ASPE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION | OFFICE OF HEALTH POLICY

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Addressing the Opioid Overdose Crisis Through Better Data

The opioid overdose epidemic has continued to grow over the past decade. Between 1999 and 2019, overdose deaths involving synthetic opioids excluding methadone increased 50-fold and deaths involving prescription opioids increased four-fold.[2] In 2020, there were 91,799 drug overdose deaths, with 68,630 of these overdose deaths involving opioids.[3] The COVID-19 pandemic potentially worsened the opioid epidemic due to disruptions of support networks and medication distribution and treatment programs. To address the continued opioid overdose crisis and overdoses from other substances, the Department of Health and Human Services (HHS) released an overdose prevention strategy in 2021, focusing on primary prevention, harm reduction, evidence-based treatment, and recovery support. The HHS overdose prevention strategy is guided by four principles (Exhibit 1); "data and evidence" is a key principle in preventing overdoses from opioids and other substances.[4]

Ensuring that robust and reliable data are available to researchers within and outside the federal government is critical to 1) understanding and tracking the crisis, 2) informing treatment and prevention efforts, and 3) reducing opioid-related morbidity and mortality. However, the data infrastructure—including data collection, completeness, quality, and timeliness of the data—requires complex curation and management that can make research a challenge.[5,6] Under the Office of the Secretary's 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) building capacity for the collection of patient-reported outcomes (PROs), and 3) building linkages to address co-morbid conditions that affect patient outcomes.

"…Like any public health crisis, real-time data are needed to understand who is at risk for overdosing, what services are available and who has access and how to provide broader availability of evidence-based prevention and treatment interventions to all in need.

Although abundant administrative data are collected at national and local levels, severe constraints in availability, timeliness, harmonization, sharing and linkage limit its usefulness to develop and guide effective response strategies. We are mostly fighting the drug overdose crisis blindfolded."[1]

NORA VOLKOW, ET AL. (2022)

EXHIBIT 1.
FOUR PRINCIPLES OF THE HHS OVERDOSE PREVENTION STRATEGY[4]

- Equity
- Data and evidence
- Coordination, collaboration, and integration
- Reducing stigma

Improving Timeliness and Quality of Outcomes Data

Information on clinical outcomes (such as opioid-related overdose and mortality) is often not timely and of insufficient quality, which limits its usefulness for researchers. Within the Centers for Disease Control and Prevention (CDC), three projects are addressing the networks through which data flow to researchers. One project focuses on improving the National Vital Statistics System (NVSS), specifically the quality, availability, and timeliness of opioid-related mortality data being reported. Two projects are 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 health care and treatment decisions.

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

Completed in 2021, this CDC-led project addressed the lack of quality and timely information on opioid overdose deaths. It redesigned and enhanced the systems that feed data into the NVSS. Specifically, the project replaced the existing Medical Mortality Data System (MMDS) that codes and processes death certificate records with a new medical coding system, MedCoder. Using MedCoder, the project enhanced the quality of death information data captured in the NVSS and enhanced the Vital Statistics Rapid Release (VSRR) to make a broader array of geographic and demographic data available. The project supported the exchange of mortality data between states' electronic death registration systems (EDRS) and medical examiner/coroner offices, successfully developing and piloting a Fast Healthcare Interoperability Resources (FHIR®) application programming interface (API) for the exchange of these data. **The project modernized the capture of death certificate data and improved the quality, timeliness, and amount of supplemental information on drug overdose deaths involving opioids, thereby enhancing capabilities for public health surveillance and research. This will help researchers study population health trends and risk factors for opioid-related mortality, which could inform new policies and interventions to prevent overdose deaths.**

KEY PRODUCTS

- Enhanced NVSS data dashboards cover multiple facets of mortality data, including state-level crude and age-adjusted death rate quarterly data and national-, state-, and county-level drug overdose death counts.
- The National Center for Health Statistics (NCHS) released monthly provisional drug overdose death counts.
- The NCHS published a VSRR Report on timeliness of death certificate data; a National Health Statistics Report on drug overdose deaths involving fentanyl; a National Health Statistics Report on drug-involved infant deaths; and a National Health Statistics Report on opioid-involved emergency department visits.
- A research letter using drug overdose data from the project was published in *JAMA Internal Medicine* in February 2021: "Association of Medical Stimulants with Mortality in the U.S. from 2010 to 2017."
- The Vital Records Death Reporting (VRDR) FHIR® Implementation Guide describes interoperability enhancements to allow for exchange of data between medical examiner/coroner offices and EDRS.
- The NVSS Modernization Tool Kit includes training materials, technical tools, and guidance documents to prepare systems to be compatible with CDC tools and to utilize EDRS and FHIR® APIs.

PROJECT AGENCY: CDC

MAT-LINK: MATernaL and Infant NetworK to Understand Outcomes Associated with Medication for Opioid Use Disorder during Pregnancy

The CDC seeks to improve the quality and timeliness of outcomes data related to opioid use disorder (OUD) in pregnancy through the MAT-LINK surveillance network. There is a need to fill information gaps when it comes to treatment and care for pregnant women with OUD and their infants. Initiated in 2019, the MAT-LINK project established a network consisting of four clinical sites across the U.S. (Phase I)—Boston Medical Center, the Ohio State University, University of Utah, and Kaiser Foundation Research Institute Northwest in Oregon and Washington—to collect linked data on over 2,000 maternal-infant dyads examining outcomes associated with medication for OUD during pregnancy. MAT-LINK sites are active clinical settings which allow for real-time collection of data and health outcomes for mother and child. **Results from MAT-LINK can be used to improve understanding of maternal, infant, and child health outcomes following medication for OUD during pregnancy and the role of mediating and moderating factors on maternal and infant outcomes.**

In 2021, MAT-LINK expanded by adding three clinical sites (Phase II)—University of New Mexico, University of Rochester, and University of South Florida—and extended child follow-up from two years to six years of age for all clinical sites. The expansion adds geographically diverse clinical sites with varied racial, ethnic, and socioeconomic

KEY PRODUCTS

- The MAT-LINK project webpage provides background information about the project, including partners, clinical sites, goals, and example variables. Once data collection is complete, instructions on how to access MAT-LINK data will be available on this webpage.
- In 2020, the project team published an article in the *Journal of Women's Health* that describes medications and herbal supplements used by pregnant women for OUD and how MAT-LINK can address gaps in knowledge about the management and treatment of OUD during pregnancy.
- An article describing MAT-LINK surveillance methods and population characteristics from the first four clinical sites will be published in early 2023.

PROJECT AGENCY: CDC

characteristics, and enables the capture of data on over 5,000 linked dyads that includes more comprehensive developmental data of children who were prenatally exposed to opioids. **With this expansion, MAT-LINK data may help inform future decision-making and recommendations related to maternal OUD during pregnancy. Already, multiple partners have reached out to the project team to include additional variables and exposures of interest, and the flexibility of the system allows for the easy addition of new variables.**

Building Capacity for Collection of Patient-Reported Outcomes

Clinical data alone cannot provide a complete understanding of a patient's health behavior and outcomes. Collecting 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 (NIH/NIDA) have been seeking to increase data collection and enhance the health system's capacity to collect PROs related to OUD. One project targeted emergency departments (EDs), which have seen many OUD cases, while the other created 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

Now known as Project CODE-PRO (Capturing Opioid Use Disorder Electronically and Patient-Reported Outcomes), this 2018 project led by NIDA aimed to enhance the capacity to track OUD patients in a standardized way when they were seen in the ED. Because EDs are an important point of entry into the health care system for many OUD patients, the project identified common data elements (CDEs) relevant to opioid misuse and OUD and facilitated reporting of these CDEs to the American College of Emergency Physicians' Clinical Emergency Data Registry (CEDR). The project also explored the feasibility and acceptability of electronic PRO data collection via the development and pilot testing of a prototype mobile application. The pilot study was conducted among ED patients with non-medical opioid use or opioid overdose and used electronic surveys to collect PROs after patient visits. **This work led to several data infrastructure improvements within the ACEP CEDR. ACEP CEDR subsequently proposed development of opioid-relevant quality measures including "Discharge Prescription of Naloxone after Opioid Poisoning or Overdose" and "Avoidance of Opiates for Low Back Pain or Migraines."**

KEY PRODUCTS

- A project final report details Project CODE-PRO objectives, methodology, accomplishments, lessons learned, and considerations for the future.
- A July 2020 publication in *Addiction Science & Clinical Practice*, "Assessing the readiness of digital data infrastructure for opioid use disorder research," discusses existing CDEs for OUD relevant to the ED setting.
- Findings from the pilot were published in the November 2021 *Addiction Science & Clinical Practice* paper, "Feasibility and acceptability of electronic administration of patient reported outcomes using mHealth platform in emergency department patients with non-medical opioid use."
- A January 2020 publication in *PLoS One*, "Emergency department utilization for substance use disorders and mental health conditions during COVID-19," analyzes changes in ED use for SUD and mental health conditions during COVID-19.
- An Implementation Guide assists researchers with the management of electronic data on PROs for ED patients with non-medical opioid use.
- A Compendium and Data Dictionary of CDEs and PROs are available in the NIH/NIDA CTN Dissemination Library.

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 opioid-related data, NIDA's 2019 project, AMNet, is establishing a practice-based research network and patient registry. AMNet connects office-based practices and their data to other clinicians and researchers, rapidly providing data on OUD patient characteristics, care and treatment delivery, and patient outcomes. The project took an existing registry (the American Psychiatric Association's PsychPRO) and adapted it to collect patient-reported data on OUD and treatments. The project 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 (SUDs), and treatment delivery in office-based settings. These improvements to addiction data infrastructure will increase data capacity to combat the opioid overdose epidemic. **By providing real-time data, AMNet is improving clinical decision-making and supporting patient-centered outcomes research (PCOR) studies that can address questions in a timely manner. In addition, the project is creating**

a foundation for a research network for community-based clinical trials. To date, AMNet has been able to reach hundreds of stakeholders through webinars and publications. Between September 2020 and February 2022, the project hosted nine webinars, with a range of 160 to 500 participants per webinar. The project's publication in *Substance Abuse and Rehabilitation* has also been viewed over 2,800 times.

Building Linkages to Address Co-Morbidities

Co-occurring disorders, including mental health issues and other SUDs, 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 across databases. Three 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 (NSDUH), 14.6 percent of adults with a serious mental illness misused opioids in the past year.[7] This type of co-morbidity 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 Institute of Mental Health (NIMH), initiated this project in 2019. The project aimed to build an enhanced, linked dataset on mortality, opioids, and co-occurring mental health issues to provide much needed data for research. This involved taking a set of files (already linked) from the NCHS, National Hospital Care Survey (NHCS), the National Death Index (NDI), and the NVSS's restricted-use mortality files on Drug-Involved Mortality (DIM) dataset and merging them with additional information on co-occurring disorders. **Through data linkages, the project has made it more efficient to conduct retrospective analyses on patterns and risk factors for OUD and co-occurring mental health disorders. This enabled greater understanding of the contributors to opioid-related mortality, which may inform data-driven treatment and management strategies for OUD.**

KEY PRODUCTS

- An April 2021 journal article in *Psychiatric Services*, "Addiction Medicine Practice-Based Research Network (AMNet): Building partnerships," describes the project's collaborative efforts with the APA, American Society of Addiction Medicine, Friends Research Institute, and NIH/NIDA to create AMNet.
- A June 2021 journal article in *Substance Abuse and Rehabilitation*, "Addiction Medicine Practice-Based Research Network (AMNet): Assessment Tools and Quality Measures," summarizes results of an environmental scan and efforts to identify, review, and select assessment tools and quality of care performance measures for OUD and SUD for inclusion in AMNet.

PROJECT AGENCIES: NIH/NIDA

KEY PRODUCTS

- The completed 2016 NHCS/NDI/DIM enhanced dataset with information on patients with opioid-involved encounters with co-occurring disorders is available for use by researchers through the NCHS Research Data Center.
- The report Identifying Co-Occurring Disorders among Opioid Users Using Linked Hospital Care and Mortality Data describes the completed dataset.
- The report Characteristics and Mortality Outcomes of Opioid-involved Hospital Encounters with Co-occurring Disorders describes characteristics of patients experiencing opioid-involved hospital encounters with co-occurring SUD and mental health issues.
- A final project report identifies co-occurring disorders among opioid users using linked hospital care data and summarizes project accomplishments, lessons learned, and future implications.

PROJECT AGENCY: CDC

Child and Caregiver Outcomes Using Linked Data (CCOULD)

Parental substance use is a primary risk factor for child maltreatment and involvement in child welfare systems, which are both highly predictive of poor health outcomes over the short and long term.[8] SUDs and behavioral health issues are particularly disruptive to families and the health outcomes of the children involved. Initiated in 2019, the CCOULD project is co-led by ASPE and the Administration for Children and Families (ACF). The pilot project aims to increase data availability for research on parents receiving services for SUD and other behavioral health issues through Medicaid who have children in the child welfare system. In partnership with state agencies in Kentucky and Florida, the project is linking data between state Medicaid records and child welfare records to produce research-use datasets. These datasets 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). These deidentified datasets will enable researchers to better understand the treatment needs of parents with SUD and co-occurring behavioral health issues who have children in the child welfare system.

The CCOULD datasets will enable research on SUD and social determinants of health (SDOH) related to child welfare services. Improving the ability to understand the relationship between child and family outcomes and parental SUDs will allow researchers to answer a multitude of questions relevant to SUD-focused PCOR and health equity research.

KEY PRODUCTS

- The Child and Caregiver Outcomes Using Linked Data Informational Sheet summarizes the project and will be used in outreach efforts to expand knowledge about the project.

PROJECT AGENCIES: ASPE, ACF

Enhancing Identification of Opioid-Involved Health Outcomes Using Linked Hospital Care and Mortality Data

National-level statistics on opioid-related hospitalizations are limited and often incomplete. Researchers need comprehensive data on opioid-related ED visits, inpatient hospitalizations, and deaths to identify and test strategies to reduce the morbidity and mortality from misuse and overdose of opioids. Since 2018, the NCHS has been helping address this need by developing enhanced methods that link available data from three data sources: 1) the NHCS, 2) the NDI, and 3) the DIM file. Linking these data sources offers broad, national-level data on hospital care and deaths related to opioid-involved drug overdoses. In addition to creating linked data files, the project developed an enhanced algorithm to improve identification of opioid-involved hospital encounters and reporting tools to support research on hospital encounters involving opioids. **This project improves data capacity for PCOR through creating new research data with opioid terminology related to ED visits, hospitalizations, and deaths. Researchers outside of the CDC have applied to the CDC's Research Data Center to use the linked datasets to research opioid-involved health outcomes and risk factors for opioid overdose hospitalizations and deaths.**

KEY PRODUCTS

- The linked 2014 NHCS data, 2014/2015 NDI data, and 2014/2015 DIM dataset are available through the NHCS Research Data Center. A summary report provides a detailed description of the data sources and methods.
- The Linkage of the 2014 National Hospital Care Survey to the 2014/2015 National Death Index: Methodology Overview and Analytic Considerations describes the linkage process between the 2014 NHCS and the 2014/2015 NDI data.
- The linked 2016 NHCS data, 2016/2017 NDI data, and 2016/2017 DIM dataset are available through the NCHS Research Data Center. A summary report briefly describes the data sources for the linked file.
- The report Enhancing Identification of Opioid-involved Health Outcomes Using National Hospital Care Survey Data describes the development of the enhanced opioid-identification algorithm utilizing the 2016 NHCS data.
- A National Health Statistics report, Opioid-involved Emergency Department Visits in the National Hospital Care Survey and the National Hospital Ambulatory Medical Care Survey, utilizes the enhanced opioid algorithm developed by this project.

PROJECT AGENCIES: CDC

Looking to the Future

The opioid overdose crisis is a complex national issue. The OS-PCORTF portfolio represents a continuous, coordinated effort to enhance the capacity of research on OUD. These projects establish better data, networks, and registries; improve the standardization of key metrics and indicators; and support robust linkages across a range of data sources. Ultimately, strengthening the research data infrastructure will provide a better understanding of risk factors that contribute to the opioid overdose epidemic and identify the prevention and intervention strategies that will help mitigate the crisis.

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