Medicine) on the nature of a 'learning health care system'. (IOM 2006) This was followed by funding for CER under the American Reinvestment and Recovery Act (ARRA) in 2009. In 2010, the discipline quickly evolved further into Patient-Centered Outcomes Research (PCOR) through funding provided by the Patient Centered Outcomes Research Institute (PCORI) under the Patient Protection and Affordable Care Act (PPACA). Identification of needs to both train research scientists to create evidence, and users to understand and take up this evidence were immediately apparent. (IOM, 2011; (Murray, 2011).

Overview of the University of Washington (UW) Graduate Certificate in CER: The CER Certificate was developed in response to these needs, specifically to "train adequate numbers of individuals capable of conducting CER and implementing the findings of such research." While we at the UW were already training graduate students to conduct CER, creation of this certificate has provided the framework for a more focused curriculum in CER; and better integration of this training across academic disciplines. Our initial proposal was motivated by receipt of grant funding from the PhRMA (Pharmaceutical Research and Manufacturers Association) Foundation to establish a graduate training program in CER. The Graduate Certificate in CER consists of 18 credits (PORPP) or 16 credits (Health Services) of advanced coursework through courses currently offered in the Schools of Pharmacy and Public Health. (see Table 4)

In building on existing, solid, multi-disciplinary doctoral training programs, we have leveraged the Graduate Certificate in CER into a CER Center of Excellence, and integrated it into the UW Centers for Comparative and Health System Effectiveness (CHASE) Alliance–an interdisciplinary, multi-unit (Medicine, Pharmacy, Public Health, and Nursing) research and training center for CER within the UW Health Sciences campus. The CHASE Alliance partnership also includes the Fred Hutchinson Cancer Research Center (FHCRC), Group Health Research Institute (GHRI), and the Veterans Affairs Puget Sound Health Care System (VAPSHCS).

Additional information can be found at https://sop.washington.edu/department-of-pharmacy/pharmaceutical-outcomes-research-policy-program-porpp/certificate-programs/graduate-certificate-program-in-comparative-effectiveness-research-porpp

Administrative Arrangement: The Certificate is jointly offered by the Pharmaceutical Outcomes Research and Policy Program (PORPP), Department of Pharmacy, School of Pharmacy, and the Department of Health Services, School of Public Health. The CER Certificate is also available to students in epidemiology, biostatistics, nursing, medicine, and other health-related graduate programs. The CER Certificate is administratively housed in PORPP, Department of Pharmacy.

Objectives of the CER Certificate Program: The objectives of the CER Certificate were, and still are, the following:

1: Support the development of educational and training programs that clearly and efficiently teach students and practitioners how to conduct rigorous, useful, and effective CER;
2: 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;
3: Furnish the necessary resources that can be used to develop corroborating evidence on the usefulness and value of sound CER;
4: Convene public forums and seminars for interested members of the public from the wider university/college community to discuss topical CER issues;

5: 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 researchers and practitioners;
6: Sponsor lectures and presentations on different programs and in different venues, e.g., AHRQ, NIH, Industry, and universities, that promote conscientious discussions on important CER topics;
7: Work with representatives from government, industry and academia to determine the number and types of CER trained experts needed to fill the personnel demands of these societal sectors;
8: 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 PhRMA Foundation.

2. Faculty

Members of the leadership team and core faculty for the CER Certificate remain constant, yet some have changed roles since program inception. All remain involved in the certificate program. Table 1 lists the original and current roles, respectively, of the members of the leadership team and core faculty.

Table 1: Leadership and core faculty, original and current roles

Name	Position	Role on CER Certificate
ORIGINAL ROLES		
CER Certificate Leadership Team		
Lou Garrison, PhD	Professor & Associate Director, PORPP; Adjunct, Health Services	Program Director
Anirban Basu, PhD	Professor, Health Services; Adjunct: PORPP	Leadership Team
Beth Devine, PhD, PharmD, MBA	Associate Professor, PORPP; Adjunct: Health Services	Leadership Team
CER Certificate Core Faculty		
Sean Sullivan, BScPharm, PhD	Professor & Director, PORPP; Joint, Health Services	Core Faculty
Larry Kessler, ScD	Professor & Chair, Health Services; Adjunct: PORPP	Core Faculty
David Veenstra, PharmD, PhD	Professor & Director, Graduate Program, PORPP; Adjunct: Public Health Genetics	Core Faculty
David Grembowski, PhD	Professor & Director, Graduate Program, Health Services	Core Faculty
CURRENT ROLES		
CER Certificate Leadership Team		
Beth Devine, PhD, PharmD, MBA	Associate Professor & Director, Graduate Program, PORPP; Adjunct: Health Services	Program Director (as of late 2014)
Anirban Basu, PhD	Professor & Director, PORPP; Joint: Health Services	Leadership Team
Lou Garrison, PhD	Emeritus Professor, PORPP; Adjunct, Health Services	Emeritus Leadership Team
CER Certificate Core Faculty		
Sean Sullivan, BScPharm, PhD	Dean, School of Pharmacy; Professor, PORPP; Joint, Health Services	Retired from role on CER Certificate
Larry Kessler, ScD	Professor, Health Services; Adjunct: PORPP	Core Faculty
David Veenstra, PharmD, PhD	Professor & Associate Director, PORPP; Adjunct: Public Health Genetics	Core Faculty
David Grembowski, PhD	Professor & Director, Graduate Program, Health Services	Core Faculty

In late 2014, Dr. Garrison transitioned the CER Certificate Program Director role to Dr. Devine. All other advancements in professional responsibilities have taken place in 2015 and 2016.

We have extensive collaborations with faculty across departments, schools, programs, and health-systems. Table 2 provides a partial list, each with their current appointments. At any point in time, the list of faculty fluctuates, as collaborations are established, and projects are launched and completed.

Table 2: Extended Faculty

Name	Title
University of Washington and Fred Hutchinson Cancer Research Center	
Aasthaa Bansal, PhD	Research Assistant Professor, PORPP
Carrie Bennette, PhD	Acting Assistant Professor, PORPP
Brian Bresnahan, PhD	Research Associate Professor, Radiology, Health Services, PORPP
Josh Carlson, MPH, PHD	Associate Professor, PORPP
Beth Ebel, MD, MSc, MPH	Professor, Medicine, Public Health, Seattle Children's Hospital
Joann Elmore, MD, MPH	Professor, Medicine, Public Health
Ruth Etzioni, PhD	Professor, Health Services; Full Member, FHCRC
David Flum, MD, MPH	Professor, Surgery, Health Services
Jana Friedly, MD	Associate Professor, Rehabilitation Medicine
Ryan Hansen, PharmD, PhD	Research Assistant Director, PORPP
Jeffrey (Jerry) Jarvik, MD, MPH	Professor, Radiology, PORPP
Tom Hazlet, PharmD, DrPH	Associate Professor, PORPP, Health Services
Danielle Lavallee, PharmD, PhD	Research Assistant Professor, Surgery
Pam Mitchell, PhD, RN	Professor, Nursing, Public Health
Donald Patrick, PhD	Professor, Health Services; Full Member, FHCRC
Scott Ramsey, MD, PhD	Professor, Medicine, PORPP; Full Member, FHCRC; Director, Hutchinson Institute for Cancer Outcomes Research
Andy Stergachis, PhD	Professor and Associate Dean, School of Pharmacy; Professor, Public Health, Global Health
Edward Weaver, MD, MPH	Professor, Medicine
Group Health Research Institute	
Denise Boudreau, PhD	Senior Investigator
Kathy Bradley, MD, MPH	Senior Investigator
Diana Buist, PhD	Senior Investigator
Paul Fishman, PhD	Senior Investigator
Eric Larson, MD, MPH	Senior Investigator and Executive Director
Michael Von Korff, PhD	Senior Investigator
VA Puget Sound Health Care System	
David Au, MD, MS	Professor, Medicine
Stephen Fihn, MD, MPH	Professor, Medicine

FHCRC = Fred Hutchinson Cancer Research Center

3. Students

The Certificate was approved by the Board of Regents in January 2012, marketing commenced in April and May 2012, and the first students enrolled in the Fall of 2012. To market the program, the Leadership Team created a website and announced the Certificate on listservs in the Schools of Pharmacy, Public Health, Medicine and Nursing. The website was launched in April 2012 (https://sop.washington.edu/department-of-pharmacy/pharmaceutical-outcomes-research-policy-program-porpp/certificate-programs/). The website initially included three types of enrollment forms: 1) application for the Pre-doctoral Fellowship, 2) application for the Dissertation Fellowship, 3) simple registration form. The website has been a useful tool to explain the program to interested students. Each year since 2012, a one-page flyer has been distributed to students in the UW Health Sciences campus to announce the application cycle for each year. (Appendix: Figure)

To heighten awareness of and interest in the CER Certificate, we created two awards to support graduate students in developing expertise in CER. These were funded through the initial grant from the PhRMA Foundation:

1) **PhRMA Foundation Pre-Doctoral Fellowship in CER** – this fellowship was intended for second or third year PhD students who intended to complete both the CER Certificate and a CER-related dissertation. The fellowship consisted of one four-quarter research assistantship and three quarters of tuition.

2) **PhRMA Foundation Dissertation Fellowship Program in CER** - this fellowship was intended for fourth of fifth year PhD students whose CER-related dissertation was underway, and who needed extra support to purchase a needed dataset or for travel to present CER-related work at national meetings. This stipend was $10,000 per student.

The PhRMA Foundation funding ended in November 2014. Our judicious use of funds enabled us to provide fellowship support for one fellowship for the 2014-2015 academic year, through a no-cost extension. Since then, we have encouraged students to register at any time to pursue the certificate. Table 3 lists the status of the students who have completed the program. Three students have completed the pre-doctoral fellowship, five received the dissertation fellowship, and three have completed or are currently enrolled in the Certificate program without funding. To date, five students have completed the Certificate and one is in process. Nine of the eleven students who have benefited from participating in the CER Certificate program have earned their PhDs and are well-positioned to achieve success in their chosen career paths, in academia or in a non-profit research firm (Kaiser). The final two are well on their way to graduating, both having already secured professional positions, one in the non-profit sector (Washington Research Foundation), the other with the federal government (Veterans Affairs).

The amount of funding we received, and the number of students that have completed the certificate is consistent with what was outlined in the original proposal.

Table 3: Students Completing the UW Graduate Certificate in CER

Student	Department	Year of CER Funds	Year PhD Obtained	Title of Capstone Project	Current Position
CER Certificate Pre-Doctoral Fellowship Students (funded on one, full-year research assistantship)					
Cara McDermontt, PharmD, PhD	PORPP	2013-2014	2016	*McDermott C, Lockart C, Devine EB. Directly observed therapy for hepatitis C treatment: a systematic review and meta-analysis. (in preparation)*	Senior Fellow, Cambia Palliative Care Center of Excellence UW School of Medicine
Laura Chavez, PhD	HServ	2013-2014	2015	*Chavez LJ, Bradley K, Tefft N, et al.Preference weights for the spectrum of alcohol use in the U.S. Population. Drug Alcohol Depend. 2016 Apr 1;161:206-13. doi: 10.1016/j.drugalcdep.2016.02.004.PMID:26900145*	Senior Fellow, Health Services Management and Policy, The Ohio State University
David Kim, PhD	HServ	2014-2015	2015	*The cost-effectiveness of treatments for individuals with alcohol use disorders: A Reference Case Analysis. Kim DA, Basu A, Duffy SQ, Zarkin GA. In: Cost-effectiveness in Health and Medicine. 2nd edition. Neumann PJ, Sanders GD, Russell LB, Siegel JB, Ganiats TG. Oxford University Press, 2016.*	Assistant Professor, Center for the Evaluation of Value and Risk in Health, Tufts Medical Center Institute for Clinical Research and Health Policy Studies

Table 3 (continued): Students Completing the UW Graduate Certificate in CER

Student	Department	Year of CER Funds	Year PhD Obtained	Title of Capstone Project	Current Position
CER Certificate Dissertation Fellowship Students (funded with one $10,000 stipend)					
John Dickerson, PhD	HServ	2012-2013	2014	Not required	Investigator, Kaiser Northwest Center for Health Research, Portland, OR
Carrie Bennette, PhD	PORPP	2013-2014	2014	Not required	Acting Assistant Professor, PORPP
Jeannette Birnbaum, PhD	HServ	2014-2015	2014	Not required	Research Scientist, Center for AIDS Research, UW
Sean Rundell, PT, DPT, PhD	Epi	2013-2014	2014	Not required	Assistant Professor, Department of Rehabilitation Medicine, UW
Maria Agapova, PhD	PORPP	2014-2015	2015	Not required	Research Scientist, PATH, Seattle, WA
CER Certificate Dissertation Fellowship Students (not funded but registered to complete the certificate)					
Amy Cizik, PhD	PORPP	None	2016	*Cizik AM, Lee MJ, Martin BI, et al. Using the spine surgical invasiveness index to identify risk of surgical site infection: a multivariate analysis. J Bone Joint Surg Am. 2012 Feb 15;94(4):335-42. doi: 10.2106/JBJS.J.01084.PMID: 22336972*	Research Scientist, Department of Orthopedic Surgery, UW
Will Canestaro, PhD Candidate	PORPP	None	Anticipated 2017	*Canestaro WJ, Forrester SH, Raghu G, et al. Drug Treatment of Idiopathic Pulmonary Fibrosis: Systematic Review and Network Meta-Analysis. CHEST. 2016 Mar;149(3):756-66. doi: 10.1016/j.chest.2015.11.013. Review. PMID:26836914*	PhD student, PORPP, UW; Manager, Strategic Investments Washington Research Foundation
Mark Bounthavong, PhD Candidate	PORPP	None	Anticipated 2018	*Bounthavong M, Bae Y, Vanness DJ, et al. Comparison of clinical remission among biologics for moderate-to-severe Crohn's disease: A Bayesian network meta-analysis. (in preparation)*	PhD Student, PORPP, UW; Data Pharmacist Program Manager, Pharmacy Benefits Management National Academic Detailing Program Office Veterans Health Administration

Epi=Epidemiology; HServ=Health Services; PORPP=Pharmaceutical Outcomes Research & Policy Program

4. Changes to the CER Certificate Program since Inception

The curriculum, faculty and staff involved in the CER Certificate program have all remained stable since inception. As anticipated, the grant funding from the PhRMA Foundation covered the first three years of the program and supported meritorious students as described above. Although we were initially hopeful that the PhRMA Foundation would offer a second round of grant funding, their leadership made the strategic decision not to do so. Although we discussed this option with them, they reasoned that the program had already achieved the success they had originally envisioned, as six academic institutions had seeded new programs in CER (UW, Johns Hopkins, Harvard, University of Utah, University of Maryland, and University of Illinois, Chicago). Thus, as outlined in our original proposal to the Graduate School, we have retained the program and encourage students to complete the required course motivated by their desire to learn the material as an investment in their own future.

5. Progress of the CER Certificate Program

Our respective graduate programs have incorporated recruitment strategies to enable application of under-represented students. For our graduate programs, our departments welcome students who have varied cultural experiences or educationally or economically disadvantaged backgrounds, who therefore contribute to the intellectual and social enrichment of the graduate programs. To the extent these students are admitted to the PhD programs in PORPP and Health Services, they have had the opportunity to apply for the CER Certificate program. Enrollment in the Graduate Certificate in CER is entirely voluntary.

The CER Certificate is comprised of 19 (PORPP) or 17 (Health Services) credit hours of advanced coursework including a capstone project, and varies according to the core curricular requirements for each program. (Table 4)

Table 4: Graduate Certificate in CER, Credit Totals, per PhD Program

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
BIME 541/EPI 541/HSERV 529/PHARM 529: Introduction to Meta-Analysis	3	3
BIOSTATS 578A: Bayesian Statistics for the Health Sciences	3	3
PHARM 536: Advanced Methods in CER	3	3
CAPSTONE Project	1	1
TOTAL CREDITS FOR CERTIFICATE	18	16

BIME = Biomedical Informatics and Medical Education; BIOSTATS = Biostatistics; EPI = Epidemiology; HSERV = Health Services; PHARM = Pharmacy (Pharmaceutical Outcomes Research and Policy Program)
Core = Course is a required course for that PhD program and is therefore not eligible for inclusion in the CER Certificate.

Two new advanced methods courses were developed for the CER Certificate program: Pharm 536 (Advanced Methods in CER) and BIOSTATS 578A (Bayesian Statistics for the Health Sciences). These courses are proving quite popular, as is HSERV 525 (Advanced Health Services Research Methods, quarter 3). BIME 541 (Introduction to Meta-Analysis), is quite popular with students from Health Services, Epidemiology, Global Health, and clinical scholars from the School of Medicine. The cross-listing for the Meta-Analysis course in Pharmacy is new, having occurred in 2014. In Spring 2016, Dr. Lurdes Inoue, who teaches the Bayesian Statistics course, offered to cross-list her course in PORPP. The PORPP students and faculty are delighted and will do so prior to the next biennial course offering in Spring 2018. Functioning in parallel with the CER Certificate program are the other training programs in CER, jointly sponsored by PORPP and Health Services. These include the UW AHRQ pre-doctoral T32 training grant in Health Services Research, the Agency for Healthcare Research and Quality (AHRQ) K12s, let by Dr. Sean Sullivan. In succession, these are 1) the K12 in CER (2010-2013; 4 scholars), 2) the K12 in Patient Centered Outcomes Research (PCOR; 2012-2014; 3 scholars), and the current K12 in PCOR (2014-2019; 10 scholars).

As a part of the CHASE Alliance, the UW Surgical Outcomes Research Center Survey Center, led by Dr. Danielle Lavallee, has strengthened the patient-centeredness of CER training. The Survey Center has also enabled integration of patient-centered outcomes research (PCOR) into research projects of students and faculty, alike.

The Pacific Northwest Evidence-based Practice Center (PNW EPC; http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-practice-center/), led by Dr. Beth Devine, is one of 11 EPCs sponsored by AHRQ. The PNW EPC is a partnership between Oregon Health & Science University, the UW CHASE Alliance, and Spectrum Research, Inc. This partnership has enabled development of expertise the synthesis of evidence to inform healthcare decision-making, an integral element of CER and PCOR.

The UW CHASE Alliance "Works in Progress" sessions (CHASE WIPs) serve as the most widely used venue for presentation of CER-related topics. Both students and faculty present at these two-hour sessions, held weekly, throughout the academic year. Between October 2011 and December 2016 137 CER-related presentations were delivered in this venue by students, post-docs, and faculty. (Appendix Table)

The PheNOM Seminar series (Program in Health Economics and Outcomes Methodology; http://depts.washington.edu/phenom/seminar/), led by Dr. Basu, is a companion series to the CHASE WIPs, and provides another weekly opportunity for students, post-docs and faculty in Pharmaceutical Outcomes, Health Services, and Economics, to convene for seminars and lively discussion to advance research methods.

With support from the PhRMA Foundation, AHRQ and PCORI, members of the UW Center for Excellence CER Leadership Team (Drs. Garrison and Devine), and led by colleague Dr. Jodi Segal from Johns Hopkins University, were awarded a Large Conference Grant from AHRQ (R13; PA-06-378) to conduct the 120-person conference titled, *"Curricular Advances for Comparative Effectiveness Research".* We are grateful to Ms. Eileen Canon of the PhRMA Foundation, who led the charge in securing the many details for us. The conference was held in January 2014 at the Pew Conference Center in Washington DC and was deemed a success. The 120 attendees, representing 50 unique academic institutions, the life sciences industries, federal government, professional organizations, and health plans discussed their needs and approaches to preparing a workforce skilled in conducting CER/PCOR. The conference report is found in Appendix XX. Dr. Devine presented a summary of the conference at the Health Sciences Research Learning Consortium at the Academy Health meeting in San Diego (June 2014) in June on the topic "*Preparing a Workforce Skilled in PCOR and CER".* A companion report by Avalere Consulting Group outlined next steps in CER education, recommending that professionals be trained to be users of CER/PCOR. A follow-on invitational conference to achieve this goal is to be held in January 2017, at the Ronald Reagan Building in Washington DC. Dr. Devine is on the leadership team for this conference and Dr. Garrison will be a keynote speaker. The conference agenda is attached as Appendix XX.

Spring-boarding from our CER and PCOR training programs, in 2014-2015, Drs. Devine, Kessler and Seibel (Mechanical Engineering) developed a training program in Translational Team Science as part of the UW Clinical and Translational Science Award (CTSA), the Institute for Translational Health Sciences (ITHS). The core element of the program is forty, short, video modules, offered asynchronously to investigators at all levels of their career, and provides introductory-level material in disciplines that range from basic science to population-based science. Many CER faculty listed in this report contributed their expertise by recording a video. We are grateful to each of them. The goal of the program is to enhance the understanding of all scholars, to areas of research outside their own, and to facilitate collaborations across phases of translational science. The offerings may eventually be rolled out to investigators across the WWAMI (Washington, Wyoming, Alaska, Montana, Idaho) region.

Dr. Kessler is the principal investigator of one of five R25 grants from AHRQ (RFA-HS-14-004; *"Research Training and Workforce Development in Methods and Standards for Conducting Patient-Centered Outcomes Research Studies"*), to train clinician scholars to conduct CER/PCOR. Titled, the Patient-Centered Outcomes Research Partnership, Dr. Kessler's grant focuses on training clinician-scientists in the WWAMI region and beyond. Participating institutions include Swedish Medical Center, South Central Foundation of Alaska, MultiCare, Sanford Health of North Dakota, University of Hawaii, Idaho State University, University of Montana, and PeaceHealth Southwest. To date, 30 scholars have been trained, are pursuing projects and seeking external funding. The third and final cohort will be trained in summer 2017. Drs. Devine and Basu are active co-investigators on this grant and have developed some of the curricula.

Separately, PORPP is now in its sixth year of offering an online, distance learning program, titled the "Certificate in Health Economics and Outcomes Research" (HEOR: http://www.pce.uw.edu/certificates/health-economics.html). This certificate series, separate from the UW Graduate Certificate in CER, is being offered by PORPP, through UW Educational Outreach. This certificate program is led by core PORPP faculty (Drs. Sullivan, Garrison, Basu, Veenstra, Carlson, and Devine), trains between 60-90 students per year, from across the globe. The HEOR Certificate appeals widely to participants employed in the pharmaceutical industry.

Finally, an emerging opportunity, aligned with the mission of our CER Center of Excellence, albeit tangential to the Graduate Certificate in CER, is the interest of the Doctor of Pharmacy students in learning more about CER. Many of them currently do so through an elective course in the PharmD curriculum, taught by Drs. David Veenstra and Pete Fullerton. Through this course, PHARM 592 (Managed Care Pharmacy), they learn to apply CER methods to drug formulary decision-making in the managed care context. The PharmD curriculum does not allow students the time to complete the core graduate level coursework by which they would become eligible to complete the CER Certificate. However, PORPP faculty members do encourage students to consider completion of a master's degree in PORPP. Moreover, some eventually do complete the PhD, and are then eligible to complete the Certificate. This is a long-term investment in our students.

6. Challenges to the CER Certificate Program

Three challenges exist for the CER Certificate program. The first is the lack of external funding in the form of pre-doctoral fellowships, which held great appeal to the students in the first three years of the program. The second is that although we would very much like to welcome a greater number of students into the Certificate program, the pre-requisites, in terms of core coursework, are aligned with the PhD programs in PORPP and Health Services. Students from other departments (e.g. Economics), PharmD students, and master's level students have not completed the core coursework that makes them eligible to enroll in the CER Certificate program. The third and final challenge for the Certificate is that the methods for conducting CER/PCOR are evolving so rapidly that two courses that are currently part of the CER curriculum have proven so popular, that they have become necessary training for PORPP students. Indeed, the PORPP faculty plans to add these two courses to the required core for the incoming PhD class in Fall 2017. This will mean that new courses (see section 7.) will have to be identified to maintain the CER Certificate offering for PORPP students. Although this, in itself, is not a barrier (there are many courses from which to choose), each addition has the potential to extend the curriculum to require a greater number of years in training, a notion to which the PORPP faculty is opposed. With this in mind, the PORPP faculty plans a curricular revision in the coming months. This problem will not affect the Health Services PhD students who enroll in the CER certificate program.

7. Goals of the CER Certificate Program for the Next 5 Years

The faculty and students in the PORPP and Health Services PhD programs continue to collaborate across schools. As evidence to this, the short-term plan is to cross-list Pharm 536 in Health Services, and HSERV 525 in Pharmacy.

More broadly, as mentioned above, the CER Certificate program has been so successful that the training required is no longer optional but rather an integral part of the education of all our PhD students. As such, we will consider the following revisions in to the CER Certificate program in the near future:

1) Broaden the selection of courses to include those from several additional and emerging disciplines:

a) Data Science: Data Science has applications to healthcare. Learning how to analyze large datasets and display the results of CER/PCOR using these methods is becoming increasingly important. The University of Washington eScience Institute, as well as the Departments of Biomedical Informatics, Computer Science and Engineering, and the Information School offer courses in this emerging discipline.

b) Policy-relevant courses: The Evans School offers many policy-relevant courses to guide today's healthcare policy decisions.

c) Economics and Econometrics: The Department of Economics offers courses in labor economics and econometrics that may appeal to some of our students.

2) Realign the CER Certificate with the mission of the to-be-designated PORPP Institute: The PORPP faculty is currently awaiting approval of their proposal to be designated as a UW institute. Should that proposal be successful, there will be an opportunity to revise the CER Certificate to align with a newly refined, albeit similar, mission of PORPP.

Conclusion

In summary, we are pleased with the achievements of students and faculty involved in the UW Graduate Certificate in CER, and in the CER Center of Excellence. We are confident that this Certificate has enhanced the education of several of our students, and that our reach extends beyond UW. We look forward to continuing the Certificate program in future years.

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Five Year Report to the Graduate School
University of Washington
Graduate Certificate in Comparative Effectiveness Research

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Graduate Certificate Program in Comparative Effectiveness Research (CER) at the University of Washington

A Proposal to the
University of Washington Graduate School

November 28, 2011

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Pharmaceutical Outcomes Research and Policy Program, School of Pharmacy
Department of Health Services, School of Public Health
University of Washington
Seattle, Washington

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1. Introduction and Establishment of Need

Formal health technology assessment (HTA) in the U.S. has existed for over 30 years. More recently, in 2006, the Institute of Medicine (IOM) with the support from the Commonwealth Fund began a thorough appraisal of the state of evidence-based medicine and the nature of a 'learning health care system'. The concept and term "comparative effectiveness research" (CER) emerged out of that inquiry along with the recognition that much of current medical practice does not have a strong evidentiary base. This led to funding for CER under the American Reinvestment and Recovery Act (ARRA) in 2009 and creation of the Patient-Centered Outcomes Research Institute (PCORI) through the Patient Protection and Affordable Care Act (PPACA) in 2010. However, a recent IOM report has highlighted the talent shortage in CER and training needs (IOM, 2011), recognizing that CER requires rapid, high-quality, stakeholder-informed interdisciplinary research, and that a new cadre of researchers is needed who can not only design and conduct innovative and pragmatic CER studies, but also implement findings from CER in a variety of complex healthcare settings (Murray, 2011).

CER is the conduct and synthesis of research comparing alternative interventions designed to diagnose, treat and monitor health conditions in real-world settings. The purpose of CER is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers about which interventions are most effective for which patients under specific circumstances. An important aspect of CER is responding to priority areas identified by stakeholders with targeted and timely research intended to inform decision-making.

New investigators need to know how to collaborate with stakeholders to conceive a hypothesis, to design and conduct definitive observational and experimental research, and to translate this knowledge into high-fidelity, practical applications in clinical and community settings. Furthermore, multidisciplinary training, practical experiences, and strong mentorship are needed to create these new investigators who can facilitate the advance of clinical and CER methods and knowledge. Finally, it is the responsibility of both new and established investigators in the CER field to share their skills, expertise and knowledge in a variety of public and professional forums and to make CER training tools readily accessible to those interested in learning more about this emerging discipline.

In light of these issues and challenges, we are pleased to submit this proposal to establish a University of Washington (UW) **Graduate Certificate in CER**, specifically, to "train adequate numbers of individuals capable of conducting CER and implementing the findings of such research." While we at the UW are already training many students who will eventually become CER research scientists, this certificate will motivate and support the development of a more focused curriculum in CER and will actively encourage doctoral students to pursue this area of specialization. Although UW has strengths in many CER-related areas, our pre-doctoral training programs currently do not provide the diversity of training required for successful CER researchers, nor do we feel the training programs across various departments and schools are sufficiently integrated or reflective of the existing faculty collaboration across disciplinary lines. Formal establishment and recognition of a Graduate Certificate in CER, for our proposed pre-doctoral candidates, will enable us to diversify and integrate the training for our most promising pre-doctoral students with interests in CER.

We will build on our existing CER expertise and research, and on solid, multi-disciplinary doctoral training programs, to create our formal Graduate Certificate in CER. Our Graduate Certificate in CER will support the objectives of our **UW Centers for Comparative and Health System Effectiveness (CHASE) Alliance**–an interdisciplinary, multi-unit (Medicine, Pharmacy, Public Health, and Nursing) research and training center for CER within the UW Health Sciences campus. Created in 2009, the CHASE Alliance brings together existing successful UW research groups and community partners with a common mission to undertake multidisciplinary, high impact comparative and systems effectiveness research and implementation. The CHASE Alliance links capacity and resources across groups to promote greater collaboration and efficiencies in conducting high impact CER. It also involves participation with stakeholders in real-world settings. Our CHASE partnership institutions include the Fred Hutchinson Cancer Research Center (FHCRC), Group Health Research Institute (GHRI), and the Veterans Affairs Puget Sound Health Care System (VAPSHCS). Investigators from UW CHASE Alliance already have been successful in acquiring over $35 million in ARRA-supported CER funding and have established a K-12 post-doctoral scholars program supported by the Agency for Healthcare Research and Quality (AHRQ), an entity within the US Public Health Service.

The Graduate Certificate in CER will cross the major health science programs of the UW, representing nationally and internationally recognized academic programs in Medicine, Pharmacy, Public Health, and Nursing. The Graduate Certificate in CER will consist of cohesive training through completion of didactic course offerings and participation in pragmatic research and implementation opportunities in ongoing, funded CER projects within the UW and our partnership organizations.

2. Specific Aims to Embrace All Aspects of CER in Education and Training

The following aims describe our overarching efforts to embrace all aspects of CER in the education and training of our students. The Graduate Certificate in CER is one large component of this wider effort.

a. Build on a diverse range of existing CER expertise and research, and on solid, multi-disciplinary doctoral training programs, to create a formal **Graduate Certificate in CER.** Our **Graduate Certificate in CER** will provide all interested pre-doctoral graduate students with multidisciplinary support and training that will enable them to:

i. Build CER knowledge and methods skills,
ii. Identify and summarize important evidence gaps in clinical care, in concert with stakeholders,
iii. Design and conduct high quality CER studies to address the evidence gaps, and
iv. Implement findings from comparative effectiveness studies into clinical practice policy and care management and to evaluate the implementation.

b. Create a bimonthly Grand Rounds series on CER that integrates existing outcomes research and lecture series offered on our Health Sciences campus.

c. Conduct an annual, in-person training and skills workshop in CER, targeted toward healthcare professional and stakeholder colleagues in the greater statewide (Washington) and regional (Washington, Wyoming, Alaska, Montana, Idaho-WWAMI) catchment areas. All materials will be posted online to reach a broader audience.

d. Inform and engage other universities initiating CER-focused programs to share experiences and to assess national training needs.

3. Objectives

The program we propose will meet eight key objectives:

Objective 1: Support the development of educational and training programs that clearly and efficiently teach students and practitioners how to conduct rigorous, useful, and effective CER

We have defined a comprehensive curriculum for a new Graduate Certificate in CER. The proposed curriculum enhances the current PhD programs in the Departments of Pharmacy and Health Services. The CER Certificate will also be available to students in epidemiology, biostatistics, nursing, medicine, and other health-related graduate programs. As each of these students will likely be required to take a portion of the pre-requisite CER courses in their core curriculum, we will work with each of these students, one-on-one, to craft an individualized program of study by which they complete all courses required by the CER Certificate, while integrating CER coursework into their respective curricula and schedules.

Objective 2: 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

The UW CHASE Alliance brings together successful UW research groups and community partners with a common mission to undertake multidisciplinary, high impact comparative and systems effectiveness research and implementation. Community partnership institutions include the Fred Hutchinson Cancer Research Center (FHCRC), Group Health Research Institute (GHRI), and the VA Puget Sound Health Care System (VAPSHCS). Our CHASE collaborators also include Leah-Hole Curry, former director of the Washington State technology assessment program and a member of the PCORI Board of Directors, and our faculty members Drs. David Flum and Al Berg, who are members of the PCORI Methodology Committee.

Objective 3: Furnish the necessary resources that can be used to develop corroborating evidence on the usefulness and value of sound CER

Our UW CHASE Alliance provides access to a number of important databases that represent some of the most widely used integrated clinical and health care encounter, observational and registry data available to researchers in the US.

Our CER graduate students use AHRQ Healthcare Cost and Utilization Project and Medical Expenditure Panel Survey data sets for CER projects in courses as part of their didactic training. In addition to the diverse clinic populations and disease-specific registries found within the collaborating institutions, we have identified a variety of available resources that are maintained by the CHASE Alliance faculty and researchers. These include:

CER - Cancer Data Resources: The database systems represented by the funded CER grants include the Breast Cancer Surveillance Consortium, the Cancer Research Network (CRN, part of the HMO Research Network), Surveillance Epidemiology and End Results (SEER), SEER-Medicare, the VA Health System, and a new data base system built through the NIH-funded 'Advancing Innovative Comparative Effectiveness Research in Cancer Diagnostics' (ADVICE) Grand Opportunities (GO) grant.

Other Data Sources include:

- **GHRI:** Group Health Research Institute is a founding member of and active participant in the national Health Maintenance Organization Research Network (HMORN).
- **Tracking Quality and Comparative Effectiveness of Surgical and Interventional Care - The Surgical Care and Outcomes Assessment Program (SCOAP):** SCOAP (www.scoap.org) was developed to track hospital quality and operational efficiency measures in response to variation in the safety and effectiveness of surgical care in Washington State. SCOAP datasets are comprised of inpatient data from 56 of the 60 hospitals in Washington State.
- **ThomsonReuters (TR) MarketScan database:** We have negotiated a 2-year agreement, initially for the 2007-2010 database. In the second year of the contract, 2011 data will be added to the database. Access to data is unlimited for University-affiliated faculty/students/post-docs; CHASE is the administrator; it is also available for UW faculty members who work at affiliated institutions.
- **United Healthcare - i3, Ingenix Data Resources:** The UW CHASE Alliance has licensed the Ingenix data resources in order to enhance CER at the University of Washington. InVision Data Mart is a research database containing medical claims, pharmacy claims, lab analytic results and enrollment dates for a large population of health plan enrollees.
- **Hospital Utilization and Trauma Outcomes**: These database systems represented by ongoing CER in injury and trauma include the Washington State Comprehensive Hospital Abstract Reporting System (CHARS) database.
- **Veterans Administration Data Resources - Data Warehouse:** This is a near real-time clinical data warehouse that collects and maintains a variety of clinical information on Microsoft SQL servers.

Objective 4: Convene public forums and seminars for interested members of the public from the wider university/college community to discuss topical CER issues

Our graduate programs (Pharmaceutical Outcomes Research & Policy Program-PORPP and Health Services Research-HSERV) already offer weekly seminars during the school year for our graduate students (and open to the research community) that address a range of CER-related issues. Attendance will be mandatory for Graduate Certificate-CER students. We propose to broaden and expand our existing "Cost and Outcomes Grand Rounds" to be renamed as the "CER Grand Rounds," as a lecture series featuring prominent nationally-recognized speakers, arranging for two outside speakers per quarter (six per year).

Objective 5: 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

Our proposed Leadership Team and Core Faculty as well as our broader CHASE Mentors Network for this Graduate Certificate in CER Program are visible, nationally recognized scholars, who speak often with colleagues at other universities about program development. Upon approval of our Graduate Certificate Program, we will prepare an article for publication in an appropriate journal to describe our new program and its objectives for our professional colleagues.

Objective 6: 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

As listed under RFP Objective 4 above, we will establish a Grand Rounds lecture series to invite public and private thought leaders to promote discussion of key CER issues.

Objective 7: 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

We would be delighted to work with national public and private bodies on this important but very difficult question. The state-of-the-art review and analysis provided by Hersch et al. in the recent IOM report highlights the challenge of defining and measuring the CER workforce given its complex and multidisciplinary nature. Dr. Lou Garrison, the proposed Director of our Graduate Certificate Program, was trained as a labor and health economist, and has a long-standing interest in health workforce issues, going back to physician workforce issues in the early 1980s and up to his current research studying the substitutability of pharmacists for physicians in HIV care in Uganda.

Objective 8: 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 PhRMA Foundation

In September 2010, the UW Institute for Translational Health Sciences (ITHS), the UW CTSA, hosted a 1½ day symposium on methods and applications for CER. Topics included stakeholder engagement, community-based registries, methods for indirect and mixed treatment comparisons, value-of-information methods, pragmatic trials, and innovative approaches in CER. In late 2010, the UW ITHS was awarded a supplemental grant through the NIH National Center for Research Resources (NCRR) to design and host an expanded CER institute, and to develop a corresponding web-accessible toolkit. One aim of the institute and toolkit was to expand and enhance research opportunities in the American Indian/Alaskan Native (AI/AN) and WWAMI (Washington, Wyoming, Alaska, Montana, Idaho) communities; to that end, significant recruitment efforts yielded many participants from these communities. The weeklong institute, co-sponsored by the UW CTSA and the CHASE Alliance, was held on September 19-23, 2011, and featured a broad overview of CER methodologies, as well as focused discussions of cutting-edge techniques and "hot button" issues in each given methodological area. The current information can be found at https://www.iths.org/events/institute-comparative-effectiveness-research-cer-training-0. One-hundred, thirteen participants registered--52% from UW, 16% from Seattle Children's' Hospital, 6% from GHRI, 6% from other institutions (generally academic) in the WWAMI region, 3% from FHCRC, 1% from the AI/AN community, and 14% from "other" Institutions. All seminars from the 2010 and 2011 workshop are available online at the ITHS website. The 2010 information can be found at https://www.iths.org/events/methods-and-applications-comparative-effectiveness-research. We are also actively developing distance learning courses for many of our regular curriculum offerings.

4. Documentation of Demand and Need

Clearly, with the recent emphasis on comparative effectiveness research from the highest policy levels in the nation, we anticipate the demand for CER training will be high. To date, only a few health sciences graduate schools in the nation offer formal, rigorously designed, systematic CER training. The AHRQ-funded, K-12 post-doctoral program is one of a few such grants awarded in the country. Further, the Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation has also realized the importance of training a workforce of research scientists in CER. The PhRMA Foundation recently accepted grant proposals from academic institutions with health sciences graduate programs, to establish formal CER training programs. The proposal submitted by the UW Departments of Pharmacy and Health Services, proposing the UW Graduate Certificate in CER, was one of two winning proposals. On November 2, 2011, we received formal notification that we received this grant funding for a three year time-span. There may be an opportunity to renew this funding support for a second, three-year time interval beginning in 2014.

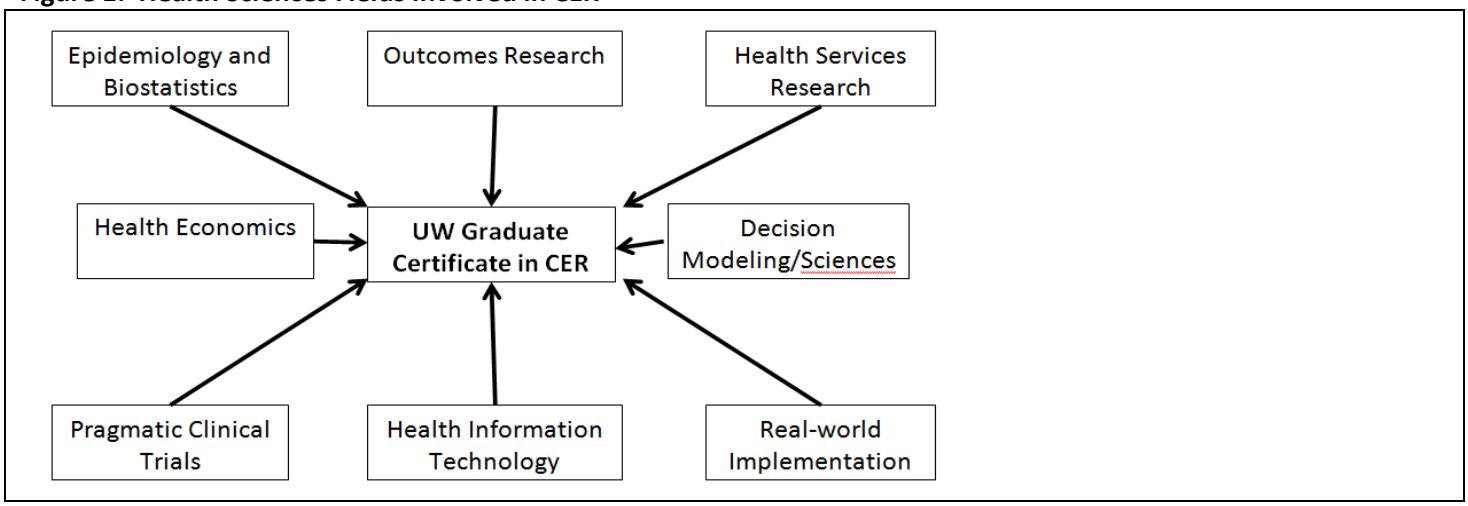
Demand for our AHRQ-funded K-12 post-doctoral training program in CER is evidence of the growing demand for training in CER methods. The selection process for our K-12 was highly competitive; we received 22 applications for 4 funded slots. Our selected scholars include one graduate from Epidemiology, one from Public Health Genetics/Pharmaceutical Outcomes, one general surgeon and one pediatric rheumatologist. Together these four scholars represent the UW Schools of Public Health, Pharmacy and Medicine. Since receipt of the AHRQ-funded K-12, interest in CER has spread throughout the UW Health Sciences campus. Our weekly K-12 scholars "work in progress" seminars attract up to 30 attendees, spanning programs from bio-engineering to cardiology, from biostatistics to vascular surgery. These are attended by PhD students, post-doctoral fellows, junior faculty, and senior faculty.

5. Training Program Overview, Learning Objectives and CER Certificate Program Structure

a. Overview

We will train CER practitioners by synthesizing knowledge and skills from eight key disciplines: 1) epidemiology and biostatistics, 2) health services research, 3) outcomes research, 4) health economics, 5) pragmatic clinical trials, 6) health information technology, 7) decision modeling and sciences, and 8) collaboration with stakeholders and implementation in real-world settings (Figure 1). We will develop CER researchers through a comprehensive, integrated, and multidisciplinary training program, coordinated by a Steering Committee/Leadership Team.

Figure 1: Health Sciences Fields Involved in CER



b. Learning Objectives

Upon completion of the CER Certificate, pre-doctoral students will be prepared to:

i. Use rigorous, state-of-the-art research methods to conduct CER projects,

ii. Design and execute well-designed CER studies,

iii. Disseminate the results of CER studies to local, regional and national stakeholders through presentations and publications in the peer reviewed and gray literature,

iv. Engage a variety of stakeholders (clinicians, payers, patients, caregivers, employers) in discussions about CER,

v. Understand, appreciate, and perhaps be involved in policy discussions around implementing the results of CER studies at the local, regional and national levels,

vi. Identify a group of like-investigators with whom to collaborate on future projects as their careers unfold.

c. Proposed CER Certificate Program Structure

Current doctoral students will formally apply to the CER Admissions Committee (the Leadership Team and Drs. Grembowski and Veenstra of the Core Faculty) to enter the Graduate Certificate-CER Program and, will list one of these faculty as the supervisor for the Certificate experience. The Leadership Team will evaluate whether the student has satisfactorily completed the prerequisites to enter the certification program. Students will be eligible only after they have passed their preliminary examinations. The ideal candidates will be enrolled in the PhD program in PORPP or Health Services. Serious consideration will also be given to graduate students who already have a clinical doctorate (MD or PharmD), and who wish to pursue advanced training in CER. Annually, a select few physicians and pharmacists apply to PORPP or Health Services to obtain a master's degree to complement their professional degree. Students in these programs will be offered an opportunity to complete the Graduate Certificate in CER, although this will likely lengthen their time to completion of their master's degree. We will work with each of these students on an individual basis to craft a course of study that enables them to meet all requirements the CER Certificate, should they be motivated to do so.

To obtain the Graduate Certificate, students are required to complete a set of advanced courses in CER that will count toward their electives in their respective PhD programs. The trainees must also complete a capstone project that

represents independent work in CER performed under the supervision of a CER core or affiliate faculty member. The qualifying paper must be approved by three members of the Steering Committee (i.e., the Leadership Team plus Core Faculty).

The Graduate Certificate in CER is intended to provide **advanced** coursework in CER. The UW provides great depth in rigorous courses. These are outlined in Section 6. The multi-disciplinary nature of these courses is evidenced by the cross-listing of several of them among the departments of Epidemiology (EPI), Biostatistics (BIOSTAT), Pharmacy (PHARM), Health Services (HSERV), and Medical Education and Biomedical Informatics (MEBI). Several courses in the CER Certificate coursework, core PhD coursework, and elective coursework require scholars to complete a class project within each quarter; these courses are so designated. These projects will contribute to the development of the new CER investigators, as they practice the new skills they learn each quarter. CER scholars may use any of these class projects as a springboard to their capstone project. What will distinguish the capstone project from a class project is that we will require the capstone project to be of publishable quality. Indeed, we will require the capstone project be submitted for peer-reviewed publication. Further, the capstone project may be used as a cornerstone to thesis or dissertation research, but will constitute, at most, a part of this larger degree requirement.

6. List of required coursework for CER Certificate, for core courses, and for electives, including course descriptions
a. Curriculum for the Graduate Certificate in Comparative Effectiveness Research
The Graduate Certificate in CER will require enrolled students to have completed all advanced coursework listed in Table 1. Students receive rigorous training in Advanced Health Services Research Methods (HSERV 523, 524, 525), Cost-effectiveness Analysis/ Decision Modeling (HSERV 583/PHARM 534), and Patient-Reported Outcomes (HSERV 584/PHARM 535). The Advanced Health Services Methods sequence has recently been revamped with a CER focus and will be implemented for the first time this academic year (2011-2012). Students also complete two courses in evidence synthesis – a method that is fundamental to conducting CER. The first, EPI 541/HSERV 529/MEBI 541 is a class that presents the concepts of systematic reviews and focuses on meta-analysis. Building on this experience, we will next require the scholars to complete a course in Bayesian statistics (Center for Statistics and the Social Sciences-CS&SS 564). Together, these two courses will prepare scholars for the course that culminates the Certificate Program in CER – Advanced Methods in CER. This course is currently under development and will focus on Bayesian methods. Topics will include advanced decision modeling (probabilistic sensitivity analysis, Markov modeling, and indirect/mixed treatment comparisons using Bayesian hierarchical modeling). Other tools for use in conducting CER will be explored, including discrete event simulation, the conduct of pragmatic trials, and value of information techniques. Many courses require students to complete a CER project. These are designated with an asterisk (*). One credit will be awarded for required completion of the capstone project. Certificate courses are intended to advance students' knowledge and skills in CER, preparing them to fill positions in government, academia and industry upon completion of their training.

Capstone Project
The capstone project will be an individual project and will be completed in collaboration with investigators at one of our real-world participating institutions. These are short-term projects, intended to provide students with maximum hands-on experience and a product of direct use to participating organizations. The capstone project should result in a peer-reviewed publication. The student may use their CER capstone project as part of their dissertation.

Table 1: Advanced Coursework and Capstone Requirements to Complete Graduate Certificate in CER

Health Services Advanced Methods - Apply program implementation and evaluation, and data analysis using advanced methods	
This sequence provides an overview of many important analytic methods frequently used when conducting CER (methods for risk adjustment, addressing selection bias (propensity scores, instrumental variables), factor analysis, bootstrap techniques, missing data, population-weighting techniques, and more.	**HSERV 524, 525: Advanced Health Services Research Methods, quarters 2 and 3** **(HSERV 523, quarter 1, is a core requirement)** *Scholars complete a year-long CER project analyzing a large health database of their choice and culminating in a journal article. 2nd and 3rd of 3 quarters-4 credits/quarter
Cost-Effectiveness Research/ Decision Modeling: Understand and employ cutting edge qualitative and quantitative methods incorporating the latest statistical, econometric, and outcomes research techniques	
Apply methods and techniques for evaluating costs and cost-effectiveness of health, medical, and pharmaceutical interventions, including decision modeling and value of information analysis.	**HSERV 583/ PHARM 534: Economic Evaluation in Health and Medicine** *Scholars complete a course project related to Scholars' CER interests. 3 credits
Patient-Reported Outcomes Research: Understand and employ cutting edge qualitative and quantitative methods incorporating the interests of patients as stakeholders in their own healthcare	
Master theory, concepts and methods for assessing patient reported outcomes, including measurement, analysis, psychometrics, and cross-cultural applications.	**HSERV 584/ PHARM 535: Assessing Outcomes in Health and Medicine** *Scholars complete a course project related to Scholars' CER interests. 3 credits
Evidence Synthesis: Understand the rapidly evolving field of evidence synthesis and the important role it plays in CER	
Gain knowledge of methods used to synthesize evidence; utilize systematic literature review techniques and meta analysis	**EPI 541/ HSERV 529/ MEBI 541: Introduction to Meta Analysis** *Scholars complete a meta-analysis of their choice 3 credits
Bayesian Methods for CER: Understand the theory of Bayesian statistical methods in preparation for application to CER	
Statistical methods based on the idea of probability as a measure of uncertainty. Topics covered include subjective notion of probability, Bayes' Theorem, prior and posterior distributions, and data analysis techniques for statistical models.	**CS&SS 564: Bayesian Statistics for the Social Sciences** 4 credits
Advanced Analytic Methods in CER: Learn cutting edge techniques to conduct CER and to model CER research questions	
Apply Bayesian concepts to decision modeling - probabilistic sensitivity analysis and Markov models; Introduction to other topics: adaptive study designs; advanced policy tools – risk sharing; budget impact models; conducting cost-effectiveness alongside clinical trials; directed acyclic graphs, causal modeling; indirect treatment comparisons; discrete event simulation, pragmatic studies; value of information	**HSERV 585/ PHARM 536: Advanced Methods in CER** 3 credits (585 and 536 have not yet been assigned; these are 'placeholder numbers for purposes of this application, to illustrate that this is the third quarter of the three-quarter sequence of classes in this series.)
Capstone Project: Gain CER experience by conducting a capstone project in a real-world setting. Collaborate with stakeholders to design, development, and implementation using CER at a partner institution	
a. Conduct formal evidence synthesis to inform specific policy decisions b. Communicate results of CER using various approaches to wide range of audiences c. Assess promoters & barriers in implementing policies & practices based on CER d. Address resource constraints in real-world settings, particularly related to timeliness of CER data e. Mitigate limitations of conducting research using observational data such as claims data f. Collaborate with stakeholders/decision makers to implement CER results into practice	(1) Group Health Research Institute (GHRI) - AHRQ-funded DEcIDE, CERT - NCI-funded CRN - HMO Research Network (2) Fred Hutchinson Cancer Research Center (3) VA Puget Sound Healthcare System (4) Other health-systems by arrangement (i.e. Premera/Blue Cross; Washington State Health Technology Assessment Program)

CS&SS=Center for Statistics and the Social Sciences; MEBI=Medical Education & Biomedical Informatics; VA=Veterans Administration

The Graduate Certificate in CER will require 19 (PORPP) or 17 (HSERV) credit hours, including the capstone project. (Table 3) The difference in certificate coursework is due to the fact that the core coursework for the PORPP and HSERV students differs slightly, creating a 'domino effect' in the number of credits required to complete the Certificate. Thus, the Graduate Certificate courses in CER courses are presented as a "menu" from which students in each program will choose. Upon completion of the Graduate Certificate in CER, all students will have completed the same set of courses, regardless of the PhD program in which each is enrolled. PORPP students complete HSERV 583/PHARM 534 (Economic Evaluation in Health and Medicine) and HSERV 584/PHARM 535 (Assessing Outcomes in Health and Medicine) as core

requirements, while HSERV students take these two courses as Certificate courses. On the other hand, HSERV students take HSERV 524 and 525 (second and third quarters of Advanced Health Services Research Methods) as core requirements, while PORPP students take these two courses as Certificate courses. Students in both programs take HSERV 523 in the core. Creating the Certificate in this way meets the requirements of the UW Graduate School; that is, the Certificate must be comprised of a minimum of 15 credits, and none of these credits can overlap with core coursework in a PhD program.

Table 2: Graduate Certificate in CER, Credit Totals, per PhD Program

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/ MEBI 541: Introduction to Meta Analysis	3	3
CS&SS 564: 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

CS&SS=Center for Statistics and the Social Sciences; MEBI=Medical Education & Biomedical Informatics

b. Core PhD Curriculum for PORPP and HSERV PhD Students

All certificate courses build on the core courses required in the PORPP and HSERV PhD programs (Table 3). For both PORPP and HSERV students, the core curriculum requires one year of basic Epidemiology (512 & 513) and Biostatistics (511, 512, 513), the courses required of majors in these two disciplines. A two-quarter option is offered in Biostatistics (517, 518), for those who have had previous training and wish to complete the work at a faster pace. These courses form the fundamental framework on which more advanced skills are overlaid. The Health Services students are required to complete a 3-quarter sequence that describes the United States Healthcare system (512), health policy (513), and population health (514). The majority of the PORPP students have this background as many of them already hold professional healthcare degrees (PharmDs, MDs). In lieu of the basic Health Services coursework (512, 513, 514), PORPP students complete a class in Medical Product Development and Policy (PHARM 532) and Pharmacoepidemiology (533). As explained above, HSERV students are also required to complete the yearlong Advanced Methods sequence in Health Services (523, 524, 525) as part of their core requirements. PORPP students are also required to complete HSERV 523. In lieu of completing HSERV 524/525, PORPP students are required to take two of the three second-year Epidemiology/Biostatistics courses, and to select the two of these that are most relevant to their research (BIOSTATS/EPI 536-Categorical Data Analysis, BIOSTATS/EPI 537-Survival Analysis, BIOSTATS 540-Correlated Data Analysis). As described above, PORPP students are also required to complete the class in cost-effectiveness research (HSERV 583/ PHARM 534-Economic Evaluation in Health & Medicine) and the class in patient-reported outcomes (HSERV 584/PHARM 535-Assessing Outcomes in Health and Medicine). A course in intermediate Health Economics completes the list of core courses in both programs.

Students pursuing the Graduate Certificate in CER will be required to complete all the core courses required for their doctoral degree, in PORPP or Health Services. Table 3 lists the core curriculum for PORPP and Health Services PhD students.

Table 3: Core PhD Curriculum for PORPP and HSERV PhD Students
(required of students in both programs unless otherwise specified)

Epidemiology and Biostatistics: Understand the basic requirements and methods of clinical research and use of patient registries	
a. Understand the basic structure and threats to validity of common research designs, including time series data, case-control, cohort, and randomized trials b. Apply analytical issues related to control of confounding, statistical power, sample size estimation, measures of effect size, and hypothesis testing c. Recognize the different purposes and requirements of explanatory and pragmatic clinical trials	**EPI 512 & 513: Epidemiologic Methods I & II** **BIOST 511, 512, 513: Medical Biometry** **or** **BIOST 517 & 518: Applied Biostatistics**
Health Services Research: Understand structure and incentives of healthcare systems and quality improvement initiatives	
Understand the organization and financing of healthcare, markets, patient safety, quality improvement, patient-centered care, health policy and analysis, population health, and health disparities	**HSERV 512 (U.S. Health and Health Care), HSERV 513 (Health Policy), HSERV 514)Population Health);** Scholars complete a CER literature review, research proposal and a policy analysis. *Required of HSERV students
Medical and pharmaceutical product development and policy; safety and effectiveness: includes pharmaceuticals, devices and diagnostics	
Introduction to the tools used in and the framework and dominant contexts for pharmaceuticals policy development and analysis. Methods reviewed in a series of sessions presenting a specific method and case analyses involving pharmaceuticals development.	**PHARM 532: Medical Product Develop & Policy** *Required of PORPP students
Pharmacoepidemiology: includes information about the study of drug effectiveness and safety	
Overview of pharmacoepidemiology including drug development and approval; application of epidemiologic methods to study drug safety and effectiveness; exploration of the interplay between research and public policy; introduction to resources for information about drugs; introduction to pharmacology principles pertinent to pharmacoepidemiology.	**EPI 533/ PHARM 533: Pharmacoepidemiology** *Required of PORPP students
Health Services Advanced Methods - Apply program implementation and evaluation, and data analysis using advanced methods	
See description in Table A-1	**HSERV 523, 524, 525: Advanced Health Services Research Methods** *Required of HSERV students (all 3 quarters) *Required of PORPP students (523 only)
Epidemiology and Biostatistics: Understand the advanced requirements and methods of clinical research and use of patient registries	
a. Summary of univariate categorical data analysis; introduction to multivariate analysis of categorical epidemiologic data using multiplicative models. Experience at interpretation; familiarity with available programs gained by analysis of bona fide data, critiques of analyses appearing in literature. b. Introduction to multivariate analysis of survival data using multiplicative models. Application to epidemiologic studies. Familiarity with interpretation and available computer programs gained by analysis of bona fide sets of data and critiques of analyses appearing in the literature. c. Introduction to regression modeling of longitudinal and clustered data from epidemiology and health sciences. Interpretation and familiarity with available programs gained by analysis of bona fide data; critiques of analyses appearing in literature.	**BIOST 536/EPI 536: Categorical Data Analysis;** **BIOST 537/ EPI 537: Survival Analysis** **BIOST 540: Correlated Data Analysis** *2 of 3 required of PORPP students
Cost-Effectiveness Research: Understand and employ cutting edge qualitative and quantitative methods incorporating the latest statistical, econometric, and outcomes research techniques	
See description in Table A-1	**HSERV 583/ PHARM 534: Economic Evaluation in Health and Medicine** *Required of PORPP Students
Patient-Reported Outcomes Research: Understand and employ cutting edge qualitative and quantitative methods incorporating the interests of patients as stakeholders in their own healthcare	
See description in Table A-1	**HSERV 584/ PHARM 535: Assessing Outcomes in Health and Medicine** *Required of PORPP students

Table 3 (continued): Core PhD Curriculum for PORPP and HSERV PhD Students (required of students in both programs unless otherwise specified)

Health Economics: Master key economic concepts and analytical tools needed to analyze human economic behavior	
Apply microeconomic principles to analyze major issues of the healthcare sector; understand key institutional and market factors that affect incentives of stakeholders in healthcare markets; understand perspective and limits of economic analysis applied to healthcare; gain historical economic perspective on the evolution of major health policy issues	**HSMGT 514/ PHARM 568: Intermediate Health Economics** (an introductory class in microeconomics is a pre-requisite for PHARM 568)

c. Elective Coursework

To complete degree requirements for their PhD degrees (approximately 120 credit hours, including dissertation credits), students can select from over 30 electives. Those deemed by the faculty to be highly relevant to CER are listed in Table 4.

Table 4: Electives Highly Recommended for CER Certificate Students

Epidemiology and Biostatistics: Understand the advanced requirements and methods of clinical research and use of patient registries
BIOST 524: Design of Medical Studies *Scholars design a randomized controlled trial protocol
Health Services and Outcomes Research: Politics, theory, methods of evaluation, from simple health programs to evaluation of large-scale interventions.
HSERV 522: Health Program Evaluation *Scholars develop a CER program evaluation proposal
Grant Writing: Develop skills in preparing and writing research proposals
EPI 588/ HSERV 588: Preparing and Writing Research Proposals *scholars prepare a K or R application for submission
Health Informatics: Develop an understanding of informatics and potential applications in each phase of CER
MEBI 533: Public Health and Informatics MEBI 537: Biomedical & Health Informatics Research Methods
Pragmatic clinical trials: Develop research "toolkit" of methods for delivering an intervention (and measuring exposure) and assessing the response in a 'real-world' setting
EPI 528: Exposure Measurement EPI 573: Methods and Issues in Using Biological Measurements in Epidemiologic Research HSERV 527: Survey Research Methods HSERV 552: Health Policy Development

MEBI=Medical Education & Biomedical Informatics

d. Training in the Responsible Conduct of Research

A fundamental premise of our application is that research training includes instruction in the scientific integrity and ethical principles of research. All UW Masters and PhD students receive formal and informal instruction in the responsible conduct of research. **Formal instruction** consists of the "Biomedical Research Integrity Series" (BRI) offered by the School of Medicine, Department of Medical History and Ethics. The series is designed to satisfy the Public Health Service's (PHS) research responsibility requirement for Scholars, and over 450 individuals from all University of Washington and Fred Hutchinson Cancer Research Center health science disciplines participate annually in the series. Attendance is recorded and reported to departments that monitor Scholars' participation. All CER students will attend the lectures and discussion groups. **Informal instruction** occurs through individual relationships with faculty who mentor trainees on their CER research projects. Scholars also receive instruction through course readings and lectures, seminars, and journal clubs. The program seminars include sessions on work in progress and program expectations regarding scholarly integrity. Evaluation of this component includes monitoring Scholar attendance at the BRI series, completing the Human Subjects training sessions and the seminars, and verifying that Scholars are conducting ethical research as presented in Works-In-Progress.'

7. Administrative Location, Oversight, and Name of the Director

A major strength of this application is our proposed Steering Committee/ Leadership Team and the Core Faculty who are department leaders, experienced mentors, and skilled in designing and conducting CER. This includes innovative research being conducted by long-standing and highly integrated faculty across the Health Sciences Centers and with our key collaborators. The Steering Committee/ Leadership Team plus the Core Faculty will comprise the program's Steering Committee, which will meet quarterly. The Program Director is Lou Garrison. Other members of the Steering Committee/ Leadership Team are Anirban Basu and Beth Devine.

8. Steering Committee/ Leadership Team, Core and Extended Faculty

a. Steering Committee/ Leadership Team

The Graduate Certificate in CER will be led by a Steering Committee/ Leadership Team of three faculty members: Program Director (Lou Garrison) and two additional steering committee members (Anirban Basu and Beth Devine). The Steering Committee/ Leadership Team will be responsible for all activities of the Graduate Certificate in CER. The program will be housed within the Department of Pharmacy, School of Pharmacy and the Department of Health Services, School of Public Health. All three members of the Steering Committee/Leadership Team currently hold an adjunct appointment in the alternate department – Drs. Garrison and Devine in Health Services and Dr. Basu in the Pharmaceutical Outcomes Research & Policy Program. Each of these faculty members is also a member of the Graduate Faculty with privileges to chair theses and dissertation committees.

Lou Garrison, PhD, Director - Dr. Lou Garrison is Professor in the Pharmaceutical Outcomes Research & Policy Program in the Department of Pharmacy and Adjunct Professor in the Departments of Global Health and Health Services, UW, where he joined the faculty in 2004. He brings a unique blend of private and public experience and expertise to lead this program. Since coming to the UW, he has published over 50 peer-reviewed articles on a wide range of technologies and health policy issues, and has given numerous talks not only in U.S. venues, but also in Europe, Asia, and Africa. For the previous 12 years, he worked as an economist in the pharmaceutical industry. Most recently, he was Vice President and Head of Health Economics & Strategic Pricing in Roche Pharmaceuticals, and was based in Basel, Switzerland, in 2002-4. He oversaw the development of the economic and pricing strategies, and research plans for all Roche compounds. Prior to this, he was Director of the Project HOPE Center for Health Affairs. In eight years there, he worked on a wide variety of health policy issues, including studies of health care reform both in the U.S. and overseas. Before this, he worked at the Battelle Human Affairs Research Centers in Seattle, where he carried out studies of the adequacy of physician manpower supply and the cost-effectiveness of kidney and heart transplantation. He received a B.A. in economics from Indiana University, and a Ph.D. in economics from Stanford University. Dr. Garrison's research interests include national and international health policy issues related to pharmacogenomics/personalized medicine, regulatory risk-benefit analysis, insurance, pricing, reimbursement, and risk-sharing agreements, as well as the economic evaluation of pharmaceuticals, diagnostics, devices, surgical procedures, and vaccines, particularly as related to organ transplantation, renal disease, influenza, measles, and cancer. From 2007-9, he served on the Board of Directors of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Anirban Basu, PhD - Associate Professor in Department of Health Services and PORPP. His research focuses on methods and applications that study observed and unobserved heterogeneity in clinical and economic outcomes and attempts to establish the value of individualized care. Using micro-econometric theory and models, Dr. Basu strives to conduct health economic evaluations that are in line with public policy decision-making. Dr. Basu has extensive experience in using innovative methods in comparative effectiveness and cost-effectiveness research. He has written extensively on modeling health expenditure data and the use of econometric methods for causal inference. He has also worked on the theoretical and empirical foundations in cost-effectiveness analyses and value of information analyses in the context of prostate cancer and schizophrenia. Some of his work includes establishing the value of individualized care based on patient preferences, developing models to predict quality of life of patients with multiple comorbidities, measuring the effect of patients' health on the quality of life of their partners, estimating the future value of research in diagnosing and finding a cure for Duchenne muscular dystrophy, developing simulation models for evaluating the cost-effectiveness of pharmacological treatment algorithms in schizophrenia, and comparative effectiveness research on the dynamic intensification of glucose lowering therapies in diabetes. Dr. Basu is the recipient of numerous awards, including the

NARSAD Wodecroft Young Investigator Award for his work on modeling the long-term risk of diabetes and cardiovascular disease due to atypical antipsychotics medications in patients with schizophrenia, the 2007 Research Excellence Award for Methodological Excellence and the 2009 Bernie O'Brien New Investigator Award from ISPOR, the 2008 Alan Williams Health Economics Fellowship from the University of York, UK, and the 2009 Labelle Lectureship from McMaster University, Canada. Dr. Basu was a faculty member at the University of Chicago from 2004-2010.

Beth Devine, PharmD, MBA, PhD – is an Associate Professor in PORPP and Adjunct Associate Professor in Health Services and in the Division of Biomedical and Health Informatics, School of Medicine. Dr. Devine's research program is centered at the intersection of clinical research informatics and comparative effectiveness research. She is the lead co-investigator for the Comparative Effectiveness Research Core of the Surgical Care and Outcomes Assessment Program Comparative Effectiveness Research Network (SCOAP-CERTN) – one of the AHRQ-funded grants in the Enhanced Registries for Quality Improvement and CER portfolio – where she leads the prospective cohort study comparing medical to surgical interventions in the treatment of intermittent claudication. On this same grant she leads the research study that is validating the extraction of semi-automated data from disparate electronic health records across select hospitals in Washington State. She is an active participant in Academy Health's Electronic Data Methods Forum. A second area of research interest is evidence synthesis, where she compares treatment alternatives to inform comparative effectiveness decision-making using indirect and mixed treatment comparison methods in a Bayesian framework. In 2009-2010, she served as a member of the ISPOR Task Force on Indirect/Mixed Treatment Comparisons. She served briefly on the PhRMA Foundation Committee that developed the RFP to which this proposal responds. Dr. Devine is a past recipient of an AHRQ Mentored Clinical Scientist Training Award (K-08) and served as co-investigator and project lead on an AHRQ THQIT (Transforming Healthcare Quality through Technology) implementation grant where her team studied the impact of a computerized provider order entry system in the largest independent medical group in Washington State. She earned her PhD in Health Services Research in 2008. In addition to obtaining her PhD, in the past ten years she has published 36 articles, 16 of them with graduate students. She has served on dissertation committees for 4 PhD students and 2 MS students; in addition has mentored 5 PhD and 4 MS students and 1 post-doctoral fellow.

b. Core Graduate Certificate in CER Program Faculty

The other four Core Faculty (Grembowski, Kessler, Sullivan, Veenstra) will work jointly with the Steering Committee/Leadership Team to form the CER Graduate Certificate Program Steering Committee to ensure graduate students receive rigorous training and rich experiences while in the Certificate Program. Dr. Kessler holds an adjunct appointment in the Pharmaceutical Outcomes Research and Policy Program while Dr. Sullivan holds a full joint appointment in Health Services. Dr. Veenstra holds an adjunct appointment in Public Health Genetics. Each of these faculty members is also a member of the Graduate Faculty with privileges to chair theses and dissertation committees.

David Grembowski, PhD – Dr. Grembowski, Professor of Health Services, also holds an appointment in the Department of Dental Public Health Sciences, School of Dentistry. Professor Grembowski teaches social determinants of population health and health program evaluation, and his evaluation interests address prevention and the performance of health care systems. His studies have examined efforts to improve quality by increasing access to care in integrated delivery systems; managed care and physician referrals; managed care and patient-physician relationships; cost-effectiveness of preventive services for older adults; fluoridation effects on oral health and dental demand; financial incentives and dentist adoption of preventive technologies; effects of dental insurance on dental demand, and the link between mother and child access to dental care.

Larry Kessler, ScD - Dr. Kessler is chair of the Department of Health Services, UW School of Public Health. He directs a department with 45 full time faculty and 270 clinical and associate faculty who span the broad range of academic disciplines. In various degree (MPH, MHA, PhD) and professional certificate programs, the Department faculty reaches approximately 500 students per year. Dr. Kessler has had a distinguished career in mental health services and cancer surveillance research. He spent 13 years at the Food and Drug Administration directing two separate offices, hiring and mentoring junior scientists and amassing significant regulatory knowledge. He is the co-PI (along with Sullivan, Ramsey and Buist) of a research team investigating the comparative effectiveness of cancer diagnostics under the ADVICE GO Grant from NIH. This $4 Million grant will serve as the basis for mentorship opportunities for these scholars.

Sean D. Sullivan, PhD - Dr. Sullivan is a pharmacist, health services researcher and Professor of Pharmacy, with a joint appointment in the Department of Health Services. He also is Adjunct Professor of Allergy and Infectious Disease in the School of Medicine, and Full Member of the Public Health Sciences Division of the Fred Hutchinson Cancer Research Center. He is co-PI of the ADVICE GO grant and co-PI of the Dept. of Defense funded surgical options in obesity CER study. He is co-Director of the Implementation, Epidemiology and Outcomes Emphasis area for the NIH Roadmap K-12 (now KL2) training program at the UW and is mentor for several T-32 programs. He is the principal investigator on the AHRQ-funded UW K-12 in CER. Dr. Sullivan has a long record of training young scholars in clinical and health services research, including 10 PhD students, 27 MS/MPH/MHA students, 23 post-doctoral fellows, and 3 NIH/AHRQ Career Development (K) awardees. In the past ten years, he has published 149 research papers - 65 of these with PhD/MS/MPH/MHA students, and an additional 34 with postdoctoral trainees.

David Veenstra, PharmD, PhD - is a Professor in the Department of Pharmacy and Director of the Graduate Training Program for PORPP. Dr. Veenstra has mentored 7 PhD and 3 MS students over the past 10 years, including 4 post-doctoral scholars. He has published 82 peer-reviewed papers in the past 10 years, 35 of which are with PhD students. His methodological focus is in decision modeling and disease simulation, particularly in the genomics area. He is currently PI of a CDC-sponsored research agreement to develop a risk-benefit framework for assessing genetic tests, and is a Co-Investigator with the CANCERGEN project led by Scott Ramsey at the Fred Hutchinson Cancer Research Center, and with the UW Center for Genomics and Healthcare Equality (Burke, W., PI). Dr. Veenstra serves on the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) evidence-based recommendation group.

c. Extended Faculty in CHASE Alliance

The Steering Committee Leadership Team and core program faculty will also invite members of the extended faculty in the CHASE Alliance to participate as mentors. The following faculty members will be invited:

Extended Faculty—Potential Mentors for UW Graduate Certificate in CER

Name	Title	School or Organization
Potential Mentors-University of Washington & FHCRC		
Brian Bresnahan, PhD	Assistant Professor	Radiology, Health Services Research, PROPP
Beth Ebel, MD, MSc, MPH	Associate Professor	Medicine, Public Health, Seattle Children's Hospital
Joann Elmore, MD, MPH	Professor	Medicine, Public Health
Ruth Etzioni, PhD	Full Member, Professor	FHCRC, Public Health
David Flum, MD, MPH	Professor	Medicine, Public Health
Tom Hazlet, PharmD, DrPH	Associate Professor	Pharmacy, Regulatory Affairs
Pamela Mitchell, PhD, RN	Professor	Nursing, Public Health
Donald Patrick, PhD	Professor	Public Health, FHCRC
Scott Ramsey, MD, PhD	Full Member, Professor	FHCRC, Medicine, Pharmacy
Andy Stergachis, PhD	Professor	Public Health, Pharmacy
Edward Weaver, MD, MPH	Associate Professor	Medicine
Potential Mentors-Group Health Research Institute		
Denise Boudreau, PhD	Associate Investigator	GHRI, PORPP
Diana Buist, PhD	Associate Investigator	GHRI, Public Health
Paul Fishman, PhD	Senior Investigator	GHRI, Public Health
Eric Larson, MD, MPH	Senior Investigator and Exec. Dir.	GHRI, Medicine
Mike Von Korff, PhD	Senior Investigator	GHRI, Public Health
Potential Mentors-VA Puget Sound Health Care System		
Stephen Fihn, MD, MPH	Prof and Head, Div of Gen Int Med	Medicine, Public Health
Katharine Bradley, MD, MPH	Associate Professor	Medicine, Public Health
David Au, MD, MS	Associate Professor	Medicine, Pharmacy

9. Expected Enrollment for the First Three Years and Sustainability in Subsequent Years

We are fortunate to have just received seed funding from the Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation to launch the Certificate in CER. This funding will support launch of the Certificate Program and will sustain it over the first three years, as it gains traction. The PhRMA Foundation may renew their support for an additional three years. If they do, we will continue the funding support using the framework illustrated by the timeline below (Figure 2).

The funding from the PhRMA Foundation will support five students enrolled in the Graduate Certificate in CER during the first three years. With the PhRMA Foundation funding, we plan to make three Pre-Doctoral Fellowship awards (tuition plus 50% RAship) and two Dissertation Fellowship awards (stipends for support, data, and travel) within the first three years of the Certificate Program. The RAships are intended for those who will be in the second and third years of their doctoral training. The RAships will be awarded to students who formally enroll in the Certificate Program. Should a greater number of students apply than can be funded, we will develop a set of selection criteria based on merit (academic grades, number of previous CER projects completed, number of manuscripts published). Those students who meet the eligibility criteria, but who do not merit an RAship will be encouraged to enroll in the CER Certificate Program under other funding mechanisms available in their home department. The Dissertation Fellowship awards will be awarded to fourth and fifth year students; those who have completed their coursework and who are completing dissertation work in CER. These fourth and fifth year students will not be formally enrolled in the CER Certificate; instead, they will be student mentors to the students enrolled in the CER Certificate Program.

The timeline below illustrates the distribution of support funds to seed the CER Certificate Program for the first three years. (Figure 2)

Figure 2: Timeline for CER Certificate for first Three Years – with support from the PhRMA Foundation

2011	2012				2013				2014			
Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Apply to for GC-CER Program	Launch Certificate program											
		Solicit applications; Select fellows										
			Award 1 Pre-doctoral fellowship									
			Award 1 Dissertation fellowship									
						Solicit applications; Select fellows						
							Award 2 Pre-doctoral fellowships					
							Award 1 Dissertation fellowship					
	Grand rounds 2 per Quarter			Grand rounds 2 per Quarter				Grand rounds 2 per Quarter				Grand rounds
	Submit manuscript on program			Year 1 Report				Year 2 Report		Prepare and submit final report		

Students may enroll in the Graduate Certificate in CER regardless of whether they receive support from the PhRMA Foundation. ***Enrollment in the graduate Certificate in CER is in no way dependent on PhRMA funding.***

Given the number of graduate students with interests in CER-related fields, regardless of funding, we expect that five students per year will be pursuing the Graduate Certificate in CER by the end of year three. We anticipate that by the end of year five, as many as ten students may be enrolled in the Graduate Certificate in CER each year.

10. Recruitment Strategy

Pending approval of the Graduate Certificate in CER, we will make a program announcement and solicit student enrollment for Fall quarter 2012. The program announcement will take three forms: 1) an announcement on the websites of both the PORPP and Health Services PhD programs, 2) a brochure, delivered electronically, included in the packet of materials provided each potential graduate student applying for enrollment in the PhD program in both PORPP and Health Services, and 3) flyers posted in strategic elevators in the Health Sciences Building, announcing the Certificate. Using this recruitment strategy, we will spur interest both external to and within the UW health sciences

schools (Pharmacy, Public Health, Medicine, Nursing). To the extent that we recruit for graduate students at professional meetings, we will also announce the Graduate Certificate in CER in these venues.

Our respective graduate programs have incorporated recruitment strategies to enable application of under-represented students. For our graduate programs, our departments welcome students who have varied cultural experiences or educationally or economically disadvantaged backgrounds, and will therefore contribute to the intellectual and social enrichment of the graduate programs. To the extent these students are admitted to the PhD programs in PORPP and Health Services, they will have the opportunity to apply for the CER Certificate program.

11. Budget for the Program, Resource Requirements and Source of Funds

With funding just received from the PhRMA Foundation we will adhere to the following budget over the first three years of the Certificate Program:

1. Support for Leadership Group (5% FTE support for Garrison, Devine, and Basu for 36 months)…….. $ 78,834
2. Three Pre-Doctoral Fellowships for CER program graduate students
   (Tuition + 50% Salary Support) for 12 months ($48,327 each)…… $144,981
3. Two Dissertation Fellowships ($10,000 stipend)…….. $ 20,000
4. Other expenses (Grand Rounds, travel, announcements)…….. $ 6,185

Total Budget…… $250,000

The Departments of Pharmacy and Health Services each currently employ a graduate program coordinator who is already managing the curricular affairs of graduate students and is providing guidance on course selection. As the requirements of managing the CER Certificate are marginal, these two individuals will be able to absorb the record-keeping duties required of the CER Certificate Program.

12. Sustainability

We will continue to offer the CER Certificate Program regardless of funding from the PhRMA Foundation. Indeed, we are committed to continuing the Graduate Certificate in CER without any outside financial support. The Certificate simply offers us a unifying structure that will enable students to focus on CER as an area of specialization. Should our support from the PhRMA Foundation not be renewed, we will cease to offer the incentives of the pre-doctoral fellowships and dissertation fellowships. As CER is highlighted as an important tool for healthcare decision-making at national policy levels, we remain confident that the program will be in high demand and will continue to draw students.

The faculty of the Departments of Pharmacy and Health Services are committed to mentoring students in CER, in teaching these courses, and providing this enriching research environment for all PhD students. Current courses, faculty mentors, strategic partnerships with other institutions, and databases with which to conduct projects are secure and are already operating separate and apart from PhRMA funding; indeed, separate and apart from the Graduate Certificate in CER. Even the new course titled, 'Advanced Methods in CER' is being developed and will be taught independent of the CER Certificate.

13. Tracking and Evaluation Mechanism

Our tracking mechanism will be comprised of the following metrics, reported annually to the Steering Committee/ Leadership Group and to the faculty of the Pharmaceutical Outcomes Research and Policy Program and the faculty in the Department of Health Services. Tracking these metrics will enable us to assess whether or not we have met the Learning Objectives for the CER Certificate Program, as outlined in Section 5b of this document.

- Number of pre-doctoral students who apply for the CER Certificate Program
- Number of pre-doctoral students who enroll in the CER Certificate Program
- Number of pre-doctoral students who complete the coursework for the CER Certificate Program
- Number of pre-doctoral students who complete the capstone project of the CER Certificate Program
- Number of pre-doctoral students who complete both the coursework and the capstone project and who therefore receive the CER Certificate
- Background of each student that completes the Certificate program (previous degrees and related employment)*

- Number of credits completed, per student, to complete Certificate Program
- List of courses completed, per student, to complete Certificate Program*
- Number of quarters spent, per student, in completing the CER Certificate Program*
- Mean and median number of quarters spent by all students (cumulative) in completing the CER Certificate Program
- Name and department of primary advisor for each Certificate student*
- Name and short description of each student's capstone project
- Indicator (yes/no) of whether students who complete the CER Certificate complete a dissertation in a CER-related field
- Name and short description of each CER student's dissertation*
- Number of poster/podium presentations made internally at UW by each Certificate student both while in the Certificate Program and until graduation*
- Number of poster/podium presentations made locally and regionally by each Certificate student both while in the e Program and until graduation*
- Number of poster/podium presentations made at national professional organizations by each Certificate student both while in the Certificate Program and until graduation*
- Number of manuscripts published by each Certificate student both while in the Certificate Program and until graduation*
- Employment after graduation (post-doctoral fellowship, industry, government, academia, consulting, other)*

Asterisks (*) indicate the metric is captured for all doctoral students, regardless of Certificate status.

We will also track:
- Lessons learned in the first 3-5 years of offering the Certificate Program
- Status of CER educational programs offered at peer institutions within the US (Harvard, Johns Hopkins, Duke, University of North Carolina, University of Arizona)
- Number of annual CER workshops provided by faculty and statistics associated therewith, annually
- Number of CER-related faculty publications, annually
- Number of dollars spent on the CER Certificate Program, annually

14. Summary of Qualifications on Key Evaluation Criteria

- **Qualifications of faculty members and mentors:** We have proposed an outstanding Leadership Group and core group of faculty mentors, and will extend mentorship opportunities to 19 other potential mentors who are part of the CHASE Alliance, including UW departments and community-based partners.
- **Facilities, including experiential learning partners:** UW has outstanding departments in the range of health sciences. Our CHASE partnership institutions include the Fred Hutchinson Cancer Research Center, Group Health Research Institute, and the VA Puget Sound Health Care System.
- **Curriculum/Plan of Study:** We have developed a CER Certificate Program curriculum that builds on our strong existing interschool and interdepartmental collaboration. It will address our weaknesses in terms of the need for the diversity of training required for successful CER researchers. This pre-doctoral CER Certificate Program will enable us to integrate and diversify the training for our most promising pre-doctoral students with interests in CER.
- **Prior faculty and school or college experience:** Our CHASE Alliance and associated training programs, our over $35 million in ARRA CER work, and our faculty on the PCORI committees demonstrates important experience and commitment.
- **Dissemination Strategy**: Our proposed implementation of a new Graduate Certificate in CER will be disseminated through website announcements, brochures, and in other venues.
- **Process for internal evaluation:** We propose a steering committee consisting of the Leadership Team and the core faculty (Drs. Grembowski, Kessler, Sullivan and Veenstra), who will meet quarterly to review program progress.

- **Institutional Support:** Letters of support from our two Deans are attached. We will formally apply (Nov. 1, 2011) for UW commitment to the Graduate Certificate in CER Program as well as formal endorsement of the CHASE Alliance prior to that.

15. References

Hersch WR, Carey TS, Ricketts T, et al. Comparative Effectiveness Workforce—Framework and Assessment. In IOM 2011.

IOM (Institute of Medicine). 2011. *Learning What Works: Infrastructure Required for Comparative Effectiveness Research: Workshop Summary*. Washington, DC: The National Academies Press.

Murray MD. Curricular considerations for pharmaceutical comparative effectiveness research. Pharmacoepidemiol Drug Saf., 20: 797-804, 2011

Appendix Table: UW CHASE Alliance - Works in Progress Presentations, October 2011 to December 2016

Date of Presentation	Speaker	Role at UW	Title of Presentation
10/3/2011	Brian Bresnahan, PhD	Faculty	Economic evaluation of the BOLD CER project
10/10/2011	Beth Devine, PhD, PharmD, MBA	Faculty	Validation of Electronic Clinical Data for Comparative Effectiveness Research: The SCOAP CERTAIN Validation Study
10/10/2011	Karen Wernli, PhD	AHRQ K-12 Scholar; Research Scientist-Group Health	The comparative effectiveness of colorectal cancer screening strategies
10/24/2011	Dave Veenstra, PhD, PharmD	Faculty	A comparative effectiveness study of genome sequencing in colon cancer
10/31/2011	Larry Kessler, DSc	Faculty	STILL: Surveillance Trial to Increase Longevity among Lung cancer patients
11/14/2011	Thomas Varghese, MD	Faculty	Assessing the Impact of Esophageal Cancer Surgical Interventions
11/28/2011	Timo Hakkarainen, MD	Senior Fellow	Beyond Mortality: Qualitative and Quantitative Assessment of Quality of Life, Functional, Psychological, and Financial Outcomes for Survivors of Necrotizing Soft Tissue Infections Significance/Background
11/28/2011	Sarah Ringold, MD	AHRQ K-12 Scholar; Faculty	Using Pharmacy Benefit Manager Data to Assess Injectable TNF-alpha Use in Pediatric Rheumatic Diseases
12/5/2011	Heather Evans, MD	AHRQ K-12 Scholar; Faculty	Developing a natural language processing system for screening chest radiographs in trauma patients suspected of having ventilator associated pneumonia
12/5/2011	Leah Backhus, MD	Faculty; Graduate Student	Quality and Patterns of Surveillance and Survivorship Care in Lung Cancer Patients
12/12/2011	Laurie Gold, PhD	Research Scientist-UW; PhD student	Patterns of use and treatment paths in breast cancer patients who received advanced diagnostic breast imaging compared to those who received only diagnostic mammography
12/12/2011	Josh Carslon, PhD, MPH	AHRQ K-12 Scholar; Faculty	Impact of Oncotype Dx on Chemotherapy Use, Short-Term Costs, and Recurrence
12/14/2011	Jim C. Hu		Comparative effectiveness of robotic prostatectomy
1/30/2012	Richard Kim, MD	Senior Fellow	Cost Minimization Analysis of a Multi-Site RCT of Home-Based versus Lab-based Diagnosis of Obstructive Sleep Apnea
3/26/2012	Karen Wernli, PhD	AHRQ K-12 Scholar; Research Scientist-Group Health	Comparative effectiveness of imaging modalities in breast cancer survivors
4/2/2012	Sean Sullivan, PhD	Faculty	Challenges in Designing Stakeholder-informed, Pragmatic CER Trials in Oncology
4/2/2012	Tara Karamlou		Designing a multi-center comparative-effectiveness trial to study surgical pulmonary valve replacement versus transcatheter pulmonary valve replacement

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
10/24/2012	Andrew Willan, PhD	Guest Speaker	Value and Uncertainty in Pricing New Health Care Interventions
10/29/2012	Anirban Basu, PhD	Faculty, University of Toronto	Comparing alternative design mechanisms for comparative effectiveness trials
10/29/2012	Scott Ramsey, MD, PhD	Faculty	Institute for Cancer Outcomes Research and Evaluation (ICORE)
11/5/2012	Carlos Gallego, MD	AHRQ K-12 Scholar, Faculty	
11/5/2012	Ryan Hansen, PharmD, PhD	AHRQ K-12 Scholar, Faculty	Prescription Opioids and Motor Vehicle Crashes: Investigating the Dose-Response Relationship
11/19/2012	Heather Evans, MD	AHRQ K-12 Scholar, Faculty	
11/19/2012	Kenn Daratha, PhD	Faculty, Washington State University	End of Life Hospitalization for Patients with ESRD in Washington State
11/26/2012	Karen Wernli, PhD	AHRQ K-12 Scholar, Faculty	Are there differences in short-term harms due to type of sedation and administration at colonoscopy?
11/26/2012	Joseph Babigumira, PhD, MBChB	Faculty	Potential Cost-Effectiveness of Malaria Rapid Diagnostic Testing for Febrile Illness Management
12/3/2012	Davine Wright, PhD	Faculty	A Theoretical Framework for Estimating Collateral Health Benefits within Social Networks
12/3/2012	Julia Slejko, PhD	Senior Fellow	Exploring Patient-Level Variation in Medication Adherence
12/10/2012	Dori Rosenberg, PhD, MPH	Assistant Investigator, Group Health	Use of Physical Activity Programs by Medicare Beneficiaries at Group Health
1/7/2013	Timo Hakkarainen, MD	Senior Fellow	Missing morbidity of post-surgical and post-trauma patients discharged to skilled nursing facilities
1/14/2013	Allison Devlin, MA	Program Director	PCORI methods grants
1/28/2013	Karen Wernli, PhD	AHRQ K-12 Scholar, Faculty	Comparative effectiveness of imaging modalities in breast cancer survivors
2/4/2013	Lonnie Nelson, PhD	AHRQ, K-12 Scholar, Faculty	Feasibility of a Weight Loss Intervention Using Mobile Technology for Urban American Indian and Alaska Native New Mothers
2/11/2013	Josh Carslon, PhD, MPH	AHRQ, K-12 Scholar, Faculty	Economics Framework for Personalized Medicine
2/11/2013	Larry Kessler, DSc	Faculty	Using the Multi-payer Claims Database for Comparative Effectiveness Research
2/25/2013	Danielle Lavallee, PharmD, PhD	Survey Center Manager	Patient involvement in research priority-setting
2/25/2013	Meera Kotagal, MD	Senior Fellow	Determining Risk Factors for Perforated Appendicitis in Children in Washington State

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
3/4/2013	Jerry Jarvik, MD, MPH	Faculty	The NIH Collaboratory and Pragmatic Trials: Lumbar Imaging with Reporting of Epidemiology (LIRE)
3/4/2013	Mary Hasselquist, PhD	Faculty	Optimizing the Visual Presentation of Your Message
3/11/2013	Elaine Morrato, DrPH, MPH	Faculty, University of Colorado Denver	Marketing: What Can We Learn to Improve Health Dissemination and Implementation
4/1/2013	Norma Coe, PhD	Faculty	Sticky Ages: Why is Age 65 Still a Retirement Peak
4/8/2013	Larry Kessler, DSc, Dave Veenstra, PharmD, PhD; Sean Sullivan, PhD; Dave Flum, MD, MPH; Danielle Lavallee, PharmD, PhD	Faculty	What is PCOR?
4/15/2013	John Ney, MD	Faculty	Outcomes from Continuous EEG Monitoring in the Intensive Care Unit
4/22/2013	Julia Slejko, PhD	Senior Fellow	Using Latent Class Probability Estimation and Residual Inclusion to Address Confounding in Medication Adherence Monitoring
4/22/2013	Raj Mehrotra, MD	Faculty	Comparative Effectiveness of Dialysis Therapies
4/29/2013	John Gore, MD	Faculty	Patient-centered pathology reports and urologic cancer care
5/6/2013	Carlos Gallego, MD	AHRQ K-12 Scholar, Faculty	Next Generation Sequencing in clinical care: patient's preferences and disparities in access to genomic health
5/13/2013	Todd Edwards, PhD	Faculty	Development and Testing of a Patient-Centered Treatment Decision Aid for Children and Adolescents with Appearance-Related Medical Conditions
5/13/2013	Rajiv Sethi, MD	Faculty	System Approaches to Safety in Complex Spinal Surgery: How can we move from a single center to multicenter data collection?
5/20/2013	Lonnie Nelson, PhD	AHRQ K-12 Scholar, Faculty	Locally Controlled DataQUEST
5/20/2013	Ann O'Hare, MD; Kenn Daratha, PhD	Faculty; Faculty, Washington State University	Utilization and Cost Trajectories in Patients with Kidney Disease
6/3/2013	Tom Varghese, MD	Faculty	Strong for Surgery: Development of an innovative electronic health platform to improve pre-operative patient preparation
6/3/2013	Ryan Hansen, PharmD, PhD	AHRQ K-12 Scholar	Premier Data Primer
9/30/2013	Tao Sheng Kwan-Gett	Faculty	An Overview of the Northwest Center for Public Health Practice

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
10/14/2013	Rajiv Sethi, MD; Karen Wernli, PhD	Faculty; Assistant Investigator, Group Health	10 years of complex spine surgery in Seattle: effect of system approaches and multidisciplinary screening processes
10/21/2013	Lonnie Nelson, PhD	AHRQ K-12 Scholar, Faculty	Screening for Cognitive Impairment in Tribal Court Defendants: Reducing Recidivism through Rehabilitation and Redesigned Supervision
10/28/2013	Val Simianu, MD	Research Fellow	Uncertainty forecasts simulate risk-seeking behavior in healthcare providers
11/4/2013	Beth Hacker, PhD; Bas de Veer	Research Navigator; Senior Computer Specialist	Introduction to the ITHS and REDCap
11/18/2013	Jean McDougall, PhD	Senior Fellow	Relationship between out-of-pocket cost and consumption of oral tyrosine kinase inhibitors
11/25/2013	Carlos Gallego, MD	AHRQ K-12 Scholar, Faculty	Perception of Genomic Health in Hispanics
12/2/2013	Randall Curtis, MD, MPH	Faculty	Measuring and Improving Communication about End-of-life Care
12/9/2013	Ryan Hansen, PharmD, PhD	AHRQ K-12 Scholar, Faculty	Estimating Quality of Life Among People with Inborn Errors of Metabolism: Comparing Nutritional Support to Liver Transplantation
1/27/2014	Sarah McCoy, PhD	Faculty	Improving Decision-Making for Rehabilitation Services in Families of Children with Cerebral Palsy
2/3/2013	Jay Mendoza, MD, MPH	Faculty	A wearable mHealth device to promote teenagers' physical activity: a pilot RCT
2/10/2014	Douglas Zatzick, MD	Faculty	A Comparative Effectiveness Trial of Optimal Patient-Centered Care for US Trauma Care Systems
2/24/2014	Margo Bergman, PhD, MPH; Neil Abernethy, PhD	Faculty	Emotion in Decision Making: Comparing a comprehensive theory to the status quo
3/3/2014	Josh Carslon, PhD, MPH	Faculty	Primer on PriMER
3/10/2014	Dawn Ehde, PhD	Faculty	Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis
3/17/2014	Gary Lyman, MD, MPH	Member, Fred Hutchinson Cancer and Research Center	HICOR
3/31/2014	Jin Lee, PhD	Research Consultant, Humana	Academic Partnerships at Humana's Comprehensive Health Insights
3/31/2014	Todd Edwards, PhD	Faculty	Measures for Craniofacial Clinical Studies: Outcomes for Infants with Cleft Lip with or without Cleft Palate
4/7/2014	Jerry Jarvik, MD, MPH	Faculty	Lumber Imaging with Reporting of Epidemiology (LIRE) Update- A Pragmatic Cluster RCT

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
4/14/2014	Janna Friedly, MD	Faculty	Lumbar Epidural Steroid Injections for Spinal Stenosis (LESS) clinical trial: Understanding What Outcomes are Most Important to Patients
4/21/2014	Sharon Kwan, MD	Faculty	Active steps toward a passively managed national hepatocellular carcinoma registry: radiology's call to action
4/21/214	Carrie Bennette, MPH	PhD Candidate	Value of Information Analyses to Prioritize Cancer Clinical Trial Funding
4/28/2014	Janie Lee, MD	Faculty	Optimizing Imaging Surveillance for Breast Cancer Survivors
5/5/2014	Brian Bresnahan, PhD; Rafael Alfonso, MD, PhD	Faculty	Novel methods to disseminate knowledge regarding molecular imaging of cancer
5/12/2014	Christoph Lee, MD	Faculty	Adoption of Emerging Breast Imaging Technologies and Access to Screening
5/19/2014	Sean Rundell, PhD	Senior Fellow	The relationship between knee or hip osteoarthritis and back outcomes over 1 year among older adults with new visits for back pain
6/2/2014	Benjamin Wilfond, MD	Faculty	Assessing public attitudes about the ethics of research on medical practices
6/23/2014	William Hollingworth, PhD, MSc	Faculty, University of Bristol	Can variation in hospital procedure rates identify candidates for health technology reassessment and disinvestment?
10/6/2014	Karen Wernli, PhD; Jerry Jarvik, MD, MPH	Investigator, Group Health Research Institute; Faculty	The PCORI Review Process: The Inside Scoop
10/13/2014	Danielle Lavallee, PharmD, PhD	Faculty	Eugene Washington Engagement Award: Supporting Patient Involvement in the Learning Healthcare System
10/20/2014	Sean Rundell, PhD, DPT	AHRQ K-12 Scholar, Faculty	Application of New Data Abstraction Methods for Comparative Effectiveness Research in Back Pain
10/27/2014	Patricia Purcell, MD; Greg Davis, MD, MPH	Faculty	A claims-based comparison of health care costs and utilization trends in medical and surgical management of chronic rhinosinusitis
11/3/2014	CERTAIN Patient Advisory Network	Faculty	CERTAIN Patient Advisory Network Annual Symposium
11/17/2014	Josh Roth, PhD, MHA	AHRQ K-12 Scholar, Assistant Member, Fred Hutchinson Cancer Research Center	Engaging patients to develop tools to optimize the roll out of lung cancer screening: An overview of my K12 training and research objectives
11/24/2014	Josh Carlson, PhD, MPH	Faculty	Precision Medicine in Cancer: Moving toward biomarker-based individual level treatment planning

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
12/2/2014	Carlos Gallego, MD	AHRQ K-12 Scholar, Faculty	Next generation sequencing panels for the diagnosis of colorectal cancer and polyposis syndromes: a cost-effectiveness analysis
12/8/2014	Justin Robertson, PhD, MS	AHRQ K-12 Scholar, Faculty	Understanding Rheumatoid Arthritis Patients' Preferences for Outcomes and Treatment Choices
1/5/2015	Farhood Farjah, MD, MPH	Faculty	Population-based Evaluation of the Prevalence, Management, and Outcomes of Individuals with Lung Nodules
1/12/2015	Amber Sabbatini, MD, MPH	AHRQ K-12 Scholar, Faculty	Designing High-Value Alternatives to Admission for Emergency Patients: The Effectiveness of a Transitional Care Clinic Model
1/26/2015	Erin Bowles, MPH	Research Associate, Group Health Research Institute	Use of Natural Language Processing to extract breast cancer pathology procedures and results
2/2/2015	Karen Wernli, PhD	Investigator, Group Health Research Institute	End of life care in adolescent and young adult cancer patients
2/9/2015	Vlad Simianu, MD	Resident	A population-based approach to evaluating the impact of elective surgery for diverticulitis
2/23/2015	Anne Pugel, MD	Resident	Alvimopan use, outcomes, and cost
3/2/2015	Carrie Bennette, PhD	AHRQ K-12 Scholar, Senior Fellow	Improving treatment & management decisions for women with DCIS
3/9/2015	PCOR K12 Scholars	Faculty	Updates
3/30/2015	Doug Conrad, PhD, MBA, MHA; Dave Grembowski, PhD, MA	Faculty	The Healthier Washington Project: Evaluating Innovation in Medical Care and Population Health
4/6/2015	Lotte Steuten, PhD, MSc	Associate Member, Fred Hutchinson Cancer Research Center	Value of consumer-directed information for decisions about cancer test and treatment options
4/13/2015	Josh Roth, PhD, MHA	Assistant Member, Fred Hutchinson Cancer Research Center	Design of a clinical trial to evaluate the comparative effectiveness of next generation sequencing to inform treatment decisions in patients with advanced cancer
4/20/2015	Andrea Hartzler, PhD	Assistant Investigator, Group Health Research Institute	User-centered design: How to personalize health information technology (HIT) through stakeholder engagement

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
4/27/2015	Aasthaa Bansal, PhD	Faculty	Evaluating the value of updating markers over time for risk prediction and treatment prioritization in cystic fibrosis
5/4/2015	Catherine Richards, PhD, MPH	Staff Scientist, Fred Hutchinson Cancer Research Center	Impact of hospital financial distress on cancer outcomes
5/11/2015	Sean Sullivan, PhD; Aasthaa Bansal, PhD	Faculty	Designing and Implementing a PCORI-funded Pragmatic, Randomized Trial of CSF Use in Cancer
5/18/2015	Sean Rundell, PhD, DPT	AHRQ K-12 Scholar, Faculty	Developing a prognostic tool for musculoskeletal pain conditions
6/1/2015	PCOR K12 Scholars	Faculty	Updates
10/12/2015	Sean Rundell, PhD, DPT	AHRQ K-12 Scholar, Faculty	Lumbar Stenosis Prognostic Subgroups for Personalizing Care & Treatments
10/19/2015	Amber Sabbatini, MD, MPH	AHRQ K-12 Scholar, Faculty	Understanding the Effectiveness of Observation Units as an Alternative to Admission for Patients with Acute Illnesses
10/26/2015	Beth Devine, PhD, PharmD, MBA	Faculty	Leveraging a Clinical Data Repository to Characterize the Landscape of Pharmacogenomic Biomarker-Guided Medication Use
11/2/2015	Carrie Bennette, PhD	AHRQ K-12 Scholar, Senior Fellow	Evaluating policy interventions to address rising chemotherapy prices
11/9/2015	Josh Roth, PhD, MHA	AHRQ K-12 Scholar, Assistant Member, Fred Hutchinson Cancer Research Center	An evaluation of the potential radiation harms of long-term low-dose computed tomography lung cancer screening
11/16/2015	Zach Marcum, PharmD, PhD	Faculty	Longitudinal Medication Adherence in Older Adults with Multiple Chronic Conditions
11/30/2015	Amber Sabbatini, MD, MPH	AHRQ K-12 Scholar, Faculty	Access to follow-up care after discharge
12/7/2015	Justin Roberston, PhD, MS	AHRQ K-12 Scholar, Faculty	Understanding Rheumatoid Arthritis Patients' Preferences for Outcomes and Treatment Choices
1/25/2016	Jerry Jarvik, MD, MPH	Faculty	Antibiotics for Back pain-Chronic (ABC) Trial- An Infectious Idea??

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

Date of Presentation	Speaker	Role at UW	Title of Presentation
2/1/2016	Lucas Thornblade, MD	Fellow	Preoperative healthcare utilization as an indicator of elective surgery for Diverticulitis
2/8/2016	Bryan Luce, PhD, MBA	Senior Advisor, Evidera	The Learning Health Care System Meets the Response-Adaptive Platform Trial: Moving from Deming toward a Clinical Analytical Construct
2/29/2016	Cordelie Witt, MD	Fellow	Transcranial Doppler monitoring for blunt cerebrovascular injury
3/7/2016	Molly Fuentes, MD	Fellow	The association of functional outcome and facility type during inpatient pediatric rehabilitation
3/28/2016	Nita Khandelwal, MD, MS	Faculty	Developing and Implementing Methods for Assessing Costs Associated with Palliative Care Quality Metrics
4/4/2016	Annie Pugel Ehlers, MD	Fellow	Treatment Patterns of Achalasia
4/11/2016	Theresa Hoeft, PhD	Faculty	Patient Preferences for Engagement Strategies to Inform Patient-Centered Care for Post-Traumatic Stress Disorder
4/18/2016	Cameron Gaskill, MD	Fellow	mPOWEr: mobile-based post-operative wound evaluator app
4/25/2016	Lotte Steuten, PhD, MSc	Associate Member, Fred Hutchinson Cancer Research Center	Development and validation of a method for measuring the Value of Patient-Directed Information
5/2/2016	Carrie Bennette, PhD	AHRQ K-12 Scholar, Faculty	Crafting a strategic research plan
5/9/2016	Carrie Bennette, PhD	AHRQ K-12 Scholar, Faculty	Will there be enough patients? Informing targeted enrollment of minorities in cancer clinical trials
5/16/2016	Amber Sabbitini, MD, MPH	AHRQ K-12 Scholar, Faculty	Impact of the Washington State "ER is for Emergencies" Program
5/23/2016	Karen Wernli, PhD	Assistant Investigator, Group Health Research Institute	Models of Patient Engagement: Real-world examples
10/10/2016	Anirban Basu, PhD	Faculty	Developing a new diabetes model

Table 3 (continued): UW CHASE Alliance - Works in Progress Presentations, October 2011 through June 2014

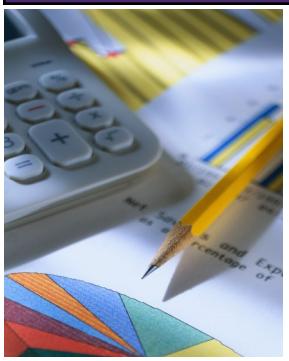
Date of Presentation	Speaker	Role at UW	Title of Presentation
10/17/2016	Laura Panattoni, PhD	Staff Scientist, Fred Hutchinson Cancer Research Center	Cost Estimates for Designing and Implementing a Novel Team Care Model for Chronically Ill Patients
10/24/2016	Cyndy Snyder, PhD, MEd, MA	AHRQ K-12 Scholar, Faculty	Racism, Microaggressions, and Multiracial Families in the Health Care Setting
11/7/2016	Carrie Bennette, PhD	AHRQ K-12 Scholar, Faculty	Disparities in Cancer Clinical Trials: A Multi-level Analysis of Access and Enrollment
11/14/2016	Molly Adrian, PhD	AHRQ K-12 Scholar, Faculty	Development of adaptive treatment strategies for suicidal adolescents
11/21/2016	Sarah Knerr, PhD, MPH	AHRQ K-12 Scholar, Faculty	Implementation of guideline-recommended personal risk assessment for breast cancer prevention and control
11/28/2016	Zach Marcum, PharmD, PhD	AHRQ K-12 Scholar, Faculty	Longitudinal Medication Adherence in Older Adults at Risk for Dementia
12/5/2016	Nita Khandelwal, MD, MS	AHRQ K-12 Scholar, Faculty	Financial Impact of Critical Illness and Understanding Stressors (the FICUS study)

AHQR = Agency for Healthcare Research and Quality; CER = Comparative Effectiveness Research; CERTAIN = Comparative Effectiveness Research Translation Network; CHASE = Centers for Comparative and Health-System Effectiveness; RCT = Randomized Controlled Trial

UNIVERSITY of WASHINGTON

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

Graduate Certificate in Comparative Effectiveness Research



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,

Apply Now
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Notification: 3 weeks after submission

Visit our website for details about how to apply:

Who Should Apply?

Eligibility restricted to current University of Washington graduate students.

Requirements:
To obtain the Graduate Certificate, students are required to complete a set of advanced courses in CER that will count toward their electives in their respective PhD programs. The trainees must also complete a capstone project that represents independent work in CER performed under the supervision of a CER core or affiliate faculty member.

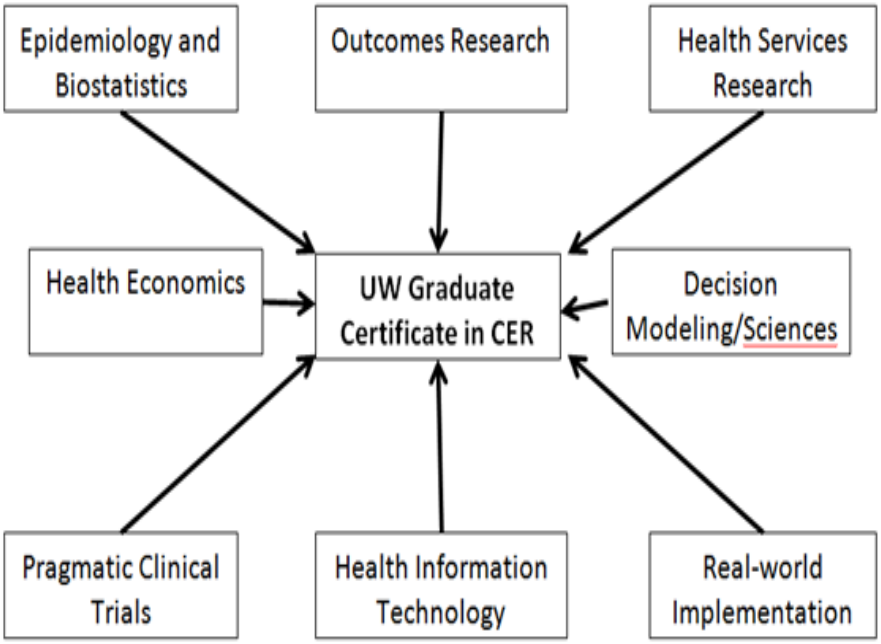
Contact:
206-616-1383
http://sop.washington.edu/porpp/certificate-programs/certificate-programs.html
Beth Devine: bdevine@uw.edu

Graduate Certificate in CER Credit Totals, per PhD Program and Pre-Requisites

This table reflects requirements for PORPP and HSERV students. Curriculum can be tailored to interested students in other UW PhD programs on an individual basis.
Pre-requisites classes include:
BIOSTATS 511/512/513 Or 517/518
and
EPI 512/513

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
PHARM 534/HSERV 583: Economic Evaluation in Health and Medicine	Core	3
PHARM 535/HSERV 584: Assessing Outcomes in Health and Medicine	Core	3
PHARM 536: Advanced Methods in CER	3	3
PHARM 529/EPI 541/ HSERV 529/ MEBI 541: Introduction to Meta Analysis	3	3
BIOST/STAT 578: Bayesian Biostatistics	3	3
CAPSTONE Project	1	1
TOTAL CREDITS FOR CERTIFICATE	18	16

Health Sciences Fields Involved in CER



Faculty

Leadership Team:

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

Anirban Basu, PhD, Director, Pharmaceutical Outcomes Research & Policy Program, Professor, Pharmacy & Health Services

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

Additional Steering Committee Members:

David Grembowski, PhD, Professor, Health Services

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

Admissions Information
Eligibility Limited to Current UW Graduate Students

Rolling Application Submission
Notification: 3 weeks after submission of application

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

Capstone Project

Several courses in the CER Certificate coursework, core PhD coursework, and elective coursework require scholars to complete a class project within each quarter; these courses are so designated. CER scholars may use any of these class projects as a springboard to their capstone project. What will distinguish the capstone project from a class project is that the capstone project is to be of publishable quality and is to be submitted to a peer-reviewed journal for publication. The capstone project may be used as a cornerstone to thesis or dissertation research, but will constitute, at most, a part of this larger degree requirement.

Curricular Advances for Patient-Centered Comparative Effectiveness Research: A Conference Report

Jodi Segal, MD, MPH,[1]

Beth Devine, PhD, PharmD, MBA,[2]

Louis P. Garrison, PhD,[2]

Jean Paul Gagnon, PhD[3]

[1]Johns Hopkins University School of Medicine,
[2]University of Washington Pharmaceutical Outcomes Research and Policy Program,
[3]PhRMA Foundation

Abstract

Comparative effectiveness research (CER) and patient centered outcomes research (PCOR) gained national prominence with passage of the Affordable Care Act. Accordingly, the Pharmaceutical Research and Manufacturers Association (PhRMA) Foundation embarked on a new path with funding of five programs to train research scientists and users of CER/PCOR. Researchers from these five academic Centers of Excellence in CER/PCOR recently convened a conference to discuss training issues and curricula.

Curricular advances for CER and PCOR was held in Washington D.C. on January 28 and 29, 2014. The conference was funded jointly by the Agency for Healthcare Research and Quality, the PhRMA Foundation and the Patient Centered Outcomes Research Institute. The 120 attendees, representing 50 unique academic institutions and life sciences industries, also included representatives from the Federal government, professional organizations and health plans.

Conference objectives were to compare existing competencies, define the scope of CER/PCOR and academic approaches to training, and discuss the need for standardized competencies. Directors of the five Centers shared their curricula and training approaches; leaders from PCORI, AHRQ, the Food and Drug Administration, the Center for Medicare and Medicaid Services, industry, and academia shared their perspectives; conference attendees discussed relevant issues in small groups. Keynote speakers addressed incorporating CER into policymaking (Dr. Gail Wilensky) and discussed the future of CER (Dr. Mark McClellan). The conference closed with a discussion of curricular needs in the field.

Observations included that CER/PCOR is a team science and training may need to be increasingly multidisciplinary. Scientists conducting CER/PCOR must possess a breadth of knowledge but also substantial depth in one or more areas of expertise. Many gaps in training exist including about methods for patient engagement, dissemination and implementation, the decision sciences, and use of big data. As a next step, conference attendees will be surveyed to learn how the conference impacted teaching at their institutions.

Acknowledgement: We extend special thanks to Eileen Cannon of the PhRMA Foundation for her exceptional facilitation of this conference.

Table of Contents

Introduction

This report is the proceedings of the Curricular Advances for Comparative Effectiveness Research and Patient Centered Outcomes Research Conference which took place on January 28th and 29th, 2014 at the Pew Charitable Trust Conference Center in Washington D.C. This conference brought together 120 academics from 50 unique institutions and life sciences industries, the Federal government, professional organizations and health plans with interest in improving how we train investigators to conduct comparative effectiveness research and patient centered outcomes research CER/PCOR and how we train individuals to use and apply the results of this research.

This conference came to be upon the urging of Dr. Jean Paul Gagnon of the PhRMA Foundation, as a way to disseminate the work of the PhRMA Foundation-supported Centers of Excellence in Comparative Effectiveness Research Training. In 2012, two of the current five Centers for Excellence in Comparative Effectiveness Research Training were funded – the center at Johns Hopkins University led by Dr. Jodi Segal, and the center led by Beth Devine and Lou Garrison at the University of Washington. Soon after, the PhRMA Foundation funded the center at Harvard University and the University of Utah, and, most recently, the center at the University of Maryland. With these five Centers established, Dr. Gagnon suggested to the Centers that they might organize a conference to advance thinking about best methods for training researchers to conduct and use CER/PCOR.

Dr. Jodi Segal was awarded a conference grant from the Agency for Healthcare Research and Quality (AHRQ) for this purpose. The PhRMA Foundation committed additional funds to make the conference feasible, and then the Patient Centered Outcomes Research Institute also contributed. The planning and preparation for this conference was highly collaborative – involving all five centers as well as PhRMA Foundation, PCORI (specifically Dr. David Hickam) and AHRQ with the involvement of Dr. Jennifer Moore. (Box 1)

The planning team was responsible for selecting invitees. The group first created a list of CER/PCOR-involved people. The names came from the Key Function Committee from the Clinical and Translational Science Award (CTSA) consortium; from the leaders of AHRQ's Evidence-based Practice Centers and observational research centers, from the review panels of AHRQ Health Economics and Outcomes Research study section; from the academic council members of the International Society of Pharmacoepidemiology, and others who the conveners knew to be thought-leaders in CER/PCOR teaching. From this list of over 400 people, the planning group selected invitees to represent diverse universities, and diverse schools including schools of medicine, pharmacy, public health and nursing. It was important to the planning group as well to have in attendance the people who hire graduates of academic programs. The planning group sent approximately 200 invitations and did not need to send any additional. The 120 attendees are listed in **Appendix I**.

Box 1. Planning Group

Jean Paul Gagnon	PhRMA Foundation
Eileen Cannon	PhRMA Foundation
Jodi Segal	Johns Hopkins University
Beth Devine	University of Washington
Lou Garrison	University of Washington
Sonia Hernandez-Diaz	Harvard University
Eleanor Perfetto	University of Maryland
Michae Spigarelli	University of Utah
Carrie Mcadam Marx	University of Utah
Dianna Brixner	University of Utah
David Hickam	PCORI
Jennifer Moore	AHRQ

Conference Goals

The goals of the conference were reviewed. This conference was to be about *strengthening curricula* for comparative effectiveness research (CER) and patient centered outcomes research (PCOR). It was expected that conference attendees would depart with a forward-looking view of the scope of the field, enhanced understanding of the didactic and practical approaches institutions are using to prepare a workforce skilled in CER/PCOR, and with ideas for developing new courses or revising the offerings at their own institutions.

At the conclusion of the conference, it was proposed that attendees would be able to:

- Compare CER competencies that have been proposed by different organizations
- Describe the methodologies that are frequently used for CER and PCOR, as well as methods that should be considered outside of the scope of these activities
- Describe approaches that academic institutions are using for training learners in CER and PCOR
- Recommend training approaches that are tailored to the needs, background and anticipated roles of the learners
- State an opinion about developing a standardized competency set or curriculum

I. Five PhRMA Foundation Funded CER Educational Centers of Excellence

Each of the CER Educational Centers of Excellence was invited to make a presentation about their programs. The session was introduced by Dr. Jean Gagnon who described the origins of the Centers of Excellence.

The PhRMA Foundation was founded 48 years ago to fund scientists in disciplines essential to the development and use of safe and effective medicines. In March of 2009, the Foundation's Health Outcome Research Committee proposed developing a request for proposals for a CER curricula development program. In preparation, a Committee was formed to develop recommendations

regarding a graduate education curriculum in CER. This Committee began by organizing a workshop with 20 CER researchers and health outcomes researchers. Investigators from the University of Maryland (Daniel Mullins, Emily Reese, and Robert Beardsley) conducted an extensive literature review and surveyed their colleagues on this topic. These CER researchers convened in December 2009 for a workshop – the attendees were asked to develop a model curriculum and the results were published in 2011 as *Curricular Considerations for Pharmaceutical Comparative Effectiveness Research.* (Murray, 2011)

Soon after, a CER Curriculum Initiative and Business Case for the PhRMA Foundation Center of Excellence in CER Program was written and submitted, along with the CER committee's proposed curriculum, to the Executive Director and Foundation's Board for approval. The Board approved the program and a request for proposals for CER Education and Training Programs was released in May 2011. A CER Advisory Committee selected the CER Center of Excellence awardees in 2012, 2013, and 2014.

Synopsis of Programs

Each of the five speakers presented details about their current or planned curricula for CER at their institutions. The slides describing these programs are available as **Appendix 2.**

Questions and Answers

At the conclusion of the presentations of the programs, the floor was opened for questions and answers. There were several themes that emerged.

One discussion centered on the breadth and depth of the CER curriculum – one invitee, from industry, commented that he hires newly minted PhDs and they are not ready to do anything – they need substantial training. He wonders if these broad curriculums will make this worse – there will be tremendous breadth without depth.

Dr. Devine responded that the University of Washington expects students to have both breadth and depth upon graduation. The dissertations completed by the PhD students provide the depth to their training. They work with experts as their advisors in the particular area in which they will gain depth. The goal of CER certificate is for the students to be conversant in all of the areas – to speak knowledgeably and to know how these topics are integrated. Dr. Segal noted that this is the reason that they are not pursuing a PhD in CER. Dr. Hernandez-Diaz expects their graduates will have the skills to easily acquire new, in-depth skills on their own, as needed by their employers. Dr. Perfetto favors externships where students can learn in depth a topic from doing a project and gaining practical experience. While in industry, she would not hire a student who had not had a previous job.

Another theme discussed was the scope of the content to which CER is applied. The invitee commented that the programs described appeared to be heavily focused on pharmaceutical CER and not focused sufficiently on CER as applied to the study of behavior, health systems, devices, and procedures. The Curriculum presenters welcomed the opportunity to correct the perception and noted that they have

received many inquiries from colleagues interested in studying the comparative effectiveness of interventions other than drugs including alternative therapies like acupuncture, rehabilitation, and formularies. Dr. Gagnon reminded the group that the Affordable Care Act stresses evaluation of "treatments".

One invitee wondered what makes a good capstone project, and leads to particularly valuable students for industry, and what works particularly well in online course offerings. Dr. Spigarelli commented that he likes students to complete capstones that are partnerships with industry – it helps develop a student who can fill the need of the company so that both are winners. Regarding online teaching, Harvard has tried the "flipped classroom" model where students learn online at home and then come together for discussion and case studies. Dr. Spigarelli, at University of Utah, cautions against "talking heads" – he has found that preparing material in small segments is effective so that students can listen to as many or as few of the small segments as are necessary to meet their learning needs. Dr. Segal notes that giving individualized feedback on assignments with large online enrollment is very difficult – she and her colleagues have taped their lectures so that two lecturers have an ongoing discussion about the material on the slides; this has been perceived as more engaging (like *Car Talk* heard on public radio stations).

One invitee senses that graduating PhDs are unable to effectively communicate complex concepts (such as in CER to lay people, to clinicians, and to business people. He worries that these are the decision-makers and company employees need to be able to communicate with them. Dr. Spigarelli has had a good experience with having his "lab meetings" be very multidisciplinary – including researchers, physicians, nurses, quantitative and qualitative scientists—so that each learns to communicate effectively with the others. Each can state whether the information was conveyed clearly for an audience of their peers.

Another invitee noted that there has been little integration of CER into the training of physicians – it is not part of undergraduate clinical education and there is little training offered to practicing physicians. Dr. Hernandez-Diaz believes that the very packed undergraduate medical school curriculum leaves little room for this type of training, and since that licensing examinations do not require a great deal of this content, it is not taught. She favors modification of the exams to show that this knowledge is essential content for medical students. Dr. Perfetto notes that her department has been recently asked to train physician assistants who are now required to have master's degrees. Their curriculum will train these clinicians to be expert *users* of CER.

II. Why Educate and Train Individuals on Patient Centered Comparative Effectiveness Research?

Panelists were invited to discuss the questions of why we should train in CER/PCOR and more specifically whether this impacts on patients. The invited panelists are listed in Box 2.

Box 2. Panelists

Harold Sox (moderator)		Dartmouth Institute
Anne Beal		PCORI
Jennifer Moore	(for Francis Chesley)	AHRQ
Peter Newmann		Tufts University
Newell McElwee		Merck & Co.
Robert Temple		Food and Drug Administration
Louis Jacque		Center for Medicare and Medicaid Services

Synopsis of Panel Discussion

Dr. Hal Sox moderated the panel. He reminded those in attendance that the goal of shared decision making is to tailor the choice to the characteristics and preferences of the patient. This is generally a discussion about harms and benefits of interventions. He believes that big decisions should be a conversation among equals, and that decision aids help this conversation by educating and informing patients. A decision aid provides information to help patients make decisions about their medical care. It frames the decision in an unbiased way; it describes benefits, harms, and costs of the options. It also describes potential outcome states. A decision aid can empower patients to hold up their side of a discussion with a physician.

A decision aid could be simply a table of outcomes and their frequencies; alternatively it could be a model that predicts the gains and losses from screening. Dr. Sox is impressed by the model published by Heijnsdijk, et al, in NEJM 2012. He feels that decision aids can inform individual decision making and potentially policy.

Dr. Sox set out a CER Curriculum Synopsis derived from what he heard presented earlier in the conference.

Box 3. A Possible Curriculum for Comparative Effectiveness Research

Assessing health status and outcomes	Systematic Reviews	Research Methods of Health Policy
Principles of Epidemiology	Cohort Studies	Observational Research and Confounding
Population Health Informatics	Evaluation of Health Programs	Decision Sciences
Research Ethics	Economic Evaluation	

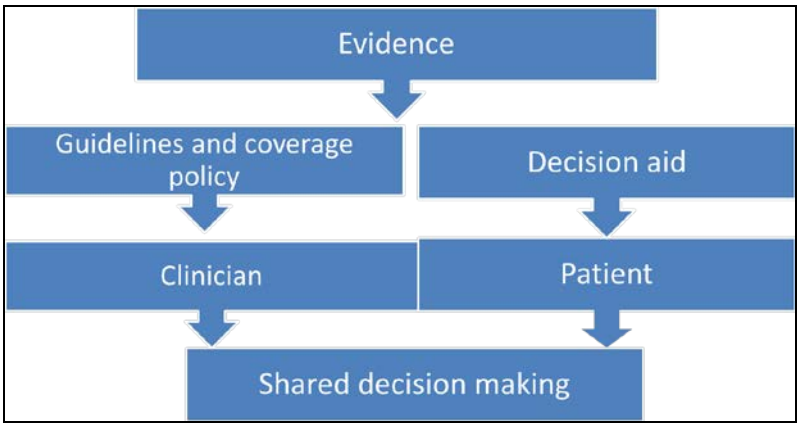
Recently, Dr. Sox has been collaborating with Drs. David Meltzer, David Flum, and Mark Helfand on a CER framework for decision sciences. They propose estimating the costs, harms, and benefits of an intervention to patients, caregivers, and other stakeholders in our complex health care environment. They envision mathematical modeling: of the diagnosis and treatment of disease, of day-to-day patient care, of simulations of clinical studies, and using modeling for priority setting. Decision-making may also be used when the patient is not able to participate meaningfully in decision making. They suggest measuring patient, caregiver, and stakeholder preferences, values, utilities, priorities, and perspectives and incorporating them into medical decision making. They stress that factors other than evidence affect medical decisions. They see innovative applications of decision science to improve clinical decisions. They urge us to use decision science to improve the uptake of research findings into individual and policy decision making.

Dr. Sox proposes a possible **curriculum in decision science**:

Box 4. A Possible Curriculum in Decision Science

Probability (estimating probability, updating probability with Bayes theorem, measuring test performance)	Decision models (the threshold model; advanced modeling methods, cost-effectiveness and cost-benefit analysis)
Expected value decision making	Measuring preferences: utility assessment
Cognitive aspects of decision making	

A figure that Dr. Sox particularly likes is as follows:



The first panelist to speak was **Dr. Anne Beal** from PCORI. She began with four points that she thinks are essential for CER practitioners. They need understanding of: 1) Patient- centeredness: language of Affordable Care Act (ACA) states that PCORI is to be a CER institution; however, PCORI's Board decided that they would take patient-centeredness seriously. These was little clarity about patient-centeredness (although this is mapped out in the Methods Standard) – she believes it really means keeping the patient central in all decisions; this doesn't mean that there is always patient engagement in the process (e.g. some IT decision and systems decisions don't require patient input as long as the patient experience is kept as the goal), and recognition that what is important to us as clinicians is not always what is most important to patients (e.g. ability to work, role functioning). 2) Patient and stakeholder engagement --PCORI Board decided that patients need to have a voice in the work – seat at the table; PCORI is aware of tokenism – they demand substantive engagement; 3) Standards for practice – how do we engage patients in this process; PCORI looked at the first three rounds of projects to identify best practices in the engagement plans (reviewed 150 projects) -- summary will be on the website of PCORI (and in the published literature); she hopes that PCORI will make a framework for talking about stakeholder engagement like how the IOM provided a framework for talking about quality and safety; 4) Evaluation of the impact of patient engagement – it is really unknown whether this helps the research process and improves outcomes; what is the utility of this process –how has this led to saved lives,

better outcomes, how did it aid dissemination of knowledge into practice. The aim is for our research to have greater relevance.

The next speaker was **Dr. Jennifer Moore** from AHRQ. She addressed AHRQ's role in PCOR training – their comprehensive grant program for PCOR. AHRQ has a multi-pronged strategy for individual and institutional funding. PCOR – K99/R00 – for emerging investigators; K18 – mid to senior investigators who want to include more PCOR into their CER; K12 – institutional for post-doctoral and faculty trainees; R24 – emerging facilities to establish infrastructure core for CER/PCOR. Dr Kronick is focused on improving health care quality by accelerating focus on PCOR. The goal is to train investigators to successfully engage patients; to train investigators to address human subjects' protection issues with involvement of patients; and to improve patient care and shared decision making. AHRQ hopes PCOR improves equity and reduces disparities. This is predicated on training programs that stress a difference between CER training and PCOR training. AHRQ feels these are unique. What does PCOR training look like (how does it differ from a CER training program)? How do we meaningfully include other disciplines in this training (like nursing and pharmacy)? How do we develop PCOR training programs that adequately address disparities and equity?

Dr. Louis Jacques spoke next, stressing that he was not speaking as a representative of CMS. Dr. Jacque thinks there is a public reluctance to see CER as anything other than a road to rationing. Are we training a workforce to do CER or use CER? How do we motivate learners? Hard to say –except they tend to follow the money. If you want more researchers in CER, put the grant money out there.

Medicals students are NOT fertile ground for teaching CER. They are not interested in primary care; they are not interested in policy.

Dr. Newell McElwee tried to answer the question posed: What is the impact of training in this field *on patients*? He does not know of any evidence about the impact of training researchers in this field – he proposed that many of us believe that the benefits outweigh the risks (diversion of funds from discovery, for example), but there is very little empirical evidence. What is the framework for looking at CER benefits and risks? How might we balance the tradeoff between discovery and translating evidence into best decision making? This is the same discussion as the difference between task-order directed research and investigator initiated research. What might we best inform with our evidence? a) Regulatory decisions , b)Payor decisions, and c) Individual patient treatment decisions. He notes that in the first two, the patient is a stakeholder; in the last, the patient is the decision maker.

Framework for workforce training – for PCOR and health outcomes research in general – we don't really know what the workforce needs and how to train these practitioners . This field does not have any licensing or credentialing. As we move forward, we should think more closely about our workforce.

He is unaware of evidence about the impact of PCOR on users of this research. Who are the users and what outcomes are we thinking about? Users may be thought of as decisionmakers, including patients. What outcomes? Is the goal that patients make informed decisions? Or just to inform their decisions? --- This probably doesn't necessarily push them to better self-care and better outcomes; this requires

patient engagement in their health care. Only the upper quartile of "activated patients' are really engaged in their health care sufficient to make a difference in their outcomes.

Dr. Peter Newmann began his discussion with a quote from Vinod Khosla –"Data science will do more for medicine in the next 10 years than biological science." This quote makes a case that we need more data science – this will separate knowledge from information and separate signal from noise.

Dr. Newmann urges that we should be teaching:

- Traditional data sciences (biostatistics, epidemiology, outcomes research, health services research)
- Decision sciences/modeling (how to characterize uncertainty)
- Economics
- Clinical effectiveness modeling and perhaps cost effectiveness
- Value of Information (is the evidence sufficient, what kind of evidence do we need)
- Behavioral science (how people process probabilistic information)
- Curricula should focus on systems
- Curricula should focus on communication
- Implementation Science - how information is incorporated into decisions

Dr. Robert Temple from FDA was the last panelist to speak. He spoke about how to conduct a valid study to determine comparative effectiveness. Everyone wants to know if one drug is better than another. Perhaps equally important is how to keep patients from stopping their drugs; how to interpret trials that fail to show superiority. (Look at the *FDA Non-inferiority Guidance for Industry* for more information). He argues that a comparative study always needs a placebo (in order to show that the drugs are effective (and not just equally ineffective). Everyone needs to understand the non-inferiority paradigm (including the non-inferiority margin). He also encourages the trial design that tests non-responders. He believes that individuals who fail therapy should then be re-randomized to the failed drug and the new drug (reasonable design for symptomatic conditions – obviously not appropriate for highly fatal conditions). There are few examples of this in the literature (examples include trials of clozapine, captopril, rofecoxib) He wants to encourage people to use these designs. There is a world of promise in genetically targeted therapies – such as in mental health.

Discussion following Panel Presentations

One invitee noted that disciplines have at their base a theory – they end in "-ist" or "-ology". Fields are "applied" and they are applied to problems. She notes many "ists" in the room – economists, pharmacists, and yet she finds that psychology and sociology are missing. She is not sure that CER/PCOR knows what "-ologists" are needed – who is missing in this new field? Are we insufficiently innovative – how do we work in an interdisciplinary field?

A panelist responded that patients yield "mega-data" – few of us are appropriately trained to use these data. Patients are also generating their own data on-line that CER researchers have largely not tapped

in to. Mathematicians and informaticists who can leverage these data will be in demand, particularly as we tailor messaging and recommendations to different types of patients. Another panel agreed: data synthesis is a skill needed in the CER field.

One invitee reminded us that costs are a patient-centered outcome. One invitee described a study that he recently conducted where he had anthropologists listen to patients describing their cancer treatment experience. He noted that sometimes patients change their preferences after going through an experience and that we are not well equipped to include these types of changes in our models.

On invitee asked us to think about how we train practicing clinicians in CER and more specifically how to train them to engage patients in decision making. Clinicians can be both investigators and information disseminators.

Dr. Jacques thinks that physician payment is the driver of spending time on patient engagement - payment for the cognitive work needs to rise to allow clinicians to spend the time doing this.

Another invitee reminded us of the added challenges of engaging patients with low health literacy, or who are otherwise disenfranchised. Dr. Beal agrees that there is some risk to putting "patients at the table" as it could exacerbate disparities; the process probably selects for the already engaged, educated patients. PCORI is trying hard to represent real patients – those who have experienced disparities in care or outcomes and those with multiple chronic conditions.

III. Keynote Speaker Highlights

Dr. Gail Wilensky, the former head of HCFA (now CMS) and an early advocate for CER, gave a keynote address on the connection between policy and CER. She began by emphasizing that CER can be an important policy lever for the United States if we can figure out how to use it to help us *treat better* and *spend smarter*. Nearly a decade ago, she was one of the first people to call for increased spending on comparative effectiveness research out of her concerns about the unsustainable growth rates in health care spending. She had come to realize how much we did not know about what works for whom and when it works well. She recognized that this knowledge would be a critical building block for achieving sustainable spending.

She reminded the audience, that CER is more established in Canada, UK and the Commonwealth countries where it is used primarily as a tool to decide whether to adopt and pay for pharmaceutical innovation. This focus is partly because they have controls on other types of spending, in contrast to the United States. She argued that we have a more open health care economy with relatively easy access to technology and without direct controls on hospital and physician spending. Hence, it would not make sense to focus on drugs or therapeutic interventions: we need to look at alternative ways to treat patients with a more expansive view of the possible comparisons. She noted that the results of the spending on CER under the Recovery Act has not received a lot of attention, which may be a good thing given the polarization in Congress. Still, it is important to convince affected patients and politicians that we need to account for differences among subgroups of patients and among different specialist providers. Ultimately, however, these are empirical questions that need empirical research.

Dr. Wilensky emphasized the political uniqueness of United States in terms of the relationship of the Executive Branch to the Congress, which makes the health system experience in other countries have limited relevance to our challenges. She acknowledged that it is particularly challenging to move forward on health issues given the current dysfunction in Congress where the House of Representatives has become polarized and insulated from local political feedback. On a positive note, she remarked that we can be hopeful that when the Congress or the President becomes "tone deaf" to the mood of the country, the electoral process generally makes some correction. Still, when we obtain information on comparative effectiveness, there will be a big challenge in presenting it to the citizens without scaring them. If we want to treat better and spend smarter, it's incumbent upon us not to be tone deaf to the politics that surrounds health issues.

In answer to questions from the floor, Dr. Wilensky commented that the ACA is here to stay and that refining it is a more reasonable objective then repealing it, especially before 2016. Thus far, the good news is that PCORI and CER have stayed off the radar screen. This is a case where no news is good news. She emphasized that is important to understand that private payers have a great need to make better decisions about both coverage and reimbursement. The public sector may best support them by convening rather than leading in these matters. In response to a question, she also commented on the need to focus on special interest groups for particular diseases in managing the dissemination of results of CER.

In closing, she emphasized that we should be spending a lot more on CER given that we are spending $2.8 trillion per year on health care. In terms of CER spending priorities, we should focus on disease areas where spending is great but there is a lot of variation in treatment, which tends to reflect uncertainty. She argues that many of these questions are empirical questions and that CER is the best tool we have to address them. Both information and incentives are important, but if we have bad information, we will only make the right decision by chance—even with good incentives.

Dr. Mark McClellan of the Brookings Institution—and former head of the FDA and later CMS—gave a keynote address on the prognosis for comparative effectiveness research.

Picking up the theme from the previous night's State of the Union address, he began by saying that the state of CER is good, largely because of the efforts of people like those in the room. The federal budget is and will be tight, and it is difficult to find funds for things like CER. There is, however, a lot going on in the health care sector that may make it easier for CER despite the limitations on direct federal support.

He cited two major factors. First, the fundamentals of where our health care system is headed create pressures for personalized CER. Talk about reforms in health care delivery needs to be driven by CER, and both are being driven by changes in financing and regulation. Second, as was reflected in his participation in the Institute of Medicine roundtable on a value-driven and science-driven health care system, a learning health care system should provide for more efficient evidence development and generation. He sees a lot of things coming together that will allow us to learn more quickly about what's working. But it will require the leadership of the conference attendees as well as changes in methods and study designs.

One fundamental factor driving health care policy in this country has been, and will remain, rising health care costs. The last 40 years has seen increasing government health care and retirement spending on the elderly. The baby boom generation will add about 1 percent of gross domestic product to federal spending. At the state level, the Medicaid program and employee retirement benefits have become the largest cost factor. In contrast, biomedical research and CER spending has been going down and will continue to be squeezed unless health care costs are controlled better, which has not historically been the case.

There are opportunities to improve efficiency and promote prevention to reduce overall health care spending and improve care coordination. One major trend is towards more personalized treatments and away from the traditional institutional orientation. Examples include things like e-mail consultation and telemedicine, as well as electronic sensors used by patients. He said there are more than 50 bills in Congress to amend Medicare to keep up with this trend towards the personalization of medical care. He also cited the case of the FDA's Mini-Sentinel active safety surveillance program as an example of a rapid learning system. He presented the case of the identification of a potential signal that a particular angiotensin-receptor blocker for hypertension causes more celiac disease than other drugs in its class. This was detected in a rapid analysis.

Dr. McClellan commented that there seems to be growing bipartisan support for moving away from our fee-for-service payment system. Historically, Congress has trying to control costs by squeezing down on provider rates. However, the disappointing experience with the sustainable growth rate adjustment illustrates the limitations of this approach.

An alternative approach is to align financing with the kind of medicine we would like to see. To improve care and lower costs we need to rely on innovative approaches to care delivery. One big challenge is that personalized medicine is going in the opposite direction; it is increasing the costs due to high-value treatments for individuals. He cited a study on treatment guidelines that found that only about 15 percent of the guidelines of the American College of Cardiology has a solid evidence base. We can expect more government funding of CER, but it is going to be difficult to change the trajectories of the long-term cost curves without better evidence to support more personalized medicine.

Other countries use health technology assessment to make coverage and reimbursement decisions but this is not happening here. We will have to build CER into provider and patient decisions in a learning health care system to actually reform care delivery and payment. The growth we are seeing in accountable care organizations represents a fundamental response to these cost-increasing trends and the need to support personalized health care more generally. PCORI is going to play a potentially important part in this area, although it has been recently criticized for not providing enough grant support for definitive research on high-priority areas. He argued that it is a good idea for PCORI to focus on a better informatics infrastructure that can be built into health care delivery. This has a lot more potential to fill the gaps of our knowledge about evidence; five or 10 more well-designed trials are not going to solve the broader problems that our health care system faces.

As presented on their website, the Brookings Institution has been working with a bipartisan coalition of policy leaders to lay out a more comprehensive and aligned approach to the financing and regulation of the health care system. There is a general recognition that our health care system needs to move in this direction regardless of the politics of the ACA implementation. This calls for alternative payment models though no one has quite figured out yet what they are. They are definitely not going to be fee-for-service and they will be much more at a personal level, including capitation tied to better results. Many of these programs are starting as pilot programs such as the Medicare shared savings program. Dr. McClellan's research team is tracking developments in over 600 accountable care organizations. Value-based insurance and value-focused health care are good examples of these trends.

He comments that they are seeing person-level payments being tied to measures of better results, as well as disease-specific medical homes. It does not make sense to pay for drugs based on dose and intensity; we should pay for better results. There need to be systems of care that provide a better way to deliver evidence. This may involve, for example, registries for providers to monitor their patients. Hopefully, in the future, more evidence will come from electronic medical record systems that can support a learning health care system. These data systems need to be able to provide sufficient statistics using a governance process that people trust. The FDA Sentinel initiative aims to eventually cover 150 million Americans. The Reagan-Udall foundation is working to open up the Sentinel Network to a range of investigators and investigations.

All of this represents a different way of doing CER. A great opportunity lies ahead, suggesting that the prognosis for CER is pretty good despite the funding and political challenges that it is likely to face.

IV. Current Information on Two CER Issues

Dr. Jodi Segal and Dr. Eugene Rich began the morning of the second day with presentations.

Current Proposed Competencies for CER

Dr. Segal reviewed six published papers that have proposed competencies or curricula for CER. The slides describing these publications are in **Appendix 3**.

Assessment of ARRA CER Portfolio

Dr. Rich spoke about the implications for CER training of their *Midstream Assessment of ARRA Comparative Effectiveness Research Portfolio.* The slides from his presentation are in **Appendix 4**. His presentation was followed by a question and answer period.

Question and Answer Period

One attendee noted that we are designing training programs using a PhD model – we are creating scientists. Perhaps we should think about the MBA model – this model stresses collaboration during training. The students learn across disciplines (accounting, supply chain, etc). The learning and evaluation depend on group projects that force everyone to work together. What if we had a training program that brought together people from many disciplines to solve problems?

Another invitee commented on the term that we are using (CER) – she reminded us that NIH has supported patient-centered outcomes research for years – the National Institute for Nursing Research has always funded this type of research. Dr. Rich says that those involved in writing the ACA had assumed the CER and PCOR were synonymous – the fact that these diverged with the creation of PCORI created measurement issues for the ARRA evaluation.

Dr. Gagnon was taught by Cecil Shep who did not like the word "training programs"; he preferred thinking about "educational programs" – education makes people think.

Another invitee commented that we should look back to the discussions that were had early in the field of health services research as it defined itself. Dr. Rich responded that it may be that funding mechanisms define the field – health services research has been very challenged by the lack of consistent funding mechanisms and this has affected how the field evolved.

V. Curricular Survey Results

Prior to the meeting, a survey was sent to the invitees. The results of the survey were presented at the meeting. The slides describing the survey results are in **Appendix 5.**

There were some comments after the presentation. One invitee commented that patient engagement and pragmatic designs are integral to practice-based research, but practice-based research is certainly broader than CER. Another question was how about how to best teach about patient engagement – this is different from community based participatory research – although related. Dr. Rich agrees there are lessons that can be learned from community based participatory research but this differs from stakeholder engagement. He reported that his advisory committee acknowledged that the field of CER is very broad – and wonders how we can possibly teach this.

One invitee commented on practicums – is this, perhaps, the best way to be teaching people to perform CER? Dr. Rich thinks this is true – if we will be conducting research in a usual care setting, then this is where we should be teaching. Dr. Gagnon wonders if we should be separating how we teach researchers from how we teach applied scientists in this field.

One invitee commented that their school of pharmacy recently went through re-accreditation. They had to think carefully about the core curriculum (for all students) and what they would make available as electives because of differing career paths. This may be relevant to the discussions of teaching CER. Dr. Gagnon thinks that accreditation may improve quality across programs.

One invitee thought that most institutions CANNOT teach in all of these disciplines adequately – and questioned if we should be making offering available across institutions through remote learning opportunities or mini-courses.

VI. Highlights of Small Group Workshops

The 10 workgroups met to discuss five topics. Workgroup attendees had two hours to discuss the topics and then reported back to the larger group.

Scope of CER and PCOR

The first topic discussed was about the scope of CER and PCOR. The attendees' discussion centered on three topics: the first was the definitional challenges that persist, the second was the relationship between CER and PCOR; and the third was the content that might be considered core to conducting these types of research.

There was agreement that there is a need to agree upon definitions for CER and for PCOR. Current definitions depend too much on an organization's perspective. A standard definition for PCOR might use the PCORI definition #4. PCOR is research that addresses "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?" There is no consistent definition about PCOR– the National Cancer Institute uses a different definition than the rest of the National Institutes of Health.

Currently the scopes of CER and of PCOR appear to be intersecting Venn diagrams; one is not contained within the other. PCOR may be necessary to doing *good* CER, but may not be absolutely necessary; likewise PCOR may not be CER. CER is a method for comparing two or more interventions; patient participation is not necessarily a component. CER is research conducted from a decision-maker's standpoint; PCOR is research conducted from a patient standpoint (and is not necessarily comparative). It is difficult to separate CER and PCOR; however PCOR has existed without CER. Quality of life research has existed for a long time.

It is important to distinguish PCOR & CER because they have different scopes. PCOR is possibly broader than CER as it includes implementation science & behavioral sciences. Patient engagement and shared decision making are within the scope of PCOR. However, one can focus too much on PCOR and lose focus on CER – focus should be patient engagement but the field needs more studies that evaluate effectiveness of therapies.

CER may appropriately focus on practitioners – it helps practitioners to know the tradeoffs in risks and benefits that will be experienced by patients. Others say that it informs decisions that patients and practitioners need to make. Some believe that all research needs to be meaningful to patients. Researchers have been conducting community based participation before patient engagement became fashionable. Some think there is little relationship between community engagement and patient-centered research, and even less relationship between community engagement and CER.

Included within the scope of CER should be questions about prevention, diagnosis, and treatment. CER should evaluate the clinical effectiveness and safety of therapies. It should involve patients cared for in the "real-world", and should engage the end user in the research process. There should be attention to the communication of results, and dissemination and implementation of results, including

communication as part of implementation. The focus on subpopulations and effect heterogeneity is a key component of CER. Most agree that cost-effectiveness is within scope for CER. If cost is part of the problem, how can it not be part of the solution? Economic effect is important to patients. Evaluation of performance/services can be considered the CER of quality improvement. Outcomes such as resource utilization should be considered within scope. Evaluating the comparative effectiveness of methods for implementation of research results seems appropriately within scope. Decisions sciences are important as well as the use of technologies to best use information for decision making. CER should include methods to generate information to improve care of disadvantaged population towards equity and reduction in disparities. The field also includes methods to understand patients' values and preferences.

CER is clearly a cross-disciplinary field and there has been insufficient identification of needs of users of the results. Serious research in CER requires multidisciplinary work – need to bring together teams around patient engagement. CER/PCOR may be considered a meta-field – a basic field is an area of expertise.

Creating a discipline around CER or PCOR requires a common philosophical approach, which may be missing here**.** Health services research seeks to alter at least one of three levers: cost, quality, access – What is CER/PCOR seeking to change? Or is it a subset of health services research? Certainly politics influenced the terminology, but basic question remains: How do we improve health care delivery to deliver the right care to the right patient at the right time?

Gaps in Teaching

The attendees also address the topic of gaps in our teaching that need to be addressed for comprehensive education in CER and PCOR.

One overarching topic may be the need to teach the philosophy of science. This may be a way to think about making the study design appropriate to the research question. This may improve the coherence across courses – there should be a structure to these curricula. That structure might be the inquiry process. Gaps should probably be those topics that are *not addressed* by other current disciplines. Perhaps none of these are actually gaps, but they are topics that might be prioritized for teaching in CER or PCOR.

Some said that teaching a bunch of courses from across existing programs does not teach the discipline. The gap is the integration across all these skills. This is predicated by the need for discussion about whether CER or PCOR is a discipline or not. It is difficult for there to be any uniformity in CER/PCOR teaching without a key textbook, although AHRQ has many resources including the AHRQ series about observational research.

There were many *gaps* identified:

- Conceptual models that allows patient and/or community engagement
- Patient engagement and involvement
- Community engagement
- Observational Research methods
- Systematic implementation of study results
- Practice Networks for research
- Implementation Science
- Communicate results of research
- Risk communication
- CER trial designs – non-inferiority trials, adaptive designs
- Mixed methods including cross-design synthesis, conducting trials that leverage "big data")
- Informatics (machine learning; natural language processing) – either as users or doers
- Social sciences including: anthropology, sociology, psychology
- Methods to better reach practitioners
- Stakeholder engagement.
- Heterogeneity of treatment effect
- Causal inference in context of CER
- Decision sciences and value of information modeling
- Shared decision-making processes
- Prioritization methods including using prior evidence
- Use of new data including consumer data
- Social determinants of health
- Creation of decision aids
- Patient-provider communication in research
- Training in collaboration and teamwork
- Synthesis of evidence and meta-analysis
- Weighing the quality of evidence especially observational studies
- Information dissemination (when is something ready for release, what are unintended consequence of information release)
- Implementation and dissemination approaches needed in study planning
- Industrial engineering, principals of reproducibility
- Marketing – understanding consumer behavior
- Business
- Written and oral communication
- Changes in health care environment

New Courses

This discussion was closely followed upon by a discussion about **new courses** that may need to be developed to meet the needs of learners.

It was thought that CER and PCOR skills need to be layered on top of existing skills. It also seems unlikely that there would be a one-size-fits-all program. There is probably the need for an introductory course that tells learners what CER or PCOR are about and how to use them, but then learners will need more advanced skills from other courses. At some institutions, students get discipline-specific skills, and then cross-cutting skills such as patient engagement, and then close out with a capstone or group projects (like business schools).

There may be courses that are structured by Methods as follows:

- *Emerging designs and methodologies*, especially pragmatic or practice-based. These designs and methodologies need to focus on the core elements of CER – for example, ensuring comparisons in designs, addressing the issue of heterogeneity in assessing effectiveness, etc.
- *Statistical techniques*- propensity scoring, structural modeling, Bayesian methods. Elements from these courses may need to be pulled out, rather than offering full courses in everything. It is likely that short courses in advanced methods may be more appropriate than full courses.
- *Secondary data analysis*
- *Community-based participatory research*
- *Heterogeneity* and how to address it through the entire process of research
- *Communication and dissemination*, including the use of social media (which relates to patient engagement, research, and dissemination) and being prepared for the press (this work can be high impact)

This would need to be followed by a course or capstone that pulls this all together.

Content that others would like to see incorporated into course work and for which new courses tailored to CER may be necessary include:

- Dissemination methods
- Implementation science
- Decision Science
- Survey Design and Implementation
- Discourse Analysis
- Grant Writing Skills in CER/PCOR
- Qualitative Methodology
- Statistical Courses that include new trial design methods
- Anthropology Research Methods
- Regulatory Aspects of CER/PCOR
- Communications
- Question identification/prioritization
- Community engagement/stakeholder engagement
- Motivational interviewing
- Information Technology or Bioinformatics for the future
- Prioritization methods
- Pragmatic Trials
- Stakeholder engagement
- Interdisciplinary journal club

Attendees also suggested courses that might work well as electives, including:

- Planning a research path
- The consumer
- Group decision processes, health technology prioritization, value of information, multi-criteria decision analyses (within operations research)
- Implementation science
- Pragmatic clinical trials/hybrid designs
- Behavioral economics; behavioral finance
- PCOR – narrative medicine, anthropology, medical sociology, patient engagement
- Presentation and writing skills
- Efficient use of meetings
- Networking skills

Structure of Educating and Training

The groups were also asked to address what may be the optimal structure of educating and training, taking into account the diversity in our learners.

It was discussed that not every institution will have the capacity to cover all CER content, and we should look for ways of sharing resources. We as a community should try to avoid having 500 programs each training 2 individuals. It may be ideal if we can nationally tap into the resources across universities rather than replicating efforts, but it is challenging to share students and resources across institutions. Within institutions, we should link to existing resources and infrastructure – research efforts in other departments, journal clubs or workshops going on through CTSA's or elsewhere. Perhaps the establishment of Institutes across departments is the best structural way to educated trainees.

The attendees largely think that CER training calls for diverse educational approaches in order to be adaptable to different kinds of learners. Who are the trainees? Who should be the targets for recruiting? What about diversity of trainees in their past experiences? How can we increase diversity of our trainees and provide a structure that meets their needs? CER training should be individualized for the learner – they all have different career goals. Importantly, we must prepare students so they are well grounded in research methods so they know the right way to conduct this research. They have to know that the research design depends on the questions and this is particularly crucial because we are doing research to help people make decisions – we have to be confident that our "answers" are right. Our curricula need to be dynamic to reflect changes in data, methodology, and terminology.

The field may need new paradigms for education, because we do not want the breadth of education to be at the expense of depth. There is a tension between teaching broadly versus teaching a specific set of skills to enable research. However, knowing a little about a lot of topics and learning the language of CER allows for interaction; it empowers people from different domains to interact with the highly trained researchers (e.g., with the biostatisticians and informaticians). This facilitates team science.

There was discussion of a "T" model with students receiving broad training on core competencies and then a deeper dive into one specialty (e.g. clinical trial design, or patient engagement).

Many of the attendees stressed that CER is team science and needs to be taught that way. There should be team based learning and trainees should have real-life problems to work on. Ideally, the trainees would be in an implementation setting so that they have immersive opportunities. The training should be structured so as not to get in the way of workflow, which takes a lot of planning. It is acknowledged that some institutions may not be structured well for investigators to do hand-on learning: there may not be sufficient opportunities for investigators to work with patients to learn about decision-making; there may not be a good infrastructure for interacting with patients. There should be experiences embedded in the course work, so that the learner sees people coming to solve a real world problem that involves the users of CER. The education should probably be more case-based**,** so that trainees learn problem solving approaches. This would be closer to an MBA model of education. The cases could be designed to fill gaps in the didactic education.

The structure and content of education or training depends on the specific degree and the purpose of the degree**.** PhD level-education is about doing research (PhD investigators are trained to produce research); the other degrees (MS, MPH) educate people to use the results research. PhDs/and post-doctoral fellows are trained to ask their own questions; however, trainees also need skills to answer questions that others ask. This includes the skills needed to prioritize and even anticipate questions from stakeholders. The trainees should spend a lot of time looking at examples of well-conducted and poorly-conducted CER studies. When a class includes students from multiple disciplines, they learn from each other. Although the faculty are typically happy to create multidisciplinary classes, the schools are generally unhappy because of the way the money flows. PCOR/CER needs to be designated as a multidisciplinary field so that this structural issue is addressed.

Attendees discussed whether the training is to produce tenure track academics; if so, multidisciplinary team work is not helpful in the context of the need for high volume publications. It remains unclear as to how to reward faculty for involvement/engagement of CER. There may need to be a clearer path for faculty who do implementation work to demonstrate their scholarship for promotion purposes.

- *Mid-career training*

The training needs are different than those who already have terminal degrees such as clinicians who want to learn to do CER research. Many professionals may not need an entire degree, but they may need components. Training of clinicians or possibly other mid-career investigators may include:

- Formal MS or PHD programs but flexible for employed persons with diverse backgrounds
- Training programs designed for specific skills
- Sabbatical
- Certificate programs
- Symposia (like Arkansas' PCORI methodology standards symposium)
- "Boot camp" in CER methodology
- Short courses
- Professional societies may have an important role in mid-career training of their members

- Institutions may have weekly conference on the "state of the science" in CER topics
- PCORI/AHRQ could develop webinar & training programs (like NIH does) and these could be attended by university faculty
- Webinars (like the VA does for their own staff)
- An abbreviated award K-award (e.g., through the CTSA), that releases clinicians from clinical responsibility.
- On-line course work
- Intensive workshops
- Teach from example studies in a journal club
- Continuing education opportunities
- Executive training programs
- Open access courses (if federally funded, likely need to be freely available)
- Virtual University, provide courses from different institutions (financing and academic credit still not entirely clear)

➢ *Mentorship*

In addition to interdisciplinary research training, there needs to be mentorship by an interdisciplinary team. Perhaps this field may use peer learning and peer-mentoring, or perhaps the return of former trainees to act as mentors or coaches of learners.

The field needs to align incentives for mentoring, which is a particular struggle if mentee's interests do not directly align with mentor's research – it seems to be more common in CER than in basic science that mentees are not working on the same project as the mentor. Faculty should be able to earmark time for mentoring.

➢ *Training Users of CER*

Educating users creates the demand for the evidence. An example is that if payers are better educated about evidence, there would be more acceptance of and demand for CER. The user community needs to be educated; the users will increase the demand for CER. We should find better ways to integrate the users, the disseminators, and the scientists. These users are patients and patient groups, Congress, other policy makers, and those who translate evidence into practice. Possible need for immersion programs for end-users of CER that may span several days.

Other Educational Issues

The attendees were asked to speak freely about **other issues** they see in CER education and training. Many of these topics were phrased as questions suggesting that there is a need for further discussion of these topics, or phrased as challenges that the field is facing.

If we were to make a value proposition about CER, we would say: 1) it is a public good and therefore requires support; 2) it is context specific and must be catered to a specific market; and 3) it addresses diverse people in our society, and their health disparities and desires.

There is the need for freedom to allow this field to evolve. How do we encourage thinking outside of the box? How do we teach innovation, and entrepreneurship? Are researchers the right people to be conducting dissemination/implementation of research findings?

There was discussion about datasets that might be ideal for teaching research ethics and the value of adding an ethicist to research teams to further clarify the values behind the questions that are being asked. Are there ethical issues regarding the boundaries between PCOR and CER? Are there ethical concerns beyond human subjects' protection?

A larger view of the issue requires thinking about training and educating *users* of CER as well. The field needs a framework for addressing this issue. The focus has been on training researchers for the academic environment but the full CER workforce for CER extends beyond academia and may even include education of the general public. Who else might need CER training – the media personnel, payers (who make formulary and operational decisions), policy makers and politicians, manufacturers, and hospital administrators, and IRB members. What are the metrics for success of training programs: traditionally it has been whether the trainees remain in academics. This may be a poor criterion for success; training in CER can be applied in other work settings and this should be acknowledged and valued.

How can research findings be personalized to enhance understanding? We need to reach a broader audience, create persuasive arguments, and improve communication. Data make the work credible, stories make the work memorable.

Is there a need for a Board, or standard examination for certification? Is credentialing valuable or is peer-review of the products sufficient?

Challenges and Needs

There are data challenges for the conduct of CER: these include access to data, incorporation of various kinds of data into health data, and sufficiency of data storage.

There are funding challenges in this field including too little research funding in a K-award to allow young investigators to do the research. Additionally, greater flexibility in the use of funds is necessary. There is no clear pathway to hire individuals into academic who do not have funding. There may need to be more support for the K-funding to R-funding transition. There is concern about low pay lines and recognition that there may need to be philanthropic support as a potential remedy.

Perhaps the field needs a forum by which to share information, curricula, and best practices. This should be at a national level.

VII. Discussion and Next Steps

The conference ended with reminders about the next steps. The conference organizers are interested in evaluating the impact of the conference on the local environments. To this end, the academic attendees will be surveyed four months after the conference (early June 2014). They will be asked about any early applications what was learned at the conference. This may include courses implemented or underdevelopment, or initiation of new mentoring programs, or establishment of new externships for trainees. Additionally, this may include plans for new faculty recruitment, establishment of dedicated centers or institutes for CER or PCOR, or creation of new degree programs.

The non-academic attendees will be surveyed as well to learn whether there assessment of new applicants for employment has changed as a result of the conference. We envision that there may be new clarity about what the applicant was exposed to during training, and/or clarity about the breadth or his/her education. We are interested in how this has translated into the selection of applicants for positions in the life sciences industry and in government.

A summary of this conference report will be prepared for publication in the peer-reviewed literature in order to disseminate the astute observations of the invited guests and speakers. We hope that further circulation of this information will help others to develop and refine the experiences of their trainees in CER and PCOR.

To: Eileen Cannon, Executive Director, PhRMA Foundation

From: Avalere Health

Date: May 13, 2015

Re: Executive Summary: CER Centers of Excellence Strategic Evaluation

Background

The growing emphasis on attaining a value-based healthcare system has substantiated interest in and the need for comparative effectiveness research (CER). At its core, CER seeks to improve health outcomes in individuals and populations by helping patients, providers, payers, and policymakers make better informed decisions regarding optimal treatments and systems of care. In recent years, the public and private sectors have made substantial investments to advance CER methods and research. For example, the passage of the Affordable Care Act authorized the establishment of the Patient-Centered Outcomes Research Institute (PCORI), a public-private organization charged with supporting and funding CER efforts throughout the United States (U.S.).

Despite the rise of and investment in CER, key gaps remain. For example, stakeholders report that CER is not always generated and implemented with the methodological rigor required to ensure relevance and usability across different decision-making contexts. To have utility, CER must be conducted in a way that requires knowledge and consideration of different study designs and their advantages and disadvantages, assesses appropriate data sources and analytic methods, and employs mechanisms to engage patients and other stakeholders in the overall research process. Moreover, it is important that results of CER are effectively disseminated and communicated in order to impact policy and practice.

To ensure that these objectives are met, a robust, diverse, and interconnected CER workforce is needed to generate and interpret findings. However, until recently, there has been limited evidence that academic graduate programs had focused on establishing a structured curriculum that specifically addressed CER education and training needs. To address this gap, the PhRMA Foundation (PF), in collaboration with other stakeholders, developed a funded initiative that outlined key objectives and elements to foster the establishment of a CER curriculum in academic graduate programs. As a result, a request for proposal (RFP) process was established and grants were awarded through a competitive process, which ultimately funded six academic Centers of Excellence (COE) across the U.S. The overarching aims of this initiative were to educate and train a new generation of scholars in CER and to elevate the utility, rigor, effectiveness, and value of the approach through academic and multi-stakeholder engagement and dissemination strategies. As part of the RFP response, COEs were encouraged and allowed flexibility in designing and operationalizing their programs.

Our Strategic Evaluation Approach

The PF enlisted Avalere Health LLC to evaluate the overall success and viability of the initiative. In particular, Avalere sought to ascertain the progress of the COEs against the stated objectives and to provide strategic insights into the possible future directions of the program. A kick-off call provided an opportunity for Avalere to align with PF on the goals and objectives of the initiative. Avalere then reviewed key internal documents associated with the program (e.g., original RFP, applications from the universities, progress reports, and relevant conference reports) and conducted interviews with representatives of the PF and each of the six COEs. Based on our analysis of the internal document review and our interviews with PF leadership, Avalere developed an evaluation framework in Microsoft Excel comprised of a set of success criteria for each of the main objectives of the COE initiative. Data from the internal documents and PF and COE interviews were then used to assess areas where the initiative met or exceeded the key objectives success criteria and to identify opportunities for improvement and future directions for the initiative. The information gathered in this process served as the foundation for our strategic recommendations.

Our Key Findings

Overview of Key Findings /

- COEs appreciate the specific targeting by the PhRMA Foundation for CER curriculum development as this initiative still appears unique in the academic landscape
- Flexibility in crafting a program around individual centers' current offerings contributes to the success and efficient use of resources
- 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
- COEs with pre-existing and strong foundation in CER were likely to offer the most comprehensive programs
- Objectives outlined in RFP could be refined to support COEs in focusing in on targeted areas of student support
- Addressing the needs of "users" through CER curriculum remains an important gap

Based on our research, the PF COE for CER education and training initiative has been highly successful. All of the COEs deemed their programs to be thriving and supported by their wider institutional organization and external colleagues and stakeholders. We found that the COEs employed a variety of approaches to developing and operationalizing their programs to meet the objectives set forth by the PF. The variation in the different programmatic approaches should be

considered a strength of the initiative, as the COEs were able to craft their programs around their individual departments' or centers' current offerings, infrastructure, and content expertise. This flexibility, as opposed to a "one size fits all" approach, contributed to the success and efficient use of resources across the COEs and resulted in maximum impact of the investments made to date in the broader initiative. The culmination of all six programs meets, and often exceeds, the original objectives outlined in the RFP. Moreover, we determined that the COEs with a strong pre-existing foundation in CER were the most likely to offer the most comprehensive programs.

All of the centers have developed either a degree- or certificate-granting award in CER at the postgraduate level, and strive to meet the diverse needs, interests, and backgrounds of students interested in the field. Depending on the program, enrolled students come from different departments within the university or bring with them varied skill sets and academic and professional experience. As a result, the COEs strived to personalize the curricula and training opportunities to the extent possible, mainly through offering elective courses, internships, and "capstone projects".

While the COEs acknowledge the importance of preparing students to be both "researchers" and "users" of CER, a goal specified in the original PF objectives, the programs as a whole tended to be more focused on developing researchers with robust methodological skills in CER. This is partly due to the strengths of particular COEs as well as the main orientation of graduate programs, especially at the doctorate level, to train future researchers. In general, the programs that principally used on-line media and tools to educate and train were more likely to attend to the needs of users, as most students in these programs were working professionals.

The COEs acknowledged that alongside the PF funding, they employ a number of strategies to leverage all available resources to develop and sustain their programs. In particular, the centers rely heavily on collaborating with other departments and faculty across their institutions to establish a robust CER presence and to enhance the comprehensiveness of their programs. Activities that relied on external engagement with specific types of stakeholders were also common, including building on existing partnerships to secure training resources (e.g., datasets) and opportunities for students, as well as maintaining a presence at key academic and professional conferences related to CER methods and dissemination. Importantly, these efforts have the additional benefit of publicizing the program beyond the respective universities and offers opportunities to recruit potential new students. These goals, in addition to building interest and progress in CER, were also achieved through university seminars and workshops and research collaborations with other CER groups. In this regard, two areas requiring further progress were identified. In particular, there is some inconsistency in efforts to engage broader external stakeholder groups (such as "users" of CER). We noted that these initiatives could be further advanced through electronic or on-line mediums, which was evidenced in at least one COE. However, interest and action in external engagement is growing among the COEs through innovative and targeted partnerships with different CER stakeholders (e.g., Academy of Managed Care Pharmacy, National Pharmaceutical Council) and offering courses or recorded lectures on-line. The COEs noted that additional resources and investment would be required to further develop and implement a more diverse and robust range of electronic offerings.

With regards to partnerships in particular, the COEs have been actively collaborating with public and private organizations, such as academic medical centers, professional societies, and especially the life sciences industry, to promote CER and afford training opportunities for their students. However, broader relationships with government stakeholders or payers remain limited, which represent two key CER funders and users. In addition, the COEs have engaged with each other on occasion, mainly through the 2014 Curricular Advances conference, but frequently responded that additional and more regular opportunities to collaborate and share best practices should be encouraged to sustain the programs.

As part of their programs, the COEs provide important guidance to students on CER career options and development by assigning students advisors and mentors and through hosting guest speakers from various stakeholder groups such as industry, PCORI, and the National Health Council, among others. The COEs are also exploring ways to generate and integrate student feedback to fine tune their programs, including course evaluations, exit interviews upon graduation, and offering opportunities for alumni to comment on the curricula, specifically with regards to whether it armed them with the knowledge and skills needed in their respective professional positions. While these are more informal approaches, all of the COEs noted the value of a formal evaluation process to systematically evaluate student performance post-graduation in the professional environment, based on the experience of individual alumni and their employers. Many of the COEs aim to roll out such processes in the future.

Remaining Challenges

Overall, the COEs are pleased with their progress to date and strongly believe their programs address an important gap in the CER landscape. Of course, designing and implementing a new academic program is not without challenges. For instance, though appropriate for the initial round of funding, the broad objectives outlined in the RFP could be narrowed to support the COEs in focusing in on targeted areas of CER education and training. Certain aspects of the academic environment also posed hurdles. The grant award sometimes occurred at a time that did not always align with the academic calendar of a particular institution. This was most evident when awards were granted soon before the start of an academic year, which made it difficult to obtain institutional approval for the program and recruit students. To that end, institutional requirements and processes involved in initiating the program were often somewhat protracted, which prolonged the start time of the program. A number of the COEs recommended that the timeline of the grant be expanded to account for these internal procedures. Finally, the COEs expressed the need to secure additional funding to bolster support for their programs and/or to improve certain aspects of the curriculum and training experience (e.g., conference attendance, student resources). The quest for additional funding was generally considered an ongoing responsibility of the academic program administration and a “fact of life”, but the COEs noted that funding opportunities for this kind of initiative were unique, limited, and increasingly difficult to obtain.

"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." - COE Respondent

Our Recommendations

Overview of Strategic Recommendations /

1. Support enhanced collaboration between COEs, along with other institutions engaged in CER, which would further benefit student academic and professional development, strengthen the generation and use of CER more widely, and stimulate increased interaction between CER "researchers" and "users"
2. Extend a collaborative grant to support cross-institutional work between the COEs and COEs and "users" of CER
3. Aid collaboration among regionally-based universities and partners through symposiums, conferences, or projects
4. Develop opportunities to teach healthcare professionals, such as physicians and pharmacists, about CER and its potential to be leveraged in patient care
5. Invest in innovative teaching platforms to extend CER curriculum and training to a broader range of stakeholders, including both "researchers" and "users"

Taken together, the PF plays an important and unique role in addressing the ongoing demand for CER training in the marketplace and, ultimately, a robust and diverse workforce that both generates and applies CER evidence to improve healthcare decision making. We recommend that the PF consider activities to move forward with the initiative that refine current objectives and are targeted towards existing gaps. Outlined below are five recommended next steps:

First, the PF should support enhanced collaboration between COEs, along with other institutions engaged in CER, which would further benefit student academic and professional development, strengthen the generation and use of CER more widely, and stimulate increased interaction between CER "researchers" and "users". Key actions to consider include organizing a follow-on conference to the 2014 event on CER curriculum education and training. Ideally, the conference would involve the participation of all of the COEs, along with other CER leaders (e.g., government, other research entities, industry, payers) to share best practices and future plans and opportunities for collaboration. The results of this evaluation could also be presented to stimulate discussion on the evolving needs of a CER workforce.

Second, the PF should consider extending a collaborative ("bridge") grant to support cross-institutional work between the COEs. It may be particularly beneficial to support a collaborative grant between one (or more) of the COEs and a non-academic CER entity, such as PCORI or

AHRQ, and/or payers. The latter would be particularly valuable to further promote the PF initiative, the COE programs, and offer additional opportunities for CER "researchers" and "users" to interact and inform each other's work and processes. These types of grants could focus on training rotations, collaborative research work involving students, or shared educational opportunities, such as online seminars or courses. For example, Johns Hopkins University is currently working with PCORI to further refine their methodological standards.

Third, given that focused CER education and training across the broader graduate program landscape remains somewhat in its infancy, the availability and reach of existing programs tends to be somewhat siloed to certain areas in the U.S. Therefore, future PF efforts could focus on aiding collaboration among regionally-based (e.g., Rocky Mountain States) universities and other partners by way of symposiums, conferences, or collaborative CER projects. Ideally, this would help grow and expand CER capabilities across the country and ensure that exposure to CER topics, approaches, and applications are accessible to a wide audience. In addition, these regionally-based collaboratives could also engage regional stakeholders such as integrated delivery networks or regional payers as partners for providing the "users" perspective and a potential opportunity to provide "real-world" data and access to clinical decision makers.

Fourth, in order to ensure investments in CER education and training reach the "users" of CER, future funding should be dedicated to developing opportunities to teach healthcare professionals, such as physicians and pharmacists, about the basic principles of CER and how it can be leveraged at the point of patient care. Such an initiative would have the dual benefit of increasing researchers understanding of the real-world applications of the evidence they generate, which is important for designing and executing studies that are "fit for purpose". As a first step, support could be extended to the existing COEs to engage students outside of the program (e.g., pharmacy students) in CER methods and training.

Finally, as the demand for CER grows, educational and training programs and opportunities will need to account for and support a robust, diverse, and interconnected CER workforce. The time is ripe for the PF to invest in innovative teaching platforms to extend CER curriculum and training to a broader range of stakeholders, including both "researchers" and "users", that could benefit from learning more about CER topics, concepts, and methods, and impart a new perspective and insights on how CER can be conducted and used in the healthcare system effectively. Suggestions for these audiences include undergraduate students, industry, patient organizations, and researchers involved in dissemination and communication science, health services research, and health promotion and education practitioners, among other related groups.

DRAFT AGENDA --- PLEASE DO NOT DISTRIBUTE

Comparative Effectiveness and Patient-Centered Outcomes Research: Enhancing Uptake and Use by Patients, Clinicians and Payers

The Ronald Reagan Building
1300 Pennsylvania Avenue, NW
Washington D.C.

THURSDAY -- January 26		
1:15 PM {TBD}	Registration	
2:00 PM {TBD}	Welcome and Opening Remarks Conference Goals and Objectives	Glen Schumock, PharmD, MBA, PhD University of Illinois at Chicago
2:15 PM {TBD} **2:45 PM** {TBD}	History and Overview of Current Landscape on Strategies to Enhance Update 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 Part 2: Experience from academic institutions supported by the PhRMA Foundation Centers of Excellence in CER Education Each institution provides no more than a 7 minute overview of their program, focusing on 1) Uptake and use by patients, clinicians, payers 2) Program accomplishments, and 3) Future directions in uptake and use by patients, clinicians, and payers	Mick Murray, PharmD, MPH Regenstrief Institute, Inc Beth Devine, PharmD, MBA, PhD University of Washington Glen Schumock, PharmD, MBA, PhD Simon Pickard, PhD University of Illinois at Chicago Eleanor Perfetto, PhD, MS University of Maryland, Baltimore
3:30 PM	Break	
3:45 PM {TBD}	Part 3: Overview and update of funding programs with emphasis on CER/PCOR uptake and use by patients, clinicians, and payers Each speaks for 15 minutes. End at 4:15 unless we find another firm that should be represented.	Bill Lawrence, MD, MS PCORI Sharon Arnold, PhD AHRQ Josephine Briggs, MD NIH - National Center for Complementary and Integrative Health (NCCIH)

4:30 PM **5:45 PM** {TBD}	Perspectives: Needs and Gaps in the Uptake and Use of CER/PCOR Audience Questions and Discussion	Moderator: Scott Smith, HHS *(Tentative)* Eleanor Perfetto, PhD, MS National Health Council Caleb Alexander, MD, MS Johns Hopkins Soumi Saha, PharmD, JD Academy of Managed Care Pharmacy Murray Ross, PhD Kaiser Permanente (*Tentative*)
6:00 PM {TBD}	Networking Reception	
7:00 PM {TBD}	Dinner with a Keynote Address	To be announced
8:30 PM	Adjourn Day 1	

FRIDAY -- January 27		
7:00 AM {TBD}	Registration	
7:30 AM {TBD}	Continental Breakfast	
8:00 AM {TBD}	Dissemination and Uptake of CER/PCOR	Elaine Morrato, DrPH, MPH, CPH University of Colorado Nilay Shah, PhD Mayo Clinic
9:00 AM **9:35 AM** {TBD} 9:50 AM	Invitee Pre-Conference Survey Results Overview of NPC Work on Stakeholder Views and Address Barriers to Use Instructions for Small Group Workshops	Simon Pickard, PhD University of Illinois at Chicago Jennifer Graff, Pharm D National Pharmaceutical Council Simon Pickard, PhD University of Illinois at Chicago
10:00 AM	Break	

FRIDAY -- January 27 (continued)		
10:15 AM *Refer to Packet*	Small Group Workshops – Each group to address two main topics: 1) How do we close the gaps in uptake and use of CER/PCOR evidence? 2) What are the best methods/approaches to deliver educational programming/tools to enhance the uptake and use of CER/PCOR evidence by patients, clinicians, and payers	
11:45 AM (Lunch) {TBD}	A learning Network to Improve the Dissemination of PCOR through Clinical Decision Support	Barry Blumenfeld, MD, MS RTI International | Division of eHealth, Quality, and Analytics (eQUA)
12:30 PM {TBD}	Workshop Group Discussion and Consensus Building to create a framework for recommendations, tools for training current and future users of CER-PCOR evidence.	Group Leaders – Picked by Workshop Groups
1:45 PM {TBD}	What is the future for CER, CER education and how will CER be integrated into practice?	Diana Brixner, RPh, PhD, FAMCP University of Utah (AMCP) Bill Galanter, MD University of Illinois at Chicago Lou Garrison, PhD University of Washington (ISPOR)
2:45 PM {TBD}	Conference Summary - o Discussion o Recommendations o Next Steps	Glen Schumock, University of Illinois at Chicago
3:00 PM	Adjourn Day 2	