

U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Print Date: 1/25/22

Title:	Drug Overdose Surveillance and Epidemiology System (DOSE)
Project Id:	0900f3eb81a4d4d1
Accession #:	NCIPC-ESB-10/24/19-4d4d1
Project Contact:	Alana M Vivolo
Organization:	NCIPC/DOP/ESB/MORB
Status:	Project In Progress
Intended Use:	Project Determination
Estimated Start Date:	09/01/2019
Estimated Completion Date:	08/31/2023
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1268

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance 45 CFR 46.102(I)(2)	5/18/21	Angel_Karen C. (idy6) CIO HSC
PRA: PRA Applies		5/18/21	Angel_Karen C. (idy6) OMB / PRA
ICRO: PRA Applies	OMB Approval date: 8/30/19 OMB Expiration date: 8/31/22	5/18/21	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description	
Priority:	Standard
Determination Start Date:	04/16/21
Description:	The Drug Overdose Surveillance and Epidemiology (DOSE) system funds 52 health departments (50 state health departments, the health department of Puerto Rico and the health department of the District of Columbia) to rapidly share existing ED data on counts of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses using two standard data forms (i.e., the Rapid ED overdose data form and the ED discharge overdose data form) and standard CDC case definitions.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	To rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level. This goal will be accomplished by standardizing and enhancing sharing of existing ED data locally collected by 52 health departments (all 50 state health departments, the health department of Puerto Rico, and the health department of the District of Columbia) with CDC.
Objective:	DOSE will improve situational awareness of federal, state, and local health departments of emerging drug overdose outbreaks and the progression of the opioid overdose epidemic. DOSE will enhance public awareness of the progression of the opioid overdose epidemic and other emerging drug overdose threats in their area: Limited timely local and state data is available on nonfatal and fatal drug overdoses. DOSE will enhance local health department surveillance of suspected drug, opioid, heroin and stimulant overdoses and assist states in mandatory reporting requirements of overdose.
Does this project include interventions,	Not Selected

services, or policy change work aimed at

improving the health of groups who have been excluded or marginalized and/or decreasing disparities?:	
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials
Target Populations to be Included/Represented:	Other - Individuals who visit an ED to receive treatment for a drug, opioid, heroin, or stimulant overdose
Tags/Keywords:	Drug Overdose
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC is providing funding
Method Categories:	Surveillance Support; Technical Assistance
Methods:	The project will leverage ED syndromic data and hospital discharge data on ED visits already routinely collected by state and territorial health departments. No new data will be systematically collected from EDs, and health departments will be reimbursed by CDC for the burden related to sharing ED data with CDC.
Collection of Info, Data or Biospecimen:	Fifty-two funded health departments (50 state health departments, Puerto Rico, and the District of Columbia) will rapidly share existing ED data with CDC on a monthly basis using the Rapid ED overdose data form and standard CDC case definitions. Data may come from different local ED data systems, but is expected to cover at least 75% of ED visits in the jurisdiction (e.g., state). Specifically, some health departments conduct rapid overdose surveillance using IOC as the Program (NSSP), which receives near real-time ED data source, CDC will require all participating health departments or their partners on approximately 60% of ED visits in the United States. Regardless of the data source, CDC will require all participating health departments to provide counts of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses by county, age group, sex, and time (i.e., month and year) in a standardized manner using the Rapid ED overdose data form, which is an Excel data template. This form also collects data quality indicators such as percent of ED visits missing data on key variables (i.e., metadata). In order to assess and improve rapid ED data sharing, all 52 participating health departments will also be asked to share counts of ED visits involving suspected drug, opioid, heroin and stimulant overdoses by county, age group, sex, and time (i.e., month and year) from more finalized hospital discharge files, the current surveillance tandard. The data will be shared with CDC on a quarterly or yearly basis using a standardized Excel data form, the ED discharge overdose data form, and standard. The data will be shared with CDC case definitions.
Expected Use of Findings/Results and their impact:	Improve local, state, and regional situational awareness of drug, opioid, heroin, and stimulant overdose trends and response to acute local and multi-state drug outbreaks.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Overdose Data to Action (OD2A)	CE19-1904	2019	4	

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No	
Estimated number of study participants		
Population - Children		Protocol Page #:
Population - Minors		Protocol Page #:
Population - Prisoners		Protocol Page #:
Population - Pregnant Women		Protocol Page #:
Population - Emancipated Minors		Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection
Clinical Trial	
Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection
Other Considerations	
Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Alana Vivolo	06/24/2024		09/14/2021		Program Lead	goz4@cdc.gov	770-488- 1244	MORBIDITY TEAM

Data

DMP

Proposed Data Collection Start Date: 9/1/19

Proposed Data Collection End Date:	

Proposed Public Access Level:

Public Access Justification:

Public

DOSE data will be available on a CDC website in the form of an interactive dashboard with options to download data into a CSV file. The website is currently under development but our current website includes some of this data: https://www.cdc.gov/drugoverdose/data/nonfatal/case.html

How Access Will Be Provided for Data:

Plans for Archival and Long Term

Downloadable CSV files from the website.

The data will live in the dashboard but will also be preserved in a CDC network user-protected folder for security.

Spatiality

Preservation:

Country	State/Province	County/Region
United States	South Carolina	
United States	Washington, D.C.	
United States	Wisconsin	
United States	West Virginia	
United States	Washington	
United States	Virginia	
United States	Vermont	
United States	Utah	
United States	Texas	
United States	Tennessee	
United States	Rhode Island	
United States	Pennsylvania	
United States	Oregon	
United States	Oklahoma	
United States	Ohio	
United States	North Carolina	
United States	New York	
United States	New Mexico	
United States	New Jersey	
United States	New Hampshire	
United States	Alabama	
United States	Alaska	
United States	Arizona	
United States	Arkansas	
United States	California	
United States	Colorado	
United States	Connecticut	
United States	Delaware	
United States	Florida	
United States	Georgia	
United States	Hawaii	
United States	Idaho	
United States	Illinois	
United States	Indiana	
United States	Iowa	

United States	Kansas	
United States	Kentucky	
United States	Louisiana	
United States	Maine	
United States	Maryland	
United States	Massachusetts	
United States	Michigan	
United States	Minnesota	
United States	Mississippi	
United States	Missouri	
United States	Montana	
United States	Nebraska	
United States	Nevada	

Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date	
Dataset yet to be added										



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