



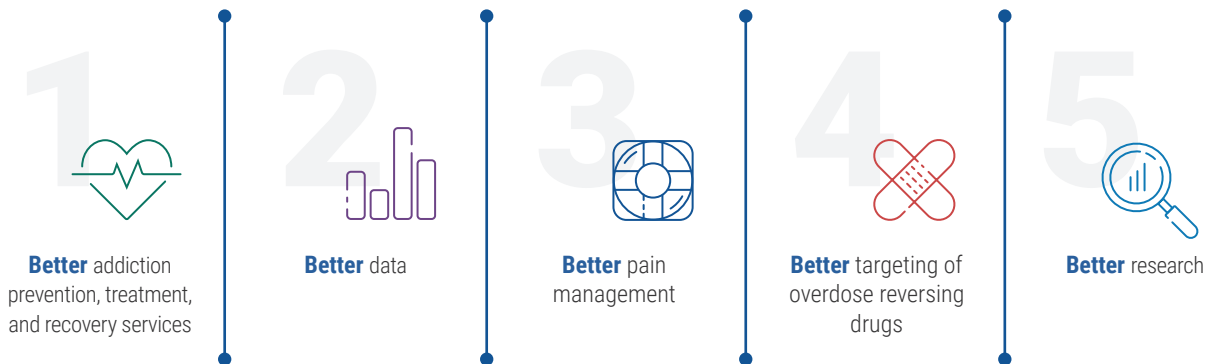
Addressing the Opioid Crisis through Better Data and Data Infrastructure

The over-prescription and misuse of opioids in the US has created a crisis characterized by a rapid increase in opioid overdose deaths within the past 20 years.¹ In 2018, Congress and the President enacted bipartisan legislation, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which includes numerous provisions to prevent opioid misuse, increase access to treatment, and control the supply of illicit drugs.² In 2017, HHS launched its 5-Point Strategy to Combat the Opioid Crisis, which includes the need for “better data” to inform research and the public health response as the crisis evolves (Exhibit A).^{3,4} Robust and reliable data that are available to researchers within and outside of the federal government are critical to understanding and tracking the crisis, informing treatment and prevention efforts, and reducing opioid-related morbidity and mortality. However, the data infrastructure (how data are produced and managed) and the quality and timeliness of the data can make research a challenge.⁵ Under the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF), the Assistant Secretary for Planning and Evaluation (ASPE) supports and coordinates a range of cross-agency projects that address the opioid crisis by: 1) improving the quality and timeliness of outcomes data, 2) increasing collection of patient-reported information, and 3) building linkages to address co-morbid conditions that affect patient outcomes.

“Extraordinary focus is being brought to the opioid crisis by all segments of our society, so now is the time to leverage this awareness to accelerate the pace of research to develop new treatments. From the standpoint of NIH and NIDA, it is “all scientific hands on deck.” NIH research can help end the crisis, and we are committed to doing so.”

NORA VOLKOW, MD
DIRECTOR OF THE NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

Exhibit A. HHS 5-Point Strategy to Combat the Opioid Crisis⁶



- **Improving Timeliness and Quality of Outcomes Data.** Information on clinical outcomes (such as opioid-related overdose and mortality) is often incomplete or lacking in quality, which limits its usefulness for researchers. Two Centers for Disease Control and Prevention (CDC) projects are addressing the networks through which data flows to researchers. One project focuses on improving the National Vital Statistics System, specifically the quality, availability, and timeliness of mortality data being reported. A second project is building an opioid-related research network focused on maternal, child, and infant health. These networks facilitate data sharing among clinicians and researchers and will ultimately help generate scientific findings that can guide treatment decisions.

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

Begun in 2018, the CDC's project, *Strengthening the Data Infrastructure for Outcomes Research on Mortality Associated with Opioid Poisonings*, addresses the lack of quality and timely information on opioid overdose deaths. It redesigns and enhances the systems that feed data into the National Vital Statistics System (NVSS). Specifically, the project is working to enhance the Vital Statistics Rapid Release (VSRR) and Medical Mortality Data System (MMDS) to make a broader array of geographic and demographic data available. This will enhance the detail available, helping researchers study population health trends and risk factors for opioid-related mortality, and it will improve the quality, availability, and timeliness of data available for this kind of program, policy, and patient-centered outcomes research.

KEY PRODUCTS

- The National Center for Health Statistics (NCHS) released **monthly provisional drug overdose death counts**
- A National Health Statistics Report feasibility study is under development, demonstrating the types of research questions that can be answered [anticipated]
- NCHS published a special report on fentanyl deaths: Spencer MR, Warner M, Bastian BA, Trinidad JP, Hedegaard H. (2019). **Drug overdose deaths involving fentanyl, 2011–2016**. National Vital Statistics Reports, 68(3)

PROJECT AGENCIES: CDC

MAT-LINK: MATernal and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy

The CDC is seeking to improve the quality and timeliness of outcomes data related to opioid use disorder (OUD) in pregnancy through the 2019 project *MAT-LINK: MATernal and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy*. OUD greatly increases the risk of an infant being born with neonatal abstinence syndrome (NAS); with NAS increasing 5 fold between 2004 and 2014.⁷ There is a need to fill information gaps when it comes to treatment and care for pregnant women with OUD and their infants and children. MAT-LINK is a surveillance network that collects data, monitors maternal, child, and infant health outcomes across four clinical sites, and disseminates information to improve care. This network will support health surveillance and research to inform patient-centered care for pregnant women with OUD and for infants and children with prenatal opioid exposure.

KEY PRODUCTS

- A manuscript has been drafted to provide the background and anticipated rationale on variable themes and key questions addressed by MAT-LINK [anticipated]
- A public-facing **webpage** shares background information, goals, example variables, partnerships, and link to CDC's implementation partner's website

PROJECT AGENCIES: CDC

- **Building Capacity for Collection of Patient-Reported Outcomes.** Clinical data alone cannot paint a complete picture of a patient's health behavior and outcomes. Collecting patient-reported outcomes (PROs) is critical for understanding the drivers of morbidity and mortality related to OUD. Two OS-PCORTF projects initiated by the National Institute on Drug Abuse (NIDA) are seeking to increase data collection and enhance the health system's capacity to collect PROs related to OUD. One project targets emergency departments, where many OUD cases are seen, and the other creates a practice-based research network and patient registry to expand data gathering in primary care.

Emergency Medicine Opioid Data Infrastructure: Key Venue to Address Opioid Morbidity and Mortality

In NIDA's FY 2018 project *Emergency Medicine Opioid Data Infrastructure: Key Venue to Address Opioid Morbidity and Mortality*, the agency's goal is to enhance capacity to track OUD patients in a standard way when they are seen in the emergency department (ED). Because EDs are an important point of entry into the health care system for many OUD patients, the project seeks to identify common data elements (CDEs) relevant to opioid misuse and OUD, and facilitate reporting of these CDEs into the American College of Emergency Physicians' Clinical Emergency Data Registry. The project is also exploring the feasibility of collecting PROs related to opioid use (such as overdose risk behaviors and substance use disorder treatment) after an ED visit through a patient-friendly app. The project team at Yale School of Medicine will pilot test the CDEs and the app, collecting PRO data after patient visits. The goal of the pilot will be to standardize OUD measurement and assess the feasibility of collecting patient-reported data to help track and ultimately improve the quality of care delivered to OUD patients in the emergency department.

KEY PRODUCTS

- Venkatesh A, Malicki C, Hawk K, D OG, Kinsman J, Taylor A. **Assessing the readiness of digital data infrastructure for opioid use disorder research.** *Addiction Science & Clinical Practice.* 2020;15(1).
- A manuscript in process: Kathryn Hawk, MD, Arjun Venkatesh, MD, MBA, Caitlin Malicki, MPH, Jeremiah Kinsman, MPH, NREMT, Gail D'Onofrio, MD, MS, Andrew Taylor, MD, MS. *Capturing Opioid Use Disorder Electronically and Patient Reported Outcomes: Results from the CODE-PRO study* [anticipated]
- An Implementation Guide to guide users in the electronic collection of PROs following ED visits [anticipated]

PROJECT AGENCY: NIH/NIDA

AMNET: An Addiction Medicine Network to Address the Opioid Crisis in the United States

To address the ongoing knowledge gaps and need for opioids-related data, NIDA's 2019 project, *AMNET: An Addiction Medicine Network to Address the Opioid Crisis in the United States* establishes a practice-based research network and patient registry. AMNET will gather data for patients treated with buprenorphine and naltrexone in office-based practices, targeting information on patient characteristics, treatments, and outcomes that are needed for research studies. The project took an existing registry (the American Psychiatric Association's PsychPRO) and adapted it to collect patient-reported data on OUD and treatments, and is developing CDEs for OUDs based on a variety of existing, validated sources. AMNET will be used to provide near real-time data to clinicians, researchers, and other stakeholders on OUD patients' mental health, pain, substance use disorders, and treatment delivery in office-based settings.

ANTICIPATED PRODUCTS

- The website AMNet, an addiction medicine practice-based research network, will be widely available
- A list of AMNet-validated measures and OUD CDEs
- Business requirements for linking AMNet to other databases and registries, including providers participating in CMS' Merit-Based Incentive Program (MIPS)

PROJECT AGENCY: NIH/NIDA

Building Linkages to Address Co-Morbidities. Co-occurring disorders, including mental health issues and other substance use disorders, are common among opioid users and are considered an important risk factor for morbidity and mortality. Understanding co-morbidities is critical to addressing the underlying factors that contribute to opioid-related morbidity and mortality. However, data on co-morbidities is often limited due to a lack of coordination among databases. Two OS-PCORTF projects are addressing co-morbidities by enhancing existing data sources to better ensure interoperability across systems and building data linkages.

Identifying Co-Occurring Mental Health Disorders among Opioid Users Using Linked Hospital Care and Mortality Data

According to the 2018 National Survey on Drug Use and Health, 14.6% of adults with a serious mental illness misused opioids in the past year.⁸ This type of comorbidity is especially dangerous and there is a need to study the association between the two conditions in terms of risk factors and outcomes; however, both types of data are highly restricted given their sensitive nature. The CDC, in partnership with NIDA, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), and the National Institutes of Health/National Institute of Mental Health (NIMH), initiated a project in 2019, *Identifying Co-Occurring Mental Health Disorders among Opioid Users Using Linked Hospital Care and Mortality Data*. The project is working to build an enhanced, linked dataset on mortality, opioids, and co-occurring mental health issues to provide much needed data for research. This will involve taking a set of files (already linked) from the National Center for Health Statistics (NCHS), National Hospital Care Survey, the National Death Index (NDI), and the National Vital Statistics System's restricted-use mortality files on drug-involved mortality (NVSS-M-DIM) dataset and merging them with additional information on co-occurring disorders. The project will make this restricted data set more widely available to researchers through the NCHS Research Data Center (RDC) and make patterns and risk factors easier to study. This will enable greater understanding of the contributors to opioid-related mortality.

ANTICIPATED PRODUCTS

- A new set of algorithms for researchers to use linked NHCS/NDI/NVSS-M-DIM files to identify hospital encounters and death records for patients with co-occurring disorders
- Data on opioid use and co-occurring disorders available through: 1) the NCHS Research Data Center, and 2) a web portal for hospitals participating in the National Hospital Care Survey
- A manuscript in process: Carol DeFrances Ph.D., Geoff Jackson M.S., Amy Brown M.P.H. The National Hospital Care Survey: Modernizing the Monitoring of the Nation's Health Care by Linking Electronic Health Records to Death Record Information and Administrative Data
- A manuscript in process: Geoff Jackson M.S. Successfully Completing a National Center for Health Statistics Research Data Center Request for National Hospital Care Survey Data

PROJECT AGENCIES: CDC, NIH (NIDA, NIMH), SAMHSA, AND FDA

Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for Opioid Use Disorder

There is a correlation between areas of the US with high overdose death rates and high rates of children placed into foster care.⁹ OUD, substance abuse disorders, and mental health issues are particularly disruptive to families and the health outcomes of the children involved. A 2019 project co-lead by ASPE and the Administration for Children and Families' (ACF), *Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for Opioid Use Disorder (OUD)*, is focused on understanding and addressing co-morbidities that affect child welfare. In partnership with several state agencies, the project is pilot testing a linkage between state Medicaid records and child welfare records into a single, harmonized dataset. These data sets will contain linked patient-level data, including Medicaid enrollment, patient diagnoses, services, and claims, combined with child welfare outcomes (e.g., length of time in foster care, repeat maltreatment). This will allow researchers to identify parents with children in the child welfare system and support research to better understand their treatment needs for substance use disorders like OUD, and co-occurring mental health problems that negatively affect the health and welfare of parents and children.

ANTICIPATED PRODUCTS

- A webinar titled "State Medicaid and Child Welfare Data Linkages for Outcomes Research" to over 80 stakeholder groups
- Data sets that link records from State Medicaid and from child welfare systems in two to four states that contain linked patient-level data, including Medicaid enrollment, patient diagnoses, services, and claims, along with child welfare outcomes
- Research findings on child welfare outcomes based on the linked data

PROJECT AGENCIES: ASPE AND ACF

Looking to the Future. The opioid crisis is a complex, national issue that requires long term and sustainable attention and investment in HHS strategic priorities. It requires better data, networks, and registries; continuing to improve the standardization of key metrics and indicators; and more robust linkages across a range of data sources to bridge gaps and bring the current data infrastructure to the next level. Finally, it requires a continuous coordinated effort that builds and leverages synergies both within and across federal and state institutions, as well as through private/public collaborations. Through the OS-PCORTF portfolio, HHS agencies have collaborated closely to improve the quality, accessibility and interoperability of data. These partnerships aim to improve the data infrastructure for patient-centered outcomes research to help address the opioid crisis.

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- ⁴ HHS. Strategy to Combat the Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy. <https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf>
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