Request for Approval Under the Generic Clearance for
Drug Overdose Response Investigation (DORI) Data Collection (OMB#: 0920-1054)

Drug Overdose Response Investigation Protocol Template

TITLE

Undetermined risk factors for fentanyl-related overdose deaths- Ohio

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INTRODUCTION

The circumstances justifying this DORI are an increase in fentanyl-related overdose deaths in the state of Ohio. The Ohio Department of Health requests CDC assistance with an investigation to identify risk factors for fentanyl-related overdose deaths in the state (Attachment 1). Fentanyl, a synthetic, short-acting opioid analgesic, is 50–100 times more potent than morphine and is approved for the management of severe or chronic pain, typically among opioid-tolerant patients. In March 2015, the U.S. Drug Enforcement Administration (DEA) issued a nationwide alert on fentanyl as a threat to health and public safety. The alert was followed by a DEA National Heroin Threat Assessment Summary, which noted that, “Beginning in late 2013, and throughout 2014, several states have reported spikes in overdose deaths due to fentanyl and its analog acetyl-fentanyl.” In 2013, there were a total of 84 fentanyl-related unintentional overdose deaths in Ohio. In 2014 in Ohio, preliminary data show 500 fentanyl-related unintentional overdose deaths in this year, almost a 500% increase. These deaths in 2014 account for 20% of all drug poisoning deaths in Ohio, compared with 4% in 2013. Press reports indicate that fentanyl-related fatalities continue to be an ongoing issue in 2015. In September 2015 it was reported that there were over 100 fentanyl-heroin overdose deaths so far this year, and in another press report, the Cuyahoga county medical examiner reported that 59 fentanyl-related fatalities occurred there in the first eight months of 2015

PURPOSE

Identifying the circumstances and risk factors that are contributing to this increase in deaths is critical to implementing prevention strategies that will prevent additional deaths. Therefore, the Ohio Department of Health requests CDC assistance with an investigation to identify risk factors for fentanyl-related overdose deaths in the state. Data will be used to inform prevention and control measures in the state.

The objectives of this DORI include:

1. Characterize the population experiencing fentanyl-related overdose deaths, and compare it with the population experiencing heroin-related (exclusive of fentanyl) and prescription opioid overdose deaths.

2. Identify key risk factors for fentanyl-related overdose deaths that can be targeted by prevention activities.
3. Provide epidemiologic and qualitative information that can aid the Ohio Department of Health in developing public health messages, response, and recommendations to health professionals, law enforcement, and populations at risk.
4. Assist in the identification of strategies to help the Ohio Department of Health monitor and prevent future fentanyl-related overdose deaths.

To meet Objectives 1, 2, and 3, CDC will:

1) Abstract and analyze data from Coroner and Toxicology reports and analyze Prescription Drug Monitoring Program (PDMP) and Vital Statistics data for all opioid-related fatalities in the 8 highest burden counties.
2) Conduct one-on-one interviews with individuals who currently use fentanyl, heroin, or other prescription opioids (Attachment 2. Interview Guide: Individual Opioid Drug Users) and harm reduction practitioners who provide services to these individuals (Attachment 3. Interview Guide: Harm Reduction Practitioners).
3) To meet objective 4, CDC will apply a previously developed syndromic surveillance tool which utilizes Emergency Room data to obtain an early warning of trends in opioid overdose.

METHODS

This GenIC requests approval for the one-on-one interviews with opioid drug users (Appendix 1) and harm reduction practitioners (Appendix 2). Other activities (abstraction, analysis, and development of tool) entail use of existing data by federal employees and therefore does not entail burden to the public.

Primary data collection will include interviews with individuals who currently use fentanyl, heroin, or other prescription opioids and harm reduction practitioners who provide services to these individuals. Recruitment will be conducted through a combination of sampling methods that have been previously used to recruit hard-to-reach populations for behavioral surveys: (a) location-based convenience sampling through recruitment at venues that provide services (e.g. overdose prevention programs, medication assisted treatment providers, and syringe exchange programs) to persons who use drugs, and (b) peer-to-peer recruitment by participants. Participants sampled through the location-based

method will be asked to recruit their peers to better ensure a wide cross-section of the population of interest, particularly to recruit people that abuse opioids but do not use the above services. To reach persons who may not frequent any of the sampling locations identified and to be able to target specific characteristics of interest (e.g. persons who ingest or insufflate opioid tablets but do not utilize services), peer-to-peer recruitment will be utilized. In this approach, participants who complete the interview will be invited to help recruit others they know who use opioids. Interviews will be used to identify drug use behaviors and describe risk and protective factors associated with drug use behaviors. Interviewers trained in qualitative methods will conduct the interviews with consented participants using a semi-structured, open-ended interview guide. Interviews will be conducted by one lead interviewer and an assistant with experience performing note-taking.

To be able to compare commonalities and differences among persons who use opioids who have ever overdosed and persons who have never overdosed, we plan to recruit a minimum of 20 from each category (ever overdosed/never overdosed) for private interviews. Overdose history will be determined based on self-report and identified through an eligibility screener that will be administered during recruitment. Given the high rates of overdose fatalities and awareness of overdose risk associated with overdosing in the opioid-using community, we believe self-report is a reliable measure of overdose status.

Data will also be abstracted from records provided by Coroner/ Medical Examiner, toxicology, and the Prescription Drug Monitoring Program

RESULTS

As proposed by the ODH this emergency public health response study will characterize the population and key risk factors of those experiencing fentanyl-related overdoses as compared to those experiencing heroin-related overdoses. For the syndromic surveillance evaluation component ODH will provide de-identified data set including: ED and hospital IDs, chief complaint, triage and diagnosis notes, and diagnosis code(s), specifically ICD-9-CM or ICD-10-CM. A preliminary data analysis plan will include descriptive analyses focused on socio-demographic, medical history, history of drug use, incident/scene factors, and toxicology variables. Additional analyses include bivariate comparisons of fentanyl cases to controls, and fentanyl cases to heroin cases, using cross tabulations and Chi-square analyses. Multiple logistic regression methods will be utilized to assess the relationship between variables identified as risk factors for fentanyl-related drug overdose deaths. Qualitative information will be gathered through one-on-one in person interviews with persons who have used (past 6 months) opioids and those who have survived an opioid-related overdose.

BURDEN ESTIMATE

Data Collection Instrument Name	Type of Respondent	Data Collection Mode	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Attachment 2: Individual Opioid Drug Users	General Public: Person who use opioids	Qualitative interview	40	1	60	40
Attachment 3: Interview Guide: Harm Reduction Practitioners	General Public: Harm reduction practitioners	Qualitative Interview	20	1	60	20
					Total	60

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