

HHS Projects to Build Data Capacity for Patient-Centered Outcomes Research: Completed Projects FY 2010 through FY 2015

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*Completed Projects
Report*

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I. Executive Summary

The purpose of this document is to provide a summary of projects that were funded through the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) and completed between fiscal years (FY) 2010 and 2015. Over this period, eight projects in the OS-PCORTF portfolio were completed. Together, these projects aligned robustly with the five ‘functionalities’ that operationalize the statutory mandate to build capacity to collect, link and analyze data for research.

In this report, descriptions of the completed projects are intended to solidify how the foundational work of the portfolio’s earliest years enables the more complex multi-agency projects that are being undertaken in subsequent years. Furthermore, the report shows where the projects address the five data ‘functionalities’ that support collecting, linking and analyzing data. Finally, synopses of each of the projects provide additional information about the projects, including achievements such as publications and related resources.

The body of completed work, along with the currently active projects, is unique among the Department’s health data infrastructures in its focus on building capacity for patient-centered outcomes research using registries, research networks, and electronic health records. This singular focus, although developed for use in comparative clinical effectiveness and patient-centered outcomes research, provides a rich resource—along with links to other Departmental program assets—for future research to address evolving health care questions affecting the nation’s health.

II. Background

Agencies in the Department of Health and Human Services (HHS) routinely collect, link, and analyze data that can be used to generate new scientific knowledge about Federal programs and the patient populations these programs serve. These data are foundational to research that expands knowledge about the outcomes and effectiveness of health care treatments and interventions. As a consumer, producer, and regulator of key national health data, HHS is uniquely positioned to coordinate its programs to build national data capacity in support of the mission, statutory authorities, and annual priorities of each HHS agency and the Department as a whole. Coordination of efforts to build data capacity across HHS strengthens its research, analyses, and public reporting programs while simultaneously reducing unnecessary duplication, inefficiencies, and reporting burdens on patients or health care providers. HHS agencies have common and converging needs for high quality, timely data that enable independent researchers and government analysts to collaborate and conduct studies quicker, more accurately, and at a lower cost.

Early in the 21st century, the need for data on patient-centered outcomes was gaining recognition. In 2010, the Patient Protection and Affordable Care Act’s (Affordable Care Act) Section 6301, Patient-Centered Outcomes Research, amended Title XI of the Social Security Act and Title IX of the Public Health Service (PHS) Act. One result of these amendments to the PHS Act is a mandate, under Section 937(f), to build data capacity for comparative clinical effectiveness research (CER). On September 26, 2014, the Secretary delegated the authority for Office of the

Secretary for Planning and Evaluation (ASPE) to carry out the activities described in Section 937(f).

The delegation of authority tasked ASPE with the following responsibilities:

- Develop and maintain a strategic plan for implementation of the activities to carry out the statutory mandate (see below);
- Lead Department-wide leadership and staff groups to carry out the activities; including obtaining input to develop a strategic plan and working on specific activities to achieve the goals of the statutory provision;
- Manage the financial responsibilities associated with implementing the activities; and
- Monitor progress on activities.

This mandate has been carried out under the auspices of the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS PCORTF).

The purpose of this document is to provide a summary of the OS PCORTF portfolio of projects that were completed between fiscal years (FY) 2010 and 2015. The document describes the work accomplished; presents a chronological description of the projects; summarizes them in relation to the five functionalities of the conceptual framework; and shows how each contributed to addressing the statutory mandate to build data capacity for research.

III. Background

Since its inception, the OS PCORTF has continued to coordinate and fund projects across the Department to help build data capacity for CER and/or patient-centered outcomes research (PCOR). The initial activities, undertaken in the first years beginning with FY 2012, focused on the seminal work proposed by the Department's agencies to address Department-wide CER issues and to focus on the basic foundations of building data capacity. Over time, the CER focus evolved primarily into the broader PCOR focus. One project, awarded in Fiscal Year (FY) 2013,¹ culminated in the development of a framework for the OS PCORTF data network which was responsive to the mandate of Section 937(f) of the PHS Act and consistent with ongoing activities reflecting the Department-wide identified issues for the conduct of PCOR. Section 937(f) mandated that:

The Secretary shall 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. (PHS Act, Title IX, §937(f))

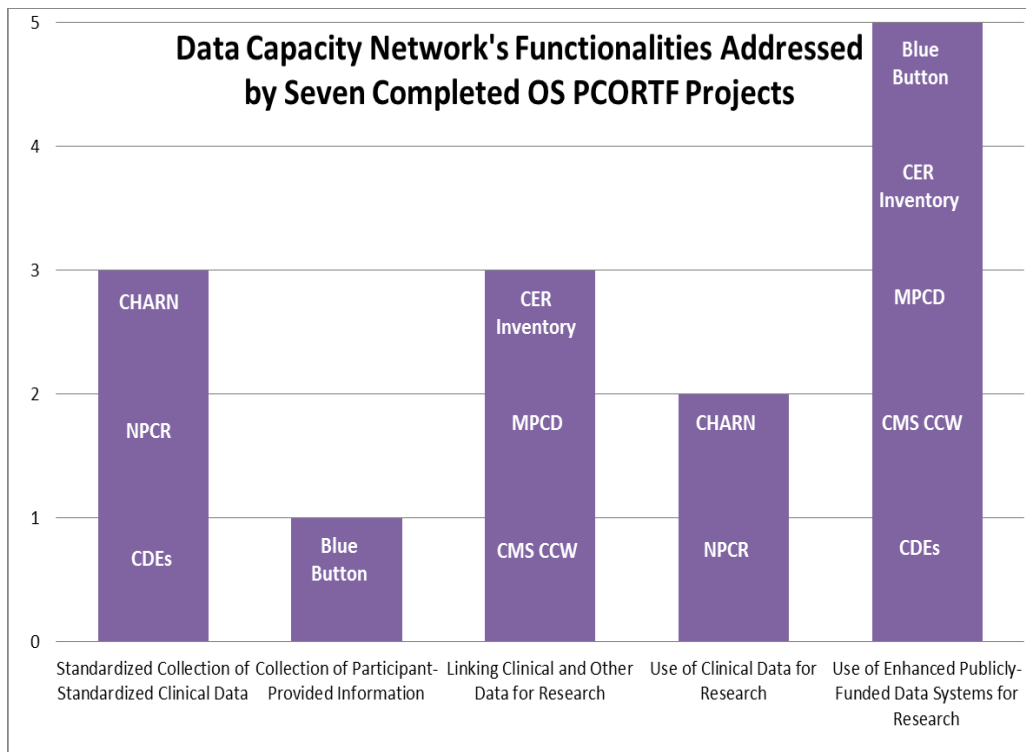
¹ HHS Strategic Roadmap for Building Data Capacity for Clinical Comparative Effectiveness Research (CER). DRAFT.

Simultaneously, the task was to develop data capacity that was conceptually substantive yet sufficiently flexible to accommodate both current and envisioned needs for PCOR. The framework contains five strong pillars, known as ‘functionalities.’ In essence, the five functionalities operationalize facets of an interoperable data network to collect, link and analyze data on outcomes and effectiveness from multiple sources. These functionalities and their contribution to PCOR, presented in the collecting-linking-analyzing paradigm of the statute, are:

- Standardized Collection of Standardized Clinical Data: Researchers will be able to use standardized clinical data based on common data element standards across research projects and networks, thereby facilitating linkage and aggregation of data across data sources;
- Collection of Participant-Provided Information: Participants, including those in safety net organizations, will be able to participate more fully in clinical research by directly providing information (i.e., data points provided by the participant such as patient reported outcomes or PROs);
- Linking of Clinical and Other Data for Research: Researchers will be able to follow patients across the care continuum over time, including those enrolled in clinical trials. Researchers will be able to capture the range of variables influencing health outcomes, and link clinical and other types of data (e.g., other clinical data, claims data, participant-provided information, and environmental data) required for research regardless of where the participant goes;
- Use of Clinical and Other Data for Research: Researchers will be able to utilize and analyze routinely collected clinical data for implementation of clinical studies (observational and interventional) including data relevant to assessing safety, efficacy and adherence, as well as genetic data and PROs; and
- Use of Enhanced Publicly-Funded Data Systems for Research: Researchers will be able to readily use, retrieve, link and aggregate publicly-funded data for research due to enhancements in publicly-funded data systems.

Essentially, these five functionalities are part of the strategic framework that operationalizes the statutory mandate. The functionalities are categories within collecting, linking and analyzing data which provide structure for research. Projects categorized under *Standardized Collection of Standardized Clinical Data* and *Collection of Participant-Provided Information* help to operationalize collecting data for research. Projects connecting data from different agencies or unconnected sources fall into the categories of *Linking of Clinical and Other Data for Research*. Finally, *Use of Clinical and Other Data for Research* and *Use of Enhanced Publicly-Funded Data Systems for Research* include projects that utilize the Department’s resources for conducting comparative clinical effectiveness and/or patient-centered outcomes research.

Table 1. Data Capacity Network’s Functionalities Addressed by Seven Completed OS PCORTF Projects



Between FY 2012 and FY 2015, eight projects were completed. These projects involved twelve separate awards. Six awards were single-agency projects; one project involved two consecutive awards (CCW in graph above); and another project (CDEs in graph above) was conducted jointly by two agencies over two years with each agency receiving an award each year. One of these projects, known as the Strategic Opportunities Project or SOP, provided support for development of the framework and is not depicted in Figure 1 above. All eleven other awards were dedicated to developing aspects of the interoperable data capacity network.

IV. Completed OS PCORTF Projects, FY 2012 through FY 2015

An overview of the completed projects follows. Fuller descriptions of each project are located in Appendix A.

Completed FY 2012 Projects

The OS PCORTF first projects that were awarded in fiscal year (FY) 2012 and 2013 were not synchronous with the framework, yet were compatible with two of the functionalities each. Of note, within the OS PCORTF, three of the projects were directed at developmental activities.

These focused on identifying strategic opportunities,² developing and conducting a formative and summative evaluation,³ and providing support and assistance to the OS PCORTF staff and awardees.⁴ The project identifying strategic opportunities is the only one of these three that is complete to date.

The first set of the seven completed projects to initiate the task of building the data capacity was awarded in FY 2012. Four projects were awarded, the first of which—in chronological order—was a multi-agency project that began developing the infrastructure for use of electronic health records in comparative effectiveness research. The second project continued work begun in response to Section 723 of the Medicare Modernization Act of 2003 (MMA) to improve the quality of care and reduce the cost of care for chronically ill Medicare beneficiaries. The third and fourth extended activities initiated under the American Recovery and Reinvestment Act (ARRA) and focused on CER/PCOR. The projects are described in chronological order by and within the fiscal year of award. No projects were awarded prior to FY 2012.

Development of Data Infrastructure for Use of EHRs in Comparative Effectiveness Research (ONC/NLM CDEs)

The first OS PCORTF project funded in FY 2012 began the Development of Data Infrastructure for Use of EHRs in Comparative Effectiveness Research in its first award, and in FY 2013, added Development of Meaningful Use (MU) Standards for CER Data Elements to the title and scope of its second award. The second award was essentially a continuation of the first with the added MU expansion. Taken together, the two phases of the project addressed four overall goals. The goals were to support CER by:

- 1) selecting and requiring the use of health information technology (IT) standards-based common data elements (CDEs);
- 2) developing and validating a health IT standards-based extensible electronic case report form (eCRF) to be used in electronic health records (EHRs);
- 3) enhancing health IT standards infrastructure to support effective maintenance, distribution, and use of the definitions of CDEs and patient assessment instruments, with particular emphasis on the standard terminology value sets required to define them; and
- 4) establishing the standards, services and policies that would integrate PCOR activities into the clinical health IT.

This project was conducted jointly by the Office of the National Coordinator for Health Information Technology (ONC) and the National Institutes of Health's National Library of Medicine (NIH/NLM or NLM). This project has continued to be built upon to address various other OS PCORTF projects. The project addressed the functionalities of Standardized Collection of Standardized Clinical Data, and Use of Enhanced Publicly-Funded Data Systems for Research.

Maintenance and Support of the Chronic Conditions Warehouse (CCW) for Comparative Effectiveness Research

² Strategic Opportunities for Building a Patient-Centered Outcomes Research Data Infrastructure (FY 2013 – 2015).

³ OS PCORTF Evaluation (FY 2015 – 2017).

⁴ Patient-Centered Outcomes Research Resource Center for Data Infrastructure (FY 2016 – 2019).

The second project was associated with the MMA and had two foci. One focus was the Maintenance and Support of the Chronic Conditions Warehouse (CCW) for Comparative Effectiveness Research. This entailed continuing maintenance and licensing and support for CER enhancements to the CCW hardware and software, and support to researchers in building their analytic files. The project also created and funded 19 user 'seats' in the Virtual Research Data Center (VRDC) for researchers to conduct their approved studies. These two activities were supported from FY 2012 through FY 2013. The data capacity network functionalities addressed by this project were Linking Clinical and Other Data for Research and Use of Enhanced Publically-Funded Data Systems for Research.

Beta Testing the Multi-Payer Claims Database (MPCD)

The third, an ARRA-affiliated project, was Beta Testing of the Multi-Payer Claims Database (MPCD). The objectives of the work funded by the PCORTF were threefold: 1) modify the MPCD web portal home page in preparation for conducting beta-testing of the MPCD; 2) conduct three CER analyses on the beta release of the MPCD; and 3) evaluate beta testers' experiences requesting and using data from the MPCD. The project was successful in achieving the key objectives of building a pilot database and having it evaluated by a substantial number of researchers with many of their studies coming to fruition in the form of presentations, publications, and even a thesis. The beta testers provided a wide range of suggestions and feedback on how the resource could be improved, which was sometimes reflective of their prior experience working with claims data. The primary data network functionalities addressed by project were Linking Clinical and Other Data for Research and Use of Enhanced Publically-Funded Data Systems for Research.

Comparative Effectiveness Research (CER) Inventory

The last FY 2012 project, the CER Inventory, was also formerly an ARRA project. OS PCORTF support was initially intended to ensure continued maintenance, updating, and transition of the CER Inventory over the next year as a key component of the data capacity network. During the course of this work, it became evident that there were some inherited challenges to the Inventory. As a result, the project was modified and refocused on conducting a benchmarking exercise and developing a report on Lessons Learned. The CER Inventory addressed two functionalities: Linking of Clinical and Other Data for Research, and Use of Enhanced Publicly-Funded Data Systems for Research. The Agency for Healthcare Research and Quality (AHRQ) now hosts a Web-library for PCOR, the Library of PCOR Resources.

Completed FY 2013 Project

In FY 2013, one new project was awarded and is now complete: Expanding Data Collection for the National Program of Cancer Registries (NPCR) for Comparative Effectiveness Research.

Two of the FY 2012 projects received a second phase of funding in FY 2013. The work undertaken with the FY 2013 award was included descriptions above. The two completed projects were the CMS CCW and the ONC/NLM CDEs.

In FY 2013, the project Strategic Opportunities for Building Data Infrastructure for Comparative Effectiveness Research was also awarded and is now complete. This project did not directly conduct work that built the data infrastructure, but, in collaboration with ASPE, developed a strategy for maximizing the impact of the OS PCORTF in building a comprehensive, interoperable and sustainable PCOR data capacity network. A description of this project is in Appendix B.

Expanding Data Collection for the National Program of Cancer Registries (NPCR)

To support CER, the newly-awarded Expanding Data Collection for the National Program of Cancer Registries (NPCR) project focused on enhancing cancer registries in 10 States to report standardized patient outcome data items to CDC's national cancer surveillance system. In addition, it expanded EHR reporting to central cancer registries for CER. Enhancing specialized cancer registries entailed extending and continuing longitudinal follow-up of colon, rectum and breast cancer patients to assess vital status, disease recurrence, disease progression, and additional type of treatment for a year. By the end of the project, the data set included an average follow-up of over three years, which was submitted to CDC to provide for researchers through CDC's National Center for Health Statistics' (NCHS) Research Data Center (RDC).

Expanding EHR reporting addressed the CMS and ONC Final Rule for Stage 2 MU. The goal of the project was to build the infrastructure and capability for state cancer registries to receive, process, and utilize EHR data in support of CER activities. To accomplish this, it was necessary to develop a new consolidation process and software tools for consolidating data from EHRs into the central cancer registry data system. The NPCR addressed the two functionalities, Standardized Collection of Standardized Clinical Data, and Use of Clinical Data for Research.

Completed FY 2014 Project

Strengthening and Expanding the Community Health Applied Research Network (CHARN)

In FY 2014, the OS PCORTF provided funding to the Health Resources & Services Administration's (HRSA) Community Health Applied Research Network (CHARN) project. CHARN was initially created as an infrastructure with the capacity to pool the experiences of patients across different sites to build research capacity and infrastructure across a national network of community health centers (CHCs) and to carry out PCOR, ultimately leading to improved patient care and outcomes.

CHARN is a safety net community, practice-based network, comprised of four nodes and one data coordinating center. The nodes are coalitions of health centers—both community health centers and HIV clinics—and an affiliated academic center. At the outset, data covered calendar years 2008 through 2010, and included demographic and insurance data on the total CHARN population as well as diagnosis, laboratory, and medication data on patients with six health conditions: cardiovascular disease; diabetes; dyslipidemia; hypertension; hepatitis A and B; and AIDS and AIDS-related conditions.

The OS PCORTF CHARN project had four aims: 1) expand and enhance the centralized CHARN data warehouse (CDW), adding new data elements and covering more time; 2) build capacity for collaborative research within and among participating health centers that encouraged, engaged, and supported the participation of health center clinicians and investigators in all phases of research; 3) create a de-identified analytic file and associated codebook that are usable and available to researchers outside the CHARN network; and 4) develop and implement a process to broaden access to CHARN data and infrastructure so that researchers outside of CHARN could gain access to the data, thereby enhancing the value of the national infrastructure and maximizing the use of data. The network represents more than 1,000,000 diverse safety net patients across nine (9) States. CHARN addressed two functionalities, the Standardized Collection of Standardized Clinical Data, and Use of Clinical Data for Research.

Completed FY 2015 Project

Improving Beneficiary Access to Health Information: A Plan to Enhance “Blue Button”

The Blue Button symbol signifies functionality for patients to go online and download their health records. CMS established a Blue Button service in 2010 to give Medicare beneficiaries access to their Parts A and B claims and Part D event data. However, the initial Blue Button service has limited functionality and scalability because it only allowed Medicare beneficiaries to download their data in text or PDF form, limiting beneficiaries’ ability to use and share their health information.

This OS PCORTF project developed a plan to redesign the CMS Blue Button to include a developer-friendly, standards-based Application Programming Interface (API) that enables beneficiaries to connect their Medicare claims data to the applications, services, and research programs they trust. The functionalities addressed by the CMS Blue Button project were Collection of Participant-Provided Information, and Use of Enhanced Publicly-Funded Data Systems for Research.

V. Evolution of the Interoperable Data Capacity Network’s Five Functionalities

This section is organized in the order of the five functionalities depicted in the graph above. The descriptions highlight which aspects of each project address a specific functionality. Each of the seven completed data capacity-building projects addressed two functionalities. The number of projects addressing each of the functionalities ranged between one and five, as evident on the graph above.

Standardized Collection of Standardized Data

The first functionality, Standardized Collection of Standardized Clinical Data, is interpreted to mean the ability to use standardized clinical data, based on common data element standards, across research projects and networks, thereby facilitating linkage and aggregation of data across data sources. Three projects fall into this category. The first is the CDE and eCRF work of ONC and NIH/NLM. The work of this project laid the foundation for the standardized collection, i.e., eCRFs, of standardized clinical data, i.e., CDEs.

Although the two other completed projects associated with this functionality, NPCR and CHARN, were not conducted in sufficient chronological order with the ONC and NIH/NLM project to: 1) merit rigorous compliance with the definition of this functionality; or 2) build upon the work of ONC and NIH/NLM, the inherent standards and content of the NPCR and CHARN projects to enhance their databases warrant their inclusion/consideration in this category of functionalities.

Development of Data Infrastructure for Use of EHRs in Comparative Effectiveness Research (ONC/NLM CDEs)

The CDE project of ONC and NLM was developed to standardize the collection of standard data with its focus on creating standardized terms for the collection and exchange of data, i.e., CDEs. For the eCRFS, the project developed the standards for the eCRF structure/template as well as the CDEs that were used with them. These forms were ‘extensible forms’ which means that they were developed in a high-level computer language. This computer language facilitates defining the form as a single, stand-alone object. Taken together, these two ONC/NLM CDE products make evident that the project fits the functionality of Standardized Collection of Standardized Data.

Expanding Data Collection for the National Program of Cancer Registries (NPCR)

The NPCR is a national program administered by CDC that supports state health departments in 45 states, DC, Puerto Rico, and U.S. Pacific Island Jurisdictions to collect data about cancer cases and cancer deaths for 96% of the U.S. population. The OS PCORTF project focused on enhancing the capacity of 10 NPCR registries to expand the treatment and patient outcome data reported to CDC’s national cancer surveillance system for breast, colon and rectum cancers. In addition, the project developed tools for use when reporting EHR data to the central cancer registries for CER at the CDC/NCHS RDC. The process of aggregating State registries into a single, national, centralized dataset for research purposes supports the inclusion of NPCR in the functionality, Standardized Collection of Standardized Clinical Data.

Strengthening and Expanding the Community Health Applied Research Network (CHARN)

CHARN is a practice-based research network of Federally-funded community health centers (CHCs) with four community research nodes, each with several affiliated safety-net CHCs and an academic center. CHARN was created to develop an infrastructure that had the capacity to pool patient experiences across different sites to conduct CER observational and interventional studies. Because Federally-funded CHCs serve a particularly vulnerable population of low-income and otherwise diverse individuals, they constitute a unique cohort within the larger population of recipients of health care.

To standardize data collection/reporting and facilitate data use across the CHARN networks, protocols for data collection, extraction, encryption, and validation were developed along with a data access plan. CHARN utilized the OS PCORTF funds to include clinical encounters for all patients and all conditions seen at the CHCs during the consecutive calendar years 2006-2013 in the CHARN data warehouse (CDW). The CDW also included patient vital signs and smoking status. In addition to the CDW, a de-identified analytic file and associated data codebook were developed to support the use of CHARN analytic files by other researchers outside of the CHARN network. Taken together, CHARN’s developmental process, structure and supportive

documents, support the inclusion of CHARN as a standardized collection of standardized clinical data.

Collection of Participant-Provided Information

One of the completed projects addressed the functionality, Collection of Participant-Provided Information. This functionality is defined as participants, including those in safety net organizations, being able to participate more fully in clinical research by directly providing information.

Improving Beneficiary Access to Health Information: A Plan to Enhance “Blue Button”

The CMS project addressing this functionality, Improving Beneficiary Access to Health Information: A Plan to Enhance ‘Blue Button’, developed a plan to redesign and improve the CMS Blue Button, including an implementation strategy and roadmap for a Data-As-a-Service platform for PCOR. The project addressed limitations that made it difficult for Medicare beneficiaries to use and share their health information.

CMS has a website for patients/beneficiaries to use to gain access to their Blue Button health information (<https://www.mymedicare.gov/>). This website has a sign and icon to download the individual’s Blue Button data, after creating an account. Patients/beneficiaries can provide additional data and can choose to share it. These capabilities fit the definition of the functionality, Collection of Participant-Provided Information.

Linking Clinical and Other Data for Research

The functionality, Linking Clinical and Other Data for Research, as defined in the strategic roadmap, means that researchers will be able to follow patients across the care continuum over time, including those enrolled in clinical trials. Researchers will be able to capture the range of variables influencing health outcomes, and link clinical and other types of data (e.g., other clinical data, claims data, participant-provided information, and environmental data) required for research regardless of where the participant goes. Three early projects addressed this functionality: CMS CCW, MPCD, and CER Inventory.

Maintenance and Support of the Chronic Conditions Warehouse (CCW) for Comparative Effectiveness Research

The CMS CCW provides researchers with Medicare and Medicaid beneficiary, claims, and assessment data. The CCW data is linked by a unique beneficiary key, permitting researchers to analyze data across the continuum of care in Medicare and Medicaid administrative data.⁵ The OS PCORTF project provided maintenance and support for the CCW database and analytic files as well as provided one year funding to support 15 PCOR focused research studies conducted via the CMS VRDC. Approved researchers using Medicare and Medicaid data may be permitted to link clinical and other data to address their studies’ hypotheses.

⁵ Information retrieved on March 6, 2017 from: <https://www.ccwdata.org/web/guest/about-ccw>

Of the three OS PCORTF projects under this functionality, one, the CER Inventory, has been superseded by the Agency for Healthcare Research and Quality's Library of PCOR Resources (<https://www.ahrq.gov/pcor/library-of-resources/index.html>⁷). The CMS CCW continues to make research data available for approved PCOR focused projects.

Beta Testing the Multi-Payer Claims Database (MPCD)

The MPCD brought together a longitudinal individual-level database of composed of multi-year claims data from private and public sector payers. The OS PCORTF project funded three CER analyses of patient outcomes of three clinical interventions/treatments, the addition of a web portal home page in preparation for conducting beta-testing of the MPCD, and an assessment of beta testers' (researchers) experiences applying for customized data extracts through the web portal and working with project staff, having data extracts transmitted to them, and their initial impressions working with the data. This pilot project provided these beta testers with the ability to address questions using a unique database that differed from previous research. The beta test evaluated the value of merging patient-matched, de-identified data from public and private payers for CER involving alternative treatment strategies and health care delivery system designs. Results of the beta test found that the MPCD project team was successful in achieving the key objectives of building a pilot database. The report then addressed identified issues related to usability and user-friendliness of the MPCD and made recommendations. This project attested to the capacity and value of linking claims data from private and public payers.

Comparative Effectiveness Research (CER) Inventory

The purpose of the CER Inventory was to optimize coordination and reduce duplication of CER research. The CER Inventory was based on five classifications, among which were medical conditions, populations, and types of interventions. These five categories provided the array of data linked into the CER Inventory to be used as a reference for developing PCOR studies. The information contained in the CER Inventory was planned to stimulate linkages of clinical with other data for new research.

Use of Clinical and Other Data for Research

Two OS PCORTF projects addressed the functionality, Use of Clinical Data for Research. This functionality is defined as researchers being able to utilize and analyze routinely collected clinical data for implementation of clinical studies (observational and interventional) including data relevant to assessing safety, efficacy and adherence, as well as genetic data and patient-reported outcomes (PROs). The projects are the CDC's NPCR and CHARN.

⁶ Retrieved on March 6, 2017.

⁷ Retrieved on March 6, 2017.

Expanding Data Collection for the National Program of Cancer Registries (NPCR)

The CDC's NPCR focused on three activities to enhance the cancer registries and expand data collection for active assessment or recurrence, progression and vital status of breast, colon, and rectum cancers and to expand EHR reporting to central cancer registries for CER. The activities included: expanding specialized cancer registries by extending and continuing longitudinal follow-up; enhancing specialized cancer registries to allow active follow-up of cancer patients to identify progression and recurrence of breast, colon, and rectal cancer; and creating tools that facilitate expanded EHR reporting to central cancer registries for CER.

The specific purpose of the OS PCORTF project was to support CER. In doing so, the major activity was to expand the collection of clinical data. Taken together, these two foci address the definition of the functionality, Use of Clinical Data and Other Data for Research.

Strengthening and Expanding the Community Health Applied Research Network (CHARN)

HRSA's CHARN project, Strengthening and Expanding Community Health Applied Research Network, was designed to maintain, strengthen, and leverage the CHARN infrastructure for the sake of advancing research and analysis to improve quality, outcomes, and disparities in underserved communities. As described above, the four activities that were undertaken enable researchers to utilize and analyze routinely clinical data in clinical studies. CHARN has generated a considerable body of clinical research and can be considered as addressing the functionality, Use of Clinical Data and Other Data for Research.

The number of publications from these two recently completed projects demonstrates the implementation of the functionality, Use of Clinical Data and Other Data for Research.

Use of Enhanced Publicly-Funded Data Systems for Research

Five projects addressed the functionality, Use of Publicly-Funded Data Systems for Research. Four of them addressed one of the functionalities described above as well. This functionality can be understood to mean that researchers will be able to readily use, retrieve, link and aggregate publicly-funded data for research due to enhancements in publicly-funded data systems.

Development of Data Infrastructure for Use of EHRs in Comparative Effectiveness Research (ONC/NLM CDEs)

First, the joint project of ONC and NIH/NLM conducted seminal work toward the use of publicly-funded data systems for research. Activities involved developing an infrastructure to facilitate the use of EHRs in CER. This project initiated the development and use of health information technology (health IT) standards-based CDEs; provided the foundation for development and validation of health IT standards-based eCRF for use in EHRs; and an enhanced health IT standards infrastructure to support effective maintenance, distribution and

use of the CDEs and eCRFs. These activities enhanced publicly funded data to assist data systems become available for research.

Maintenance and Support of the Chronic Conditions Warehouse (CCW) for Comparative Effectiveness Research

The second project is the CMS CCW. The CCW contains Medicare and Medicaid data and makes these data available for approved research studies. The OS PCORTF funded 15 approved studies and 19 VRDC ‘seats’ were granted to the researchers associated with the studies. Examples of the published articles resulting from the research are located in Appendix A. The enhancement provided by the CCW is the individualized attention and support in setting up the CCW data files for each researcher’s analyses.

Beta Testing the Multi-Payer Claims Database (MPCD)

The third of the five projects is the MPCD. The MPCD was publicly-funded, originally by ARRA and supplemented by the OS PCORTF to conduct a beta test to assess the functionality of the project’s web portal and the value of the MPCD’s claims data from public and private payers to facilitate CER. Beta testers included both researchers from Federal agencies as well as Universities and the study’s contractor. The purpose of the overall MPCD project was to enhance publicly funded data systems for research and the Beta test assessed the MPCD.

Comparative Effectiveness Research (CER) Inventory

The CER Inventory is the fourth project addressing this functionality, Use of Enhanced Publicly-Funded Data Systems for Research. The CER Inventory consisted of Federal and non-Federal CER activities that were classified and catalogued through a web-based tool for inventorying Federal and non-Federal outputs and activity. The OS PCORTF contribution to the CER Inventory was to ensure its continued development and included user testing, a benchmarking exercise, and plans to migrate the inventory to a government domain. The structure of the classification and cataloguing, and search methods for CER addressed the functionality, Use of Enhanced Publicly-Funded Data Systems for Research.

Improving Beneficiary Access to Health Information: A Plan to Enhance “Blue Button”

Fifth, the Blue Button project laid the foundation for enhancements to the Medicare beneficiaries’ access to their personal health information. This information includes: current medications; medical treatments, laboratory tests; and health insurance claims information. It was intended to promote use with other Federal health data systems.

VI. Overview of Completed Projects' Contribution to Interoperable Data Network Functionalities

Taken together, the completed OS PCORTF projects provide a spectrum of patient-centered information focused on collecting, linking and analyzing data. Table 2, below, crystallizes the contributions of each project to the five data network functionalities. At the time these projects were envisioned, awarded, and conducted, the formal structure of the functionalities had not been finalized. Agencies and OS PCORTF staff were working to address agency priorities and interpret the statutory mandate.

The relationship of the functionalities and the projects was not predetermined. It is the result of separate streams of work, i.e., the process of identifying agency needs and the conceptual and strategic development of a 'living' interoperable data capacity network for PCOR.

Table 2 presents the five functionalities and the projects associated with the functionality and their contributions. With the statutory end of the OS PCORTF mandate approaching in FY 2019, the interoperable data capacity network will continue to be available for future PCOR and other research. For instance, the 21st Century Cures Act indicates a multitude of research opportunities to which the OS PCORTF research data capacity could contribute. Further opportunities arise among the multiple HHS agencies which have one or more data infrastructures. With the addition of the current 20 active projects' contributions and those of future OS PCORTF projects to the functionalities, this resource may become an especially fruitful resource for expanding PCOR research questions and the capability to conduct the research.

As previously noted, the eighth completed project—the Strategic Opportunities Project—provided support to the OS PCORTF staff. The final project was a Strategic Roadmap that set out the five functionalities, identified milestones for their development and adoption, and specified components leading to the achievement of the milestones. This Strategic Roadmap became a living document, undergoing adaptation to the evolution of the development of the data infrastructure and priorities of the Department's agencies. It continues to simultaneously evolve and provide conceptual guidance. It provides an evolving conceptual overview of what the mandated data capacity infrastructure should entail. A synopsis of the Strategic Opportunities Project is in Appendix B.

The body of completed work, along with the currently active projects, is unique among the Department's health data infrastructures in its focus on the capacity for patient-centric data devoted to outcomes from registries, research and administrative data networks, and electronic health records. To reiterate, this singular focus, although developed for use in patient-centered outcomes research, provides a rich resource—along with links to other Departmental data infrastructures—for research to address evolving health care issues and questions.

The advantages of building the national data capacity for research are not limited to current programs in HHS. An expanded data capacity also supports independent research programs in academia, industry, and private nonprofit organizations. Expanding data capacity aligns with several new legislative provisions for patient-centered research within HHS agencies like the

patient-focused drug development provisions in 21st Century Cures Act and the value-based provisions of the Medicare Access and CHIP Reauthorization Act (MACRA). Moreover, it contributes to the pathway for the future of HHS research programs to leverage the power of extremely large datasets and new computational tools that can be applied to understand the patterns and determinants of health care interventions on patient outcomes.

Table 2. OS PCORTF Completed Projects' Contribution to the Interoperable Data Network's Five Functionalities: FY 2012 – 2015.

Functionality	Completed Project	Contribution
Standardized Collection of Standardized Data	CDEs	<ul style="list-style-type: none"> The CDEs provide for the standardization of the data and the eCRFS provided for standardized collection forms to contain the standardized health information
	National Program of Cancer Registries	<ul style="list-style-type: none"> Enabled 10 State cancer registries to develop and report a standardized set of clinical and treatment-related longitudinal CER data items into CDC's national cancer surveillance system Increased national capacity and availability of cancer-related CER outcome data
	Community Health Applied Research Network	<ul style="list-style-type: none"> Pooled data from 17 Federally-funded community health centers of a unique population of vulnerable, safety net, low income, and otherwise diverse patients Standardized data collection/reporting and facilitated data use across the CHARN networks by developing protocols for data collection, extraction, encryption, and validation along with a data access plan Created a de-identified analytic file and associated data codebook to support the use of CHARN analytic files by other researchers Taken together, CHARN's developmental process, structure and supportive documents suggest a reasonable degree of standardization
Collection of Participant-Provided Information	Blue Button	<ul style="list-style-type: none"> Facilitated user-friendly beneficiary access to their own Medicare health information Beneficiaries able to download their data Website allows beneficiaries to enter and share additional health information
Linking Clinical and Other Data for Research	CMS Chronic Conditions Warehouse	<ul style="list-style-type: none"> Unique beneficiary key permits researchers to link Medicare and Medicaid data Includes plan, pharmacy and prescriber characteristics for Medicare Part D
	Beta Test Multi-Payer Claims Database	<ul style="list-style-type: none"> Contained longitudinal, individual-level data All-payer (public and private), all-claims Related to this functionality, Beta test only assessed the user-friendliness
	CER Inventory	<ul style="list-style-type: none"> Web-based tool classified and catalogued Federal and non-Federal (for profit and non-profit) CER Web searches identified CER to optimize coordination, reduce duplication and suggest new ideas
Use of Clinical Data for Research	National Program of Cancer Registries	<ul style="list-style-type: none"> Expanded specialized cancer registries by extending and continuing longitudinal cancer outcome data through active follow up of breast, colon, and rectal cancer cases Public-use national cancer outcome CER database housed at CDC/NCHS/RDC Multiple research publications and presentations completed; Active research ongoing
	Community Health Applied Research Network	<ul style="list-style-type: none"> Network represents over 1,000,000 safety net patients being served in 17 community health centers across 9 states Developed for conducting CER observable and interventional studies, includes clinical encounters for all patients and all conditions seen in the CHCs during the 2006-2013 period
Use of Enhanced Publicly-Funded Data Systems for Research	CDEs	<ul style="list-style-type: none"> Developed an infrastructure to facilitate the use of EHRs in CER. Developed Health IT standards and forms for the representation of eCRF forms and CDEs Enhanced health IT standards infrastructure to support effective maintenance, distribution and use of CDEs and eCRFs
	CMS Chronic Conditions Warehouse	<ul style="list-style-type: none"> Enhanced publicly-funded data systems to analyze data from Medicare fee-for-service institutional and non-institutional claims' files, Medicaid files, and Part D Prescriptions, including plan, pharmacy and prescriber characteristics
	Beta Test Multi-Payer Claims Database	<ul style="list-style-type: none"> MPCD compiled public and private payer data OS PCORTF project supported the MPCD beta test Recommendations from beta test assessed the user-friendliness and utility of using the MPCD, as well as initial impressions of working with the data
	CER Inventory	<ul style="list-style-type: none"> CER studies were entered into classification categories and catalogued entered into the CER database. Test users evaluated the CER Inventory to identify CER studies to enhance coordination and reduce duplication of CER
	Blue Button	<ul style="list-style-type: none"> Developed a plan to enable Medicare beneficiaries to connect their claims data to applications, services, and research programs they trust.

**Appendix A. Synopses of Completed OS PCORTF Data Capacity
Projects: FY 2012 through FY 2015**

Development of Data Infrastructure for Use of EHRs in Comparative Effectiveness Research

The joint project of the Office of the National Coordinator for Health Information Technology (ONC) and the National Institutes of Health's National Library of Medicine (NIH/NLM or NLM) was conducted under the auspices of two Memoranda of Understanding (MOU) and four interagency agreements (IAAs) with the Office of the Secretary for Planning and Evaluation (ASPE). The first MOU covered the initial steps in establishing an infrastructure for the use of electronic health records (EHRs) in comparative clinical effectiveness research (CER). Two IAAs, one each to ONC and NLM, outlined the work to be started. Within a year, the second MOU was signed, adding to the scope of work; extending the timeframe five years; and stating that specific tasks would be described in greater detail in each year's funding request and in each agency's IAA. This synopsis of the project covers the work completed under the first two MOUs and their accompanying IAAs, which taken altogether cover two years of joint work.

Background: The guiding principle of the work was that applicability and power of CER studies would be increased by the use of structured data definitions—common data elements (CDEs)—which comply with the consensus-derived health data standards established for “meaningful use” of EHRs. The challenge was to define and collect patient data (e.g., lab test results, marital status, and patient-reported depression) in a standardized way in different CER studies, to enable the comparison of results and facilitate use of EHR systems as a source of valid CER data.

At the time, various clinical and health services research groups and specialty societies were already engaged in independent initiatives to standardize data collection. Work was needed to build upon these individual efforts to make it easier to conduct CER in diverse community health care settings, by reducing the data collection burden on health care providers and patients and the need to make site-specific modifications to EHR system capabilities in order to enable community participation. The infrastructure that would accommodate this goal consists of two components: 1) an authoritative repository to maintain and distribute up-to-date CDEs, and patient assessment specifications, with underlying terminology values sets, for researchers and EHR developers; and 2) a standardized mechanism that would enable an EHR to capture structured data for a specified use case. With this infrastructure in place, researchers would have ready access to standardized electronic versions of data collection instruments relevant to CER.

Objectives: The four goals of the work to be accomplished during the five years were to:

- Select and require the use of health information technology (IT) standards-based CDEs and patient assessment instruments in CER and patient-centered outcomes research (PCOR);
- Develop and validate a health IT standards-based ‘extensible electronic case report form’ (eCRF) to be used within EHRs to enable efficient capture of data on individual patients for specified use cases for merger with comparable data for other relevant patients and use in CER;
- Enhance health IT standards infrastructure to support effective maintenance, distribution, and use of the definitions of CDEs and patient assessment instruments, with particular emphasis on the standard terminology value sets required to define them; and

- Establish the standards, services and policies that integrate PCOR activities into the clinical health IT.

Accomplishments: ONC's role in this project was to identify a community of public and private stakeholder groups and facilitate their active participation and contribution to the identification and development of standards through a public and virtual platform called the Standards & Interoperability Framework (S&I). Through this initiative, ONC developed CDEs and the standards for eCRF structures/templates in a human-readable and machine-readable format. During the project's timeframe, lack of consensus among the project's national stakeholders precluded the identification of the particular CDEs that could population any eCRF. Stakeholder consensus was crucial. That step was later accomplished. The results of this endeavor were the initial entries into the NIH/NLM's CDE Repository.

During the FY 2012/2013 project, the NIH/NLM's role was to create and populate the NIH CDE Repository (<https://cde.nlm.nih.gov/home>).⁸ The CDE Repository currently contains 12 classifications of CDEs totaling 1,131,344 elements across the classifications. This same website also contains 10 classifications of eCRFs with a total of 1,684 individual eCRFs (<https://cde.nlm.nih.gov/cde/search>⁹) in 28 subject areas (https://www.nlm.nih.gov/cde/subject_areas_1.html¹⁰).

Subsequent use and/or dissemination of project: Subsequent projects have been undertaken involving the products of this work. The CDEs and eCRFs were more fully developed and validated. One project is building upon common data elements to develop common definitions in order to meaningfully interpret results of studies and use the results to improve patient outcomes.

Additional work builds upon this foundation to develop a standards-based Common Data Model, which will enable the development of a consensus framework among data networks.

Data network functionalities addressed by project: The research functionality addressed in this project was the Standardized Collection of Standardized Clinical Data. This functionality enables researchers to use standardized clinical data based on common data element standards across research projects and networks, there by facilitating linkage and aggregation of data across data sources. The standards to answer practice and population level questions using electronic clinical data constitute the component also addressed within this functionality. The other functionality which this project addressed was Use of Enhanced Publicly-Funded Data Systems for Research. The standardization afforded by CDEs and eCRFs greatly enhanced publicly-funded data systems used in research.

Potential for follow-on work: One potential future activity could potentiate work to develop linkages across existing Federal, non-Federal, and non-profit health infrastructures, e.g., OS PCORTF, Sentinel, and PCORnet, to optimize the utility of a range of existing Federal health-related data to address important health issues.

⁸ Retrieved on March 9, 2017.

⁹ Retrieved on March 9, 2017.

¹⁰ Retrieved on March 9, 2017.

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Fiscal Year of OMB approval: FY 2012: FY 2013

Project period of performance:

NLM FY 2012: 06/01/2012 to 09/30/2019

ONC FY 2012: 08/29/2012 to 09/30/2013

NLM FY 2013: 06/01/2012 to 09/30/2019

ONC FY 2013: 07/15/2013 to 09/30/2017

Publications and other publicly available information:

CDE Repository Website: <https://cde.nlm.nih.gov/home>

This website was initially developed as part of the 2012 award from OS PCORTF. There have been continuing entries through to the present since that time, as previously noted.

Sheehan, J., Hirschfeld, S., Foster, E., Ghitza, U., Goetz, K., Karpinski, J., Lang, L., Moser, R.P., Odenkirchen, J., Reeves, D., Rubinstein, Y., Werner, E., and Huerta, M. (2016, December). Improving the value of clinical research through the use of Common Data Elements. *Clinical Trials*, 13 (6), 671-676.

Maintenance and Support of the Chronic Conditions Warehouse (CCW) for Comparative Effectiveness Research (CER)

The purpose of this project was to supplement the Centers for Medicare & Medicaid Services (CMS) Chronic Conditions Warehouse's (CCW) expanded data infrastructure to support its use for patient-centered outcomes research (PCOR).

Background: CMS had previously received funding from the American Recovery and Reinvestment Act (ARRA) which was used to: expand the amount of Medicare data available; make Medicaid MAX data available; create new research products; and provide security enhancements among other investments in the potential for the CCW's utility for PCOR. Although the ARRA funding supported expansion of the CCW infrastructure through these one-time investments, they resulted in an increase to the cost of continued maintenance, licensing and support for the CCW that could not be fully covered by the CMS appropriated budget.

An interagency agreement (IAA) was awarded in fiscal year 2012 (FY 2012) and in FY 2013 to plan and carry out the activities to support the enhancements to the CCW undertaken with ARRA funding.

Objectives: The overarching objectives of the project were to provide access, continued maintenance and renewal of licensing for the PCOR. Access for researchers focused on supporting approximately 20 approved researchers conducting PCOR project via the CCW Virtual Research Data Center (VDRC). VDRC operations and maintenance included such activities as creating SAS dataset files, exploring new data files, renewing and tracking equipment maintenance, updating data dictionaries.

Accomplishments: During the course of the two consecutive interagency agreements, two sets of activities were accomplished that focused on maintaining and developing the CCW. The first set involved renewing licenses, and other maintenance agreements to support the infrastructure enhancements. The second set was the development of 19 'seats' in the VRDC for research which often required additional analytic space to accommodate large volumes of data, such as multiple years or large cohorts. These 19 'seats' were approved for the researchers of 15 approved studies. Support for researchers using the VDRC seats was provided.

Subsequent use and/or dissemination of project:

1. A list of the five publications from the research conducted by the researchers in the 19 VDRC seats is located in the section below. The VRDC 'seats' at the CCW exist for a one-year period of time.
2. OS PCORTF provided support for 19 seats used to conduct 15 research projects, i.e., some projects had seats for more than one researcher. Their one-year period expired. Other agencies are supporting seats for their priority projects.

Other articles have been submitted for publication and are under review. Additional manuscripts are in different stages of preparation. One researcher has applied for an additional year's use of

one of the CCW's VRDC seats; another is currently seeking funding to support use of a VRDC seat.

Data network functionalities addressed by project: This project addressed two data infrastructure functionalities: first, the Use of Enhanced Publicly-Funded Data Systems for Research and, second, to assist in Linking Clinical and Other Data for Research

Potential for follow-on work: It would be fruitful to support an additional year of funding for the OS PCORTF projects that could not complete their analyses within the previous one year of support. The analyses in the original year of funding were complex and involved particularly large databases, which took more 'set-up' time' that cut into the time left to conduct the analyses. Any of this support would be limited only to OS PCORTF projects previously funded for use of VRDC 'seats' for completion of their projects.

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Fiscal Year of OMB approval: FY 2012; FY 2013

Project periods of performance: 07/11/2012 to 07/31/2013; 09/30/2013 to 09/29/2014

Publications and other publicly available information:

Gillespie, E.F., Matsuno, R. K., Xu, B., Triplett, D. P., Hwang, L., Boero, I. J., Einck, J. P., Yashar, C., & Murphy, J. D. (2016, October). Geographic Disparity in the Use of Hypofractionated Radiation Therapy among Elderly Women Undergoing Breast Conservation for Invasive Breast Cancer. *International Journal of Radiation Oncology Biology Physics*. (96) 2, 251-258.

McNeely, C., Markwell, S., & Vassileva, C. (2016, September). Readmission after inpatient percutaneous coronary intervention in the Medicare population from 2000 to 2012. *American Heart Journal*. 179:195-203.

McNeely C, Markwell S, Vassileva C. (2016, July). Trends in Patient Characteristics and Outcomes of Coronary Artery Bypass Grafting in the 2000 to 2012 Medicare Population. *Annals of Thoracic Surgery*. 102 (1):132-8.

Medicare Payment Advisory Commission. (2016, June). Report to the Congress: Medicare and the Health Care Delivery System- Improving Medicare Part D (Chapter 6). <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf?sfvrsn=0> (Chapter 6 draws on the results and policy recommendations from Daniel Miller's study regarding risk adjustments in CCW VRDC supported by OS PCORTF).

Mooney, J.J., Weill, D., Boyd, J.H., Nicolls, M.R., Bhattacharya, J., Dhillon, G.S., (2016). Effect of Transplant Center Volume on Cost and Readmissions in Medicare Lung Transplant Recipients. *Annals of the American Thoracic Society*. 13 (7):1034-41. PMID 27064753.

Beta Testing the Multi-Payer Claims Database

The goal of the Multi-Payer Claims Database (MPCD) was to evaluate the benefits of consolidating longitudinal health care claims data from public and private payers, to facilitate comparative effective research. As part of its development, the MPCD underwent a beta test to evaluate its utility by surveying the experiences of federal and contracted researchers who requested and used customized data extracts for comparative clinical effectiveness research (CER) studies. The beta test was supported by an award from the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS PCORTF).

The purpose of this project was to conduct a beta test of the Multi-Payer Claims Database (MPCD). During the beta test, the contractor supplied data extracts to researchers accessing the database. Beta test participants included: 14 Federal researchers from FDA, AHRQ, NIH, ASPE HRSA, and SAMHSA; and 12 contracted researchers from eight universities.

In addition to supplemental analyses conducted by federal staff and academic researchers, this project funded three analyses by the contractor to assess the value of the MPCD's data for CER. The first analysis evaluated comparative effectiveness in patient outcomes of having interventional radiologist establish central venous access versus health care providers who were not interventional radiologists; the second analysis evaluated and compared the use of uterine artery embolization, myomectomy, and laparoscopic hysterectomy to treat clinically significant leiomyomata; and the third was designed to evaluate the capacity of the MPCD to answer CER questions based on public health style interventions, such as case management of medical home initiatives. As part of the beta test, the contractor collected information on the beta testers' experiences requesting and using data from the MPCD.

Background: Development of the MPCD was supported through funding from the American Recovery and Reinvestment Act (ARRA), which created a Federal Coordinating Council (FCC) and charged it with developing recommendations on how to invest funds made available to the Secretary for CER. The Council received feedback from the public suggesting that linking longitudinal claims data would help support CER. The MPCD represented a unique effort to link data between public (Medicare and Medicaid) and private payers on a national scope.

Objectives: The objectives of this OS PCORTF project were threefold: 1) to modify the MPCD web portal home page in preparation for conducting beta-testing of the MPCD; 2) to conduct three CER analyses on the beta release of the MPCD; and 3) to assess beta testers' experiences requesting and using data from the MPCD.

Accomplishments: The MPCD Beta Test assessed the value of merging patient-matched, de-identified data from public and private payers for CER involving alternative treatment strategies and health care delivery system designs. The basic thought was that by combining data across payers this would allow for larger sample sizes to study less common conditions and health care interventions across geographic areas, while also enabling researchers to compare outcomes for patients transitioning between different types of payers over time. The final report found that MPCD project team was successful in achieving the key objectives of building a pilot database.

The beta testers recommended providing better data documentation and developing a publicly available web-based aggregate data analysis tool would allow researchers to better identify what types of questions such a resource could answer, and enable them to build funding for purchasing the data into their grant applications.

Subsequent use and/or dissemination of project: Later work by the beta testing teams has been resulting in a number of their studies coming to fruition in the form of presentations, publications, and even a thesis. At least four articles, using the Beta-test data, have been published.

Data network functionalities addressed by project: Two high priority research functionalities were addressed by this project's contribution to the MPCD: one was Linking Clinical and Other Data for Research; and the other was the Use of Enhanced Publicly-Funded Data Systems for Research.

Potential for follow-on work: The database from the Beta Test is no longer operational.

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Fiscal Year of OMB approval: FY 2012

Project period of performance: 09/24/2012 to 09/15/2013 for Beta testing component within the longer period of performance for the full Multi-Payer Claims Database project which was 09/14/2010 to 09/15/2013.

Publications and other publicly available information

DeLia, D., Tong, J., Gaboda, D., & Casalino, L.P. (2014). Post-Discharge Follow-up Visits and Hospital Utilization by Medicare Patients, 2007-2010. *Medicare & Medicaid Research Review*. 4 (2) E1-E19.

Parashuran, S., Kim, S. & Dowd, B. (2017, April 7). Inappropriate Utilization in Fee-for-Service Medicare and Medicare Advantage Plans. *American Journal of Medical Quality*. 32(2), DOI: <https://doi.org/10.1177/1062860617702240>.

Schoenbaum, M., Sutherland, J.M., Chappel, A., Azin, S., Goldstein, A.B., Rupp, A. & Heinssen, R.K. (2017, April 7). Twelve-Month Health Care Use and Mortality in Commercially Insured Young People with Incident Psychosis in the United States. *Schizophrenia Bulletin*. doi: 10.1093/schbul/sbx009. <https://www.ncbi.nlm.nih.gov/pubmed/28398566> (retrieved on May 24, 2017).

Yun, H., Yang, S., Chen, L., Xie, F., Winthrop, K., Baddley, J.W., Saag, K.G., Singh, J., & Curtis, J.R. (2016). Risk of Herpes Zoster in Autoimmune and Inflammatory Diseases: Implications for Vaccines. *Arthritis and Rheumatology*, 68 (9), 2328-2337.

Comparative Effectiveness Research (CER) Inventory

The purpose of the Office of the Secretary Patient-Centered Outcomes Research Trust Fund's (OS PCORTF's) specific contribution to the Comparative Effectiveness Research (CER) Inventory was initially to maintain, update, transition, and test the CER Inventory. The original plan was that the project would transition the operations of the inventory to HHS staff at the end of the year. During the course of this year, it became evident that inherited factors were inhibiting the user-friendliness and utility of the inventory. As a result, the project was modified to conduct a benchmarking exercise that examined how the inventory performed compared to other databases, i.e., Google Scholar, PubMed.gov, and ClinicalTrials.gov.

The outcome of the comparisons showed that Google Scholar, PubMed and ClinicalTrials were relatively comparable with the CER Inventory when CER Inventory experts were involved in the tests. Otherwise, the CER Inventory did not perform as well. Other challenges to the Inventory's utility were identified. They included the evolving definition of CER, the broad scope of the inventory, and the lack of a defined audience, among others. In addition, other limitations included the retrospective algorithm, and the search-engine approach for handling the evolving definition of CER, and the ability accommodate manual submissions methods, such as those adopted by ClinicalTrials.gov. The project submitted the Lessons Learned Report along with final technical documentation and database copy of the Inventory.

Taken together, the advantages of addressing the challenges to the CER Inventory were outweighed by the cost involved. After much deliberation, the decisions were made not to pursue the necessary and sustained investment and to retire the CER Inventory.

Background: The overall CER Inventory project was to design and implement a system for the categorization and cataloging of CER activities through a web-based tool for inventorying Federal and non-Federal outputs and activity. This work had grown out of a larger project supported by the American Recovery and Reinvestment Act (ARRA) of 2009. ARRA had established the Federal Coordinating Council for CER (FCC) to foster optimum coordination of CER conducted and supported by Federal Departments and agencies. The FCC submitted a report to the President and Congress defining CER and its purpose; describing the then-current Federal CER infrastructure and a partial inventory of CER activities; and making recommendations for investment. A simultaneous report of the Institute of Medicine assisted in catalyzing the creation of an inventory of existing and ongoing CER activity and data infrastructure.

Objectives: The primary objective of the larger ARRA CER project was to accurately and comprehensively inventory Federal and non-Federal CER activities (within both for-profit and not-for-profit organizations), utilizing the definition for CER adopted by the FCC for CER.

Accomplishments: Due to the rapidly evolving technologies supporting web-based search engines, and the improved methods for identification of more recent CER studies, the development of the CER Inventory (as a web-based search engine using a retrospective

algorithm) was determined to have been superseded by existing search engine tools available. The benchmarking exercise found the Inventory to be comparable to but less user-friendly and algorithm challenged than other common public search engines.

The Lessons Learned Report, which identified the challenges and offered recommendations to address them, can serve as a useful resource for consideration in ongoing and future projects.

Subsequent use and/or dissemination of project: The Agency for Healthcare Research and Quality (AHRQ) now hosts a Web-library for patient-centered outcomes research (PCOR), the Library of PCOR Resources (<https://www.ahrq.gov/pcor/library-of-resources/index.html>). This resource provides up-to-date information; it was last reviewed in October of 2016.

Data network functionalities addressed by project: The high priority research functionalities addressed by the full project's contribution to the CER Inventory were Linking Clinical and Other Data for Research, and Use of Enhanced Publicly-Funded Data Systems for Research.

Potential for follow-on work: The AHRQ Library of PCOR Resources contains PCOR findings and evidence-based tools that have appeared in the published literature in addition to studies and projects in progress. The information is intended for researchers conducting new studies and policymakers, consumers, and for others who seek access to evidence-based health information.

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Fiscal Year of OMB approval: FY 2011 and FY 2012

No award was made in FY 2011. \$17,000 of the FY 2011 approved funding was carried over and added to the approved FY 2012 request.

Project period of performance: 09/30/2012 to 09/29/2013

Publications and other publicly available information:

The Lewin Group. Comparative Effectiveness Research Inventory: Final Report Task 6 Lessons Learned. (2013, September 27).

Expanding Data Collection for the National Program of Cancer Registries (NPCR) for Comparative Effectiveness Research

The purpose of this project was two-fold: to expand the data collection infrastructure of the National Program of Cancer Registries (NPCR) to support comparative clinical effectiveness research (CER). In particular, the project focused on enhancing State cancer registries, supported by the Centers for Disease Control and Prevention (CDC), to collect specialized data and expand electronic health record (EHR) reporting to central cancer registries for CER.

Background: Enhanced data collection and data linkages between central cancer registries and other health related datasets can provide researchers with essential real-world and population-based data for comparative clinical effectiveness research (CER). This project built upon funding from the American Recovery and Reinvestment Act (ARRA) of 2009 that became available in 2010. It was provided to central cancer registries operated by 10 states, which were collecting detailed treatment data that could be obtained through claims or other existing electronic data sources.

One result of these efforts, Cancer Reporting from Eligible Professionals to State Cancer Registries was included as an objective in the Centers for Medicaid & Medicare Services (CMS) and Office of the National Coordinator (ONC) Final Rule for Stage 2 Meaningful Use (MU). Inclusion in MU offered providers the potential of receiving CMS payment incentives and improved the ability of physicians' offices, specialty providers (e.g., dermatology, urology, hematology, and oncology), and other non-hospital facilities to identify and send cancer registry related information and for central cancer registries to receive data for cancers diagnosed outside the hospital systems.

In addition to detailed treatment and outcome data for breast, colon and rectum cancer cases, expanded patient information, including body mass index, occupation, co-morbidities, and smoking history was collected for all cases in the population areas covered by the 10 NPCR Registries. The project also extended longitudinal follow-up of these cancer patients to assess vital status, disease recurrence, disease progression, and additional treatment; thus enabling patient-level CER of cancer outcomes.

Objectives: The two foci of this Office of the Secretary Patient-Centered Outcomes Research (OS PCORTF) project were to 1) enhance specialized cancer registries by creating datasets for CER with extended longitudinal follow-up and data collection of disease recurrence, progression, and vital status for 2011 breast, colon and rectum cancer cases; and 2) expand electronic health record (EHR) reporting to central cancer registries for CER by addressing requirements to implement MU reporting to central cancer registries including enhancement of software tools and methodology for management and consolidation of electronic data reported on a real-time basis from EHRs and through data linkages.

Specifically, the project undertook to:

- Expand specialized cancer registries by extending and continuing longitudinal follow-up;

- Enhance specialized cancer registries to allow active follow-up of cancer patients to identify progression and recurrence of breast, colon and rectal cancer; and
- Create tools that facilitate expanded EHR reporting to central cancer registries for CER.

Accomplishments: Through the funding provided by this intra-agency agreement, the CDC extended and continued longitudinal follow-up of these cancer patients to assess vital status, disease recurrence, disease progression, and additional type of treatment over a one year time period for breast, colon, and rectum cancers and an average follow-up period of over 3 years. Treatment data, including the most recent information includes actual chemotherapy doses received and reasons for treatment cessation or alteration for each case, was submitted each year to CDC and provided for researchers through the CDC’s National Center for Health Statistics (NCHS) Research Data Center (RDC).

Subsequent use and/or dissemination of project: This project engendered over thirty publications, presentations and poster sessions. Among the publications, ten journal articles are referenced in the section, Publications and other publicly available information, below in this synopsis. One of the publications described the methodology and work conducted by CDC and the NPCR specialized registries in collecting data in the cancers of interest, including the selection of data variables, and characteristics of the study populations (Chen, V.W., et al., 2014). Others describe the use of biomarkers and associated cancer treatment (Styles et al, 2017; Rico et al, 2017); the highest incidence rates of colorectal cancers in one geographical area of the United States which indicates the possibility of a genetic disposition (Karlitz, J.J., et al, 2014); and post-surgical chemotherapy for stage III colon cancer and the association of comorbidities as an indicator for the use of adjuvant chemotherapy and the type of chemotherapy regimen (Hsieh, M-C., et al., 2016). The latter study found that both the number and severity of comorbidity were significantly associated with the receipt of guideline recommended chemotherapy, which underscored the need for more personalized care. Ground-breaking population-based research examined Lynch Syndrome using microsatellite testing in young patients. Among the strengths of the study was that it was conducted using a statewide registry (Karlitz, et al., 2015). A follow-up study of this research was conducted to assess state-side types and extent of operative practices for these early-onset cases (Karlitz, 2017).

Data network functionalities addressed by project: This project addressed two high priority research functionalities: one was Use of Clinical Data for Research, and the other was Standardized Collection of Standardized Clinical Data.

Potential for follow-on work: It might prove interesting to expand the link of information in the state cancer registries to the registries of death records in all CDC supported NPCR registries to enable outcome research that would be applicable to future health care decision-making and treatment. The success of expand EHR reporting to central cancer registries for CER will be relevant and necessary to expand in order to study the uptake and outcomes in the rapidly evolving field of personalized medicine.

Additional OS PCORTF ongoing work with registries may provide opportunities for partnering with CDC to further enhance NPCR in the future.

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Fiscal Year of OMB approval: FY 2013

Project period of performance: 04/08/2013 to 08/31/2015

Publications and other publicly available information:

Chen, V.W., Eheman, C.R., Johnson, C.J., Hernandez, M.N., Rousseau, D., Styles, T.S., West, D.W., Hsieh, M., Hakenewerth, A.M., Celaya, M.O., Rycroft, R.K., Wike, J.M., Pearson, M., Brockhouse, J., Mulvihill, L.G., & Zhang KB. (2014, Fall) Enhancing cancer registry data for comparative effectiveness research (CER) project: overview and methodology. *Journal of Registry Management*. 41(3), 103 – 112. PMID: 25419602 [PubMed - indexed for MEDLINE] February 28, 2017 from <https://www.ncbi.nlm.nih.gov/pubmed/25419602> .

Eheman C, O’Neil ME, Styles TS et al. Use of adjuvant chemotherapy among stage II colon cancer patients in 10 population-based National Program of Cancer Registries. *Journal of Registry Management*. 2016; 43(4): 179-186. Retrieved on May 16, 2017 from http://www.ncra-usa.org/files/public/JRM_Winter_2016.v43.4.pdf

Freeman M. Capture and Coding of Occupation and Industry Measures: Findings from 10 Central Cancer Registries. [Accepted May 15, 2017 to *Journal of Industrial Medicine*.]

Hsieh, M-C., Thompson, T., Wu, X. C., Styles, T., O’Flarity, M.B., Morris, C.R., & Chen, V.W. (2016, May). The effect of comorbidity on the use of adjuvant chemotherapy and type of regimen for curatively resected stage III colon cancer patients. *Cancer Medicine*, 5 (5), 871-880. DOI: 10.1002/cam4.632
PMCID: PMC4864816
PMID: 26773804 [PubMed - indexed for MEDLINE] Retrieved on February 28, 2016 from <http://onlinelibrary.wiley.com.ezproxyhhs.nihlibrary.nih.gov/doi/10.1002/cam4.632/full> .

Karlitz, J.J., Blanton, C., Andrews, P., Wu, X., Chen, V.W., Wu, X., Fontham, E. (2014, October). Colorectal Cancer Incidence Rates in the Louisiana Acadian Parishes Demonstrated to be Amongst the Highest in the United States. *Clinical Translational Gastroenterology*. 5(10) e60. DOI: 10.1038/ctg.2014.10. Retrieved on February 28, 2017 from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4218930/> .

Karlitz, J.J., Hsieh, M.-C., Liu, Y., Blanton, C., Schmidt, b., Jessup, J. M., Wu, X.-C., & Chen, V.W. (2015, July) Population-based Lynch Syndrome screening by microsatellite

instability in patients ≤ 50 : Prevalence, testing determinants, and result availability prior to colon surgery. *The American Journal of Gastroenterology*, 110, 948-955.

DOI: 10.1038/ajg.2014.417

PMID: 25601013 [PubMed - indexed for MEDLINE] Retrieved on February 28, 2017 from

<http://www.nature.com.ezproxyhhs.nihlibrary.nih.gov/ajg/journal/v110/n7/full/ajg2014417a.html>.

Karlitz, J.J., Sherrill, M.B., DiGiacomo, D.V., Hsieh, M-C., Schmidt, B., Wu, X-C., & Chen, V.W. (2016, April). Factors associated with the performance of extended colonic resection versus segmental resection in early-onset colorectal cancer patients: a population-based study. *Clinical and Translational Gastroenterology*, 7(4), e163. Published online 2016 Apr 14. DOI: 10.1038/ctg.2016.17

PMCID: PMC4855160 Retrieved on March 1, 2016 from <https://www.ncbi.nlm.nih.gov.ezproxyhhs.nihlibrary.nih.gov/pmc/articles/PMC4855160/> .

Rico A, Pollack LA, Thompson T, et al. KRAS testing and first-line treatment among patients diagnosed with metastatic colorectal cancer using population data from ten National Program of Cancer Registries in the United States. *Journal of Cancer Research & Therapy*. 2017; 5(2):7–13. Retrieved on May 16, 2017 from

<http://nobleresearch.org/Doi/10.14312/2052-4994.2017-2>

Styles T, Wu M, Wilson R, Babcock F, Butterworth D, West DW, Richardson LC. Population-Based Testing and Treatment Characteristics for Chronic Myelogenous Leukemia.

Journal of Registry Management. 2016 Fall; 41(3):134-142. Retrieved on May 16, 2017 from http://www.ncra-usa.org/files/public/JRM_Fall2016_V43.3.pdf

Weiss, N.S., Cooper, S.P., Socias, C., Weiss, R.A., Chen, V.W. (2015, Fall). Coding of Central Cancer Registry Industry and Occupation Information: The Texas and Louisiana Experiences. *Journal of Registry Management*, 42(3): 103-10. Retrieved on March 1,

2017 from http://www.ncra-usa.org/files/public/JRMFall2015_V43.3.pdf.

Strengthening and Expanding the Community Health Applied Research Network (CHARN) Registry to Conduct Patient-Centered Outcomes Research

This project supported the maintenance of the current Community Health Applied Research Network (CHARN) infrastructure and expansion of the CHARN database to include data for calendar years 2006, 2007, and 2011-2013, which completed the CHARN database from 2006 through 2013. The project also successfully supported efforts to make CHARN data available to more PCOR investigators outside of the CHARN network, by developing a public use analytic database file and associated data codebook. Five publications resulted from the project, which ended in the fourth quarter of FY 2015.

Background: CHARN is a network of the Health Resources and Services Administration's (HRSA's) community health centers (CHCs) and universities that was established in 2010 to create an infrastructure in this safety-net community that has the capacity to pool the experiences of patients across different sites for the purpose of conducting research, including observational and interventional studies among underserved populations.

CHCs are the health and medical home for over 24 million people in the United States, primarily populations who are of disproportionately low income (71%), are uninsured (28%), and half of whom reside in rural areas while the other half live tend to live in economically depressed inner city communities (National Association of Community Health Centers, 2013¹¹). CHARN consists of four safety-net research nodes, each of which has affiliated CHCs and an academic or research partner. Each node includes three or more CHCs (17 in all). The participating CHCs, representing more than 1,000,000 diverse safety-net patients, are located in nine states across the country, and all have provided standardized data to the centralized CHARN Data Warehouse.

Objectives: The objectives of the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS PCORTF) funding were to:

1. expand and enhance its centralized CHARN data registries, adding new data elements and covering more time;
2. build capacity for collaborative research within and among participating health centers that encourages, engages, and supports the participation of health center clinicians and investigators in all the phases of research;
3. create a de-identified analytic data file that is usable and available to researchers outside the CHARN network, along with an associated data codebook; and
4. develop and implement a process to broaden access to CHARN data and infrastructure so that researchers outside of CHARN can gain access to the data, thereby enhancing the value of the national infrastructure and maximizing the use of the data.

Accomplishments: CHARN utilized the OS PCORTF funds to include clinical encounters for all patients and all conditions seen at the CHCs during the consecutive calendar years 2006-2013

¹¹ National Association of Community Health Centers. (2016). America's Health Centers. Retrieved on March 6, 2017 from: <http://www.nachc.org/wp-content/uploads/2015/06/Americas-Health-Centers-March-2016.pdf>.

in the CHARN data warehouse (CDW). Additionally, the CDW included patient vital signs and smoking status. In addition to the CDW, a de-identified analytic file and associated data codebook were developed to support the use of CHARN analytic files by other researchers outside of the CHARN network (Objectives 1 and 3).

CHARN established a process for investigators within and outside of the CHARN network to access the CDW through the development of a data access plan (Objective 2).

CHARN maintained the infrastructure for patient-centered outcomes research (PCOR) and for quality improvement in the safety net. Examples of relevant activities include the establishment of a Steering Committee and generation of four papers and four proposals to demonstrate the utility and diversity of CHARN-supported research.

Subsequent use and/or dissemination of project: Four proposals and four manuscripts using existing CHARN data were completed by the end of the project. In addition, other manuscripts were developed by CHARN network members.

A sample of five published articles is in the section, Publications and other publicly available information, below in this synopsis. One article provides a brief description of the structure, development and implementation process of the CHARN data warehouse (Laws, et al., 2014). Another article reports on the effects of social determinants of health with complex diabetes in CHCs from the CHARN database of nearly 1 million patients (Li, et al., 2016). A third identifies the prescription of effective medication assisted treatment (MAT) for a CHARN population of age 18 or older with an opioid or alcohol diagnosis to study these prescriptions of MAT for treating patients and evaluate whether patient demographics and clinical characteristics were associated with prescribing this effective treatment (Rieckmann, T., et al, 2016).

Data network functionalities addressed by project: This project addressed two data infrastructure functionalities. The first was to enable the Use of Clinical Data for Research, and second was to build a research resource that contained a Standardized Collection of Standardized Clinical Data.

Potential for follow-on work: Although the CHARN dataset includes data from 2006 through 2013 only, it might be possible to match the de-identified data with relevant patient characteristics, socioeconomic status, and treatment/clinical interventions to a Medicaid sample from the new Transformed Medicaid Statistical Information System (T-MSIS) files. With this matched sample, research that compares the two subsamples and the relative effects of aspects of the ACA.

The uniqueness and size of the population and diversity of health variables in the CHARN database from 2006 through 2013, affords a multitude of opportunities for research that is not elsewhere possible within the United States. Examples of papers resulting from this project focus on the effects of social determinants of health with complex diabetes in CHCs, linking social determinants to clinical practice, a study which draws upon World Health Organization work for comparison; cholesterol medication management in diabetes mellitus among a one-year sample of 28,251 from the CHCs' socioeconomically disadvantaged population; HIV and

Hepatitis C virus screening practices from a subset of 437 CHARN providers nearly 600,000 primary care patients; and medication assisted treatment for a CHARN population of 24722 with substance use disorders (6,432 with opioid dependence; and 18,290 with alcohol dependence). With an extensive database of the population characteristics and clinical information, rich analyses were conducted to flesh out the multiple factors involved in the studies.

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Fiscal Year of OMB approval: FY 2013

Project period of performance: 02/04/2014 to 08/30/2015

Publications and other publicly available information:

Laws, R.; Gillespie, S., Puro, J., Van Rompaey, S., Quach, T., Carroll, J., Chang Weir, R., Crawford, P., Grasso, C., Kaleba, E., & McBurnie, Mary.A. (2014). The Community Health Applied Research Network (CHARN) Data Warehouse: a resource for patient-centered outcomes research and quality improvement in underserved, safety net populations. *eGEMs (Generating Evidence & Methods to improve patient outcomes)*, 2(3) *Article 11*. Retrieved on February 27, 2017 from DOI: <http://dx.doi.org/10.13063/2327-9214.1097> and from <http://repository.edm-forum.org/egems/vol2/iss3/11>.

Li V., McBurnie, M.A., Simon, M., Crawford, P., Leo, M., Rachman, F., Cottrell, E., Dant, L., Oneha, M., & Chang Weir, R. Impact of Social Determinants of Health on Patients with Complex Diabetes Who Are Served by National Safety-Net Health Centers. (2016, May-June). *Journal of the American Board of Family Medicine*. 29(3), 356-370. Retrieved on February 28, 2017 from <http://www.jabfm.org/content/29/3/356.full.pdf+html>

Mayer, K.H., Crawford, P., Dant, L., Gillespie, S., Singal, R., Vandermeer, M., Muench, J., Long, T., Quach, T., Chaudhry, A., Crane, H.M., Lembo, D., Mills, R., & McBurnie, M.A. (2016, June). HIV and Hepatitis C Virus Screening Practices in a Geographically Diverse Sample of American Community Health Centers. *AIDS Patient Care and STDS*, 30(6). 237-246. DOI: 10.1089/apc.2015.0314
PMID: 27286294 [PubMed - in process] Retrieved on February 28, 2017 from <http://online.liebertpub.com/doi/pdfplus/10.1089/apc.2015.0314> .

Rieckmann, T., Muench, J., McBurnie M.A., Leo, M.C., Crawford, .P, Ford, D., Stubbs, J., O'Cleirigh, C., Mayer, K.H., Fiscella, K., Wright, N., Doe-Simkins, M., Cuddeback, M., Salisbury-Afshar, E., & Nelson, C. (2016, Oct-Dec) Medication-assisted treatment for substance use disorders within a national community health center research network. *Substance Abuse*, 37(4), 625-634. DOI: 10.1080/08897077.2016.1189477

PMID: 27218678 [PubMed - in process] Retrieved on February 28, 2017 from <http://www-tandfonline-com.ezproxyhhs.nihlibrary.nih.gov/doi/full/10.1080/08897077.2016.1189477>.

Song, H., Li, V., Gillespie, S., Laws, R., Massimino, S., Nelson, C., Singal, R., Wagaw, F., Jester, M., & Chang Weir, R. Results of the Community Health Applied Research Network (CHARN) national research capacity Survey of Community Health Centers. (2015, Summer). Progress in Community Health Partnerships: Research, Education, and Action. The Johns Hopkins University Press, pcph.press.jhu.edu, 9.2, 229-242. Retrieved on February 28, 2017 from <https://www.ncbi.nlm.nih.gov/pubmed/26412764>.

Improving Beneficiary Access to Health Information: A Plan to Enhance “Blue Button”

The purpose of this project was to develop a plan to redesign the Centers for Medicare & Medicaid Services (CMS) Blue Button to enable it as a ‘Data-as-a-Service’ platform to empower patients and enable the use of the data with third party applications.

Background: “Blue Button” is a service that allows patients to access their own health information in electronic form. CMS established a Blue Button platform in 2010 to give Medicare beneficiaries access to their own health information: however, this service had limited functionality and scalability, making it difficult for beneficiaries to use and share their health information.

To realize the full potential of sharing Medicare claims with beneficiaries, CMS needed to make data available to beneficiaries in a scalable and patient-friendly format, i.e., a Data-as-a-Service platform. In addition, the Blue Button platform would be redesigned to allow third party services to build computer applications (apps) and other tools that can easily collect, present, and share the data—in a manner that ensures privacy and security of the data—which would make the data more actionable for patients.

Objectives: The overall goals of the one-year initiative were to award a contract for the design and implementation planning services, to include:

- Identification and collaboration with HHS internal stakeholders, the private sector developer community, and third party services to define functional requirements; and
- Development of a plan to improve Blue Button, including implementation strategy and roadmap for a ‘Data-as-a-Service’ Platform.

Accomplishments: The overall goals were successfully addressed and stakeholders engaged. The Blue Button plan was developed including an implementation strategy. Additional, current information for patients and families is located on the Blue Button website:

<https://www.healthit.gov/patients-families/blue-button/about-blue-button>.

Subsequent use and/or dissemination of project: In FY 2016, a subsequent project was awarded, ‘Improving Beneficiary Access to their Health Information through an Enhanced Blue Button Service’. This project focuses on developing an Application Programming Interface (API) for the CMS Blue Button. The project uses the HL7 Fast Health Interoperability Resource (FHIR) framework for the Medicare claims data to ensure data is in a structured format that can be accepted by a wide range of applications. This advancement was one early step that addressed the vision for the National Institutes of Health’s (NIH) All of Us Research Program.

Data network functionalities addressed by project: Two high priority research functionalities were addressed by this project: the first was to support the Collection of Participant-Provided Information, and the second was to enable Use of Enhanced Publicly-Funded Data Systems for Research. These functionalities provided a service, a component of the interoperable data

capacity network, to beneficiaries to facilitate their contribution and use of their own health information in conjunction with other data for research.

Potential for follow-on work: Additional applications facilitating beneficiaries' access to their personal health data and submission of their information for research continue to be developed, for example projects utilizing the FHIR-enhanced Blue Button, and projects to develop new applications of Blue Button and expand beneficiary participation continue to be deliberated.

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Fiscal Year of OMB approval: Supported as part of FY 2014 OS PCORTF personnel

Project period of performance: 10/01/2014 to 09/30/2015

Publications and other publicly available information:

CMS Blue Button Webpage: <http://go.cms.gov/bluebutton>

This website provides a brief overview of the development of the current CMS Blue Button service. Under the section, The Proposed Solution, the plan developed under this proposal is noted and its implementation described.

Blue Button Developer Documentation:

<https://github.com/HHSIDEAlab/blue-button-developer-docs>

This website provides technical documentation for Blue Button Application Programming Interface (API) Application Developers. Technical specifications to support the development of the CMS Blue Button API are made available to the public to encourage the development of applications that can help consumers better utilize their own health information.

ONC Informational Website about Blue Button: <https://www.healthit.gov/patients-families/blue-button/about-blue-button>

This website explains to beneficiaries and their caregivers the utility of Blue Button; what health information is accessible through Blue Button; and a link to find out if the beneficiary's provider(s) currently participate in Blue Button.

**Appendix B. Synopsis of Completed OS PCORTF Support Project:
Strategic Opportunities for Building a Patient-Centered Outcomes
Research Data Infrastructure FY 2013 through FY 2015**

Strategic Opportunities for Building a Patient-Centered Outcomes Research Data Infrastructure

The purpose of this project was to provide background research, technical and analytic consultation, and meeting and document preparation assistance to HHS as it shapes its strategy for building its data capacity.

Background: In fiscal year (FY) 2013, the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS PCORTF) awarded an Interagency Agreement (IAA) to the Office of the National Coordinator for Health Information Technology (ONC) to develop a strategy for maximizing the impact of the OS PCORTF in building a comprehensive, interoperable and sustainable patient-centered outcomes research (PCOR) data network infrastructure. The vision was to build a national network of patient data for PCOR linking access to private and public claims, electronic health records (EHRs), biobank, registry, and other sources of data to perform high quality observational PCOR studies through representative databases, and enable low-cost, pragmatic clinical PCOR trails through focused enrollment and incorporation of real-world settings.

Objectives: The purpose of the project, noted above, was to provide background research, technical and analytic consultation, and meeting and document preparation assistance to HHS. The objectives to fulfill this purpose included creating a data infrastructure document to provide the conceptual basis/framework for further information gathering and reporting on strategic opportunities; performing an environmental scan of the current landscape of public and private data infrastructure activities; developing series of policy papers to identifying gaps and opportunities for achieving key goals; and preparing a written draft strategic plan to articulate concrete, strategic opportunities where HHS could influence and invest in building PCOR data infrastructure. The work was conducted under a contract to NORC at the University of Chicago.

Accomplishments:

The conceptual framework and environmental scan were completed early in the project, providing a solid foundation for the work to follow. A series of advisory meetings produced policy documents ranging from patient-initiated data, through research data on care processes, transitions and coordination, to researcher access to claims data. The culmination of this project was the draft for the Strategic Opportunities Report, the ‘HHS Strategic Roadmap for Building Data Capacity for Clinical Comparative Effectiveness Research (CER)’ (Strategic Roadmap or Roadmap).

As specified in the Roadmap, there are two ways to ‘build data capacity’: 1) create more data (via creation of registries, new data networks, and the like: and 2) create what is needed to make existing and future electronic health data more usable for PCOR. Both of these methods were applied to the development of the OS PCORTF data capacity. HHS focused on developing needed standards, services, policies and governance structures that would help make private sector data more usable for PCOR. These four strategic components, established in consultation within HHS and with members of the research community, addressed the core research functions

of collecting, linking, and analyzing data. They provide evidence for milestones in achieving improvements in data capacity.

Subsequent use and/or dissemination of project: The Roadmap, currently referred to as the Strategic Plan or Framework, has become a ‘living document’. It is used as a guide for managing the OS PCORTF investment portfolio, for annually planning the next phase of data capacity development and as an allocation strategy for investment. The Strategic Plan now includes objectives, milestones and their related timeframes in response to the mandated review of General Accountability Office (GAO)¹².

Data network functionalities addressed by project: This project addressed the data infrastructure functionalities by identifying and providing the framework a set of five priority functionalities relevant for developing the data capacity for comparative clinical effectiveness research in keeping with the statutory mandate. The identified functionalities are: 1) Standardized Collection of Standardized Clinical Data; 2) Linking Clinical and Other Data for Research; 3) Collection of Participant-Provided Information; 4) Use of Clinical Data for Research; and 5) Use of Enhanced Publicly-Funded Data Systems for Research.

Potential for follow-on work: The OS PCORTF is funded through FY 2019. Because this funding is ‘no-year’ money, all obligated funds may continue to be used beyond FY 2019.

The data capacity will continue to serve as the basis for research for use in clinical decision-making and may be broadened for research for other purposes. For example, the 21st Century Cures Act contains many Sections that are compatible with the parts of the OS PCORTF portfolio for research purposes. In addition, the OS PCORTF data capacity infrastructure is consistent with the research requirements for the 21st Century Cures Act, Section 2011, Advancing Precision Medicine; Section 2012, Privacy Protection for Human Research Subjects; and Sections 4003—Interoperability, 4005—Leveraging Electronic Health Records to Improve Patient Care, and 4006—Empowering Patients and Improving Patient Access to their Electronic Health Information.

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Fiscal Year of OMB approval: FY 2013

Project period of performance: 02/15/2013 to 06/15/2015

¹² Government Accountability Office. Comparative Effectiveness Research: HHS Needs to strengthen Dissemination and Data-Capacity Building Efforts. (GAO-15-280). March 2015.