March 2015

COMPARATIVE EFFECTIVENESS RESEARCH

HHS Needs to Strengthen Dissemination and Data-Capacity-Building Efforts Á

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Why GAO Did This Study

PPACA imposed new requirements on HHS related to CER—research that evaluates and compares health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments or services. Among other things, PPACA required AHRQ to broadly disseminate findings from federally funded CER and the Secretary of HHS (who, by delegation, charged ASPE) to coordinate federal programs to build data capacity for CER. PPACA also mandated that GAO review HHS's CER activities. This report examines (1) AHRQ's activities to disseminate the results of federally funded CER and (2) ASPE's activities to coordinate federal programs to support CER by building the capacity to collect, link, and analyze data, among other objectives. GAO reviewed relevant legal requirements and HHS documentation; interviewed HHS officials; and obtained information from five stakeholder groups that AHRQ targeted to receive disseminated information or were otherwise involved in AHRQ's dissemination efforts.

What GAO Recommends

GAO recommends that HHS direct (1) AHRQ to take several actions related to its dissemination efforts, including identifying and documenting time frames for the implementation and distribution of marketing plans and informational tools, and (2) ASPE to include clearly defined objectives, milestones, and time frames, or other indicators of performance, in its strategic road map used to identify its CER-funded projects. HHS concurred with the recommendations.

View GAO-15-280. For more information, contact Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov.

What GAO Found

The Agency for Healthcare Research and Quality (AHRQ), an agency within the Department of Health and Human Services (HHS), has taken some steps to disseminate comparative clinical effectiveness research (CER), as required under the Patient Protection and Affordable Care Act (PPACA), but has not taken other actions to help it fully address its dissemination requirements. The steps it has taken include the creation of tools that organize and disseminate research findings to certain targeted stakeholder groups and the development of plans for a publicly available database that includes CER. For example, AHRQ's marketing plans—customized plans to help convey key messages about AHRQ's research—include various informational tools to disseminate CER, such as research summaries that communicate research findings to clinicians, consumers, caregivers, and policymakers. However, the agency has not clearly defined how to disseminate information to certain stakeholder groups specified in the law, nor has it identified and documented time frames to implement the marketing plans and distribute the associated informational tools, as would be consistent with federal internal control standards, which state that significant events need to be clearly documented to ensure management goals are carried out. Additionally, in order to implement PPACA's requirement for developing a publicly available database that contains CER evidence, AHRQ officials told GAO that they plan to create a web page to list and provide users with links to existing publicly available databases that could be used to search for CER, but they have not documented a specific implementation plan that includes time frames and strategies to address known potential limitations, such as difficulties that certain users may face in searching the databases for CER results.

HHS's Assistant Secretary for Planning and Evaluation (ASPE) has coordinated among various agencies to fund projects intended to build data capacity for CER, but its approach lacks key elements needed to ensure its effectiveness. For example, these projects include an effort to better standardize data that could be used in multiple research projects. However, HHS's approach to building data capacity for CER lacks key elements, such as defined objectives, milestones, and time frames, that are necessary to ensure effectiveness. ASPE officials worked with the Office of the National Coordinator for Health Information Technology to develop a strategic road map to guide both the identification and selection of ASPE's projects beginning in fiscal year 2014 through fiscal year 2019. Although the February 2014 strategic framework for the road map highlighted several priority objectives, such as enabling the collection of standardized clinical data, these objectives were broad and not clearly defined. For example, although ASPE identified and considered related, ongoing federal and non-federal data infrastructure projects in an attempt to identify needs or gaps, among other things, its strategic road map is unclear on the timing and level of coordination that would be necessary for its projects to work together with these related projects to improve data capacity. Standard practices for project management call for agencies to conceptualize, define, and document specific goals and objectives in the planning process, along with the appropriate steps, milestones, time frames, and resources needed to achieve those results.

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March 3, 2015

Congressional Committees

Comparative clinical effectiveness research (CER)—research that evaluates and compares health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services, or items such as health care interventions—can help provide both patients and clinicians with more complete information to make health care decisions. CER includes comparisons of drugs, medical devices, tests, surgeries, and ways to deliver health care. Specifically, it can help determine which intervention may be most effective or beneficial for a given patient. However, the availability of this information is often limited, resulting in more than half of medical treatments that may be delivered without clear evidence of their effectiveness, according to the Institute of Medicine.[1] This uncertainty contributes to high variability in managing clinical problems, with costs and outcomes differing markedly across the country. Furthermore, even when research is conducted, applying research findings to improve health care practice can be a challenging and lengthy process.[2]

Congress has aimed to expand CER efforts to improve evidence for medical decision-making. Under the American Recovery and Reinvestment Act of 2009 (Recovery Act), the Department of Health and Human Services (HHS) received significant funding to support and disseminate results of CER.[3] The Recovery Act appropriated $1.1 billion to HHS specifically for CER: $400 million to the Secretary of HHS, $400 million to the National Institutes of Health (NIH), and $300 million to the Agency for Healthcare Research and Quality (AHRQ),[4] an agency

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[1]Institute of Medicine of the National Academies, *Initial National Priorities for Comparative Effectiveness Research*, (Washington, D.C.: June 2009).

[2]E. A. Balas and S.A. Boren, "Managing Clinical Knowledge for Health Care Improvement," *Yearbook of Medical Informatics* (2000).

[3]The term "disseminate" is used to refer to developing and distributing messages derived from CER for target stakeholder groups such as clinicians, consumers, or policymakers in order to inform health care delivery or practice.

[4]For more information about AHRQ, see GAO, *Comparative Effectiveness: Agency for Healthcare Research and Quality's Process for Awarding Recovery Act Funds and Disseminating Results*, GAO-12-332 (Washington, D.C.: Feb. 29, 2012).

within HHS.[5] In addition, the Patient Protection and Affordable Care Act (PPACA) established new CER requirements for HHS to:

1. broadly disseminate findings from federally funded CER, including findings published by the Patient-Centered Outcomes Research Institute (PCORI)—a non-profit corporation established under PPACA to improve the quality and relevance of CER. HHS is required to implement this requirement through AHRQ, in consultation with NIH.

2. establish a grant program to train researchers on CER methodological approaches. HHS is required to implement this requirement through AHRQ, in consultation with NIH.

3. coordinate relevant federal health programs to build data capacity for CER, in order to develop and maintain a comprehensive, interoperable data network that collects, links, and analyzes CER data. HHS is implementing this requirement through the Office of the Assistant Secretary for Planning and Evaluation (ASPE).[6]

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[5]See Pub. L. No. 111-5, 123 Stat. 115, 176-78 (2009). As authorized by the Recovery Act, the Secretary of HHS also allocated $174 million of its $400 million CER appropriation to AHRQ. Other HHS agencies that received a portion of HHS's CER appropriation included the Centers for Medicare & Medicaid Services, the Food and Drug Administration, NIH, and the Centers for Disease Control and Prevention.

[6]PPACA enacted the new CER requirements by adding section 937 to Title IX of the Public Health Service Act. Pub. L. No. 111-148, § 6301(b), 124 Stat. 119, 738-740 (codified at 42 U.S.C. § 299b-37). Section 937 requires HHS's AHRQ to carry out specified functions with respect to the dissemination of CER, incorporation of research findings, collection of feedback, and the establishment of a grant program to train researchers. Section 937(a)-(c), (e). In contrast, section 937 does not specify a particular HHS entity to carry out the functions specified under subsection (f) related to the coordination of federal programs to build data capacity for CER. The Secretary of HHS has delegated responsibility for carrying out section 937(f) to HHS's ASPE, which advises the Secretary on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives, coordinates the department's evaluation, research and demonstration activities, and manages cross-department planning activities such as strategic planning, legislative planning, and review of regulations.

PPACA also mandated GAO to report on, among other things, HHS's implementation of CER-related activities every 5 years, with the first report due in March 2015.[7] This report examines (1) AHRQ's activities to disseminate the results of federally funded CER; (2) AHRQ's activities to support training related to CER; and (3) ASPE's activities to coordinate federal programs to support CER by building the capacity to collect, link, and analyze data.

To examine AHRQ's activities to disseminate the results of federally funded CER, we reviewed the relevant legal requirements as well as documentation on the process AHRQ uses to disseminate CER. We reviewed relevant documents including spending plans from fiscal years 2011 through 2013 and any evaluation studies the agency developed for its dissemination activities. We interviewed AHRQ officials to understand the extent to which the agency had disseminated CER since February 2012, when we last reported on AHRQ's dissemination activities.[8] Because the law requires AHRQ to consult with NIH regarding dissemination of PCORI and other government funded research, we gathered information on AHRQ's collaboration with NIH and other organizations. We also inquired about AHRQ's efforts to develop a publicly available database that collects and contains federally funded CER evidence and research from various sources, because the law requires that such a database be part of AHRQ's dissemination efforts. We also obtained information from targeted stakeholder groups identified in PPACA to understand their perspectives about AHRQ's CER dissemination efforts and use of materials disseminated by AHRQ,

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[7]PPACA, § 6301(a), 124 Stat. at 736. PPACA also mandated GAO to review PCORI's CER activities, such as identifying research priorities and conducting research. This work is currently ongoing.

We also issued two prior reports on CER in response to a mandate and congressional request, and completed annual reviews mandated by PPACA of PCORI's financial statement audits. See GAO, *HHS Research Awards: Use of Recovery Act and Patient Protection and Affordable Care Act Funds for Comparative Effectiveness Research*, GAO-11-712R (Washington, D.C.: June 14, 2011); GAO-12-332; *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2012 and 2011,* GAO-13-390R (Washington, D.C.: March 29, 2013); and *Patient-Centered Outcomes Research Institute: Review of the Audit of Financial Statements for 2013 and 2012*, GAO-14-415R (Washington, D.C.: March 27, 2014).

[8]GAO-12-332.

among other things.[9] To identify stakeholder groups, we took several steps. First, we selected four CER studies as examples from among 101 studies for which information was disseminated to targeted stakeholder groups from June 2012 to June 2014. The four studies we selected were systematic reviews—syntheses of existing comparative clinical effectiveness research—and each aligned with one of AHRQ's 14 priority conditions and with one of the top four chronic diseases and conditions for adults identified by the Centers for Disease Control and Prevention.[10] We then requested the marketing plans for these four studies and compared the organizations listed in those plans to the targeted groups specified in PPACA.[11] We selected and obtained information from four stakeholder groups—a physicians' group; a health care providers' group; a professional association; and a patient advocacy group—that appeared most frequently in the marketing plans, from among 56 stakeholder organizations mentioned in the plans two or more times. For stakeholder groups that were specified in PPACA but not included in the marketing plans for the four studies, we requested additional documentation from AHRQ to determine the extent to which these stakeholder groups may have appeared in other marketing plans. We also interviewed an official from an additional stakeholder group—a health plan—because AHRQ staff indicated that they partnered with this organization to disseminate information, although it was not included in the marketing plans. Findings based on information we obtained from these stakeholders cannot be generalized to all targeted groups. In addition, we reviewed relevant

[9]Targeted stakeholder groups identified in PPACA as the audience for AHRQ's dissemination efforts are physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and federal and private health plans.

[10]AHRQ's 14 priority conditions include: arthritis and nontraumatic joint disorders; cancer; cardiovascular disease; dementia; depression and other mental health disorders; developmental delays, attention-deficit hyperactivity disorder, and autism; diabetes mellitus; functional limitations and disability; infectious diseases; obesity; peptic ulcer disease and dyspepsia; pregnancy; pulmonary disease/asthma; and substance abuse. For a list of the most prevalent chronic diseases and conditions for adults identified by the Centers for Disease Control and Prevention, see GAO, *National Institutes of Health: Research Priority Setting, and Funding Allocations across Selected Diseases and Conditions*, GAO-14-246 (Washington, D.C.: March 31, 2014).

[11]AHRQ develops customized marketing plans to help convey key messages about AHRQ research and tools to specific targeted stakeholder groups. Marketing plans use a variety of AHRQ's communications tools, including newsletters, LISTSERVs, and social media, to reach targeted stakeholder groups.

internal control standards and key collaboration practices and compared them against AHRQ's dissemination activities.[12]

To examine AHRQ's activities to support training related to CER, we reviewed the relevant legal requirements related to training. We also reviewed AHRQ documentation, such as its spending plans for fiscal years 2011 through 2013 and funding announcements for the grants associated with its training grant program for CER. These funding announcements describe the purpose of the grants and funding amounts. Additionally, we interviewed relevant AHRQ officials responsible for managing the training grant program and inquired about their consultation with NIH officials.

To examine ASPE's activities to coordinate federal programs to support CER by building the capacity to collect, link, and analyze data, we reviewed the relevant legal requirements, as well as relevant agency documentation such as ASPE's spending plans for fiscal years 2011 through 2013, which describe the office's proposed projects for its CER-related data capacity activities. We also reviewed other documentation, such as meeting minutes with HHS senior leadership and interagency agreements with other HHS agencies that describe specific CER projects ASPE has supported. We interviewed relevant ASPE officials responsible for implementing these efforts, inquiring about how they monitor projects, and their coordination with other HHS officials on the CER projects that ASPE supports, as well as with PCORI on its PCORnet initiative.[13] We also reviewed relevant standard practices for project management, in

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[12]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives. Also see GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005) and *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms,* GAO-12-1022 (Washington, D.C.: Sept. 27, 2012).

[13]PCORnet is a project funded by PCORI that aims to create a large, highly representative, national network for conducting CER. See http://www.pcori.org/content/pcornet-national-patient-centered-clinical-research-network.

addition to internal control standards, regarding information used by agencies to compare them against ASPE's CER activities.[14]

To assess the reliability of AHRQ and ASPE cost data for dissemination, training, and building data capacity, we collected information from AHRQ and ASPE officials regarding the accuracy of data entry and the systems that contain the data. We determined the data were sufficiently reliable for the purposes of our review.

We conducted this performance audit from April 2014 through March 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform our work to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

PPACA requires HHS to perform several duties related to CER, including disseminating, training, and building data capacity for research. (See table 1.)

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[14]See GAO/AIMD-00-21.3.1 and Project Management Institute, *A Guide to the Project Management Body of Knowledge* (PMBOK® Guide), 5th ed. (Newton Square, PA: 2013). *A Guide to the Project Management Body of Knowledge* provides standards for project management.

Table 1: Selected Duties Related to Comparative Clinical Effectiveness Research (CER) for Entities within the Department of Health and Human Services (HHS) Required by the Patient Protection and Affordable Care Act (PPACA)

CER-related duties	Description
Dissemination	PPACA directed • the Agency for Healthcare Research and Quality (AHRQ), in consultation with the National Institutes of Health (NIH), to broadly disseminate research findings produced by the Patient-Centered Outcomes Research Institute (PCORI) and other government funded CER. • AHRQ to create tools that organize and disseminate research findings for physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and federal and private health plans. • AHRQ to develop a publicly available database that collects and contains government-funded evidence and research from public, private, not-for-profit, and academic sources. Disseminated information should include a description of considerations for specific subpopulations, the research methodology, and the limitations of the research, among other things.
Training	PPACA directed AHRQ, in consultation with NIH, to establish a training grant program to build capacity for CER. Such a grant program shall provide for the training of researchers in the methods used to conduct CER, including systematic reviews of existing research and primary research such as clinical trials.
Building data capacity	PPACA directed the Secretary of HHS (who, by delegation, charged the Assistant Secretary for Planning and Evaluation) to provide for the coordination of relevant federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

Source: Summary of PPACA, § 6301(b) adding section 937 to Title IX of the Public Health Service Act. | GAO-15-280

Note: PPACA also directs AHRQ to establish a process for receiving feedback from entities to which information is disseminated about the value of the disseminated information.

Although PPACA did not direct HHS to complete these duties by a specified deadline, it appropriated funds to the Patient-Centered Outcomes Research Trust Fund (PCORTF) through fiscal year 2019 to enable HHS and PCORI to implement their respective requirements. PPACA specified that 20 percent of the amounts appropriated or credited to PCORTF be transferred to the Secretary of HHS in each of fiscal years 2011 through 2019. In total, HHS estimates that about $731 million will be transferred to AHRQ (16 percent of the PCORTF) and about $190 million will be transferred to ASPE (4 percent of the PCORTF).[15] With the

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[15]The statutory percentages on the transfer of PCORTF funds to HHS are constant from fiscal years 2011 through 2019, although the level of PCORTF funding is not. PCORTF's appropriation for a given fiscal year depends on the specific sum appropriated by PPACA, amounts transferred from the Medicare trust funds, and, starting in fiscal year 2013, net revenues from fees on health insurance and self-insured plans. See 26 U.S.C. § 9511(b),(d).

exception of the amounts transferred to HHS, PPACA designates the remaining PCORTF funds for PCORI's CER work—an estimated $3.5 billion from fiscal year 2010 through fiscal year 2019.[16]

AHRQ Has Taken Some Steps to Disseminate Comparative Clinical Effectiveness Research, but Has Not Taken Other Actions to Help It Fully Address Its Dissemination Requirements

AHRQ has taken some steps to disseminate CER as required under PPACA, including the creation of systematic reviews to develop CER findings, tools to disseminate CER, plans for a website to list and provide links to research databases that include CER, and plans for receiving feedback from stakeholders to whom information is disseminated. However, AHRQ has yet to take other actions that would help it address all PPACA dissemination requirements.

AHRQ Has Taken Some Steps to Implement Key Dissemination Requirements

AHRQ has taken some steps to implement the law's key requirements for disseminating federally funded CER, that is to (1) broadly disseminate—develop and distribute—CER in consultation with NIH, (2) create tools that organize and disseminate research findings to certain targeted stakeholder groups, (3) develop a publicly available database, and (4) establish a process for receiving feedback from entities to which information is disseminated. From fiscal year 2012 through 2013, AHRQ has obligated about $37 million of the estimated $731 million it expects to receive through 2019 from the PCORTF on its dissemination activities.

Development and distribution of CER findings. AHRQ contributes to the dissemination of CER in various ways, including through the development of systematic reviews, technical briefs, and research

[16]The funds transferred to HHS through PCORTF are available until expended, but PCORI may not make any expenditures from PCORTF after September 30, 2019, at which point any remaining funds are to be transferred to the general fund of the U.S. Treasury. See 26 U.S.C. § 9511(d)(2)(B),(f).

summaries that explore the benefits and harms of treatments. In particular, a key method to disseminate CER is through systematic reviews—syntheses of existing research that compare the effectiveness and harms of different healthcare interventions. A systematic review is an assessment and evaluation of all research studies that address a particular clinical issue. Researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic. Systematic reviews typically include a description of the findings from the research studies.

AHRQ identifies topics for systematic review of CER, such as cardiovascular disease and arthritis, by evaluating topics nominated by individuals or groups against program selection criteria, in order to determine if the topic is appropriate or not appropriate for review.[17] In addition to using its own criteria to identify CER topics for systematic reviews and dissemination, AHRQ documentation states that the agency will consult with experts, such as those from NIH, and review literature to determine whether any similar systematic reviews of relevant studies have already been conducted by other agencies or research organizations in order to reduce potential duplication.[18] Topics selected for a systematic review are further refined with input from key stakeholder groups, technical experts, and patients to develop focused research questions.[19] According to AHRQ officials, research funded by PCORI is not yet included in these systematic reviews because PCORI research is not yet complete.[20]

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[17]AHRQ has adopted specific criteria for use in prioritizing all nominated topics for systematic reviews: appropriateness, importance, feasibility, desirability of new research or potential duplication, and potential value.

[18]To do this, AHRQ searches various databases to determine if a relevant study has been conducted or is currently underway.

[19]Focused research questions guide the systematic review process, including specific information as to what is to be addressed in the review.

[20]AHRQ officials stated that although they expect to utilize the same dissemination strategy to share CER results funded by PCORI, it is too soon to tell how they will approach this until PCORI's dissemination plans have been issued. PCORI has entered into a contract for the development of a dissemination and implementation plan, which was still underway as of February 2015.

For each systematic review AHRQ synthesizes CER findings from existing research, and the agency disseminates these findings to various targeted stakeholder groups. From June 2012 to June 2014, AHRQ synthesized CER findings through 74 systematic reviews. (See appendix I for a listing of the 74 systematic reviews for which AHRQ disseminated CER findings.) Once a systematic review is complete, AHRQ follows procedures included in its dissemination guidance materials to develop a marketing plan that identifies key messages and targeted stakeholder groups, as well as the types of dissemination mechanisms it will use to conduct outreach.[21] AHRQ officials told us they distribute CER results generally by using the same mechanisms as we previously reported in 2012.[22] These mechanisms include social media, as well as AHRQ's website and AHRQ's Effective Healthcare Program website.[23] According to AHRQ officials, the agency determines which specific mechanisms will be used to disseminate CER results by considering the unique characteristics of the research, such as its type, potential impact, and stakeholder groups most likely to use its findings. For example, CER identified as being of particular interest to specific specialties may be disseminated to certain clinical professional associations.

Tools to organize and disseminate CER. AHRQ's marketing plans include various informational tools to disseminate CER. Informational tools include (1) patient decision aids that walk patients through options and choices that patients should consider in working with their clinicians to make informed health care decisions; (2) continuing education and medical education modules to help clinicians understand and use CER findings; (3) slide sets to assist clinicians, researchers and other health professionals with education and training needs; and (4) short, plain-

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[21]AHRQ's dissemination materials include *AHRQ Publishing and Communications Guidelines,* which outline the standards for the development and distribution of agency products developed in-house and by contractors, and the *AHRQ National Initiative: Individual Micro-Marketing Plan Process Guide*, which serves as a reference for developing individual marketing plans for newly released CER products from AHRQ.

[22]GAO-12-332.

[23]The agency employs social media tools to disseminate notices of CER results, including electronic newsletters, audio podcasts, and Twitter. AHRQ's website provides access to CER results through search tools and links to its written and social media formats. The Effective Health Care Program reviews and synthesizes published and unpublished scientific evidence, generates new scientific evidence and analytic tools, compiles research findings that are synthesized and/or generated and translates them into useful formats for various audiences.

language research summaries that communicate research findings to clinicians, consumers, caregivers, and policymakers. For example, the marketing plan for the systematic review titled, *Childhood Exposure to Trauma: Comparative Effectiveness of Interventions Addressing Maltreatment*, was developed for a systematic review that examines evidence about interventions for maltreated children. The marketing plan included the specific informational tools to be used to disseminate this project's findings, such as research summaries for clinicians, a summary of treatments for parents and caregivers, a continuing education module for health care providers, and a slide presentation on the topic.

Publicly available database. In order to implement the law's requirement for developing a publicly available database that contains CER evidence, AHRQ officials told us they plan to create a new web page on AHRQ's website that would list and provide users with links to existing publicly available databases that could be used to search for CER. The new webpage will include instructions on how users can best search for CER.[24] Referenced databases on the web page are expected to include PubMed, Clinicaltrials.gov, and HSRProj, which are all maintained by the U.S. National Library of Medicine at NIH.[25] AHRQ officials said that they also will provide links to AHRQ's Grants On-Line Database and the agency's Effective Healthcare Program website.[26] They told us that they would identify and recommend specific CER terms for users to consider when searching a database for a particular project. According to these officials, developing a new database could be duplicative of existing databases and would require AHRQ to make decisions about which studies are CER-related, which could unnecessarily narrow the pool of studies for potential users. AHRQ officials also note that users may face two potential limitations: (1) difficulty searching through a large number of results, many of which may be unrelated to CER and (2) lack of assurances that the databases, as well as the Effective Healthcare Program website, will contain results

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[24]AHRQ defines a publicly available database as an electronic resource that is accessible to users in multiple ways, but principally via the internet.

[25]For example, AHRQ officials noted that AHRQ CER-related documents can be accessed from PubMed and the following U.S. National Library of Medicine website: *http://www.ncbi.nlm.nih.gov/books/NBK16710/*.

[26]AHRQ's Grants On-Line Database is a searchable database of AHRQ grants, working papers, and HHS Recovery Act projects.

on all CER that has been conducted. National Library of Medicine officials told us that they have informally consulted with AHRQ on its plans and agree with this approach. In November 2014, AHRQ officials told us that they were sharing their planned approach with senior HHS officials for review and approval.

Feedback and evaluation process. As required by PPACA, AHRQ officials told us they receive feedback on dissemination efforts and materials from stakeholders, both formally and informally. For example, officials said that for some of their projects, AHRQ convenes focus groups and advisory panels to assess the needs of stakeholder groups and determine how best to disseminate materials. Some stakeholders we spoke to told us that they have provided feedback to AHRQ on materials the agency has disseminated; however, they were uncertain about the extent to which their feedback was incorporated into AHRQ's dissemination efforts. AHRQ conducted a feedback assessment and issued a March 2012 feedback report that highlighted stakeholders perspectives about the agency's disseminated materials. In this report, AHRQ noted that although there is a growing awareness about its disseminated materials, clinicians raised concerns about the timeliness of the information included in the materials, among other things. Officials told us that the agency may conduct future feedback assessments, but they do not know when these will occur and which targeted stakeholder groups will be included.

AHRQ also has funded an evaluation to assess its CER dissemination activities and materials supported by the Recovery Act. In September 2013, IMPAQ International—the contractor that conducted the evaluation—issued presentation slides as its final report. The evaluation indicated that stakeholders' exposure to AHRQ's CER information, such as the number of website visits and dissemination materials requested, increased over time with AHRQ's dissemination efforts. The final report also included feedback from certain stakeholder groups through focus groups and surveys. For example, clinicians who participated in focus groups indicated that they typically had little to no experience with the CER information that AHRQ disseminates to clinicians, and suggested that AHRQ more visibly promote the benefits and credibility of this information and then integrate the results and products into existing, easy-to-access sources of medical information focused on point-of-care decision-making. AHRQ officials told us that they plan to award a contract to evaluate the CER dissemination mechanisms—along with the materials they use to share CER findings—that they continued under PPACA. This evaluation project, according to officials, is under

development as staff and senior leadership determine the objectives and methods for the study. Although AHRQ staff have not documented their plans as of November 2014, they told us that the evaluation is likely to measure progress on process and intermediate outcome goals of dissemination activities—similar to the last CER evaluation conducted for Recovery Act investments where the agency assessed the level of awareness, understanding, use, and perceived benefits of CER. Officials said the evaluation will also address longer term goals, such as improving health care practice.

AHRQ Has Not Taken Other Actions to Help It Fully Address Its Dissemination Requirements

AHRQ has not taken other actions to help it fully address requirements for disseminating CER in PPACA. Specifically, AHRQ has not taken actions to help it fully address (1) the time frames for disseminating CER, (2) how it will disseminate to all targeted stakeholder groups, (3) its implementation plans for the publicly available database, and (4) how it will coordinate with NIH.

Time frames for certain aspects of the dissemination process have not been identified and documented. Although AHRQ has outlined its dissemination process in various documents, it has not clearly identified and documented time frames for one of its key dissemination activities—to implement marketing plans and distribute associated informational tools. According to GAO's Standards for Internal Control in the Federal Government, significant events need to be clearly documented to ensure management goals are carried out.[27] AHRQ has several documents which together describe the key activities of its dissemination process, including the steps the agency takes to identify key CER findings from systematic reviews, draft and finalize its marketing plans, and distribute its informational tools to the public. While certain AHRQ documents highlight time frames associated with key dissemination activities, we did not identify any documents that specify time frames for when the marketing plans are to be implemented and associated informational tools are to be distributed to stakeholder groups. Once the marketing plans are finalized, the informational tools are to be distributed to targeted stakeholder groups after results of the research have been posted online, such as publication in a major journal. AHRQ officials said they would expect to distribute the informational tools as soon as the results of the

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[27]See GAO/AIMD-00-21.3.1, sections related to control activities.

research have been posted; however, the dissemination guidance materials we reviewed did not specify time frames for the completion of the implementation of the marketing plans and distribution of informational tools. Without identifying and documenting time frames for these key activities, AHRQ cannot ensure that CER findings are disseminated in a timely manner or that the dissemination process is consistently implemented by all parties. Setting time frames is especially important for dissemination given the length of time and uncertainty inherent in applying CER findings; the large volume of CER research expected from PCORI in the near future, which will increase AHRQ's dissemination responsibilities; and the need to maximize the investment of PCORTF appropriations made through fiscal year 2019.

Dissemination plan for some stakeholders identified in PPACA has not been clearly defined. Additionally, AHRQ has not determined how it will disseminate information to certain stakeholder groups identified in law, and its dissemination to some of these groups has been limited. While AHRQ's marketing plans include informational tools aimed at most of the targeted stakeholder groups— physicians, health care providers, patients, and appropriate professional associations—federal and private health plans, and vendors of health information technology focused on clinical decision support are not included.[28] Without a defined plan for dissemination to all of the targeted stakeholder groups, AHRQ may be missing opportunities to reach the key stakeholder groups identified in the law. Although as of October 2014 there were no specific marketing plans that identified private or federal health plans to receive disseminated CER information, AHRQ officials told us they have conducted outreach to these groups. For example, we spoke to a representative at a private health plan who confirmed receipt and use of AHRQ disseminated CER materials. For federal health plans, AHRQ officials said that they worked with the Office of Personnel Management, which manages the Federal Employees Health Benefits Program, and this program encouraged health plans to use an AHRQ report on the comparative effectiveness of autism treatments when determining coverage decisions. AHRQ officials noted that some health plans told them that CER information without a corresponding cost analysis is insufficient in informing coverage

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[28]Clinical decision support provides clinicians, staff, patients, or other individuals with knowledge and individual-specific information to enhance health care decision-making. Many clinical decision support applications operate as a part of an electronic health record system.

decisions. Officials also told us that AHRQ found challenges translating CER findings into clinical decision support applications; plans are underway to determine next steps.

Implementation plans for addressing the requirement to create a publicly available database have not been documented. As of November 2014, AHRQ officials also have not developed and documented a specific implementation plan to create a publicly available database for CER.[29] GAO's Standards for Internal Control in the Federal Government state that management should compare actual performance to plans, and as previously noted, should document significant events. The agency formerly acknowledged its plan to address the PPACA requirement to build a publicly available database during our prior work in 2012,[30] but AHRQ has since modified this plan, and the new plan to use existing databases has not been documented and is in the process of being fully vetted with senior leadership. Additionally, while AHRQ officials told us that their instructions on how to search databases for CER will be aimed at the general public, they have not yet determined how effective these tactics will be to meet the needs of various user groups, such as non-researchers who may be unfamiliar with research databases. For example, officials have not determined if or how they may seek feedback from potential users or test the instructions or search terms to see if they meet potential users' needs. Additionally, AHRQ officials told us they have not determined how to address potential limitations with this new approach. Without taking steps to develop and document an implementation approach that includes time frames and strategies to address potential limitations and AHRQ's plans to assess whether its tactics meet the needs of various users, the agency does not have reasonable assurance that it will implement the PPACA requirement in a timely or effective manner.

NIH's consultation role regarding AHRQ's dissemination efforts is unclear. AHRQ is required by law to consult with NIH regarding dissemination efforts, and agency officials told us they meet informally with NIH staff. NIH officials concurred. AHRQ officials said that they have

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[29]See GAO/AIMD-00-21.3.1, sections related to control activities.

[30]GAO-12-332. AHRQ noted that at the time of our prior report, it was assessing whether a research database being developed by ASPE could be used to, among other things, store and make publicly available CER funded and generated by PCORI.

had interactions with NIH on specific dissemination projects of interest to specific NIH institutes or centers, such as the National Cancer Institute.[31] AHRQ and NIH have not determined what role NIH should take in the dissemination process, or which NIH officials should be involved. Previous GAO work has identified key practices that can help federal agencies collaborate effectively when they work together to achieve goals.[32] This work highlighted, for example, the importance of agreeing on roles and responsibilities and establishing compatible policies, procedures, and other means to operate across organizational boundaries. While coordination between the two entities has been informal and limited to specific NIH institutes or centers at this time, AHRQ officials told us that there is a designated AHRQ official that serves as a liaison to NIH to work on this effort. Additionally, AHRQ officials told us that the agency's senior management is currently working with NIH to determine how best to more formally coordinate on AHRQ's dissemination activities, but the officials did not state when this effort will be complete. Without specific plans on how it will collaborate, AHRQ officials lack reasonable assurance that they have buy in from NIH regarding dissemination activities or that their independent efforts are not unnecessarily duplicative.

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[31]AHRQ and NIH officials also told us that they coordinate as participants on PCORI's Board of Governors regarding PCORI-related dissemination activities, among other things. See 42 U.S.C. § 1320e(f).

[32]GAO-06-15 and GAO-12-1022.

AHRQ Has Implemented a Comparative Clinical Effectiveness Research Grant Program to Support Researcher Training

As required by PPACA, AHRQ has implemented a training program aimed at individual researchers and academic institutions that is designed to increase the supply and expertise of CER investigators. Through this program, AHRQ awards grants to support graduate training on CER, career enhancement of beginning and midcareer investigators who utilize CER methods, and institutional CER teaching programs.[33] (See table 2.) AHRQ provides grants to individuals it selects and also to institutions that can select a number of individuals to train on CER.[34] During the planning stages for AHRQ's training program, AHRQ officials told us they consulted with NIH staff members with expertise on the design and management of training grants.

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[33]AHRQ issues funding opportunity announcements, which provides applicants with information about grants for each program. Grant applications submitted to AHRQ for each funding announcement are evaluated through AHRQ's peer review process, which involves an assessment conducted by a panel of experts.

[34]The institutions have to provide AHRQ with a recruitment plan, which describes their plans for recruiting and retaining individuals that will be trained on CER methodologies.

Table 2: The Agency for Healthcare Research and Quality's (AHRQ) Training Development Program Awards for Comparative Clinical Effectiveness Research (CER), Fiscal Years 2012 through 2014

Training development programs	Description of program	Number of awards	Total funds obligated[a] (in millions)
AHRQ Patient-Centered Outcomes Research Institutional Award	This program supports institutional programs for the career development of post-doctoral fellows or junior faculty in academic and applied settings, such as a health care delivery system, on CER methods such as clinical trials and systematic reviews. AHRQ intends to fund approximately 8 to 10 awards, for up to a total of $7.5 million.	5	$4.48
AHRQ Mentored Career Enhancement Award in Patient-Centered Outcomes Research	This program supports short-term mentored career enhancement for midcareer and senior investigators in CER. The size of each award varies based on the nature and scope of the proposed career development.	11[b]	$3.49
Patient-Centered Outcomes Research—Pathway to Independence Award	This program targets junior investigators early in their careers and helps facilitate their transition to become stable independent researchers. It provides support for up to 5 years, totaling about $4.5 million per award. During the first 2 years, or phase 1, the investigator must continue CER training and complete and publish research under the guidance of a mentor. The individual may then request up to 3 years of additional support, or phase 2, to conduct CER as an independent scientist, at a sponsoring institution as a tenure-track professor or equivalent. It is anticipated that AHRQ will make approximately 10 awards.	11[c]	$2.71
The Patient-Centered Outcomes Research—Infrastructure Development Award	This program supports efforts at emerging academic and applied research organizations to enhance and expand their capacity to train researchers in CER. Applicants can request funding of up to $1 million per year for a project period of up to 5 years.	7	$13.62
Institutional Mentored Career Development Award Program in Patient-Centered Outcomes Research	This program proposes to launch a multi-year large-scale effort to support the development of CER researchers in academic and applied settings (e.g., the health care delivery system, state and local governments, health plans, research networks).	10	$6.81
Researcher Training and Workforce Development in Methods and Standards for Conducting Patient-Centered Outcomes Research Studies Award	This program supports institutional education programs for researchers on CER methods and standards. Recipients develop programs that could include design and analysis of systematic reviews, clinical trials, observational studies, or technology assessments. Applicants can request funding of up to $500,000 per year for a project period of up to 5 years.	5	$2.43

Training development programs	Description of program	Number of awards	Total funds obligated[a] (in millions)
AHRQ Patient-Centered Outcomes Research Mentored Research Scientist Development Award	This program prepares qualified individuals for careers utilizing complex CER methods to resolve clinical and health systems PCOR issues, involving stakeholders, as appropriate, in the design, execution, and dissemination of the research.	4	$0.62
Total			**$34.15**

Source: AHRQ. | GAO-15-280

[a]Due to rounding, obligation amounts do not add to total.

[b]AHRQ made a total of 11 awards for this grant. One grant award was funded in 2012 and ended in 2013. Seven other grant awards began in 2013 and continued into 2014. Three new awards were made in 2014.

[c]AHRQ made a total of 11 awards for this grant. Nine grant awards were funded in 2013 and continued into 2014. Two of these awards transitioned into another phase of the grant in 2014.

An AHRQ official told us that funding will continue for the existing grants awarded to date through 2018. For example, there are currently some training awards that AHRQ will continue to fund through 2018. However, because AHRQ's allocation from the PCORTF is scheduled to end in 2019, AHRQ officials told us that they do not expect to create or initiate additional individual grants. Additionally, AHRQ does not expect that additional funding announcements will be made for the institutional grants, since these grants are on a 5-year cycle with current grants running through 2018. For any grant on a 2-year cycle, there will likely be new awards made, but only up until 2018.

In order to monitor the various training grant awards funded since 2012, AHRQ collects progress reports from training grantees on an annual basis. AHRQ officials told us that participants learn about CER methods and apply what they learn to conduct research projects as part of their training. AHRQ requires that grantees annually submit progress reports to assess their performance on these activities. These reports include performance information, such as (1) a description of career development and research-related activities undertaken; (2) a list of accomplishments including publications, scientific presentations, dissemination activities, new collaborations, inventions, or project-generated resources made; (3) any methodological changes implemented; (4) key preliminary findings from research; and (5) an annual evaluation statement of the award recipient's progress by the mentor.

AHRQ officials told us that they are considering an interim evaluation of the training grant program for fiscal year 2016 and an overall evaluation after the program is complete in fiscal year 2019. Officials stated that they expect to document specific details about their plans before the

evaluations occur, which would be consistent with findings in our prior work that a plan for data collection and evaluation is a key attribute of effective training and development programs and can guide an agency in a systematic approach to assessing effectiveness and efficiency.[35] AHRQ officials emphasized that the training program is ongoing and grantees are not yet expected to have outcomes. For these evaluations, they have collected baseline data from progress reports and they plan to collect additional data once the grant program ends to help inform their evaluations, such as a recipient's promotion and tenure status to measure academic progress.

ASPE Has Coordinated and Funded Projects to Build Data Capacity for Research, but Its Approach Lacks Key Elements Needed to Ensure Its Effectiveness

ASPE has coordinated among various agencies to fund projects intended to build data capacity for CER. However, its approach to building data capacity for CER lacks key elements, such as defined objectives, milestones, and time frames, that are necessary to ensure effectiveness.

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[35]See, for example, GAO, *Human Capital: A Guide for Assessing Strategic Training and Development Efforts in the Federal Government*, GAO-04-546G (Washington, D.C.: Mar. 1, 2004). In this report, we found that implementing such a plan can set priorities for evaluations; systematically cover the methods, timing, and responsibilities for data collection; and explain how the results of the evaluations will be used. Additionally, this plan can highlight the importance of having clear goals about what the training or development program is expected to achieve and agreed-upon measures to ascertain progress toward these goals.

These attributes also align with those identified in *Standards for Internal Control in the Federal Government*, which call for agencies to document the plans, methods, and procedures used to meet missions, goals, and objectives and support performance-based management practices.

ASPE Has Coordinated Activities and Funded Projects Intended to Build Data Capacity for Comparative Clinical Effectiveness Research

ASPE officials have coordinated and funded projects that they say will help build data capacity for CER. According to ASPE officials, building CER data capacity involves improving data infrastructure, such as facilitating the creation of new health data sets or the sharing of existing health data via the creation of needed standards, services, policies, federal data, and governance structures. ASPE officials say the agency intends these projects to enable interoperable data networks that could support the efficient collection, linkage, and analysis of data for CER from multiple sources. ASPE officials told us that the agency's goal is to identify a number of investment opportunities through fiscal year 2019 for enabling the development of a CER data infrastructure using funds from the PCORTF.

Beginning in fiscal year 2013, ASPE officials worked with the Office of the National Coordinator for Health Information Technology (ONC) to develop a strategic road map to guide both the identification and selection of ASPE's PCORTF projects beginning in fiscal year 2014 through fiscal year 2019. The strategic framework for the road map, completed in January 2014, specified five component types—standards, services, policies, federal data, and governance structures—necessary to build CER data capacity. As of October 2014, ASPE has funded a total of 10 projects. (See appendix II for descriptions and funding amounts for the 10 ASPE projects.) ASPE has obligated about $23 million of the total estimated $190 million it expects to receive through FY 2019 from the PCORTF.

Prior to the development of the road map, ASPE worked with HHS's Leadership Council, responsible for overseeing ASPE's PCORTF investment process, to identify and fund new projects that utilized the expertise of an HHS agency.[36] Some projects extended the work of existing Recovery Act projects, with the initial projects beginning in 2011.[37] These projects focused on developing new or enhancing existing data resources, such as expanding administrative and clinical data sets for CER and establishing health information technology standards to

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[36]The Leadership Council comprises senior managers from various HHS divisions, including ASPE, AHRQ, NIH, and ONC, among others. The council will be involved throughout the project development, prioritization, and investment process. For example, it will prioritize and approve specific PCORTF projects.

[37]Once the investments were approved by HHS's Leadership Council, ASPE established interagency agreements with other HHS agencies to conduct the work.

leverage electronic health records for CER. For example, ASPE funded a new project conducted by ONC known as the Structured Data Capture initiative. For this project, ONC identifies standards for common data elements that consist of structured data definitions and electronic case report forms, to capture patient data from electronic health records for CER studies.[38]

ASPE's Approach to Building CER Data Capacity Lacks Key Elements Needed to Ensure Its Effectiveness

ASPE's approach to building data capacity for CER through investments in data infrastructure lacks key elements necessary to ensure its effectiveness. Specifically, ASPE updated the strategic framework for the road map in February 2014, but did not define specific objectives linked with performance metrics or establish milestones and time frames that could be used to gauge its progress toward the goal of coordinating relevant federal health programs to build data capacity, as required by PPACA. Without these key elements, ASPE may be unable to gauge its progress towards meeting the requirements of the law. Standard practices for project management call for agencies to conceptualize, define, and document specific goals and objectives in the planning process, along with the appropriate steps, milestones, time frames, and resources needed to achieve those results.[39]

Although the updated February 2014 strategic framework for the road map highlighted a purpose—to identify a set of investment opportunities for developing CER data infrastructure to build CER data capacity—and included guiding principles and objectives, it did not clearly define those objectives, nor did it include other elements such as milestones or time frames that would help allow for monitoring and reporting on progress. Specifically, ASPE identified several guiding principles, such as ensuring that data infrastructure projects are "non-duplicative of other related federal and non-federal investments" and "achieve synergy with PCORI and AHRQ." It also included priority objectives, such as further enabling the collection of standardized clinical data, but many of the objectives

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[38]Electronic case report forms are mechanisms used to assemble all the data from different electronic- and paper-based systems—that is, they capture and organize diverse data in a manner that satisfies the study protocol and enables the data to be systematically reviewed and analyzed.

[39]GAO/AIMD-00-21.3.1 and Project Management Institute, *A Guide to the Project Management Body of Knowledge*.

were broad and not clearly defined—and did not specify milestones or time frames—as would be consistent with effective project management.

Although ASPE identified and considered related, ongoing federal and non-federal data infrastructure investments in an attempt to identify needs or gaps, opportunities where contributions could be made, and ways to avoid duplication, its strategic road map was unclear on the timing and level of coordination necessary for its investments to work together with existing projects—such as PCORI's PCORnet initiative—to improve data capacity. For example, ASPE officials were not clear on how precisely the standards for common data elements resulting from the ONC Standard Data Capture initiative could be incorporated into PCORnet or other existing publicly funded data networks, although ASPE does plan to make them available for use, and officials told us that they will work with other HHS agencies and PCORI to determine adoption strategies.[40] Furthermore, the ONC Standard Data Capture initiative is not expected to be completed until 2016, which occurs after PCORI's common data model for the PCORnet initiative is expected to be used for conducting research, beginning in September 2015.[41] Having more clearly defined objectives and establishing milestones and time frames can also help ASPE assess how it expects the results of its CER investments to build data capacity, and how they will be coordinated in a timeline with many other entities' existing and planned efforts. Moreover, this information can help ASPE officials understand the extent to which their efforts are not duplicative and align with other federal efforts.[42]

ASPE officials told us that as of October 2014, they are planning to award a contract for developing an evaluation framework that will be used to assess the effectiveness of their CER data infrastructure projects. They also told us that they monitor and assess the 10 individual projects by

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[40]The PCORnet data research network utilizes a common data model to standardize the format and content of data, so applications, tools and methods can be applied to them. According to PCORI officials, the common data model is expected to be updated over time.

[41]HHS stated in February 2015 that although the Standard Data Capture initiative was not complete, some early deliverables from it were being discussed with PCORI for potential incorporation into PCORI's common data model.

[42]GAO, *2013 Annual Report: Actions Needed to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits,* GAO-13-279SP (Washington, D.C.: April 9, 2013).

collecting quarterly reports and assessing progress against the statements of work that were developed for each project. However, it is unclear from ASPE's strategic road map whether these efforts will be sufficiently timely and coordinated with other federal and non-federal efforts to result in improvements to CER data capacity.

Conclusions

Comparative clinical effectiveness research can give health care providers information to help decide which treatments may be most beneficial for a given patient, and it also can inform decisions by patients and caregivers. However, this information is often incomplete or unavailable. While HHS has multiple, ongoing efforts to meet its requirements under PPACA related to CER, it has not determined how it will fully address some of these requirements, particularly those related to dissemination and data capacity building.

Disseminating CER in a timely manner is particularly challenging given the length of time and uncertainty inherent in applying research findings to help improve health care practice. AHRQ, for instance, has taken steps to disseminate CER and documented these processes, including time frames for some, but not all, of its key dissemination activities. Such time frames may become especially important due to the large volume of CER research expected from PCORI in the near future, which will increase AHRQ's dissemination responsibilities, and the need to maximize the investment of PCORTF appropriations made through fiscal year 2019. Additionally, effective dissemination of research findings involves multiple stakeholders, some of which are specified in PPACA. Without clear plans to target each of these stakeholder groups, including federal and private health plans and vendors of health information technology focused on clinical decision support, it is unclear whether pertinent CER findings are being directed to key targeted stakeholders identified in PPACA and presented in a meaningful way to those groups. Other aspects of AHRQ's dissemination process, such as its plans for a publicly available database of CER—including whether AHRQ's instructions and CER search terms will be effective to meet the needs of various potential users in the general public—and its collaboration with NIH on dissemination activities, have not been fully defined.

HHS's plan to build data capacity involves identifying projects that would enhance existing data resources for CER. While HHS has a strategic road map with information on projects that it is funding to build the capacity for CER data, the road map does not include key elements, such as clearly defined objectives, milestones, and time frames needed to

assess the agency's progress toward the goal of building data capacity for CER, as would be consistent with practices for effective project management. Without defining these key elements, for example, it is unclear to what extent ASPE's projects will build on or contribute to other similar federal or non-federal activities, rather than being duplicative. ASPE officials, for instance, could use more defined objectives and time frames to help them better assess the extent to which the CER projects they choose to fund will be useful and timely for other relevant federal and non-federal work, such as PCORI's PCORnet initiative.

Recommendations for Executive Action

To help ensure that HHS fully addresses its dissemination requirements under PPACA, we recommend that the Secretary of Health and Human Services direct AHRQ to take the following four actions:

1. identify and document time frames for the implementation and distribution of marketing plans and informational tools;

2. expand dissemination efforts to federal and private health plans and vendors of health information technology focused on clinical decision support;

3. document and complete plans to develop a publicly available database, including plans to meet the needs of various potential users in the general public; and

4. develop specific plans on how it will collaborate with NIH on its dissemination activities.

In addition, to ensure that HHS fully addresses the PPACA requirements to build data capacity for CER, the Secretary should direct ASPE to include clearly defined objectives, milestones, and time frames, or other indicators of performance, in its strategic road map that is used to identify its PCORTF projects.

Agency Comments

We provided a draft of this report to HHS, and HHS provided written comments, which are reprinted in appendix III. HHS concurred with all five of our recommendations and provided additional information about its work to build data capacity for CER. Additionally, HHS provided technical comments, which we incorporated as appropriate.
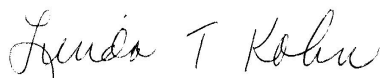
Specifically, for the first four recommendations, HHS—including AHRQ—stated that it would

- ensure that starting and ending time frames for the implementation and distribution of patient-centered outcomes research findings are clearly specified and documented.

- continue and expand dissemination activities that target federal and private health insurance plans, as well as vendors of health information technology focused on clinical decision support. HHS stated that it recently issued a funding opportunity announcement focused on the use of clinical decision support to disseminate and implement patient-centered outcomes research findings.

- document and complete its plans to ensure that multiple potential users, including the general public, have access to patient-centered outcomes research studies and their findings. As noted in our findings, these plans include creating a web page to list and provide users with links to existing publicly available databases that could be used to search for these studies. Complete plans would include time frames, strategies to address potential limitations, and whether the needs of various users are being met.

- continue to collaborate with NIH institutes and centers, and develop and document specific collaborations around patient-centered outcomes research dissemination activities. HHS stated that AHRQ has begun regular meetings with NIH—through its Office of Science Policy and the NIH Deputy Director for Science, Outreach, and Policy—to discuss how NIH's and AHRQ's activities can best complement one another.

Regarding our last recommendation, HHS stated that it intends, through ASPE, to further develop the road map by specifying milestones with corresponding time frames. HHS will also develop specific performance indicators for its portfolio of data capacity investments. Consistent with our findings and conclusions, HHS's comments also stated that its data capacity investments need to coincide with other key HHS policy initiatives and be responsive to the needs of CER data networks, including PCORI's PCORnet.

We are sending copies of this report to the Secretary of Health and Human Services, the Director of AHRQ, the Assistant Secretary for ASPE, and other interested parties. In addition, the report is also available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kohnl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

Linda T Kohn

Linda T. Kohn
Director, Health Care

List of Committees

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
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Committee on Finance
United States Senate

The Honorable Lamar Alexander
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The Honorable Patty Murray
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The Honorable Frank Pallone Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Paul Ryan
Chairman
The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: AHRQ's 74 CER Systematic Reviews Disseminated between June 2012 and June 2014

According to the Agency for Healthcare Research and Quality (AHRQ), it conducted 74 systematic reviews—syntheses of existing research—that were related to comparative clinical effectiveness research (CER) and resulted in findings disseminated between June 2012 and June 2014. Table 3 lists each systematic review with dates for each processing step leading up to posting the results of the review on AHRQ's website for the public. Based on GAO's analysis of the 74 systematic reviews, the time frame from when a systematic review began to when the findings were disseminated, including posting via AHRQ's website, ranged from 1 year to more than 4 years.

Table 3: The Agency for Healthcare Research and Quality's (AHRQ) 74 Comparative Clinical Effectiveness Research Systematic Reviews with Results Disseminated between June 2012 and June 2014

Systematic review topic	Date systematic review began	Date final product received by AHRQ	Website posting date
Abnormal uterine bleeding	July 5, 2011	October 19, 2012	March 21, 2013
Acute migraine	October 1, 2010	August 28, 2012	November 27, 2012
Alcohol misuse	December 9, 2010	March 16, 2012	July 10, 2012
Allergen immunotherapy	March 1, 2010	December 13, 2012	March 27, 2013
Antibiotic therapy	October 5, 2010	July 24, 2012	October 5, 2012
Antipsychotics adults	June 1, 2010	March 13, 2012	August 14, 2012
Atrial fibrillation treatment	October 30, 2011	March 27, 2013	June 28, 2013
Bariatric surgery	March 16, 2009	August 15, 2012	June 5, 2013
Breathing exercises for asthma	September 13, 2010	May 4, 2012	September 10, 2012
Cardiovascular risk factors for serious mental illness	June 22, 2011	November 20, 2012	April 22, 2013
Cerebral palsy feeding & nutrition	September 1, 2011	October 9, 2012	March 21, 2013
Child trauma maltreatment	April 14, 2011	September 21, 2012	April 15, 2013
Childhood trauma other than maltreatment	December 23, 2011	November 20, 2012	February 11, 2013
Childhood obesity prevention	February 15, 2011	January 30, 2013	June 10, 2013
Chronic cough	September 29, 2011	November 1, 2012	January 7, 2013
Chronic venous ulcers	November 2, 2011	July 9, 2013	December 13, 2013
Colorectal cancer	September 2, 2011	October 5, 2012	December 11, 2012
Complex care (case management)	October 15, 2010	October 26, 2012	January 7, 2013
Concomitant care	March 11, 2011	June 1, 2012	August 13, 2012
Crohn's disease	May 19, 2010	December 4, 2013	February 25, 2014
Cryptorchidism	April 1, 2011	September 20, 2012	December 11, 2012
C-section	January 2, 2011	August 1, 2012	October 22, 2012
Epoetin/Darbepoetin	April 1, 2009	December 31, 2012	April 25, 2013
Health care provider asthma guideline adherence	July 1, 2011	October 16, 2012	May 19, 2013
Heart failure	February 26, 2013	March 12, 2014	May 27, 2014
Hepatitis C screening	March 14, 2011	May 4, 2012	November 27, 2012
Hepatitis C adherence	June 2, 2011	October 1, 2012	December 20, 2012
Hepatitis C treatment	March 14, 2011	June 26, 2012	November 27, 2012
Hepatocellular carcinoma	September 2, 2011	January 29, 2013	May 24, 2013
Imaging techniques	March 28, 2011	November 20, 2012	February 26, 2013
Inguinal hernia	June 1, 2010	May 4, 2012	August 17, 2012
Insulin pump	September 15, 2010	January 4, 2012	July 10, 2012
Iron deficiency anemia	March 21, 2011	August 16, 2012	October 12, 2012
Lipids update	January 2, 2013	December 5, 2013	February 11, 2014

Systematic review topic	Date systematic review began	Date final product received by AHRQ	Website posting date
Long-term care	June 6, 2011	August 3, 2012	November 7, 2012
Lung cancer	September 22, 2011	December 20, 2012	June 12, 2013
Meditation	May 16, 2011	June 28, 2013	January 6, 2014
Migraine in adults	May 22, 2011	November 20, 2012	April 18, 2013
Migraine in children	May 22, 2011	November 20, 2012	June 11, 2013
Methicillin-resistant staphylococcus aureus screening	October 29, 2010	January 14, 2013	June 20, 2013
Natriuretic peptide	March 16, 2009	June 28, 2013	November 20, 2013
Nitrous oxide labor pain	December 15, 2010	April 12, 2012	August 23, 2012
Noninvasive positive-pressure ventilation for acute respiratory failure	February 9, 2011	May 3, 2012	July 11, 2012
Nursing homes	June 7, 2011	July 31, 2012	October 23, 2012
Oral mechanical bowel prep	October 16, 2012	January 14, 2014	April 30, 2014
Otitis media	April 15, 2011	February 28, 2013	May 4, 2013
Pediatric interventions for autism	January 2, 2011	March 20, 2012	August 27, 2012
Peripheral artery disease	October 14, 2011	February 28, 2013	May 29, 2013
Pharmacotherapy alcohol	December 14, 2012	April 14, 2014	May 13, 2014
Post acute traumatic brain injury	March 14, 2011	May 18, 2012	June 29, 2012
Postpartum depression screening	June 21, 2011	November 20, 2012	April 9, 2013
Preoperative testing	December 10, 2012	November 12, 2013	January 29, 2014
Pressure ulcer prevention	October 3, 2011	September 27, 2012	May 8, 2013
Pressure ulcer treatment	July 6, 2011	September 21, 2012	May 8, 2013
Prevention of post-traumatic stress disorder	November 7, 2011	November 30, 2012	April 2, 2013
Progestogens	September 1, 2009	May 31, 2012	September 7, 2012
Prostate cancer	May 11, 2011	October 25, 2012	April 1, 2013
Psoriasis	April 1, 2011	September 7, 2012	November 27, 2012
Physical therapy for knee pain	November 9, 2010	June 27, 2012	November 6, 2012
Post-traumatic stress disorder treatment	August 30, 2011	October 4, 2012	April 4, 2013
Pulmonary arterial hypertension	May 6, 2011	February 21, 2013	April 25, 2013
Restless leg	August 23, 2011	September 14, 2012	November 27, 2012
Seasonal allergic rhinitis	July 1, 2011	April 19, 2013	July 16, 2013
Serious mental illness	June 15, 2011	May 8, 2013	August 21, 2013
Serum free plasma	December 29, 2010	May 18, 2012	August 23, 2012
Smart pill	November 7, 2011	December 13, 2012	May 20, 2013
Stroke prevention in atrial fibrillation	October 24, 2011	June 19, 2013	August 23, 2013
Treatment for women with coronary artery disease	September 2, 2010	April 11, 2012	August 17, 2012
Treatment of tinnitus	May 1, 2011	May 22, 2013	August 23, 2013
Troponin (protein used to diagnose heart disease)	November15, 2012	April 14, 2014	August 12, 2014

Systematic review topic	Date systematic review began	Date final product received by AHRQ	Website posting date
Unstable angina	October 14, 2011	July 31, 2013	November 4, 2013
Urinary/kidney stones	August 9, 2010	February 10, 2012	July 26, 2012
Venous thromboembolism for special populations	April 1, 2011	January 31, 2013	May 29, 2013
Weight gain adults	February 1, 2011	October 25, 2012	March 25, 2013

Source: AHRQ. | GAO-15-280

Appendix II: ASPE's Comparative Effectiveness Infrastructure Projects (FY 2011-2014)

Project title	Project description	Amount obligated (dollars in millions)
CER Inventory	Create and develop • a centralized inventory of CER studies to serve as the foundation for a publicly accessible database of current publicly and privately funded CER projects, and related published policy and scientific literature. • algorithms to accurately identify and classify CER studies. • an improved web-based tool to provide a better understanding of the landscape of current CER activity to users. • a mechanism and plan to pilot test the tool prior to making it publicly accessible.	$1.7
Multi-Payer Claims Database Privacy and Security Enhancements	Enhancements to the existing database will • combine claims data from public and private sources, matching patient information as appropriate, as is necessary for cross-payer and longitudinal analysis. • pursue options to test the value of secure distributed data networks for research applications like CER.	$0.2
Chronic Condition Warehouse	• Ongoing pre-existing project to support CER through a research database that provides researchers with Medicare and Medicaid beneficiary claims and assessment data linked by beneficiary across the continuum of care. • Funded enhancements include expanding the amount of Medicaid data available and security enhancements.	$3.0
Development of Meaningful Use Standards for CER Data Elements: Structure Data Capture Initiative and National Library of Medicine Initiative[a]	• Collaboration between the Office of the National Coordinator for Health Information Technology and the National Library of Medicine to integrate clinical information and research information within a "template" that can be utilized by researchers.	$2.0
Strengthening and Expanding the Community Health Applied Research Network	• Expand the amount of data collected by a nationwide network of 19 community health centers and five research organizations in 10 states, which together collect CER-related data about patients in underserved communities.	$2.0
Expanding Data Collection for National Program of Cancer Registries for CER	• Build upon previous Centers for Disease Control and Prevention efforts by augmenting a publicly available dataset for CER with additional longitudinal follow-up data on disease recurrence and vital status for colon, rectum, and breast cancer cases. • Enhance software tools and methodology for management and consolidation of electronic data reported on a real-time basis from electronic health records to registries.	$2.6

GAO-15-280 Comparative Effectiveness Research

Project title	Project description	Amount obligated (dollars in millions)
Strategic Opportunities Project	• Identify concrete, strategic opportunities to contribute long term to building data infrastructure for CER, and help maximize the impact of the Patient-Centered Outcomes Research Trust Fund investments. • Assess the current landscape of data infrastructure for CER, identify gaps, and opportunities.	$1.5
Creating the Foundational Building Blocks for the Learning Health Care System: Structured Data Capture Initiative and Data Access Standards for Electronic Health Records[a]	• Develop, select, and validate standards for common data elements for use in CER and a template to collect data from electronic health records for research purposes. • Allow providers to access data in their own electronic health records in a standardized way to support CER. • Allow researchers outside of the organization who have remote access authorization to access an organization's electronic health record data for the purpose of CER.	$9.4

Source: GAO analysis of the Assistant Secretary for Planning and Evaluation's (ASPE) documentation. | GAO-15-280

[a]These projects have two initiatives under the same project description.

DEPARTMENT OF HEALTH & HUMAN SERVICES   OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

FEB 0 5 2015

Linda T. Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Comparative Effectiveness Research: HHS Needs to Strengthen Dissemination and Data-Capacity-Building Efforts" (GAO-15-280).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED: COMPARATIVE EFFECTIVENESS RESEARCH: HHS
NEEDS TO STRENGTHEN DISSEMINATION AND DATA-CAPACITY-BUILDING
EFFORTS (GAO-15-280)**

The U.S. Department of Health and Human Services (HHS) appreciates the Government
Accountability Office (GAO) for the opportunity to review and comment on this draft report.

GAO Recommendation 1
To help ensure that HHS fully addresses its dissemination requirements under Patient Protection
and Affordable Care Act (PPACA), we recommend that the Secretary of HHS direct the Agency
for Healthcare Research and Quality (AHRQ) to take the following actions: (1) Identify and
document time frames for the implementation and distribution of marketing plans and
informational tools.

HHS Response 1
HHS concurs with GAO's recommendation. HHS will continue to implement and distribute
marketing plans and informational tools that more fully identify and document time frames for
these activities. Generally, HHS develops marketing plans as findings, products, and
informational tools are delivered. HHS will ensure that starting and ending time frames for the
implementation and distribution of Patient-Centered Outcomes Research (PCOR) findings are
clearly specified and documented going forward.

GAO Recommendation 2
To help ensure that HHS fully addresses its dissemination requirements under PPACA, we
recommend that the Secretary of HHS direct AHRQ to take the following actions: (2) Expand
dissemination efforts to federal and private health plans and vendors of health information
technology focused on clinical decision support;

HHS Response 2
HHS concurs with GAO's recommendation. HHS will continue and expand dissemination
activities that target Federal and private health insurance plans and vendors of health information
technology focused on clinical decision support. Marketing plans have included working with
stakeholders and intermediaries, especially business groups, to produce translational products for
these audiences based on PCOR findings. HHS recently issued notice of intent fund a
demonstration grant in FY 2015 (http://grants.nih.gov/grants/guide/notice-files/NOT-HS-15-
002.html.) This funding opportunity announcement will be part of a large initiative focusing on
the use of clinical decision support to disseminate and implement PCOR findings. As stated in
the notice of intent, this work will include active engagement of vendors of health information
technology focused on clinical decision support.

GAO Recommendation 3
To help ensure that HHS fully addresses its dissemination requirements under PPACA, we
recommend that the Secretary of HHS direct AHRQ to take the following actions: (3) Document
and complete plans to develop a publicly available database, including plans to meet the needs of
various potential users in the general public; and

HHS Response 3
HHS concurs with GAO's recommendation. HHS will document and complete its plans to
ensure that multiple potential users including the general public have access to PCOR studies and

1

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their findings. The planned approach is described in this report and is based on providing access
to information that already exists, as opposed to creating a new database, which would
potentially duplicate those existing resources.

GAO Recommendation 4
To help ensure that HHS fully addresses its dissemination requirements under PPACA, we
recommend that the Secretary of HHS direct AHRQ to take the following actions: (4) Develop
specific plans on how it will collaborate with the National Institutes of Health (NIH) on its
dissemination activities.

HHS Response 4
HHS concurs with GAO's recommendation. AHRQ will continue to collaborate with NIH
Institutes and Centers (IC) regarding dissemination activities. AHRQ has begun regular
meetings with NIH through their Office of Science Policy and the NIH Deputy Director for
Science, Outreach, and Policy to discuss how NIH's and AHRQ's activities can best complement
one another's. AHRQ and NIH will continue to meet regularly and will develop and document
specific collaborations around dissemination of PCOR. NIH has expressed that it looks forward
to continuing its collaborations with AHRQ in support of its dissemination activities, providing
consultations through NIH leadership and IC subject matter experts to enhance these important
activities as mandated under the Affordable Care Act.

GAO Recommendation 5
The Secretary should direct the Assistant Secretary for Planning and Evaluation to include
clearly defined objectives, milestones, and time frames, or other indicators of performance, in its
strategic road map that is used to identify its Patient-Centered Outcomes Research Trust Fund
projects.

HHS Response 5
HHS concurs with GAO's recommendation. HHS has completed significant, initial steps toward
development of its strategic roadmap for building data capacity for comparative effectiveness
research (CER). These initial steps include achieving agreement with respect to:

- The overarching vision, goal, and guiding principles (see Appendix) that shaped
  development of the roadmap; and
- The roadmap's strategic framework, which includes specification of the types of
  components HHS will invest in as well as five, high priority functionalities (see Appendix)
  that need to be further enabled. Enabling each of these five, high priority functionalities is a
  high-level objective HHS has set in order to achieve the overarching goal for this effort.

HHS will also develop specific timelines for achieving milestones related to these high priority
functionalities although elements of this activity will take several months to complete.
Considerations include:

2

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- HHS data capacity investments need to coincide with other key HHS policy initiatives such as the Office of the National Coordinator for Health Information Technology's *Shared Nationwide Interoperability Roadmap.*
- HHS data capacity investments must be responsive to the needs of comparative effectiveness research (CER) networks and a key CER network— Patient-Centered Outcomes Research Institute's (PCORI) PCORnet—has only recently been developed. During the first phase of PCORnet (ending September 2015), HHS will have learned more about the requirements of distributed research networks—requirements that the HHS roadmap to build data capacity will need to reflect.

HHS will develop specific performance indicators for its portfolio of data capacity investments in concert with the inputs described above. HHS fully intends to further roadmap development by specifying milestones with corresponding timeframes. HHS also intends to develop specific performance indicators. As described in this report, HHS will develop an evaluation whose outputs will include specification of performance indicators. The proposal for this work is currently under development.

Appendix

The vision that guides HHS work to build data capacity for comparative effectiveness research (CER) is depicted in Figure 1. This vision displays various participants in the health care system, including patients, providers, and researchers, all sharing information seamlessly from different distributed sources in a single "virtual" network. The boxes (labeled A-F) depict a set of potential interoperable data resources that will be available within the PCOR infrastructure. The arrows depict the information flows between those data sources that enable a learning process (box D), the results of which are then disseminated back into the health system and to patients. Examples of information flows include the extraction of clinical data from EHRs and the contribution of patient-generated data to the health system and learning process.

Figure 1. The Vision for the CER Data Infrastructure
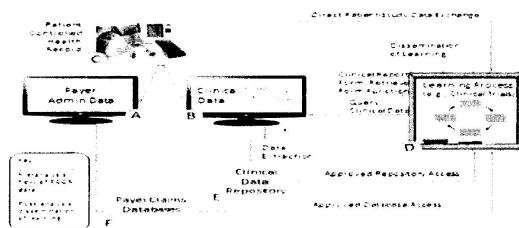
HHS builds data capacity for CER with the following goal in mind:

3

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<u>**Goal:**</u> To enable a comprehensive, interoperable, and sustainable data network infrastructure to
collect, link, and analyze data from multiple sources to facilitate comparative effectiveness
research.

The **purpose of HHS' strategic roadmap** is to identify a cohesive set of investment
opportunities through FY 2019 for enabling incremental development of the data infrastructure
described in the above goal.

HHS has adopted the following **guiding principles** in determining investments:
- Leverage unique federal assets
- Be sustainable
- Strategically build on other investments
- Be non-duplicative of other related Federal and non-Federal investments
- Synergize with PCORI and AHRQ
- Enable the engagement of all populations in research, including safety-net populations.

HHS has also adopted a strategic framework to guide its investments outlined in Figure 2.

Figure 2. The Roadmap's Strategic Framework
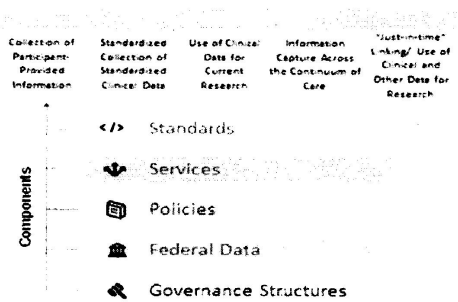
HHS data infrastructure investments are to address the collection, linkage and analysis of data
by further enabling the five functionalities noted in Figure 2: collection of participant provided
data; standardized collection of standardized clinical data; use of clinical data for current
research; information capture across the continuum of care; and "just-in-time" linking/use of
clinical and other data for research. HHS intends to enable these five high-priority
functionalities by investing in the requisite components presented in Figure 2: Standards;
Services; Policies; Federal Data; and Governance Structures.

4

GAO Contact

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Staff Acknowledgments

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