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CER Infrastructure Investments to Support Evidence Generation in a Learning Health System

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EDM Forum

Issue Brief

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About the EDM Forum

The Electronic Data Methods (EDM) Forum is a three-year grant from the Agency for Healthcare Research and Quality (AHRQ) to facilitate learning and foster collaboration across a set of eleven comparative effectiveness research (CER) projects. Collectively, these projects are designed to build infrastructure and for collecting and analyzing prospective electronic clinical data. Specific areas of focus include the governance, clinical informatics, and analytic issues that are crucial to the design and use of electronic clinical data for CER, PCOR, and QI. The EDM Forum, and the connected research projects, are funded by the American Recovery and Reinvestment Act (ARRA).

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Executive Summary

The American Recovery and Reinvestment Act (ARRA) of 2009 made a substantial new investment to build capacity for the use of electronic clinical data (e.g., distributed data networks or patient registries) for quality improvement (QI) and research. ARRA-funded infrastructure awards focus on developing data, methods, training, and governance that is sustainable, flexible, and extensible over time. Based on a review of publicly available documents, including funding opportunity announcements and contract task orders, and previous examinations of the ARRA awards for comparative effectiveness research (CER), we identified 86 infrastructure building awards across 130 grant programs. Nearly 38 percent of the total support for CER ($417.2 million), is focused on infrastructure, of which 25 percent ($276 million) is designated specifically to build infrastructure for electronic clinical data.

Specific requirements of the grants include grantees' efforts to develop governance models, build the research workforce, promote a culture of collaboration among partners, and develop strategies to ensure access to data sources. A key focus of these grants is designing infrastructure to transform research and practice into a learning health system, and generating meaningful evidence to improve patient outcomes. For all of these efforts, collaboration and transparency will be critical to advance the science and achieve meaningful improvements in population health. The information highlighted in this brief can inform decision-makers and funders about prior investments in infrastructure to guide the direction of future investments in this area.

Introduction

The goal of comparative effectiveness research (CER) is to generate evidence on the effectiveness of different health care treatments and strategies to improve patient outcomes.[1,2] Current investments in health services research (HSR) and health information technology (HIT) have focused on enhancing the ability to conduct CER, patient-centered outcomes research (PCOR), and quality improvement

The EDM Forum is supported by the Agency for Healthcare Research and Quality (AHRQ) through the American Recovery & Reinvestment Act of 2009, Grant U13 HS19564-01.

(QI). CER often requires linking large heterogeneous data sources held by different institutions,[3] emphasizing the importance of building collaborative electronic clinical data infrastructure.[4] A learning health system aligns the evidence generated through research, quality assessment, and clinical outcomes to support improvement and innovation for health care.[5]

According to the Institute of Medicine, a critical component to building capacity to achieve a learning health system is the improvement of the governance approaches, technology, and methods to gather and evaluate knowledge, which are the key components of infrastructure.[6] Figure 1 represents the cycle of evidence generation in a learning health system. A robust infrastructure (governance, data, methods, and training) is key to sustaining evidence generation in a learning health system.

The Federal Coordinating Council for CER (FCCCER) prioritized data infrastructure as one of the four major categories for CER investments and activities.[7] Likewise, the Patient-Centered Outcomes Research Institute (PCORI) includes building infrastructure as one of the five national priorities to facilitate learning from clinical experience.[8] This brief reviews the current landscape of the American Recovery and Reinvestment Act (ARRA) of 2009 CER award programs building electronic clinical data infrastructure and identifies the required infrastructure components for electronic clinical data outlined by funding agencies supporting CER. Examining the current requirements and approaches to building electronic data infrastructure is important when considering the mechanisms to ensure the sustainability of evidence generation in a learning health system.

Allocation of ARRA-CER Funds for Electronic Data Infrastructure

In 2009, ARRA provided $1.1 billion in funding for CER[9], allocating nearly 38 percent of the funding to improve the infrastructure, capacity, and methods for conducting CER.[10] The ARRA-CER funds were provided to the Agency for Healthcare Research and Quality (AHRQ) ($300 million); the National Institutes of Health (NIH) ($400 million); and the Office of the Secretary (OS) of Health and Human Services ($400 million). Approximately $100 million of that investment is managed by AHRQ to build the infrastructure for conducting CER with electronic clinical data, including the Electronic Data Methods (EDM) Forum.

Figure 1: **Building the Data Infrastructure: Generating Evidence in a Learning Health System**

This figure represents the cycle of evidence generation in a learning health system. Innovative approaches and new development within the components of the supporting infrastructure are key to sustaining evidence generation in a learning healthcare system.

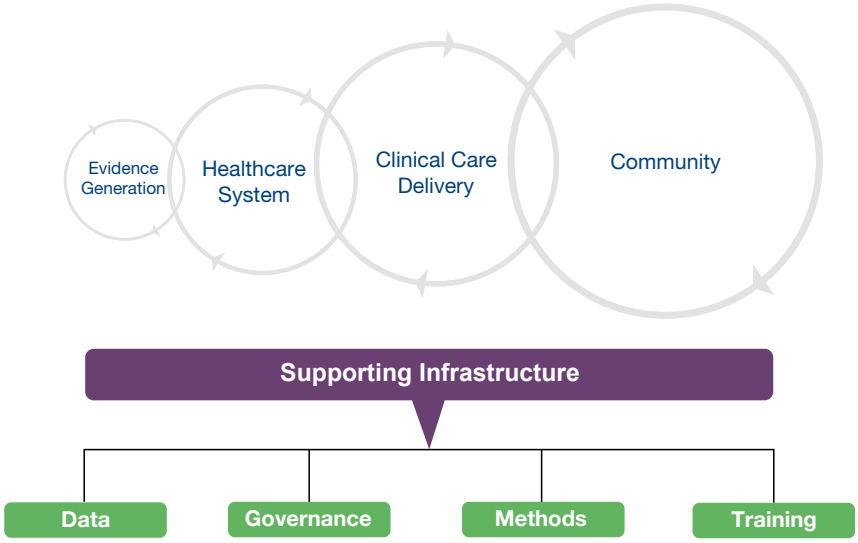


Figure derived from: IOM (Institute of Medicine). 2011. Engineering a learning health system: A Look at the future: Workshop summary.

Based on a review of publicly available documents, including funding opportunity announcements (FOAs) and contract task orders, and previous examinations of the ARRA-CER awards, 130 award programs were identified as building infrastructure and developing methods for CER (one of the four priorities defined in the FCCCER strategic framework). Of the 130 infrastructure and methods development award programs identified, 30 were focused on building electronic clinical data infrastructure (see Figure 2), a total of 86 awards supporting the linkage, exchange, collection, and use of electronic clinical data for CER. These represent about $276 million in funding, over a quarter of the ARRA-CER funds (see Figure 3).

Common Requirements for Electronic Data Infrastructure Awards

There are common infrastructure requirements across the awards designed to ensure sustainability of electronic clinical data infrastructure used for CER, specifically related to governance, building the workforce, promoting a culture of collaboration, and ensuring access to data sources. The following identifies the common infrastructure requirements found in the FOAs and task orders.

Governance

- Project management support, legal and policy oversight (e.g., governance boards and committees) and establishing data sharing partnerships in nearly all of the award programs.

- Validated security systems and protocols are critical in the design to ensure protection of privacy and proprietary information, which may include encryption tools and methods, data use agreements and defined access and user roles.

Figure 2: **List of ARRA-CER Electronic Clinical Data Infrastructure Award Programs**

Award Program	Supporting Agency[i]	Funding Mechanism[ii]	# awards	Funding Amount	% of ECD Funding
PROSPECT Studies: Building New Clinical Infrastructure for Comparative Effectiveness Research (CER) [iii]	AHRQ	R01	6	$47,666,244	17.27%
Research and Research Infrastructure "Grand Opportunities"	NIH	RC2	17	$30,291,716	10.98%
Scalable Distributed Research Networks for Comparative Effectiveness Research (CER) [iii]	OS	R01	3	$25,000,000	9.06%
Enhanced Registries for Quality Improvement (QI) and Comparative Effectiveness Research (CER) [iii]	OS	R01	2	$24,000,000	8.70%
Enhancing Cancer Registry Data for Comparative Effectiveness	OS	Contract - R	1	$18,961,389	6.87%
Multi-Payor Claims Database	OS	Contract - R	1	$16,436,482	5.96%
Chronic Care Warehouse (CCW) Enhancement to Support Comparative Effectiveness Research (CER)	OS	Contract - B	1	$15,500,000	5.62%
Expansion of Research Capability to Study Comparative Effectiveness in Complex Patients	OS	R24	1	$12,000,000	4.35%
Medicaid Analytic Extracts (MAX) Data Warehouse to Support Comparative Effectiveness Research	OS	Contract - B	1	$10,249,783	3.71%
Enhanced State Data for Analysis and Tracking of Comparative Effectiveness Impact: Improved Clinical Content and Race-Ethnicity Data	OS	R01	8	$10,000,000	3.62%
Comparative Effectiveness Research Public Use Data Pilot Project	OS	Contract - R	1	$8,699,454	3.15%
Cooperative Multicenter Reproductive Medicine Network	NIH	U10	5	$8,691,518	3.15%
Comparative Effectiveness Research Data Infrastructure Medicaid Analytic Extract Production, Enhancement, and Data Quality	OS	Contract - R	1	$7,649,725	2.77%
NIH Challenge Grants in Health and Science Research	NIH	RC1	13	$6,179,809	2.24%
Registry of Registries	OS	Contract - R	1	$4,997,998	1.81%
Partnership in Applied Comparative Effectiveness Science (PACES)	OS	Contract - A	1	$4,662,128	1.69%
Clinical and Translational Science Awards (CTSA)[iv]	NIH	U54	10	$4,646,538	1.68%
Electronic Data Methods (EDM) Forum	AHRQ	U13	1	$3,856,340	1.40%
Maternal and Child Health (MCH) Pediatric Research Network Program	OS	UB5	1	$3,500,000	1.27%
Comparative Effectiveness of Health Care Delivery Systems for American Indian and Alaska Natives Using Enhanced Data Infrastructure	OS	Contract - R	1	$3,070,882	1.11%
CHARN Central Data Management Coordination Center	OS	UB3	1	$2,000,000	0.72%
Comparative Effectiveness of Quality Improvement Efforts Among American Indian and Alaska Native Communities	OS	Contract - R	1	$1,686,484	0.61%
Comprehensive Minority Institution/Cancer Center Partnership	NIH	U54	1	$1,259,003	0.46%
Leveraging Health Data for Rapid Comparative Effectiveness Analysis Pilot Test	OS	Contract - R	1	$1,177,898	0.43%
Strategic Design for an All-Payor, All-Claims Database to Support Comparative Effectiveness Research	OS	Contract - R	1	$1,013,374.50	0.37%
NIDA Core "Center of Excellence" Grant Program	NIH	P30	1	$877,841	0.32%
Development of a Medicaid/CHIP Environmental Scanning and Program Characteristics Database	OS	Contract - A	1	$858,436	0.31%
Comparative Effectiveness Research (CER) Data Infrastructure Medicaid Analytic eXtract (MAX) Long-Term Care- Assessment (LTC-A) File	OS	Contract - A	1	$528,288	0.19%
Statistical Coordinating Center for the Breast Cancer Surveillance Consortium	NIH	U01	1	$491,087	0.18%
Centers for Research to Reduce Disparities in Oral Health	NIH	U54	1	$13,103	< .01%
			86	**$275,965,521**	**100.00%**

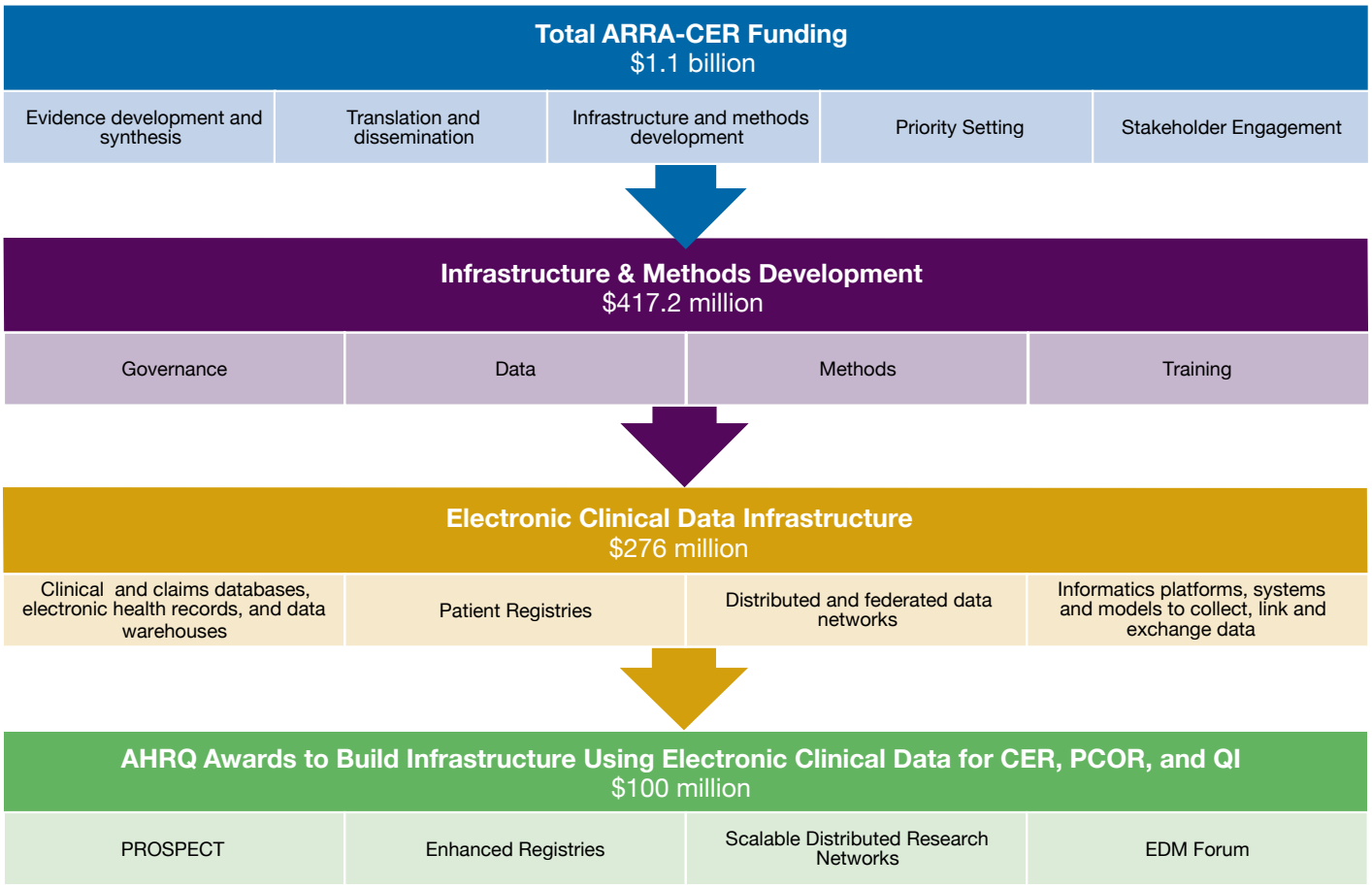
i AHRQ = Agency for Healthcare Research and Quality; NIH = National Institutes of Health; OS = Office of the Secretary for Health and Human Services

ii Activity codes are used to differentiate the wide variety of research-related programs supported by AHRQ and NIH. Contracts are identified by 'Classification Codes': 'R -- Professional, administrative, and management support services'; 'A -- Research & Development'; 'B -- Special studies and analysis - not R&D'; and, 'D -- Information technology services, including telecommunications services'

iii Participate in the EDM Forum

iv The FOA for the CTSA grant program was reissued three times , therefore four separate FOAs were reviewed

Figure 3: **Flow Chart of Electronic Clinical Data Infrastructure Funds from the Total ARRA-CER Funding**



Workforce Development and Scientific Collaboration

- For large, multi-site, collaborative research projects, multiple investigators must participate as key personnel. A mix of time for senior and junior scientists is required to help train new investigators.
- For three large R01 programs the required level of staffing includes: PD/PI at least 20 percent effort annually (2.4 calendar months); Program manager/coordinator for 30-100 percent of effort annually (3.6-12 calendar months).
- Participation in the EDM Forum is required for three large R01 programs to share lessons learned.

Scalability and Access

- Clinical informatics and technical systems must be readily scalable and interoperable across a variety of software platforms and architectures, and supports a diverse set of needs. In particular, projects supported by one large R01 award program must enable near-real time data extraction and analysis that supports clinical care, operations, and research.
- The research, operational, and clinical workflow systems must employ applicable data models and data standards that are widely accepted across health care venues.
- The use of open-source software and data platforms and linkages are strongly encouraged.
- Resource and data sharing plans are an explicit requirement for many funding programs.

Discussion

There are high expectations for CER to transform the research process and generate evidence that can improve health care and population health. Building a robust electronic clinical data infrastructure is critical to the effort and is a focus of over one quarter of the ARRA-CER awards. Many of the FOAs characterize the ability to explore and develop systems that could be leveraged and expanded, contributing to the horizon scanning for future research and healthcare system activities.

For both funders and investigators it is important to share lessons learned in the process of building infrastructure to use electronic clinical data, such as participating in convening networks like the EDM Forum. Collaboration and transparency will be critical to advance the science and improve patient outcomes. The current infrastructure investments will establish the foundation for future research to support a

learning healthcare system and will help to inform the next round of funding for infrastructure and CER, PCOR, and QI.

Conclusion

The information in this brief highlights current efforts to build a sustainable infrastructure for CER, PCOR, and QI, and will have implications for policy in two ways: 1) informing decision-makers and funders about the investment in infrastructure development; and 2) identifying the areas where resources are currently allocated to inform new funding opportunities in regard to infrastructure and management needs. The distribution of the ARRA-CER funding reflects current priorities which should be considered and addressed in the next round of funding for infrastructure available as part of the PCOR trust fund.

References

1. U.S. Department of Health and Human Services. Comparative Effectiveness Research Funding [HHS Recovery Act web site]. June 2010. Available at: http://www.hhs.gov/recovery/programs/cer/index.html
2. Comparative effectiveness research (CER) 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. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances (Patient protection and Affordable Care Act, Part D).
3. VanLare JM, Conway PH, Rowe JW.Building academic health centers' capacity to shape and respond to comparative effectiveness research policy. Acad Med. 2011 Jun;86(6):689-94.
4. Agency for Healthcare Research and Quality. American Recovery and Reinvestment Act Investments in Comparative Effectiveness Research for Data Infrastructure . Rockville (MD): AHRQ; 2010 Jun. Available http://www.ahrq.gov/fund/cerfactsheets/osfsinfra.htm
5. Olsen LA, Aisner D, McGinnis JM, eds. *Roundtable on Evidence-Based Medicine*. National Academies Press: Washington, DC.
6. Institute of Medicine. Initial national priorities for comparative effectiveness research. Washington (DC): National Academies Press; 2009.
7. U.S. Department of Health and Human Services, Federal Coordinating Council for Comparative Effectiveness Research. Report to the president and the Congress. Washington (DC): HHS; 2009 Jun 30. Available from: http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf
8. Selby JV, Beal AC, Frank L. The Patient-Centered Outcomes Research Institute (PCORI) national priorities for research and initial research agenda. *JAMA*. Apr 18 2012;307(15):1583-1584.
9. U.S. Department of Health and Human Services. op. cit.
10. U.S. Department of Health and Human Services, Federal Coordinating Council for Comparative Effectiveness Research. op. cit.
11. Agency for Healthcare Research and Quality. op. cit.
12. Agency for Healthcare Research and Quality. AHRQ and the Recovery Act. Rockville (MD): AHRQ; 2010 Jun. Available http://www.ahrq.gov/fund/cefarra.htm
13. Benner JS, Morrison MR, Karnes EK, Kocot SL, McClellan M. An evaluation of recent federal spending on comparative effectiveness research: priorities, gaps, and next steps. *Health Aff (Millwood)*. Oct 2010;29(10):1768-1776.
14. Benner et al reported $375.9 million in funding for 'infrastructure and methods development' based on their findings in 2010. Since 2010, more ARRA funding was awarded and announced. Based on new information made available on federal government websites, we found that the total funding for 'infrastructure and methods development' is $417.2 million.
15. Federal Business Opportunities. Washington (DC): FedBizOpps.gov; 2012 May 1. Available from https://www.fbo.gov/
16. National Institutes of Health. NIH Research Portfolio Online reporting Tools (RePORT). Bethesda (MD): NIH; 2012. Available from http://projectreporter.nih.gov/reporter.cfm
17. "Use of Recovery Act and Patient Protection and Affordable Care Act Funds for Comparative Effectiveness Research." *HHS Research Awards*, June 14, 2011 (GAO-11-712R). Washington: Government Printing Office, 2011.

Methods

The research for this brief focused on grants and contracts funded through the ARRA-CER awards building electronic clinical data infrastructure. Infrastructure and methods development award programs were identified (n = 130) based on review of publicly available information on the Agency for Healthcare Research and Quality (AHRQ) website[11, 12] and an evaluation of ARRA-CER spending in 2010.[13, 14] The identified projects were subsequently used to review the FBO (Federal Business Opportunities) website[15] and the NIH Research Portfolio Online reporting Tools (RePORT) to find links to the FOAs and the contract task orders.[16] The Government Accountability Office (GAO) report on the 'Use of Recovery Act and Patient Protection and Affordable Care Act Funds for Comparative Effectiveness Research' was reviewed to verify funding amounts.[17]

The electronic clinical data infrastructure grants and contracts were identified (n= 30) in a two-step process, 1) executive summaries for all 130 FOAs and task orders were reviewed; and 2) keyword search of terms related to electronic clinical data infrastructure (based on descriptions of 'data infrastructure' from the AHRQ website) was conducted, including: electronic health record(s), electronic medical records(s); data, database(s), warehouse; distributed data network(s); link(s), linking, linkage(s); collect, collection; claim(s); exchange(s); informatic(s), bioinformatic(s); (health information) technology; repository, repositories; and, registry, registries. The full FOA or task order was reviewed for the 30 award programs identified as building electronic clinical data infrastructure, to compare key infrastructure requirements and sustainability mechanisms.

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