BUILDING DATA CAPACITY FOR PATIENT-CENTERED RESEARCH IN HHS

ASPE | Office of Health Policy

OVERVIEW

Harnessing the power of data for research holds tremendous potential to improve the value, quality, and outcomes of health care in the United States. Over the past decade, multiple laws have been enacted by Congress and the President to build data capacity and expand research on the outcomes and effectiveness of interventions used in health care.[1]

These laws recognized the need for better scientific evidence to inform the real world decisions of individual patients, providers, and policy makers about the benefits and risks of health care interventions. Furthermore, Congress recognized that the growing volume of existing health data could be better utilized for research that discovers new treatments as well as assesses the long-term health outcomes of therapies.

Health care data are held by a wide variety of disparate entities and in many different formats including billing claims, administrative data, surveys, and electronic health records. More than 150 exabytes of data are generated by the U.S. care system and the volume is increasing exponentially because of breakthroughs in digital health like wearable devices, telehealth, genomics, and personalized medicine. Furthermore, new technologies like artificial intelligence, machine learning, and blockchain are being applied to large data sets for researchers to find new ways to cure or manage costly health conditions such as cancer, heart disease, and Alzheimer's. With U.S. health care spending reaching $3.5 trillion in 2017, there is a growing recognition that big data and new technologies will transform the diagnosis, treatment, and prevention of disease in the 21st century health care system.

Since 2010, the Office of Health Policy (HP) of the Assistant Secretary for Planning and Evaluation (ASPE) has funded and supported a portfolio of approximately 40 projects to build data infrastructure on topics such as opioids, mortality data, real world evidence, emergency preparedness/response, and the interoperability of electronic health records. ASPE works with HHS agency leaders to oversee the development and approval of projects to address Department priorities that build data capacity for patient-centered outcomes research. Twelve HHS agencies and offices currently participate in the ASPE managed data infrastructure program under the auspices of the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) portfolio. The program facilitates intradepartmental collaborations that address HHS data and analysis priorities. This paper highlights illustrative projects in the portfolio. Please visit ASPE's website for more information about OS-PCORTF at https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund.

Ultimately, high quality Federal data enables HHS to better serve the public and foster innovations in medicine, public health, and social services. While the modern potential is great for secondary uses of data, the current use of clinical and administrative data for research on nationally important issues is limited by a dearth of data standards, services, policies, and governance structures that would substantially improve the utility of many more data sources for research.

[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (PL 108-173), American Recovery and Reinvestment Act of 2009 (PL 111-5), and the Patient Protection and Affordable Care Act of 2010 (PL 111-148).

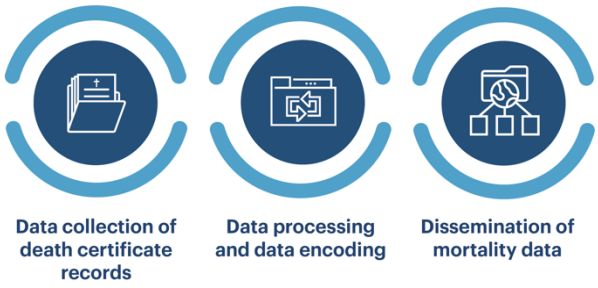
Improving the Nation's Mortality Data Infrastructure

The timely reporting of death information is critical for public health surveillance and patient-centered outcomes research. Comprised of all U.S. mortality events since 1979, the National Death Index (NDI) database allows researchers to match death entries in the NDI with their research populations (e.g., those participating in longitudinal clinical and epidemiologic studies) to determine both death "status" and cause of death. Mortality is an important outcome for any public health crisis, including the opioid crisis, and therefore having access to more accurate, timely, and complete data via NDI is critical for researchers, providers, and patients alike.

A significant challenge with the NDI is the lag between the occurrence of an individual's death and the availability of their record for matching purposes. This has limited the NDI's utility for timely patient follow up and survival outcomes determination. Three CDC projects contributed to improving the timeliness, quality, and completeness of data in the NDI that is leveraged for research where mortality is a key outcome.

Strengthening the Data Infrastructure for Outcomes Research on Mortality Associated with Opioid Poisonings

This project began work in March 2018. The purpose of this project is to strengthen the mortality data infrastructure for outcomes research on deaths associated with opioid poisoning by:

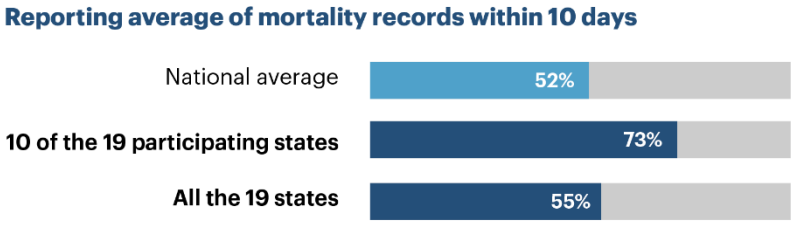


- Redesigning the Medical Mortality Data System to electronically code and process a larger percentage of death certificate records including deaths involving opioids using new technologies and the information in the literal text fields of death certificate records;
- Incorporating supplemental information from the literal text fields of death certificate records, especially information related to deaths involving opioids, as new variables in the National Death Index (NDI) and the National Vital Statistics System's restricted-use multiple cause of death mortality files for use by approved researchers;
- Improving the specificity of drug information on death certificates supplied by states;
- Improving the depth and timeliness of national reporting on drug deaths involving opioids;
- Aligning changes in the mortality data system with end-users' (i.e., researchers') needs; and conducting targeted engagement and dissemination activities with the drug overdose research community.

This project will engage and use innovations from researchers and other federal partners (i.e., HHS ASPE, the Food and Drug Administration, and the National Library of Medicine) to produce higher quality, timelier and supplemented information on drug overdose deaths involving opioids. The outcome of this project will be the production of critical data resources for researchers, policymakers and other end-users to be used for drug-involved mortality surveillance and analysis of the national opioid epidemic in the United States.

Improving the Mortality Data Infrastructure for Patient Centered Outcomes (completed in May 2018)

This project addressed three gaps in mortality infrastructure by: increasing the electronic reporting of mortality data from states to the CDC; piloting national standards for exchange of mortality data between electronic health records (EHRs), state vital records systems, and the NDI; and successfully linking the NDI with mortality datasets from the National Hospital Care Survey of in-patient and emergency departments.



OS-PCORTF funds were used to assist nineteen states to improve their transmission of mortality data by engaging stakeholders, enhancing technology, training staff, and making upgrades to internal systems and processes. Despite challenges facing local and state vital records offices, almost every jurisdiction's timeliness improved; ten of the nineteen states reported 73 percent of their mortality records within 10 days, all 19 states reported 55 percent of their records within 10 days; all exceeding the national reporting average of 52 percent.

In addition to improving transmission, OS-PCORTF funds were also used to integrate EHR systems with vital records systems to improve the quality and timeliness of mortality data collection and distribution, through standardization and reduction of duplicative data entry. The CDC used the Health Level Seven International (HL7) standards to support the bi-directional exchange of mortality data from Epic EHRs to California's state vital records system, and the state vital records system to CDC's NDI. The exchange of data in this format demonstrated the feasibility of implementation, and if implemented more broadly will support improvement in the quality and timeliness of mortality data, clinical care assessments, and PCOR.

The result of this project is better quality data from state-level systems, better electronic reporting, and therefore more complete mortality data for researchers to easily utilize standardized components, including publishing HL7 death reporting standards and implementation guides to enhance standardization.

Enhancing Data Resources for Researching Patterns of Mortality in PCOR (completed in May 2018)

This project allowed CMS to link the National Death Index (NDI) data for known Medicare and Medicaid deaths as well as to other Medicare and Medicaid data such as claim and enrollment information for use in PCOR. Nearly 9 in 10 deaths in the nation are among individuals in these two programs.[2,3] Moreover, Medicare and Medicaid disproportionately cover individuals at risk for premature mortality including low-income individuals, individuals with disabilities, and those over age 65. CMS's Medicare and Medicaid research data only contained information on fact of death, but only certain years of Medicare data (1999-2008) and Medicaid data (1999-2007) contained information on the cause and manner of death. Linked data between health care claims, including diagnoses, and cause and manner of death enables many types of PCOR research, including descriptive epidemiology, predictive modeling to identify high value intervention targets, and comparative effectiveness. The benefit of this linkage is particularly high for recent years of data given changes to the programs, e.g., Medicare prescription drug benefits starting in 2006, and Medicaid expansion starting in 2012. The linked data sets included known deceased beneficiaries for Medicare from 2008-2017 and deceased Medicaid recipients from 2007-2013.

*After the release of the public files, **13 new studies/topics** were approved by CMS including:*

- *A Surveillance of Cancer and Blood Disorders in the General Medicare Population*
- *Medicare Co-Insurance and Risk of Death from Colorectal Cancer*
- *Surveillance of Diabetes, Prediabetes, and Prevention Efforts*
- *Enhancing the Measurement of Health Care Quality to Improve the Value of Care in Medicare and Medicaid.*

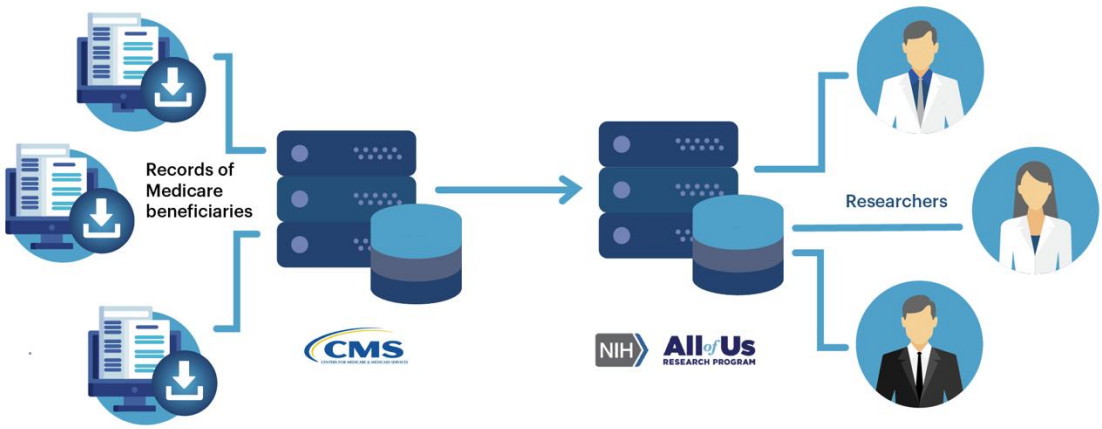
As a result of this project, CMS announced the available linked files to the public in April 2018 through the CMS research websites, ResDAC and the Chronic Conditions Warehouse (CCW). CMS has approved 13 requests for the updated NDI data through the approved process and has provided the data. The approved requestors included internal CMS components, CMS contractors, other federal agencies, states and academic research organizations. The studies/topics that were approved for the data include the following: A Surveillance of Cancer and Blood Disorders in the General Medicare Population, Medicare Co-Insurance and Risk of Death from Colorectal Cancer, Surveillance of Diabetes, Prediabetes, and Prevention Efforts, Enhancing the Measurement of Health Care Quality to Improve the Value of Care in Medicare and Medicaid.

[2] Sherry L. Murphy, 2017 National Vital Statistics Report Deaths: Final Data for 2015, Division of Vital Statistics National Vital Statistics Reports, Vol. 66, No. 6, November 27, 2017.
[3] Sherry L. Murphy, 2015 National Vital Statistics Report Deaths: Final Data for 2012, Division of Vital Statistics National Vital Statistics Reports, Vol. 63, No. 9, August 31, 2015.

Blue Button: Improving Medicare Beneficiary Access to Their Health and Claims Data

A series of awards from the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) assisted CMS to transform its 'user un-friendly' 2010 Blue Button from a patient portal into Blue Button 2.0, which enables Medicare beneficiaries to connect their claims data to the applications, services and research programs they trust. Through funding by the OS-PCORTF, CMS is now working with the National Institutes of Health's Sync for Science project to allow CMS beneficiaries the ability to donate their CMS data to NIH research studies. Medicare beneficiaries bear a disproportionate share of the nation's disease burden, yet they are often underrepresented in clinical research studies. Under this initiative, they can now more readily participate in such studies.

The first award was a one-year project entitled, 'Improving Beneficiary Access to Health Information: A Plan' to enhance "Blue Button" by redesigning the original 2010 CMS electronic Blue Button. Blue Button had been created to give Medicare beneficiaries access to their own health information, create and print reports, and to download their CMS information via MyMedicare.gov. At that time, in spite of the fact that more than a million beneficiaries had taken advantage of the MyMedicare.gov Blue Button service, they found the tool difficult to use and share their health information. The redesign focused on developing a computer platform that was user-friendly and would allow third party service providers to build software programs (apps) and other tools that could easily collect, present and share data, while simultaneously ensuring the data's privacy and security.



The second award was to carry out the new plan to create, pilot, and implement the enhanced Blue Button service. Activities undertaken in this second award introduced the Fast Healthcare Interoperability Resources (FHIR®) framework—developed by Health Level Seven International (HL7).

FHIR is designed to simplify implementation without sacrificing information integrity. It provides a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications. 'Blue Button on FHIR', as the project became known, has the potential to set a pattern for connecting consumer/patient health-related data to health applications and services and become a model that can be extended to other patient populations beyond Medicare. Blue Button 2.0 was now not only ready for beneficiaries' easy use, but for more advanced research application as well.

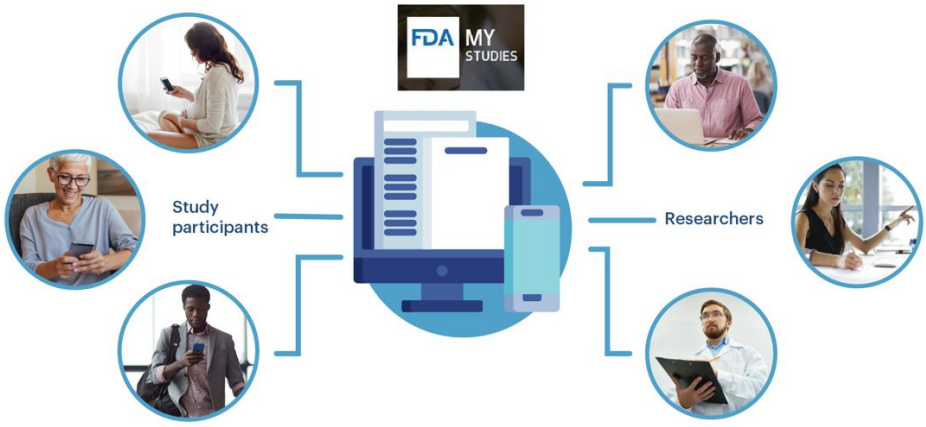
Enhancing Patient Portals

- ***Fast Healthcare Interoperability Resources (FHIR®).*** *Maintains information integrity while simplifying implementation and enabling data exchange.*
- ***Sync for Science™ (S4S) mechanism expansion.*** *Enables Medicare beneficiaries to donate their individual Medicare data to research projects. The elderly and disabled are often under-represented in clinical research, this project will allow Medicare beneficiaries to participate in research studies by sharing their data directly with researchers.*

Meanwhile, a collaboration between NIH and CMS was seeking to leverage the Sync for Science™ (S4S) as a mechanism to enable Medicare beneficiaries using Blue Button 2.0 to donate their medical claims data for scientific research studies.

The collaboration came to fruition in 2017 when OS-PCORTF awarded funding CMS to provide a safe and secure mechanism for Medicare beneficiaries to donate their individual Medicare parts A, B, and D claims data to scientific research using the NIH Sync for Science Platform. With the beneficiaries' consent, the donated, longitudinal health data gathered by the *All of Us* research study will be combined with up to one million or more people living in the United States, and will support research across a breadth of disciplines.

Using Open-Source mHealth App to Integrate Patient Data into Clinical Trials



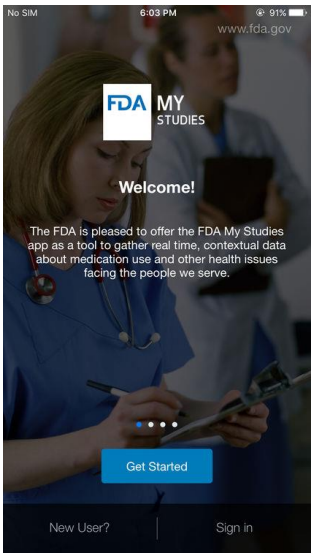
The product of this FDA effort is a generalizable mobile device application that pilot tested its application software (app) by collecting data from pregnant women (i.e., medical product exposures, outcomes, risk factors and confounders) which is linked with a single data partner, participating in a large distributed database (i.e., Sentinel and PCORnet). The complicated nature of exposure and outcome assessment in pregnant women provides a challenging use case that can be later modified to address the needs of other patient populations.

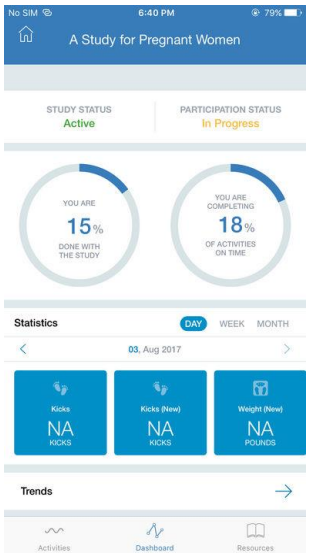
The effort included a collaboration with the HHS Office of the National Coordinator for Health Information Technology (ONC) which is engaged in a related activity, 'Conceptualizing a Data Infrastructure for the Capture and Use of Patient-Generated Health Data (PGHD)'. Specifically, the policy framework is expanded to include identifying best practices for the use of PGHD within a big data environment (the FDA's Sentinel system), which aligns with ONC's consumer eHealth policy agenda.

The product of this project is known as FDA's MyStudies App. The app allows patients to securely enroll and participate in a variety of clinical and pragmatic trials and observational studies. The open source code is compatible with both Apple iOS and Android devices, and software developers have the opportunity to access this code and improve upon the available capabilities.

Key Capabilities of the MyStudies App

- *Secure patient enrollment in clinical and pragmatic trials and observational studies.*
- *Software developers can access and improve the code due to open source*
- *Reduces study biases through patient reported data*





Among the important scientific benefits derived from this project is that pregnant women, who are typically excluded from clinical trials which means that any pregnancy related drug safety issues are unknown at the time of drug approval, will be able to send in data through the app. This app will allow them to report any side effects and researchers can then determine which might be related to a medication. This knowledge will help to improve the safety of medication use for pregnant women. Other benefits accrue from the reducing biases in research through the conjoint use of patient-reported information with medical records or healthcare claims in clinical trials. Finally, because the data are collected through mobile devices, the process is providing Real World Evidence (RWE). Researchers are able to query both the new patient-provided data and the healthcare data captured routinely by the Sentinel data provider and PCORnet, which share the same Collaborating Center.

The project serves as a pilot for three potential future applications. First, the mobile device application (content and infrastructure) could be extended to other Sentinel data providers for drug safety surveillance in pregnant women. Second, the mobile device application could potentially be linked to Clinical Research Networks and Patient Powered Research Networks engaged in comparative effectiveness research or clinical trials. Furthermore, the content of the application could be modified to address the needs of other patient populations. Third, the mobile application content could be modified in order to function as a patient-reported outcome (PRO) instrument for clinical trials used to support claims in approved medical product labeling.

Advancing the Use of Registries to Improve Research

Registries and electronic health records (EHRs) contain a variety of rich clinical information including demographics, diagnoses, medications, allergies, and laboratory values. These data have the potential to support hypothesis generation and large scale clinical research studies. To this end, vocabulary and standardization of data, and methods to electronically exchange information between EHRs and registries are a priority for federal stakeholders, developers, and researchers alike.

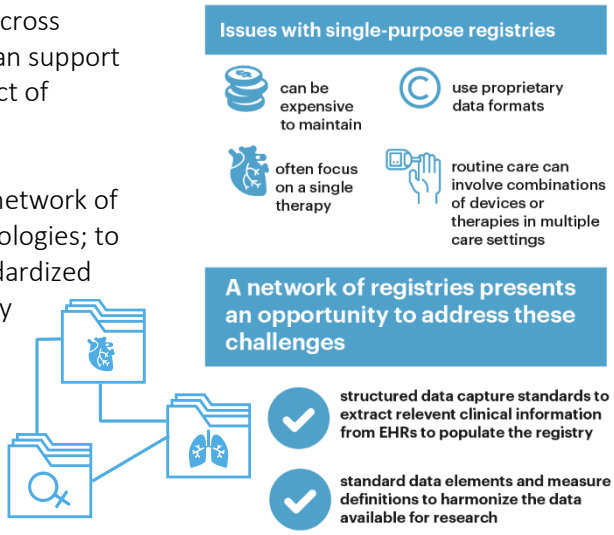
However, there is significant variation in both the types and definitions of outcome measures used in patient registries, even within the same clinical area. For example, one study investigating the impact of differing clinical definitions on study findings showed that in one registry, the rate of reported myocardial infarction was 7.2 percent when using the biomarker CKMB as the criteria, compared to 24.3 percent when using the biomarker troponin as the criteria, representing a three-fold difference. These heterogeneous data reduce the utility of registries to collect, link, and aggregate data.

Among other PCOR projects to enhance researcher's ability collect, link, and analyze data, OS-PCORTF funded two projects; one that addressed a policy area of harmonizing outcome measures across registries & EHRs. Another project addressed a technical/informatics aspect of developing tools for the collection of standardized data in registries.

Developing a Strategically Coordinated Registry Network to Support Research on Women's Health Technologies

This joint project between the FDA, NIH, and ONC, is to improve clinical evidence generation and to better answer clinical questions on medical device technologies in clinical areas specific to women. Registries provide critical infrastructure that can be used for a variety of analyses related to patient care and outcomes. While single-purpose registries can meet the demand for data on real-world patient care, they can be expensive to maintain, use proprietary data formats, and often focus on a single therapy, when routine care can involve combinations of devices or therapies in multiple care settings. A network of registries presents an opportunity to address these challenges. The project will leverage structured data capture standards to extract relevant clinical information from EHRs to populate the registry. These registries will also use standard data elements and measure definitions to harmonize the data available

for research. Finally, these data will be shared across registries using standard API interfaces, which can support more complex study designs evaluating the effect of combinations of devices or therapies.



OS-PCORTF funds are being used to establish a network of registries for research on women's health technologies; to develop and test tools for the collection of standardized data; to evaluate the completeness and flexibility of the HL7 FHIR® exchange messaging standard; and to support the evaluation of medical devices in clinical areas unique to women. Initially, the project includes uterine fibroid treatment, pelvic floor disorders, and stress urinary incontinence.

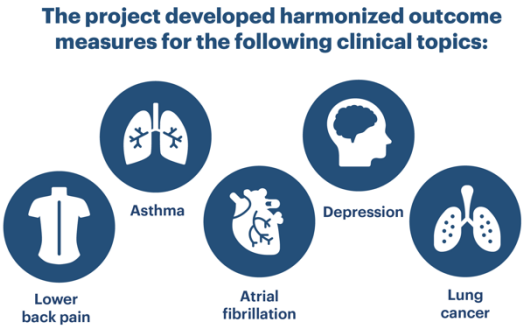
OS-PCORTF funds are also being used to convene the community of stakeholders (patients, providers, manufacturers, EHR vendors, standard development organizations, and researchers) as end-users to create a robust data governance framework for securing buy-in from the end-user community. A critical component of this project is the collaborative governance structure established between the clinical and informatics teams, designed to ensure the final deliverables retain their clinical relevance and utility for clinical care, quality improvement, and device surveillance, as well as for research.

As a result, this project has addressed standards and services across a number of the functionalities needed to build research data capacity. The use of a data exchange standard like HL7 FHIR® provides an opportunity to collect structured, standardized, analysis-ready patient data at the point of care. Capturing standardized data will streamline data collection and support exchange of data across networks. The resulting data will be not only more consistent across organizations, but also more reflective of real-world evidence, such as supporting the inclusion of both the medication (using the clinical research standards and controlled terminologies) and the implantable device data (available through links to unique device identifier (UDI) data and meta-data available in the Global UDI Database). This standardization supports the increased use of clinical data captured and will allow researchers to collect longitudinal patient information and to link data sets with other relevant information for research (e.g., other research networks such as Sentinel, PCORnet, and available state data infrastructure).

Harmonization of Clinical Data Element Definitions for Outcome Measures in Registries (completed April 2018)

This project supported the creation of both harmonized outcome measures and the AHRQ Outcome Measures Framework—a conceptual model for developing standard outcome measures. Together, these activities aimed to harmonize clinical data element definitions thereby supporting the comparison of data across registries and create a model for future outcome measure harmonization efforts between registries, EHRs, and reporting requirements.

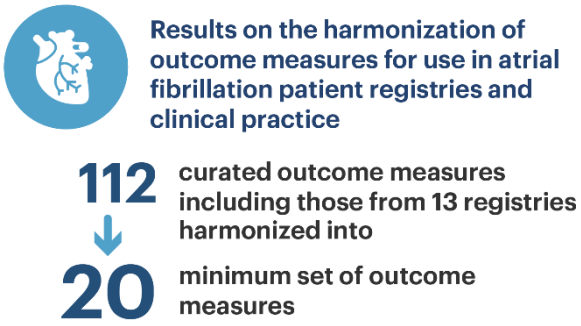
Funds were used to develop a consensus set of clinical data element (CDE) definitions that can be consistently used to represent specific outcome measures for each of five clinical topic areas: atrial



fibrillation (AF), lumbar spondylisthesis (lower back pain), lung cancer, asthma, and depression. Funds were also used to develop best practices for governance of data element definition libraries and harmonization between registries. ARHQ assembled a stakeholder group of payers, patient representatives, and health system leaders to discuss challenges and provide feedback on the harmonization efforts.

Completed deliverables include libraries of clinical definitions for atrial fibrillation, depression, asthma, lung cancer and lumbar spondylolisthesis. These libraries contain not only the clinical definitions of the outcome measures, but also the value sets, which are critical to implementation and interoperability. Value sets use standard clinical coding terminologies (i.e., RxNorm, ICD-10, LOINC, and SNOMED) to define the clinical concepts (in this context, the outcome measure itself) and to help users implement the codes in EHRs.

AHRQ continues to work with relevant professional societies (e.g., Heart Rhythm Society, the American Medical Association) to publish and seek endorsement for the AHRQ definitions in these organizations' registries. The Spine Society has invited AHRQ to speak at their annual conference to disseminate their results among its members. In addition, the American College of Cardiology is exploring a project similar to AHRQ's OS-PCORTF Capstone for Outcomes Measures Harmonization (OMH) Project, to improve the collection of registry-ready data at the point of care through EHRs.



As a result of this project and its efforts to adopt the core common outcome measures/data element sets, the data available for research will be standardized and comparable across different registries and health care organizations that collect the information.

Assessing and Predicting Medical Needs in a Disaster

HHS leads the U.S. public health and medical response to disasters and emergencies. Although disasters occur in all geographic regions, researchers are often unable to address geographic differences when designing studies, which leads to inaccurate and non-generalizable results. The nation witnessed an unprecedented number of disasters in the last several years, including hurricanes, fires, earthquakes and others which makes this project especially timely.

This project aims to close the information knowledge gap in understanding how to tailor disaster medical response to the local level for each event. The project focuses on the creation of a data platform that can be used to engage researchers in identifying data needs to conduct PCOR related to disaster response and recovery operations. This platform will test whether questions about state and county-level health care disaster-related needs can be answered and tracked over time. In turn, analyses can reflect the health needs of specific populations, thus improving information to deploy appropriate medical expertise. This project will initially explore research questions such as comparing differences between communities directly affected by disaster versus other comparable communities for outcomes. Eventually, researchers can use this data to assess different interventions based on disaster type and population.

Examples of CER/PCOR questions that this project aims to answer are:

1. *Comparing patient outcomes for various interventions such as medical treatment received in shelters versus patient outcomes in hospitals*
2. *Assessing whether new approaches to providing dialysis services in the 2017 disasters improve patient outcomes*
3. *Determining if naloxone treatment in shelters is effective in overcoming opioid overdoses when the patient history is unknown.*

Early Progress

Researchers at AHRQ conducted analyses to help the Assistant Secretary for Preparedness and Response (ASPR) refine their emergency response plans as Hurricane Florence approached the Carolinas in September 2018. Using historical data from Hurricane Irene (August 2011) and Hurricane Matthew (October 2016), AHRQ consulted with ASPR in projecting estimated changes in hospital inpatient stays and emergency department visits in the first four weeks after Hurricane Florence. From these analyses, AHRQ created a concise report with color figures summarizing their projections for all counties in North Carolina and South Carolina expected to be directly in the path of Hurricane Florence compared with counties expected to be near the

path of the hurricane. Projections were reported separately by hospital setting (emergency department visits and inpatient stays), and broken out by patient age and clinical conditions. The magnitude of the projected post-hurricane changes varied widely by age group and clinical condition, with notable surges in utilization found for endocrine disorders, infectious disease, mental and behavioral disorders, and injuries throughout the first four weeks post-hurricane.

ASPR had sufficient time to share the information in the report with federal staff and interagency liaisons in the Secretary's Operations Center for the public health and medical response to the hurricane. ASPR reported that the report was greatly appreciated by senior leadership and regional authorities to help guide decision making for overall awareness and support for the public health and medical response. It was also useful to share with hospital officials in the affected healthcare systems, so they too would know what to expect and plan accordingly.

Hurricane Florence dissipated by September 19th. At this time, AHRQ reached out to their HCUP Data Partners in North Carolina and South Carolina to share with them the results of these analyses for their respective States. One of the Partners expressed a great interest in learning more about the methodology that AHRQ used in these quick turnaround analyses, and this information was also shared with them. With their valuable local perspectives and situational awareness, States that are particularly vulnerable to disasters and interested in conducting these types of analyses in the future could build upon the methodologic approaches developed by HHS. As they move forward in their OS-PCORTF-supported collaboration, staff at AHRQ and ASPR will continue to disseminate these kinds of analytic findings and methodologic tools to stakeholders at the state and federal levels.

Case Study in the Carolinas--Hurricane Florence

Researchers at AHRQ conducted analyses to help ASPR refine their emergency response plans to Hurricane Florence. Using historical data from the HCUP State Emergency Department Databases (SEDD) and State Inpatient Databases (SID) from the periods of Hurricane Irene (August 2011) and Hurricane Matthew (October 2016), AHRQ consulted with ASPR in projecting estimated changes in hospital inpatient stays and emergency department visits in the first four weeks after Hurricane Florence. This information informed planning for first responder deployment in advance of the storm, allowing HHS to use limited resources more effectively.

The Office of the National Coordinator for Health Information Technology

AHRQ

Incorporating Patient Voices in Patient-Centered Outcomes Research

The collection of patient-reported outcomes (PROs) information can greatly support patient-centered outcomes research by offering a complementary perspective to clinician assessments providing clinicians with critical information on outcomes important to patients. Since PROs come directly from the patient and without initial interpretation by clinicians, they can provide greater insights into health status, symptom burden, adherence, and quality of life. PROs can inform the clinical management of individuals as well as support shared decision making, patient self-management support, care planning, goal setting, and goal attainment. However, the capacity of electronic health record (EHR) systems to capture PROs in a standardized format is currently limited and underutilized. This limits understanding of the patient's perspective. While some EHR systems are currently able to capture some structured PRO data, information is not commonly collected and integrated at the point of care.

Recognizing these limitations, the Agency for Healthcare Research and Quality (AHRQ) and the Office of the National Coordinator for Health Information Technology (ONC) are leading a joint project to advance the collection, use, and sharing of structured PRO data.

Standardizing the collection and sharing of PRO data

ONC developed a draft implementation guide that documents the technical specifications using an industry-recognized health information exchange standard to enable the collection and sharing of standardized PRO measures and data. The project leverages products from two ONC initiatives that were previously funded by the OS-PCORTF to both develop a conceptual model that illustrates a PRO workflow[4] and enable the creation of PRO measure instruments in standardized structured formats[5]. Collecting and storing PRO data in structured and standardized ways facilitates the sharing of this data and its potential use for secondary purposes. Currently, the technical specifications outlined in the draft implementation guide are being tested in two pilot research networks: patient-centered SCAlable National Network for Effectiveness Research (pSCANNER)[6] and Research Action for Health Network (REACHnet)[7]. As the testing is being conducted, the draft implementation guide is being vetted with the standards organization, Health Level Seven International (HL7). The draft is currently available on the HL7 website and as the guide is refined, it will continue to be publicly available for wider adoption by organizations that are integrating PROs into their health information systems.

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[4] OS-PCORTF 2015: Conceptualizing a Data Infrastructure for Capture and Use of Patient-Generated Health Data (PGHD) Project

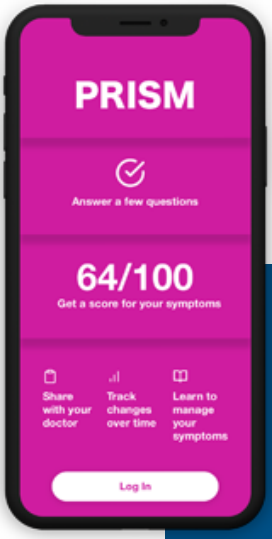
[5] OS-PCORTF 2014: Structured Data Capture (SDC) PCORTF project, now managed and maintained by the HL7 Structured Data Workgroup

[6] PCORI funded, stakeholder-governed federated network that utilizes a distributed, service-oriented architecture to integrate data from three existing networks covering over 24 million patients.

[7] PCORI funded clinical data research network (CDRN) of health systems in Louisiana and Texas covering 5 million patients.

Collecting and sharing PRO data through apps

AHRQ developed and is currently testing user-friendly PRO applications (apps) that utilize the technical specifications laid out in the implementation guide, developed by ONC. To spark the development of user-friendly PRO related apps, AHRQ launched a multi-phase challenge competition, Step Up App Challenge, in August 2018.[8] Teams competed to design, develop, and pilot test user-friendly apps that simplify the process of collecting, aggregating, and sharing PRO data related to physical function outcomes in the ambulatory care setting. The challenge teams were asked to develop applications to meet the technical, usability, and functionality requirements provided by AHRQ. The usability and functionality requirements were gathered from stakeholder interviews funded by AHRQ. The "challenge" resulted in more than 50 proposal submissions, ten of which were selected to proceed to the actual application development. The first place winner, PROMIS Reporting and Insight System from Minnesota (PRISM), is now working with Medstar Health to pilot test their application at nine practices in Washington, D.C, Maryland, and Virginia for the final phase of this challenge.



PRISM™, PROMIS Reporting and Insight System from Minnesota, enables patients to complete physical function and other PROMIS measures through an easy-to-use app, with value-added features including score trending, peer group comparisons, and personalized recommendations for follow-up actions and education materials aimed to further engage patients in their care. The platform supports any PRO instrument, and allows seamless data integration with EHRs to make data available for providers to use, in real-time, in their clinical care and shared decision making with the patient.

Visit http://bit.ly/stepupwinners for more information about the Phase 2 winners.

The results of this effort will include development of a variety of applications in different domains that utilize the technical specifications, developed by ONC, to collect PRO data and test different implementation architectures to integrate PRO data with EHR systems. The lessons learned from the pilot tests can inform future PRO implementations and support interoperable measures for application in various workflows. One promising potential use of the products from this project is on the assessment instruments for CMS Post-Acute Care (PAC) Services using the CMS Data Element Library (DEL). This data library aims to help clinicians focus on "Patients over Paperwork" by promoting an interoperable health information exchange of CMS assessment questions and response options to nationally accepted health IT standards. As a result, the tool can facilitate better care coordination, improved health outcomes, and reduced provider burden through reuse of appropriate healthcare data.[9]

As the shift to incorporating the patient perspective into the clinical point of care takes off, this effort will contribute to improving patient outcomes and reducing clinician burden by streamlining workflows.

[8] https://www.ahrq.gov/stepupappchallenge/index.html
[9] https://del.cms.gov/DELWeb/pubHome

Select Bibliography

For additional information about the OS-PCORTF resources and information about the portfolio of projects, see our general webpage: https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund

Activities Funded by the Patient-Centered Outcomes Research Trust Fund, GAO-18-311: Published: Mar 23, 2018.

Web Link: https://www.gao.gov/products/GAO-18-311

Building Data Capacity for Patient-Centered Outcomes Research in HHS: A Formative Evaluation of 2012-2016 Projects.

This report is a formative evaluation of the OS PCORTF portfolio of projects from 2012 to 2016. It summarizes achievements as well as considerations for future work to build data capacity for clinical comparative effectiveness research and patient centered outcome research.

Web Link: https://aspe.hhs.gov/system/files/pdf/259016/ASPEPCORTFEvaluation.pdf

2017 Annual Report of HHS Projects to Build Data Capacity for Patient-Centered Outcomes Research

The OS PCORTF Annual Report provides project descriptions for each of the OS-PCORTF portfolio's 21 projects that were active in calendar year 2017.

Web Link: https://aspe.hhs.gov/system/files/pdf/259016/2017AnnualReportPCORPortfolio.pdf

2016 Annual Report of HHS Projects to Build Data Capacity for Patient-Centered Outcomes Research

The OS PCORTF Annual Report provides project descriptions for each of the OS-PCORTF portfolio's 18 projects that were active in calendar year 2016.

Web Link: https://aspe.hhs.gov/system/files/pdf/259016/ASPEPCORTF508PortfolioRpt2016.pdf

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

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.

Web Link: https://aspe.hhs.gov/system/files/pdf/259016/OSPCORTFCompletedProjectsReport.pdf

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