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

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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.
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I. 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**

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Jean Paul Gagnon</td>
<td>PhRMA Foundation</td>
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<tr>
<td>Eileen Cannon</td>
<td>PhRMA Foundation</td>
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<tr>
<td>Jodi Segal</td>
<td>Johns Hopkins University</td>
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<td>Beth Devine</td>
<td>University of Washington</td>
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<tr>
<td>Lou Garrison</td>
<td>University of Washington</td>
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<tr>
<td>Sonia Hernandez-Diaz</td>
<td>Harvard University</td>
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<tr>
<td>Eleanor Perfetto</td>
<td>University of Maryland</td>
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<tr>
<td>Michae Spigarelli</td>
<td>University of Utah</td>
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<tr>
<td>Carrie Mcadam Marx</td>
<td>University of Utah</td>
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<tr>
<td>Dianna Brixner</td>
<td>University of Utah</td>
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<tr>
<td>David Hickam</td>
<td>PCORI</td>
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<tr>
<td>Jennifer Moore</td>
<td>AHRQ</td>
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**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

**II. 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.

III. 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

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tr>
<td>Harold Sox (moderator)</td>
<td>Dartmouth Institute</td>
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<tr>
<td>Anne Beal</td>
<td>PCOR</td>
</tr>
<tr>
<td>Jennifer Moore</td>
<td>AHRQ</td>
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<tr>
<td>(for Francis Chesley)</td>
<td>Tufts University</td>
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<tr>
<td>Peter Newmann</td>
<td>Merck &amp; Co.</td>
</tr>
<tr>
<td>Newell McElwee</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Robert Temple</td>
<td>Center for Medicare and Medicaid Services</td>
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**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    | Systematic Reviews | Research Methods of Health Policy |
| outcomes                      |                  |                  |
| 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**

<table>
<thead>
<tr>
<th>Probability (estimating probability, updating probability with Bayes theorem, measuring test performance)</th>
<th>Decision models (the threshold model; advanced modeling methods, cost-effectiveness and cost-benefit analysis)</th>
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<tbody>
<tr>
<td>Expected value decision making</td>
<td>Measuring preferences: utility assessment</td>
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<tr>
<td>Cognitive aspects of decision making</td>
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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. Jacques 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.

IV. 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.

V. 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.

VI. 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.

VII. 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.
VIII. **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.