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ADDRESSING THE OPIOID EPIDEMIC WITH BETTER DATA: AN OVERVIEW OF HHS PRIORITIES AND PROJECTS TO EXPAND DATA CAPACITY FOR PATIENT-CENTERED OUTCOMES RESEARCH ON OPIOIDS

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INTRODUCTION

Opioid misuse and addiction have led to a public health epidemic affecting millions of people in the United States. As the Department of Health and Human Services (HHS) directs its attention and resources toward understanding and addressing this national epidemic, the need for timely, quality and accessible data is a key priority area. In recognition of this urgent need, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) convened a workshop titled *Addressing the Opioid Epidemic: Harnessing the Power of Data for Patient-Centered Research* in December 2018, which showcased projects working to build the data infrastructure for patient-centered outcomes research around opioids. This paper builds upon the proceedings from this workshop with a targeted scan of project and peer-reviewed literature. Specifically, this paper: reviews HHS's strategy to "strengthen public health data reporting and collection to improve the timeliness and specificity of data"[1] to combat the opioid epidemic, and highlights agency-specific opioid strategies that necessitate "better data" to be fully achieved; 2) documents HHS-funded projects to build the data infrastructure around opioids and maps them to HHS priorities around "better data" on opioids; and 3) discusses the data infrastructure challenges and opportunities to enable access to "better data" for research around opioids.

While this paper provides an overview of priorities and initiatives related to research around opioids by select agencies within HHS, it does not provide a comprehensive overview of the full portfolio of work within HHS related to opioids. Moreover, the HHS-funded projects identified in the paper are at varying phases of implementation. As such, the focus of this paper is on identifying efforts underway and not necessarily individual project progress.

BACKGROUND

The United States is experiencing an opioid epidemic of historic proportions. Approximately 60 million people were given at least one opioid prescription in 2016,[2] and opioid misuse and addiction have led to an opioid epidemic characterized by a rapid increase in opioid overdose deaths within the past 20 years.[1, 3] According to the CDC, there have been three waves of the opioid epidemic, beginning with deaths attributed to increased prescriptions of opioids in the 1990s, followed by increases in heroin overdoses in 2010, and most recently, the increasing availability and overdose deaths from illicit synthetic opioids or fentanyl.[4] From 1999 to 2006 there were 10 percent annual increases in overdose deaths, followed by a jump to 16 percent annually from 2014 through 2017.[5] In 2017 alone, over 40,000 opioid-related overdose deaths occurred in the United States, accounting for nearly 68% of drug overdose mortality in 2017.[6] Over half of these deaths involved synthetic opioids or fentanyl.[7]

Solutions to the opioid epidemic require coordinated efforts, spanning the healthcare continuum in addition to human services systems, law enforcement, and the justice system. Over the past two years, Congress has appropriated billions of dollars for prevention, treatment, and recovery efforts in response to this crisis. During FY2017 and FY2018, federal funding targeted to opioid use disorder treatment and recovery increased by over $1billion dollars.[8] This includes efforts to curb the supply of both illicit opioids and unnecessary prescription opioids and to improve access to evidence-based treatment for opioid use disorder. In FY2018, appropriations provided new funding for research through the launch of the National Institutes of Health Helping End

Addiction Long-Term (NIH HEAL) Initiative. In 2018, Congress and the president enacted comprehensive authorizing legislation to address the opioid epidemic, the SUPPORT for Patients and Communities Act (the SUPPORT Act).[9] This bipartisan law includes numerous provisions to prevent opioid misuse, increase access to treatment, and control the supply of illicit drugs. The SUPPORT Act also directs government agencies to conduct studies on aspects of the opioid epidemic.[10]

Robust and reliable data that are available to researchers within and outside of the federal government are critical to understanding and tracking the epidemic, informing treatment and prevention efforts, and ultimately to reducing opioid-related morbidity and mortality.

The US health care system produces a vast amount of data which continues to grow through breakthroughs in digital health and real-time data collection.[11] Congress has enacted multiple laws in the past decade to build data capacity and expand research on healthcare outcomes, including the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, the Affordable Care Act of 2010, the Evidence-Based Policymaking Commission Act of 2016, and the 21st Century Cures Act to improve the quality, flow and exchange of electronic health information.[12] These laws underscore the need for better scientific evidence to inform healthcare decision making by patients, healthcare providers, and policy makers.

The opioid epidemic highlights longstanding data challenges within the health care system, due in part to the distinctive nature of the epidemic which transcends study populations and care settings. These gaps are related to both the data infrastructure (how data are *produced* and *maintained*) and the quality and timeliness of the data itself. Broadly, these challenges include: (1) Data standardization and interoperability to enable timely, conceptually consistent and coordinated data collection on drug supply, epidemiology, and outcomes; (2) Real-time data collection and synchronization that enables data to seamlessly follow patients across systems (3) Targeted surveillance systems for data collection among special populations where there is currently a deficit of data such as pregnant women; and (4) Better linkages across data sources, including public health, laboratory surveillance, poison center, emergency medical services (EMS), clinical laboratories, law enforcement, medical examiner, and emergency department data. [13]

APPROACH

This paper incorporates and builds upon findings from a December 2018 workshop convened by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) around *Addressing the Opioid Epidemic: Harnessing the Power of Data for Patient-Centered Research.* The workshop aimed to showcase projects funded under the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) that aim to build the data infrastructure for patient-centered outcomes research (PCOR) around opioids. The workshop consisted of four keynote presentations on federal opioid initiatives by top administrators at HHS, including agency leaders at the Centers for Medicare & Medicaid Services (CMS) and National Institutes of Health (NIH), who outlined the specific aims of their opioid-related data infrastructure projects and how these intersect with and uphold the goals of broader HHS initiatives. These were followed by two panels showcasing OS-PCORTF awarded projects, and one panel

showcasing patient-centered research on the opioid epidemic, and their synergies with the OS-PCORTF data infrastructure projects. The workshop also offered an opportunity for participants to share ideas and identify new topics and opportunities to enhance data infrastructure to address the opioid epidemic. Following the workshop, a summary report was disseminated that included a synthesis of presentations and the discussions that followed around challenges and opportunities for future work.[14]

In addition to reviewing the workshop summary report and presentations, NORC scanned HHS agency websites and strategic plans related to opioids as well as conducted a targeted scan of peer-reviewed and grey literature to identify key publically available reports and articles related to building the data infrastructure for research around opioids. **Exhibit 1** includes the search terms or materials and preliminary results from these sources.

Exhibit 1. Literature Search Preliminary Results

Sources	Materials/Search Terms	Results
Targeted literature review	■ Review of HHS, CMS, NIH, CDC, SAMHSA, FDA and VA strategic plans for combatting the opioid crisis. ■ Review of current FY 2018 and FY2019 ASPE OS-PCORTF projects related to opioids. ■ Review of PCORI projects related to opioids. ■ Review of NQF opioids initiatives.	20
Grey Literature (Google) and Published Literature (PubMed)	("Opioids)" AND ("data infrastructure") OR ("data sources") AND ("United States")	7

Results were limited to publications written in English and published in the last three years (6/4/16 – 6/4/19). The preliminary results were reviewed to ensure that the articles were based on programs in the U.S., and that they described efforts related to data infrastructure for opioids.

FINDINGS

OVERVIEW OF HHS RESPONSE TO THE OPIOID EPIDEMIC

HHS is leading the federal response to the opioid crisis, spending over $5 billion on opioids in FY2018.[15] In 2017 HHS launched its broad 5-Point Strategy to Combat the Opioid Crisis. This strategy includes the following components: 1) Better addiction prevention, treatment and recovery service; 2) Better data on the epidemic; 3) Better (more evidence-based) pain management; 4) Better targeting the availability of overdose reversing drugs; and 5) Better research on pain and addiction. [16]

The HHS strategy defines the need for "better data" as "strengthening public health data reporting and collection to improve the timeliness and specificity of data, and to inform a real-time public health response as the epidemic evolves." [17] This includes the need for real-time data, rapid data and reporting, data around health outcomes, supplementary data around causes, risk and protective factors, comorbidities and disparities, geographic data, identifying gaps in key metrics, improving data linkages, and further utilizing and developing PDMPs. Although not directly applicable to this paper, this strategy also includes building linkages with Drug Enforcement Administration (DEA) and the U.S. Customs and Border Protection (CBP) to collect data on illicit drug seizures as well as effective communication around the meaning of the data and its implications within HHS and externally.

HHS "Better Data" priorities:

(1) Real-time data: Collect and disseminate "real-time," actionable data to target interventions, deploy resources, and assess impacts of federal, state, and local efforts;

(2) Rapid data and reporting: Accelerate data collection and publication of results from HHS surveys on illicit drug use and abuse;

(3) Outcomes data: Collect data that indicate durable (e.g. opioid deaths and non-fatal overdoses) as well as surrogate outcome markers (e.g. opioid prescriptions, new drug patterns, related harms, patients receiving MAT, and Neonatal Abstinence Syndrome incidence);

(4) Supplementary data: Collect data that provide insights into causes, risk and protective factors, comorbidities and disparities around substance abuse disorder (SUD) and addiction in order to devise long term solutions to the underlying causes and drivers;

(5) Geographic data: Collect state-, county-, and zip-code specific data when feasible;

(6) Key metrics: Conduct a comprehensive assessment of current data and key metrics, and implement strategies to address gaps;

(7) Data linkages: Improve linkages between disparate data systems, including among HHS operating divisions; and

(8) PDMP development: Create incentives for states to develop, implement, and utilize PDMPs that are accessible by prescribers and pharmacies across state lines and integrated into EHR.

Source: HHS. 5-Point Strategy to Combat the Opioid Crisis
https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html

HHS's 5-point strategy has set the tone for additional, more focused opioids strategies under each of its agencies. These strategies rely on robust data to enable a range of activities including monitoring and surveillance as well as clinical effectiveness and patient-centered outcomes research. These agency strategies therefore underscore the critical need for "better data" to enable the implementation of federal strategic priorities.

Centers for Disease Control & Prevention (CDC)

The CDC plays a critical role in supplying disease surveillance data to track and understand the opioid epidemic. The CDC administers the Opioid Overdose Prevention and Surveillance (OOPS) program through which it funds 32 states and the District of Columbia through the Enhanced State Opioid Overdose Surveillance (ESOOS) program. This program aims to establish an early warning system, integrate data from unique medical examiner and coroner investigations, and share findings with state and national stakeholders to inform opioid response efforts. Through this program CDC is collecting quarterly overdose data about Emergency Department (ED) visits, emergency medical service (EMS) transports, and biannual critical death-scene investigation information on overdose deaths. The ESOOS program enhances the ability of the CDC to report high-quality, real-time data on opioid overdoses to inform responses, and was instrumental in quantifying the threat of fentanyl in 2016, documenting that more than 50 percent of overdose deaths in 10 states were fentanyl-related.[18]

National Institutes of Health (NIH)

NIH is conducting clinical research to address the opioid epidemic through the HEAL Initiative, a trans-NIH research initiative launched in 2018. HEAL is focused on improving treatments for and prevention of opioid misuse and addiction and enhancing pain management, including research around non-addictive treatments. The National Institution on Drug Abuse (NIDA) has played a leading role in the HEAL initiative, leading research to understand the complex neurological pathways involved in pain and addiction, the development and testing of new therapeutic options for opioid addiction, overdose prevention and reversal, enhancing treatments for infants born with neonatal abstinence syndrome (NAS)/neonatal opioid withdrawal syndrome (NOWS), and integrating behavioral interventions with Medication-Assisted Treatment (MAT) for opioid use disorder (OUD).[19]

Centers for Medicare & Medicaid Services (CMS)

CMS' strategic plan, the *Roadmap to Address the Opioid Epidemic*, is a three-pronged approach focused on patient safety and quality. Specifically: 1) Managing pain using a safe and effective range of treatment options that rely less on prescription opioids, 2) Expanding access to treatment for opioid use disorder; and 3) Using data to target prevention and treatment activities and identify fraud and abuse.[20] As part of this latter objective, CMS developed the Medicare Part D and Medicaid opioid prescribing mapping tools, interactive tools showing geographic comparisons at the state, county, and ZIP code levels of de-identified Medicare Part D and Medicaid opioid prescription claims (prescriptions written and then submitted to be filled). These tools allow users to see both the number and percentage of opioid claims in order to inform community awareness among providers and local public health officials.[21] [22] CMS used this tool to identify and send letters to high prescribers. This outreach resulted in a 16 percent reduction in the number of prescriptions.[23]

Food and Drug Administration (FDA)

In keeping with its surveillance and regulatory role, the FDA has outlined a strategy to combat the opioid epidemic which focuses on patient safety, improving access to treatment for pain and addition, and encouraging the development of new therapies. The FDAs 2018 Opioid Policy Work plan focuses on integrating opioids into its broader strategic framework to "reduce the

burden of addiction crises that are threatening American families." Specifically, the strategy focuses on: 1) Reducing the overall rate of misuse and abuse of opioids, including inappropriate prescriptions through trainings, and 2) expanding opportunities for new products to treat pain that are less likely to lead to addiction and advancing better and more effective treatments for addiction.[24]

Substance Abuse and Mental Health Services Administration (SAMHSA)

SAMHSA has addressed the epidemic through implementation and administration of two state-based opioid grant programs: the State Targeted Response (STR) and the State Opioid Response (SOR) grants. These programs help states, territories and jurisdictions expand prevention, treatment and recovery support services as well as make treatment medications—such as methadone, naltrexone, and buprenorphine—available.[25] In addition, SAMHSA administers 19 programs that target OUD within the Programs of Regional and National Significance (PRNS). PRNS includes Medication-Assisted Treatment for Prescription Drug and Opioid Addiction grants to states to expand their MAT systems to increase access to evidence-based treatment.[26] PRNS also includes the Strategic Prevention Framework for Prescription Drugs (SPF Rx) program which raises awareness within the medical community about the risks of overprescribing opioids and funds prescription drug misuse prevention activities.[27] SAMHSA also evaluates the buprenorphine waiver program under the Drug Addiction Treatment Act of 2000 (DATA 2000) and tracks the number of DATA-waived practitioners. [28]

BUILDING THE FEDERAL DATA INFRASTRUCTURE FOR OPIOIDS

Our targeted literature review identified several diverse and large-scale federal data infrastructure projects in various phases of implementation to support national efforts to end the opioid epidemic. These projects are contributing towards the development of national standards (e.g., specifications for capturing, storing, representing, linking and exchanging data in a secure manner), services (e.g., resources that researchers can use to capture, store, link, analyze and exchange data), policies (e.g., federal rules or guidelines around protecting patient data, that ensure standards and services are followed) and governance structures (to support efficient use of the data infrastructure across individuals and organizations) to support PCOR.

Since 2010, ASPE's Office of Health Policy (HP) has worked to build data infrastructure to address a range of topics. Within ASPE, the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) coordinates federal programs to expand data capacity and infrastructure for patient-centered outcomes research (PCOR). The OS-PCORTF currently funds 10 different opioid-related projects across HHS agencies, including the Administration for Children and Families (ACF) (1 project), CDC (5 projects), NIH/NIDA (2 projects), and the Office of the National Coordinator for Health Information Technology (ONC) (1 project). These OS-PCORTF projects seek to improve opioid related data infrastructure through the creation of specific new data standards, data sets, improved mechanisms for data capture, and engagement of researchers in the identification of research needs. Broadly, OS-PCORTF funding related to opioids focus around the following 5

OS-PCORTF Key Functionalities:
(1) Standardizing data collection
(2) Collecting participant-provided information
(3) Linking data
(4) Optimizing data for clinical research
(5) Using Federal databases for research

areas: (1) Standardizing data collection – e.g., improving the standardization and recording of specific drugs and drug types at the time of an autopsy would improve understanding of drug-related overdoses; (2) Collecting participant-provided information – e.g., identifying PROs for Opioid Use Disorder (OUD) that can be collected through EDs to complement clinically reported outcomes; (3) Linking data –e.g., linking national hospital care survey data with National Death Index data to improve identification of opioid-related deaths; (4) Optimizing data for clinical research –e.g., mining patient records to identify opioid-related deaths; and (5) Using Federal databases for research – e.g., text mining death certificates to improve the National Death Index data.

In addition to ASPE's work, the Patient Centered Outcomes Research Institute (PCORI) and the National Quality Forum (NQF) also have initiatives to further advance the data infrastructure for opioids research. PCORI has funded 26 comparative effectiveness studies related to opioid use across the care continuum, as of June 2019. In 2013, PCORI supported the development of PCORnet, the National Patient-Centered Clinical Research Network, a "network of networks" with a focus on conducting more efficient and secure patient-centered, clinical comparative effectiveness research via a distributed architecture. PCORnet provides access to data standardized into the PCORnet Common Data Model (CDM), based on the FDA Sentinel Common Data Model. The data includes electronic health record data, supplemented by other sources of data, such as, patient reported outcomes (PROs), claims data, and in some cases, registry data. PCORI funded projects using the PCORnet infrastructure to explore methods for improved data linkage between different sources and types of data. PCORI also funds descriptive analysis projects and 1 year observational studies through the Rapid Cycle Research & Projects (RCRP) Initiative to optimize the PCORnet data infrastructure in support of the conduct of rapid research, including one descriptive analysis project that explores the potential use of PCORnet to support opioid surveillance.

NQF's work has focused on engagement of thought leaders and experts in the development of health care quality guidelines and measures. Currently NQF is convening a Technical Expert Panel (TEP) of diverse multi-stakeholder experts to oversee a review of measures and concepts related to medical opioid use and opioid use disorder prevention, treatment, and recovery. This activity, which launched in April 2019, will further identify measure gaps and priorities relevant to the opioid overdose epidemic and the health care quality challenges that surround it.[29]

In total we identified 11 HHS-funded projects that are working to build the data infrastructure for opioids. Exhibit 2 summarizes these projects in terms of the specific data challenges each project is addressing, the project objectives, and the unique contribution(s) each project is making toward building the "better data" for opioids research.

Exhibit 2: Summary of Key Data Infrastructure Projects supporting Opioid Research

Project name	Challenge	Project objective(s)	Unique contribution(s)
OS-PCORTF Projects			
[ASPE-ACF] Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for Opioid Use Disorder and other Behavioral Health Issues	There is a strong correlation between areas of the US with high overdose death rates and high rates of children placed into foster care.[30] States seek to understand how services for parents through Medicaid and child welfare can be broadened in order to access funding under the Families First Prevention Services Act (2018)[31] for foster care prevention services, including treatment for substance abuse.	In partnership with several state agencies, this project will pilot test linking state Medicaid records with child welfare records for parents and children involved in the child welfare system. These data will allow identification of parents with children in the child welfare system and attempt to understand their needs for treatment of opioid use disorder (OUD), other substance abuse disorders (SUDs), and co-occurring mental health problems. The project will attempt to produce new longitudinal, patient-level datasets that will support appropriate research of Medicaid enrollment, patient diagnoses, services, and claims, along with child welfare outcomes for the purpose of program/model evaluation.	■ Develops pilot datasets that **link records from State Medicaid and from child welfare systems** in two to four states. These data sets will contain linked patient-level data including Medicaid enrollment, patient diagnoses, services, and claims, along with child welfare outcomes (e.g., length of time in foster care, repeat maltreatment). ■ Prepares a single, harmonized research use dataset and develop a process for external researchers to access the data**.** ■ **Creates a roadmap for other states to follow** that documents the process and lessons learned around linking Medicaid and child welfare data systems.
[CDC] Strengthening the Data Infrastructure for Outcomes Research on Mortality Associated with Opioid Poisonings	Lack of quality, timely and supplemental information on drug overdose deaths involving opioids.	This project is working to redesign and enhance the Vital Statistics Rapid Release (VSRR) and Medical Mortality Data System (MMDS), both subsets of the National Vital Statistics System (NVSS), to improve the quality of death information data and release. Specifically, the MMDS is being redesigned to code and process a larger percentage of death certificate records including deaths involving opioids which will improve timeliness and accuracy of data. The VSSR will be enhanced to capture a broader array of geographic, demographic and drug details in death records.	■ **Improves the quality, availability, and timeliness of mortality data** in the National Vital Statistic System for use in research on drug-involved mortality, including that of opioid deaths.

Project name	Challenge	Project objective(s)	Unique contribution(s)
[CDC] Enhancing Identification of Opioid-Involved Health Outcomes Using Linked Hospital Care and Mortality	Limited and often incomplete national-level statistics on opioid-related hospitalizations such as identification of specific opioids and inclusion of deaths occurring outside of a hospital setting.	The overall goal of the project is to improve surveillance and expand researchers' access to data on hospital care patterns and risk factors associated with opioid overdose deaths by (1) merging the National Hospital Care Survey (NHCS), National Death Index (NDI), and National Vital Statistics System Restricted Mortality Files on Drug Overdose (NVSS-M-DO) to create a new research data file with specific opioid names in ED visits, hospitalizations, and deaths, and (2) developing data collection and reporting tools to support research on hospital encounters involving opioids.	■ **Produces data files** linking data between hospital care and mortality with enhanced identification of opioid-involved hospital visits and overdoses. ■ **Makes files available to researchers** through the NCHS Research Data Center (RDC) network to investigate questions around opioid-related hospital care and outcomes. ■ **Updates drug-induced mortality vocabulary** with changes in drug nomenclature and using natural language processing to create an enhanced algorithm for identifying opioid-involved outcomes.
[CDC] Augmenting the National Hospital Care Survey (NHCS) Data through Linkages with Administrative Records	Need for linked data to follow patients across the continuum of federal support services in order to expand understanding of the opioid crisis	This project is building data capacity by linking data from the National Hospital Care Survey the only federal health care establishment survey to collect personally identifiable information (PII) across all age groups, with other data sources including death certificate information in the National Death Index (NDI) and administrative data from CMS Medicare Master Beneficiary Summary File (MBSF), CMS fee-for-service claims, and federal housing assistance data from the Department of Housing and Urban Development (HUD).	■ **Provides linked data files** with information on mortality, health outcomes associated with different types of post-acute care services, health (and mental health) care service utilization, prescription drug use, facility based patient health assessments, and receipt of federal housing/social support programs with a given patient's hospital administrative claims and EHRs. ■ Enables researchers to observe disparities in efficacy **by critical and previously unexamined subpopulations**.
[CDC] Surveillance Network: Maternal, Infant, and Child Health Outcomes Following Treatment of Opioid Use Disorder During Pregnancy	The OUD in pregnancy rates have increased 4 folds in the last 20 years,[32] however there is a lack of surveillance systems for collecting outcomes data on pregnant women with OUD or receiving MAT.	The purpose of this project is to establish a health outcomes surveillance network across multiple sites to rapidly collect data and monitor maternal, infant, and child health outcomes related to treatment for OUD during pregnancy. Outcome data will be analyzed, shared, and disseminated to inform patient-centered care for pregnant women with OUD and infants and children with prenatal opioid exposure.	■ **Develops a data platform to collect linked maternal and infant data** among women treated for OUD during pregnancy. ■ **Establishes an organizational structure** to include federal partners, clinical and public health partners, and a CDC steering committee to provide critical input on data collection approaches and analytical priorities. ■ **Creates common data elements (CDEs)** for maternal, infant and child health outcomes related to treatment of OUD in pregnancy.

Project name	Challenge	Project objective(s)	Unique contribution(s)
[CDC] Identifying Co-Occurring Disorders among Opioid Users Using Linked Hospital Care and Mortality Data: Capstone to an Existing FY18 PCORTF Project	Co-occurring disorders (defined for this project as the coexistence of both a substance use disorder and a mental health issue) occur among many opioid users and are considered an important risk factor for morbidity and mortality among this population. An estimated 1 in 8 adults (18%) have severe mental illness and misuse opioids.[33] However there is a lack of data on health outcomes of opioid users with co-occurring substance use and mental health issues.	This projects builds on the methodology from the FY18 OS-PCORTF project at NCHS,[1] which provided enhanced algorithms to more accurately identify a hospital patient's use of opioids to flag evidence of co-occurring disorders. This project will: 1) develop a new set of algorithms to find evidence of co-occurring disorders to complement existing algorithms that identify any form of opioid use and specific type of opioid agent taken, 2) formally validate the performance of algorithms from the FY18 and FY19 projects, and 3) disseminate resulting datasets and reports to end users.	■ **2016 NHCS/NDI/NVSS-M-DO enhanced dataset with additional** information on co-occurring disorders. ■ Develops a new set of algorithms to identify hospital encounters and death records involving patients with co-occurring disorders using medical code-based algorithm and **natural language processing (NLP).** ■ Validate algorithms from this project and the FY18 OS-PCORTF project, "Enhancing Identification of Opioid-Involved Health Outcomes Using Linked Hospital Care and Mortality". ■ **Makes data available through the NCHS RDC.**
[NIH] AMNet: An Addiction Medicine Network to Address the United States	Lack of standardized data on patients' characteristics, treatments, and outcomes for patients treated with buprenorphine and naltrexone in office-based practices.	This project will enhance addiction-related data collection and capacity to conduct PCOR focused on treatment of OUD by establishing a new practice-based research network and an electronic patient registry named the Addiction Medicine Network (AMNet). AMNet will: 1) adapt an existing electronic registry (APAs PsychPRO) to collect data for practice-based research on OUDs and treatments, and 2) provide near real-time data to clinicians, researchers, and other stakeholders on OUD patients' mental health, pain, SUDs, and "real world" office-based routine treatment delivery.	■ Establishes an addiction medicine practice-based research network (AMNet) ■ **Develops quality measures and CDEs** for OUDs based on a variety of existing, validated sources ■ **Provides real-time clinical and patient reported data** on patient characteristics, care delivery, and recovery service utilization. ■ Develops business requirements for **linking AMNet to other databases** and registries (e.g. CMS' Merit-Based Incentive Program).

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[1] PCORTF project awarded in FY18 (IAA #750117PE090019). Enhancing Identification of Opioid-Involved Health Outcomes Using Linked Hospital Care and Mortality

Project name	Challenge	Project objective(s)	Unique contribution(s)
[NIH] Project CODE-PRO: Capturing Opioid Use Disorder Electronically and Patient Reported Outcomes	Lack of exchangeable or common data standards and few OUD-specific CDEs to track patients presenting with OUD in the ED.	This project is working to enhance capacity to use EHR data to conduct opioid related clinical research in the ED. Specifically, this project seeks to identify CDEs related to OUD and integrate these into the American College of Emergency Physicians Clinical Emergency Data Registry (ACEP CEDR), as well as explore the feasibility of PROs.	■ **Identifies existing OUD CDEs** relevant to the ED setting by conducting an environmental scan of current, publicly available data systems, data elements, and quality measures ■ **Integrates CDEs from an EHR into the ACEP CEDR** test sites by translating and mapping electronic OUD data elements to the National Library of Medicine (NLM) Value Set Authority Center (VSAC). ■ Explores feasibility of **collecting electronic PROs** such as PROMIS and other measures (e.g., pain intensity, substance use disorder treatment/status) through Epic dashboards and HUGO, a software that allows patients to consent for their data to be used in research as well as access to their data.
[ONC] A Synthetic Health Data Generation Engine to Accelerate Patient Centered Outcomes Research	High quality, real-time health and health care data are often difficult to access because of cost, patient privacy, or other legal and intellectual property restrictions. Further, due to a variety of interoperability issues, it is often difficult to bring data together from different resources.	This project focuses on facilitating the use of synthetic data for the testing of PCOR hypotheses and supporting the HHS objective of protecting the privacy of personally identifiable information. Synthea™ is a synthetic health data generation engine that models the longitudinal medical history of synthetic patients based on publicly available data. Synthea™ has disease specific models based on the top ten reasons patients visit their primary care providers, and the top 10 years of life lost. It also contains an opioid model with age, directed-use scenarios that could lead to opioid misuse. One initial application of the generated synthetic data is identification of effective prevention methods, treatments or interventions, such as assessments related to controlled substance prescriptions that reduce the impact of mental and substance use disorders.	■ Provides **high quality synthetic, realistic but not real, patient data** and associated health records covering every aspect of healthcare. This synthetic data, based on publicly available data, is **free from cost, privacy and security restrictions** and readily available, and can complement real clinical data for research and analysis.

Project name	Challenge	Project objective(s)	Unique contribution(s)
Non-Federal Projects			
PCORnet Opioid Surveillance Demonstration	Need for better data infrastructure for rapid cycle research for surveillance of opioid epidemic.	This project seeks to evaluate and demonstrate the fitness of PCORI's PCORnet Common Data Model (CDM) to conduct opioid surveillance. Specifically, this project seeks to identify the data elements in the PCORnet CDM necessary to create a profile of the opioid epidemic risk factors, processes and outcomes of interest; identify gaps in the PCORnet CDM; and identify and assess non-CDM EHR data elements and non-EHR data sources for future integration.	■ Develops value sets for opioid surveillance queries. ■ Identifies CDEs related to opioid surveillance. ■ Provides an analytics framework and implementation guide for PCORnet CDM-based opioid epidemic surveillance that can be generalized to other data models and sources. ■ Provides a roadmap for data linkage for future projects.
NQF Opioid and Opioid Use Disorder TEP[34]	Need to identify and prioritize measure gaps in quality measurement in order to hold health care providers, payers, and policy-makers accountable; incentivize good care; direct resources appropriately; and establish best practices.	NQF has assembled a TEP tasked with the following activities: (1) Provide guidance on the environmental scan of current measures and measure concepts related to opioids and opioid use disorders; (2) Identify and prioritize measure gaps in quality measurement to inform future measure development efforts; and (3) Provide recommendations on the use of opioids and opioid use disorder measures in federal programs.	■ The TEP will assist with the identification of **specific opioid and OUD-related quality measures** or measure concepts and facilitate the inclusion of quality measures in federal quality programs

In aggregate, each of these projects is directly and indirectly contributing to HHS's overarching strategic objective for "better data" to combat the opioid crisis. Exhibit 3, below, maps each project to the specific HHS priorities around better data. Specifically, these projects are enhancing:

1. **Real-time data** through the establishment of AMNet, a practice-based research network that will enable as close to real-time clinical and patient reported data on patient characteristics, care delivery, and recovery service utilization as well as leveraging the use of synthetically generated data to provide "realistic but not real" patient data.

2. **Rapid data collection and reporting** through the enhancement of surveillance systems for tracking patients across the continuum of care – including use of synthetic data which avoids data privacy/security issues to enable faster data availability. As another solution, several projects are making data available through the NCHS Research Data Centers (RDC) network, which is a platform that protects the confidentiality of survey respondents/study subjects while also providing access to the restricted-use data from across agencies.

3. **Outcomes data** through improving the quality, availability, and timeliness of mortality data in the National Vital Statistic System Collection and facilitating the collection of clinical and patient report outcomes through EHRs, and particularly in ED settings, and through building patient registries and research networks. The projects have also leveraged the implementation of novel approaches like medical code-based algorithms and **natural language processing** to improve identification of opioid-related deaths using EHR data. Projects are also facilitating the collection of **data on vulnerable and underrepresented populations** such as pregnant women with OUD and infants and children with opioid exposure

4. **Key metrics** through the development of CDEs and quality measures for OUD based on clinical definitions as well as standardizing extraction of EHR data.

5. **Supplementary data**, particularly around co-morbidities such as links between mental health and OUD, as well as through building data linkages with other agencies (e.g., HUD and Child Welfare) to enable a greater understanding of the broader context and consequences of OUD, beyond health impacts.

6. **Data linkages** by enhancing existing data sources (e.g., EHR data) to ensure better interoperability across data systems and that high quality data is available for linkage and subsequent research; evaluating models for data linkage; and developing linkages within and across public data sources for e.g. using PII to facilitate linkages across survey and administrative data.

Exhibit 3. Contributions to HHS Strategic Priorities for "Better Data"

Project	HHS Better Data Priorities							
	Real-time data	Rapid data & reporting	Outcome data	Supp. data	Geo data	Key metrics	Data linkages	PDMP dev
[ASPE-ACF] Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for Opioid Use Disorder and other Behavioral Health Issues			X	X			X	
[CDC] Strengthening the Data Infrastructure for Outcomes Research on Mortality Associated with Opioid Poisonings		X	X					
[CDC] Enhancing Identification of Opioid-Involved Health Outcomes Using Linked Hospital Care and Mortality		X	X				X	
[CDC] Augmenting the National Hospital Care Survey Data through Linkages with Administrative Records.				X			X	
[CDC] Surveillance Network: Maternal, Infant, and Child Health Outcomes Following Treatment of Opioid Use Disorder during Pregnancy						X	X	

Project	HHS Better Data Priorities								
	Real-time data	Rapid data & reporting	Outcome data	Supp. data	Geo data	Key metrics	Data linkages	PDMP dev
[CDC] Identifying Co-Occurring Disorders among Opioid Users Using Linked Hospital Care and Mortality Data: Capstone to an Existing FY18 PCORTF Project		X	X	X				
[NIH] AMNet: An Addiction Medicine Network to Address the United States	X		X	X			X	
[NIH] Project CODE-PRO: Capturing Opioid Use Disorder Electronically and Patient Reported Outcomes			X			X	X	
[ONC] A Synthetic Health Data Generation Engine to Accelerate Patient Centered Outcomes Research	X	X						
[PCORI] PCORnet Opioid Surveillance Demonstration				X		X	X	
[NQF] Opioid and Opioid Use Disorder TEP						X		

Beyond these specific contributions to HHS priorities, these projects are contributing more broadly to data infrastructure development by establishing **organizational structures** that include federal partners, clinical and public health partners to provide critical inputs on data collection approaches and quality metrics.

CHALLENGES AND OPPORTUNITIES

While these projects are making significant progress toward building and enhancing the data infrastructure and capacity for opioids research, several specific gaps and persistent challenges remain to be addressed in order to meet HHS priorities around "better data."

Better surveillance systems are needed for real-time data collection. While several projects have made strong contributions to the collection of timely near-real time data, or created innovative solutions to approximate real-time data, there remains a need to further strengthen surveillance systems by addressing challenges around data quality (e.g., record completeness and accurate processing issues are more common with real time vs. longer time frame data collection).[35] Many states have used innovative near-real time surveillance systems which can be reviewed to extract lessons learned and best practices around overcoming these challenges at a national level – for example, Rhode Island is the first state to have used a State Unintentional Drug Overdose Reporting Surveillance (SUDORS), a flexible, near-real time system that combines multiple data sources including information related to circumstances, toxicology results, and scene evidence on opioid overdose decedents to provide insight into the who, when, and where of an overdose death.[36]

Need to balance improved data access with privacy safeguards. Finding ways to speed up the process of both data collection and sharing is particularly important for understanding and addressing the opioid crisis as it rapidly evolves. Initiatives in real-time data collection tools can help speed data collection. When it comes to sharing data, however, there is also a need to leverage solutions that balance public access to data with confidentiality and disclosure risks.[37]

These safeguards are particularly needed for working with state-level data where greater clarification around privacy restrictions is needed. [38] Governance structures such as the NCHS RDC that provide clear policies around data access can help with making data available to the research community.

Outcomes data indicators and sources need to be diversified. Current initiatives around collection of data on outcomes (e.g., opioid related overdose and mortality) need to be augmented to capture surrogate outcome data relevant to opioids to provide a more holistic picture of the impact of the epidemic. For example, NSDUH could begin collecting information on pain, pain treatment or diagnosis of OUD and the Treatment Episode Data Set (TEDS), which compiles facility-level data for substance abuse treatment admissions from State Agency data systems, could be modified to include whether pharmacotherapy (and which type) is planned or offered at discharge.[39] Sources of outcome data also need to be explored, expanding the use of EHR data (e.g., text mining clinical notes through natural language processing) as well as leveraging use of corporate data and data from emergency responders (EMS personnel). [40] Finally, there is a need for outcomes data on subpopulations to enable identification and tracking of key demographic groups (e.g., adolescents, Native Americans) as well as specific patient groups, including: 1) patients who start with prescription based opioid use and move to prescription opioid misuse and/or addiction; 2) patients who start with prescription based opioid use and move to illicit opioid abuse/addiction; and 3) patients who have never used prescription opioids and only have demonstrated illicit opioid abuse/addiction. [41]

Additional supplementary data sources and indicators need to be identified. Supplementary data is vital to identify underlying causes and drivers, protective and risk factors related to OUD, and broader consequences of OUD such as those related to family stability and child/youth development. In addition, collecting and linking supplementary data can help identify effective interventions from human services fields that can increase the likelihood of positive treatment outcomes and mitigate the consequences of OUD. For example, the CDC's *Augmenting the National Hospital Care Survey (NHCS) Data through Linkages with Administrative Records* project, funded through OS-PCORTF, has made a positive steps toward gaining a more holistic picture of the protective and risk factors for OUD by linking the NHCS with CMS Medicare Fee-for-Service claims data and HUD federal housing assistance program data. Future initiatives could continue to build linkages with data sources to leverage data around social determinants of health (SDOH) as well as co-morbidities and associated risk factors as well as the use of NLP to develop algorithms for identification of these indicators.

Geographic data is underutilized. Providing geographic data can help researchers better track the epidemic and tailor interventions. CMS' Medicare Part D and Medicaid opioid prescribing mapping tools collect state, county, and ZIP code data which enables researchers to track opioid prescription claims and target high prescribers. Researchers regularly use SAMHSA's Treatment Locator to study the geographic availability of evidence-based treatment. Future initiatives could further expand the availability of geographic data on OUD treatments to include geographic data on prescriptions of OUD treatments and provide more granular information on treatment capacity.

Key metrics need to be standardized and shared across projects. While many of the projects described above are working to standardize CDEs (e.g., creating coding standards for overdose

deaths), there is still a need for greater definition of certain key metrics – for example around indicators/measurement of pain or common definitions of neonatal abstinence syndrome. Innovative approaches such as natural language processing and EHR "phenotyping" –e.g., creating computerized queries to an EHR system using a defined set of CDEs and logical expressions in order to identify patients with specific clinical conditions or characteristics[42] – should be further leveraged in the identification and definition of these metrics. [43] Further, there is a need to standardize and share CDEs across registries. The OS-PCORTF-funded project *Harmonization of Various Common Data Models and Open Standards for Evidence Generation*, for example, could be leveraged for opioids.[44] This collaborative project between FDA, National Cancer Institute (NCI), National Institutes of Health/National Center for Advancing Translational Sciences (NIH/NCATS), ONC, and the National Library of Medicine (NLM) seeks to harmonize several existing Common Data Models (CDMs), which organize data into a standard structure in order to support research and analyses across multiple data networks. [45] The aim is to advance the utility of data and its interoperability across networks to facilitate PCOR. [46]

Data linkages need to enable inter-agency collaboration and data sharing. There are many technical and policy barriers to effectively linking clinical data sets.[47] From a technical standpoint, data quality issues are more common when processing data from multiple sources (e.g., some data have missing personally identifiable information fields which results in linkage errors).[48] Initiatives should also support methodological research to develop improved algorithms for matching individuals across and within data sources – identifying reasons for insufficient matching and developing and validating improved matching algorithms.[49] Future initiatives could also seek to create forums or repositories for sharing and exchange of best practices and methodologies for linking data.[50]

Combining individual data across sources increases the risk of the re-identification of individuals which raises not only concerns around preserving patient privacy but also ethical concerns around creating large linked data sets using an individual's data without their explicit consent.[51] Linking mortality data with other sources offers a strong solution as this data may have lower patient privacy barriers (per the Code of Federal Regulations, 2009[52]). Future initiatives could continue to build these linkages, for example by the linkage of NDI and claims data from the Transformed Medicaid State Information System (TMSIS) through developing standards and requirements for data sharing by state agencies overseeing Medicaid and mortality data.[53] While use of mortality has been an effective solution for circumventing privacy barriers in the near term, further discussion is needed around how to enable linkage and sharing of additional health outcomes data, while safeguarding patient privacy.

Finally, future federal initiatives could explore further cross-departmental linkages, e.g., linkages between EHR data and judicial/corrections data to see types of MATs provided to the inmate population,[54] but also look beyond the federal and state-level data infrastructure. A significant amount of clinical data sources are owned and controlled by private organizations, and therefore building linkages with these sources through partnerships or collaborations with the private sector would help provide a more complete picture of health care services outcomes. For example, federal data could be combined with private sector data on pharmaceutical sales and nationwide distribution to provide a holistic picture of the prescription opioid supply.[55]

Linkages with PDMP data need to be further developed. PDMPs are a valuable resource for understanding the opioid epidemic, and linking PDMPs to a variety of other data sources could greatly enhance surveillance efforts. Research sponsored by the National Bureau of Economic Research has identified challenges related to the use of PDMPs to better track and monitor opioid prescribing as well as provision of OUD treatment.[56] Specifically, data formats and inputs are not streamlined or standardized across state and sub-state data systems which make it difficult to compare/aggregate at a national level. Future initiatives could explore opportunities to standardize electronic data collection for key elements across PDMPs to facilitate cross-state sharing as well as explore linkages between PDMPs and public health, criminal justice, and other sources to further enhance surveillance.

CONCLUSION

Individually and collectively, these projects are building the data infrastructure to monitor opioids and enhance the public availability of data for research in order to combat the opioid crisis. Specifically these initiatives are geared to improve data quality, increase the availability of federal data sets and make data more accessible to the research community. While the projects detailed in this paper set the stage, there is more work to be done to fully address HHS strategic priorities around better data, including improving the standardization of key metrics and indicators and building more robust linkages across a range of data sources. Bridging these gaps and bringing the current data infrastructure to the next level, however, requires a continued coordinated effort that builds and leverages synergies both within and across federal and state institutions as well as outside of the government through private/public collaborations. These partnerships can improve the quality, accessibility and interoperability of data, ultimately creating a pathway to addressing the crisis.

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