

SUPPORTING STATEMENT: PART B

Drug Overdose Response Investigation (DORI) Data Collection

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

CDC, in collaboration with the state or local health authority requesting assistance, will identify the respondent universe for each Drug Overdose Response Investigation (DORI) based on the information needed to understand emerging trends in drug use and misuse and associated fatal and nonfatal overdoses, understand the drivers and risk factors associated with those trends, and identify the groups most affected. The appropriate respondent varies based on the specific overdose events being investigated. Respondents could include:

- Public health authorities
- Law enforcement authorities
- Medical examiners
- Individuals who have suffered from a nonfatal overdose
- Families and friends of individuals who succumb to drug overdose
- Members of the general public, and individuals who are at higher risk for overdose (e.g., those suffering from addiction)
- Health care providers/pharmacists; dispensers of prescription medication
- Emergency Medical Services personnel
- Representatives of community organizations (e.g., substance use service providers)

The chart below estimates the average number of respondents from whom data may be collected from per year – these figures are based on data from previous investigations conducted through the Epi-Aid mechanism.

Entity Covered by Data Collection	Number of Respondents
State and Local Government Offices	100
State Health Department	100
Local Health Department	100
Overdose Victim	500
Overdose Victim’s Family/Friends	500
General Public	500
Member Groups at Heightened Risk for Injury	500
Health care providers/pharmacists	100
Law Enforcement Personnel	100
EMS (first responders)	100
Representatives of Community Organizations	100
Total	2,700

Response rates from previous investigations range dramatically, depending on the type of respondent, method and mode of data collection, and urgency of the event. While response rates 80% or higher are desired, in many investigations lower response rates are acceptable given the goal of the information collection is not to contribute to the generalizable knowledge; rather, data are collected to identify trends, risk factors, and populations at risk so that effective prevention and control measures can be implemented. Measures are taken to ensure adequate response rates are obtained to achieve this purpose.

2. **Procedures for the Collection of Information**

- Type of data to be collected
 - Chart abstraction. Charts from hospitals, emergency departments, outpatient facilities, laboratories, and medical examiners/coroners provide useful medical and contextual information about nonfatal and fatal overdoses. In many cases, CDC data collectors request access to data from less than 10 hospitals, outpatient facilities, or medical examiner/coroner offices; under these circumstances, the data collection activities do not require OMB review given that the burden on these organizations does not meet the PRA threshold. However, in some instances, it may be necessary to collect data from charts from 10 or more hospitals, emergency departments, outpatient facilities, laboratories, or medical examiner offices. When this amount of information is required to meet the needs of the investigation, chart abstraction will be included in the GenIC approval request. Information extracted from charts could include type of data source (e.g., toxicology report, autopsy report, medical records, EMS run sheet, prescription drug monitoring program (PDMP)), demographics, prescription and illicit drug use history, reported medical and mental health conditions, place of overdose, place of death, drug paraphernalia on the scene, mode of administration, observers present, naloxone administration, hospital admittance, autopsy findings, and toxicology results.
 - Collection of information from representatives from 10 or more agencies. There are many organizations and agencies involved in tracking, preventing, intervening, or responding to drug overdose, such as governor's offices, public health agencies, community planning and licensing agencies, mental health and social service departments, pharmacy boards, medical boards, law enforcement authorities, medical examiners, clinicians in health systems, emergency medical services, community organizations, and dispensers of prescription drugs. It is anticipated that representatives from 10 or more agencies could be asked

to participate in surveys or interviews that are on the same topic and use similarly structured questions. For example, an agency representative from 10 or more agencies could be asked about their professional history, personal experience with drug overdose cases or investigations, prevention or intervention policies and programs implemented, perceptions of characteristics of or changes in drug overdose cases (e.g., transition from prescription opioids to heroin; increasing or decreasing rates), locations of overdoses (e.g., hot spots), experience collaborating with other agencies, and challenges and barriers encountered.

- Collection of information from 10 or more representatives from a specific agency. Because agencies serve different roles in drug overdose prevention, intervention, and response, it is possible that respondents from these agencies would be asked different questions about their role, knowledge, attitudes, and experiences. For example, the role played by clinicians in health systems is different from the role played by law enforcement personnel. However, 10 or more representatives within a specific agency could be asked to participate in surveys or interviews that are on the same topic and use similarly structured questions. For example, 10 or more clinicians in emergency departments across a city could be asked about professional experience, standard emergency department procedures followed in responding to drug overdose cases, clinical guideline adherence, standard of care, components of routine drug screening, naloxone dosage that is available, and trends in overdose cases seen. Or, 10 or more law enforcement personnel could be asked about their professional experience, direct work in drug control or drug use prevention efforts, involvement in drug overdose investigations, common street names for drugs, trends in drug overdose cases, trends in sources, distribution, customers, drug purity, and so forth. Or, 10 or more representatives from a substance use prevention and treatment community organization could be asked about their prevention programs, enrollment, reach, treatment services provided, barriers to care, patterns in drug use (e.g., shifting from prescription opioids to heroin), and so forth. For dispensers, 10 or more representatives from pharmacies (e.g., CVS) could be asked about patient education materials, standard procedure for filling controlled substance prescriptions, use of prescription drug monitoring programs, storage and inventory practices, volume of drugs dispensed, and so forth. Finally, 10 or more representatives from the state/county/city health department could be asked about their coordination with other agencies, prevention and treatment programs funded, local trends in drug overdose, data describing the epidemic, support of prescription drug monitoring programs, policy implementation, and resources available for rapid response to control epidemics.

- Collection of information from overdose victims, friends, and family.
Information about the context of drug overdose can often be obtained from those directly affected, including nonfatal overdose victims, friends, and family. It is anticipated that 10 or more victims, friends, and family could be asked to participate in surveys or interviews that are on the same topic and use similarly structured questions. For example, victims, friends, and family could be asked to report on substance use history, prescription drug history, number of providers and pharmacies used, pain history, co-occurring health conditions (e.g., changes in breathing function indicative of respiratory depression), mental health conditions (e.g., depression, anxiety disorders), enrollment in drug treatment program, sources of drugs, route of drug administration, and criminal history.
- Spatial data: Information about the location of drug overdose incidents can inform how to control local epidemics. For example, 10 or more agencies within city and county governments (e.g., planning, licensing) could provide spatial data (address) on locations of businesses, dispensers, criminal activity, liquor licenses, and entertainment venues to determine structural and environmental factors that are associated with increased drug overdose risk.

- Statistical method for stratification and sample selection

Most investigations of smaller scale drug overdose epidemics or emergencies (e.g. where a few to several hundred individuals are involved) require collecting information from all individuals affected by the condition in question. However, with some smaller scale incidents or those involving larger numbers of individuals, investigators may choose to collect information from a sample of affected individuals and appropriate controls. When statistical methods are employed in the collection of information, expert statistical assistance is available at CDC relating to sampling methodology and selection of controls. For example, cases may be randomly selected from a line list and controls may be selected based on pair-matching (i.e., one or more matching controls selected for each case based on certain characteristics such as age, sex, geographic location, having a particular risk factor, etc.). Respondents will be chosen based on the nature of the overdose events and the organizations responsible for implementing injury prevention and control measures. Advance notice will be provided to respondents when feasible.

Procedures for each investigation, including specific data collection plans, depend on the time and resources available, number of persons involved, and other circumstances unique to the urgent conditions at hand. Examples of modes which may be used to collect information include:

- Face-to-Face Interview

- o Telephone Interview
- o Web-based Questionnaire
- o Self-administered Questionnaire
- o Archival Record Abstraction and Review

Telephone or face-to-face interviews are a common mode used in DORIs because they allow for rapid data collection and are conducive to open-ended responses that are particularly useful during the hypothesis-generating stage of the investigation. Web-based questionnaires are used less frequently; due to the rapid nature of the response required in a DORI as there is often little time for developing a web-based tool. Self-administered questionnaires are often used when information interviews are not feasible and the information to be collected can be captured using straight-forward questions with fixed response options. Archival record review provides important information about medical history, symptoms, diagnoses, and services received. Ultimately, the type of mode(s) used will be determined based on the specific information needed to identify trends, risk factors, and subgroups affected so that effective prevention and control measures can be implemented. All interviews will be conducted by trained investigators, such as epidemiologists and behavioral scientists. These interviewers will be trained according to standard protocols.

- Estimation procedure

Data analysis is conducted under the advice of a statistician/data analyst from CDC or the requesting organization and will involve descriptive statistics. Additional bivariate and multivariate analyses are conducted as needed to identify drug overdose trends, risk factors, or subgroups affected so that effective prevention and control measures can be implemented.

- Degree of accuracy needed for the purpose described in the justification

The purpose of the DORI is to collect information rapidly to identify unknown information necessary for instituting effective prevention and control measures. The use of scientifically sound sampling methods ensures that CDC collects quality data necessary to identify effective prevention and control measures.

- Unusual problems requiring specialized sampling procedures

CDC does not expect unusual problems requiring specialized sampling.

- Any use of periodic (less frequent than annual) data collection cycles to reduce burden

Because of the acute nature of the events to be investigated, periodic data collection is not being employed. The purpose of data collection is to identify drug overdose trends, risk factors, and subgroups affected to allow for rapid implementation of effective prevention and control measures.

3. Methods to Maximize Response Rates and Deal with No Response

Because of the involvement of state and or local health departments, and the general interest and concern surrounding most drug overdose events, DORI data collection response rates tend to be high, but can vary dramatically. For each DORI, response rates are maximized by informing potential respondents of the critical nature of the event and the importance of collecting information to identify effective prevention and control measures. Before collecting information, investigators inform respondents that participation is voluntary, that respondents are not personally identified in any published reports of the study, and that their privacy will be protected to the extent allowed under Federal law.

4. Test of Procedures or Methods to be Undertaken

Pilot tests of procedures for DORIs are rare because of the lack of time available before an investigation proceeds. Though each data collection instrument is tailored to the needs of each specific event, questions from instruments employed in previous investigations are used when possible. A data collection instrument library is maintained by archiving the final data collection instruments administered in DORIs under this Generic clearance. Sample data collection instruments for DORIs can be found in Attachment B of Supporting Statement A.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC DORI investigators are trained in biostatistics and epidemiology. In most cases, investigators collaborate extensively with health officials of the state or local health department requesting assistance. All investigations are supervised by CDC's experienced epidemiologists with expert statistical resources available.