

## *Health Policy in Medicine: Inside the Beltway*

### **Reflecting on the Recovery Act Investment in Comparative Effectiveness Research**

by Eugene Rich, MD, FACP  
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**Note:** For this column, Dr. Rich responds to questions posed by colleagues at Creighton on a recent publication in the *Journal of Comparative Effectiveness Research* entitled "[The ARRA Investment in CER: A Description of the Midstream Evaluation and How the Funds were Allocated and CER Priorities Addressed](#)" by Eugene C. Rich, MD, Dominick Esposito, PhD, Laura D. Kimmey PhD, MPA, Christal Stone Valenzano MPH, and Pierre L. Yong MD MPH.

**ARRA:** American Recovery and Reinvestment Act of 2009

**CER:** Comparative Effectiveness Research

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**Question 1:** What do you think are the one or two most important initiatives funded by ARRA CER? Why?

**Dr. Rich's Answer:** Our evaluation of the ARRA investment in CER occurred in mid-stream, concurrent with the conduct of most of the over 420 projects funded under ARRA CER. Thus we were not in a position to identify specific projects as "most important." As my colleague Dominick Esposito notes, almost half of the 424 projects in the ARRA CER portfolio had a primary focus on Research, with the large majority (95%) focused on creating new evidence (in contrast to synthesis of existing studies). Indeed well over 50% of these original research projects were randomized controlled trials. Thus few findings were available by the time our evaluation was concluded. By now, of course, many publications have resulted from these studies. Various resources related to these studies can be found at the CER page of the National Library of Medicine. <http://www.nlm.nih.gov/hsrinfo/cer.html>

As we note in this paper, given the multiple factors that contribute to the ultimate societal impact of a research investment like ARRA CER, identifying the ultimate impact of individual projects could be a decades long undertaking. So I will defer on the challenge of identifying the "most important" individual ARRA CER initiatives. Instead I will comment on one of the most forward-looking areas of ARRA CER investment, development of *Data Infrastructure* for CER. This was the area with the second-greatest number of ARRA CER projects and accounted for nearly 23% of the portfolio and over 27% of total funding. More than two thirds of these Data Infrastructure projects "assembled or enhanced existing administrative and clinical data sets for CER"; about half the investments were efforts to leverage electronic health record data sources for future CER. Of course it would take time for these new data resources to translate into informative CER. Indeed the Patient Centered Outcomes Research Institute (PCORI) has made continuing investments in such efforts through "PCORNET."<sup>i</sup>

One additional enduring legacy of these ARRA CER investments in data infrastructure has been the "EDM Forum," <http://www.edm-forum.org/home>, established "to advance the national dialogue on the use of electronic health data for research and quality improvement." Under ARRA funding the Forum sponsored CER data infrastructure-related collaborative projects, conferences, webinars, and a special issue of *Medical Care* describing the challenges and approaches to the use of electronic clinical data. Post ARRA funding, the EDM Forum has continued and expanded, establishing *eGEMs* as a very successful open access journal "focused on

using electronic health data to advance research and quality improvement, with the overall goal of improving patient and community outcomes."

**Question 2:** Suppose someone is an investigator considering a research direction change to CER. What might be 2-4 key elements s/he should draw from the paper?

**Dr. Rich's Answer:** The ARRA CER evaluation used the Federal Coordinating Council's definition of CER: "Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in 'real-world settings'." Other articles from this special issue of JCER that focused on insights from the ARRA evaluation note (1) the importance of collaborations between investigators and real world clinical settings,<sup>ii iii</sup> and (2) the importance of engaging the patient perspective to ensure the information from CER addresses outcomes most important to patients.<sup>iv</sup>

As we note in our article, shifts in broader external societal factors could also "affect the environment and context for further development of CER projects." We point specifically to the example of the passage of the Affordable Care Act (ACA) with the founding of PCORI and the establishment of the PCOR Trust Fund to support this ongoing work. PCORI defines PCOR distinctively: "Patient-centered outcomes research (PCOR) helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions such as . . . Given my personal characteristics, conditions and preferences, what should I expect will happen to me? What are my options and what are the potential benefits and harms of those options? What can I do to improve the outcomes that are most important to me? How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"<sup>v</sup> PCORI offers substantial funding opportunities for this work and various resources to help investigators incorporate this patient perspective into their research. Investigator considering a research direction change to CER (and PCOR) will want to take full advantages of these PCORI resources.

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<sup>i</sup> <http://www.pcori.org/content/pcornet-national-patient-centered-clinical-research-network>

<sup>ii</sup> Kimmey LD, Rich E. The importance of collaboration in comparative effectiveness research. J Comp Eff Res. 2014 Nov;3(6):577-9.

<sup>iii</sup> Geonnotti KL, Rich EC, Esposito D. Workforce development for comparative effectiveness research: training programs funded by the American Recovery and Reinvestment Act. J Comp Eff Res. 2014 Nov;3(6):609-15.

<sup>iv</sup> Williams SS, Esposito D, Rich EC. Patients and clinicians as stakeholders in comparative effectiveness research: multiple perspectives and evolving roles. J Comp Eff Res. 2014 Nov;3(6):573-5.

<sup>v</sup> <http://www.pcori.org/content/patient-centered-outcomes-research>



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