Overdose **D**etection **M**apping **A**pplication **P**rogram

Research Guidance and Procedures

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Introduction

The Overdose Detection and Mapping Application Program (ODMAP) is a syndromic surveillance system that provides near real-time suspected overdose event data nationwide to support public safety and health efforts. Additionally, ODMAP acts as an early warning system to alert authorities to mobilize an immediate response to a sudden increase (spike) in overdose events. Only state, local, federal, and tribal agencies serving the interests of public safety and health as part of their official mandate may have direct access to ODMAP.

The Washington/Baltimore High Intensity Drug Trafficking Area (W/B HIDTA) developed ODMAP to help address the opioid-involved epidemic confronting our Nation. Americans now have a 1 in 96 chance of dying from an opioid overdose, with more than 130 Americans dying from opioid overdoses each day.[i] Among the 70,237 drug overdose deaths in 2017, 67.8% involved an opioid.[ii] The rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) increased by 45% between 2016 and 2017.[iii]

Deaths involving synthetic opioids increased from 2016 to 2017 across all demographic categories. The highest death rate was in males aged 25-44 years, and the largest relative increases occurred among African Americans and American Indian/Alaska Natives. While five states saw significant decreases in heroin-involved overdoses, 23 states and DC experienced significant increases in synthetic opioid-involved overdose death rates, including eight states west of the Mississippi River. The largest relative rate increases occurred in Arizona (122%), North Carolina (112.9%) and Oregon (90.9%).[iv] West Virginia, Ohio, and Pennsylvania were the three states with the highest observed drug overdose death rates in 2017.[v]

While the opioid epidemic justifiably dominates national and state priorities, another emerging threat deserves focus and attention; overdose deaths involving cocaine and psychostimulants increased by 52.4% and 33.3% respectively from 2015 to 2016.[vi] Deaths from cocaine sharply increased from 2011 to 2016, increasing by about 18% each year during the five-year period. Cocaine was the second-or third-most common cause of overdose deaths every year from 2011 to 2016. Similarly, the number of overdose deaths involving methamphetamine increased from 1,887 in 2011 to 6,762 in 2016.[vii]

Mexican transnational criminal organizations have increased the production and trafficking of methamphetamine, therefore lowering its domestic price point while increasing its availability and purity throughout the United States.[viii] The threat of methamphetamine is particularly high in the Pacific, Southwest and West regions of the United States, but its availability on the East Coast has also increased.[ix] Coca plant cultivation in South America has contributed to the rise in global cocaine production, leading to increased prevalence and heightened purity of the product.[x]

Poly-drug use introduces an additional challenge to the overdose crisis as it may place individuals at an increased risk of overdose, particularly with the introduction of fentanyl into the cocaine and methamphetamine supply. In 2016, nearly 40% of all cocaine overdose deaths also involved a synthetic opioid, such as fentanyl.[xi] Most overdose deaths involve more than one drug, with individuals who overdosed on benzodiazepines having other drugs in their system 96% of the time. Nearly 70% of fatal fentanyl-related overdoses involved more than one drug, as did 71% of fatal heroin overdoses.[xii]

Background

ODMAP enables communities to respond as quickly as practically possible to a suspected overdose incident and prevent additional overdose incidents. The near real-time aspect of ODMAP sets it apart from other overdose surveillance efforts.

The W/B HIDTA launched ODMAP as a pilot program in Maryland and West Virginia in 2017. Presently, ODMAP captures overdose events in 48 states D.C. and Puerto Rico. Efforts are underway to recruit the remaining three states – Arizona and Colorado. While ODMAP usage continues to increase, significant areas of the country still underutilize the system, which presents problems in conducting analysis on a nationwide scale. Furthermore, the data reported in ODMAP represents *suspected* overdose data, meaning that the overdose has not been confirmed through a medical laboratory's analysis. ODMAP data is used to identify overdose spikes and clusters (concentrations of overdose events in a confined geographic area), and pinpoint areas where an immediate public safety and health response is needed.

Not long after implementing ODMAP, the W/B HIDTA began receiving requests from a variety of government and non-government organizations to obtain access to ODMAP. Multiple requests came from journalists wanting to make the data available to the public, which is not allowable

and/or inappropriate as ODMAP data is a) Controlled Unclassified Information (CUI)[xiii] b) is unverified and c) an incomplete representation of overdose events. Additional requests came from researchers interested in furthering research into the opioid epidemic. Given the increased interest in ODMAP data and the potential value to public health and safety, the W/B HIDTA convened a panel of ODMAP users and nationally-recognized academic scholars to develop recommendations for the W/B HIDTA to consider re-evaluating policies and procedures to govern access to ODMAP data.

Access to ODMAP Data

As of November 2019, more than 2,800 law enforcement, public health, fire and emergency medical services (EMS) that have executed participation agreements with the W/B HIDTA and have access to ODMAP. These agencies train their members to enter overdose event data directly into ODMAP through a cell phone, computer or through an application program interface (API). Each agency can control access to their members depending on their credentials.

The W/B HIDTA is the data steward for ODMAP and, as such, manages ODMAP data pursuant to the participation arrangements made with each ODMAP participating agency. As the data steward, the W/B HIDTA is responsible for safeguarding ODMAP data and facilitating data sharing when possible.

The ODMAP participation agreement states that all information submitted to ODMAP is the property of the submitting agency. Furthermore, the participation agreement grants permission to the W/B HIDTA to use ODMAP data as the W/B HIDTA sees fit pursuant to the goals of ODMAP. This includes, but is not limited to, aggregating multiple datasets from participating agencies, combining agency information with data from other databases that the W/B HIDTA manages (e.g., Case Explorer), analyzing the information to create law enforcement and public health analysis, conducting academic research, and sharing actionable information with law enforcement and public health agencies.

Goals of ODMAP

The W/B HIDTA created ODMAP to achieve the following goals:

1. provide a near real-time drug overdose surveillance system of suspected overdose events occurring nationwide using a specialized program to collect overdose event information

2. collect and store geocoded coordinates of known and suspected overdose events uploaded from ODMAP to create digital maps that participating agencies may use to identify overdose occurrences and potential spikes in near real-time
3. provide liaison, coordination and resource assistance in the collection, storage, exchange, dissemination and analysis of ODMAP data for participating agencies
4. enable participating agencies to develop effective strategies for addressing overdose incidents occurring in their jurisdictions, and
5. enhance the development of regional strategies designed to reduce the risk of substance use disorders resulting in overdose incidents.

Value to Research Community

Similar to other surveillance systems in criminal justice and public health knowing when and where suspected overdose events take place in near real-time and learning the relationship between and among such events allows analysts to forecast suspected overdose spikes and clusters.[xiv],[xv] This makes it possible to forewarn first responders and medical personnel of the likelihood of a spike or cluster occurring in their geographic area. However, ODMAP data is unsubstantiated information about suspected overdose events. As such, the system faces limitations when used by the research community. Nevertheless, when triangulated with other data sets, the value of ODMAP data may dramatically increase.

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA (Health Insurance Portability and Accountability Act of 1996) is United States legislation that provides data privacy and security provisions for safeguarding medical information. The law has emerged into greater prominence in recent years with the proliferation of health data breaches caused by cyberattacks and ransomware attacks on health insurers and providers. HIPAA applies to "covered entities" electronically sharing Personal Health Information (PHI). PHI is defined as information about an individual PLUS at least one of 18 enumerated identifiers. The geographic location of data points is an identifier for HIPAA's purposes. Only covered entities are subject to HIPAA, and certain users are covered entities-specifically, Fire, EMS and Hospitals, certain other first responders and their business associates. Police departments are not covered entities and, therefore, not subject to HIPAA.

However, the HIPAA Privacy Rule has one method specific to allow sharing for research purposes and three exceptions that establish ODMAP's compliance with the law. The Limited Data Set Method of sharing PHI data is specifically available for research and/or public health purposes. Additionally, HIPAA has at least three exceptions to allow for sharing PHI: 1) Prevent a serious threat to health and safety of a person or the public, 2) A public health authority to avert serious threat to health and 3) Law enforcement officials to prevent a serious threat to the public [see 45 CFR §164.512(b)(f)(j)].

The requirements for a Limited Data Set are found at 45 CFR §164.514. To qualify as a Limited Data Set, the covered entity may only share the data pursuant to a specific purpose, namely either public health or research. Additionally, the covered entity must remove certain personal identifiers (which are absent from ODMAP), and the Parties must sign a Data Use Agreement covering the data set. The HIPAA Privacy Rule considers any geographic information more specific than the state level to be an enumerated identifier. The Limited Data Set method is valuable for ODMAP research purposes because it is less restrictive on the geography identifier, as it permits the covered entity to share geographic information including Zip Code, Town, City, and County- pursuant to the Limited Data Set and Data Use Agreement requirements. Under the Limited Data Set method, the parties cannot share geographic information at the street address level.

The alternative to the Limited Data Set method would be to use the exceptions to HIPAA outlined above. However, these exceptions provide access to public entities such as a health department and/or police department; academic researchers may not qualify.

Non-Disclosure Agreement

It is the policy of the W/B HIDTA only to grant access to ODMAP data to a non-participating agency, after a Non-Disclosure Agreement (NDA) has been signed between all parties, including a Data Use Agreement. The W/B HIDTA uses two documents to meet the requirements of the Data Use Agreement- the *ODMAP Participation Agreement* and the *ODMAP Policies and Procedures*.

The W/B HIDTA strongly encourages participating agencies who are covered entities to follow the same procedures, and provides these documents as templates for any party.
The NDA must indicate that the data is the proprietary information of the participating agency. All information provided by either party to the other in connection with the Program shall be deemed "Proprietary Information." Such information is for the purposes of facilitation of work on the Program only and shall be kept in confidence by the receiving party. Furthermore, the receiving party shall not use or share such information, data, documents, or other material for any other purpose without the prior written consent of the participating agency, and then only on a "need to know" basis.

Publishing Using ODMAP Data

Information in raw format in ODMAP is Controlled Unclassified Information (CUI) and may only be released to authorized personnel. Recipients of this information must have a need and right to know the information in the performance of their criminal justice and public health functions. ODMAP shall only be used for its intended purposes. Therefore, The W/B HIDTA currently has a policy prohibiting publication of research projects utilizing ODMAP raw data as it stands in contrast to the CUI principles of need to know and right to know. Additionally, as stated in the *ODMAP Policies and Procedures*, ODMAP data is neither verified nor suitable for use in representing the true occurrence of drug overdoses. Currently, ODMAP is considered a tool for exploratory analysis only. With proper acknowledgement and understanding of these legal and analytic limitations, if a research partnership is developed, the agency may grant permission to publish their data (see below).

Options for the Research Community

The best option for researchers is to get direct permission from an agency to use that agency's ODMAP data. In this case, a researcher is not bound by the *ODMAP Policies and Procedures*, and is only subject to the requirements from the agency stipulated in the Non-Disclosure Agreement and Data Use Agreement templates. This includes the ability to publish results from the data if the agency grants permission (however, the researcher will still need permission from the W/B HIDTA to reference ODMAP specifically). The W/B HIDTA can facilitate securing permissions, establishing relationships and helping researchers work with that data; however, with more than 2,500 participating agencies, research on a large scale may be impractical.

Research Policy and Procedures

Given the interest in and potential value of ODMAP data for use in research projects, the following policy and procedures will govern the researchers' access to ODMAP data.

It is the policy of the W/B HIDTA to facilitate access to ODMAP data to anyone who has received written permission from the agency that submitted that data to ODMAP, including researchers who seek to use ODMAP data to further their studies into the overdose epidemic, pursuant to the following definition.

The W/B HIDTA defines research as: 45 CFR § 46:

(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Researchers seeking access to ODMAP data to further their research agenda must complete the ODMAP Research Request Form (Form A) and submit the completed form to vpallutc@wb.hidta.org by the dates specified on the W/B HIDTA website.

The ODMAP Research Review Board (ORRB) will convene to review submissions and vote on a quarterly basis beginning in January of each calendar year. The Chair of the ORRB will promptly notify each submitting researcher of the results following each quarterly review.

W/B HIDTA will provide ODMAP data to those researchers receiving authorization from the ORRB providing that applicant fulfills all conditions the ORRB has set forth above for receiving ODMAP data. W/B HIDTA may charge a fee for any labor involved in providing the ODMAP data. The fee will be determined in advance and made a condition for receiving the ODMAP data. Any applicant who does not receive a favorable review will be permitted to reapply.

ODMAP Research Request Form (Form A)

Name of Institution/Organization

Project Title

Principal Investigator 1

Title
Mailing address
Email
Phone

Principal Investigator 2

Title
Mailing address
Email
Phone

Expected dates of Research

1. Start (month/day/year)

   End (month/day/year)

FUNDING OF RESEARCH

2. Is your research part of a grant or contract/subcontract?

- o Yes. Attach a copy of the grant or contract/subcontract.
- o No
- o

PROPOSED RESEARCH

3. Do you intend to collaborate with others on this project?

- o Yes. List the parties with whom you plan to collaborate.
- o No

4. Please state the research question(s) to be answered by this project.

5. Provide a brief summary of the research design.

6. **Will you be using secondary data in your analysis of the ODMAP data?**

   - Yes. Explain how the secondary data was collected/source of the data and how you plan to use the secondary data.
   - No

7. **Describe the participant group to be studied.**

8. **List <u>all</u> sites where this research will take place. (City, County, and State)**

9. **What benefits do you expect your project will provide?**

10. **Do you have an internal Institutional Review Board (IRB)?**

    - Yes.
    - No.

11. **If yes, have you received approvals from your IRB to proceed with the research?**

AGENCY PARTICIPATION

12. **Have you requested access to ODMAP from a participating agency(ies)?**

    - Yes. Which one(s)?

13. **Did that agency(ies) provide written permission to use their ODMAP data in your research?**

    - Yes.
    - No. Explain

DISSEMINATION OF RESEARCH

14. **Explain how you intend to disseminate the results of your research. Check all that apply.**

    - Journal article
    - Conference presentation
    - Academic white paper
    - Thesis/Dissertation
    - Other Explain

[i] National Institute on Drug Abuse. (N.D.) Opioid overdose crisis. Retrieved from https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

[ii] Hedegaard, H., Minino, A.M., & Warner, M. (2018). Drug overdose deaths in the United States, 1999-2017. NCIS Data Brief, no 329. Retrieved from https://www.cdc.gov/nchs/products/databriefs/db329.htm.

[iii] Hedegaard, H., Minino, A.M., & Warner, M. (2018). Drug overdose deaths in the United States, 1999-2017.

[iv] Scholl, L., Seth, P., Kariisa, M., Wilson, N., & Baldwin, G. (2018). Drug and opioid-involved overdose deaths – United States, 2013-2017. *Morb Mortal Wkly Rep, 67*, 1419-1427. Retrieved from https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w.

[v] Hedegaard, H., Minino, A.M., & Warner, M. (2018). Drug overdose deaths in the United States, 1999-2017.

[vi] Kariisa, M., Scholl, L., Wilson, N., Seth, P., Hoots, B. (2019). Drug overdose deaths involving cocaine and psychostimulants with abuse potential – United States, 2003-2017. *Morb Mortal Wkly Rep, 68*, 388-395. Retrieved from https://www.cdc.gov/mmwr/volumes/68/wr/mm6817a3.htm?s_cid=mm6817a3_w.

[vii] Hedegaard, H., Bastian, B., Trinidad, J., Spencer, M., & Warner, M. (2018). Drugs most frequently involved in drug overdose deaths: United States, 2011-2016. *National Vital Statistics Reports, 67*(9). Retrieved from https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf.

[viii] United States Drug Enforcement Administration. (2018). 2017 Domestic Methamphetamine Threat Assessment. Retrieved from https://www.dea.gov/documents/2018/01/11/2017-domesticmethamphetamine-threat-assessment-key-findings.

[ix] United States Drug Enforcement Administration. (2018). 2017 Domestic Methamphetamine Threat Assessment.

[x] United States Drug Enforcement Administration. (2018). 2017 Domestic Methamphetamine Threat Assessment.

[xi] Hedegaard, H., Bastian, B., Trinidad, J., Spencer, M., & Warner, M. (2018). Drugs most frequently involved in drug overdose deaths: United States, 2011-2016. *National Vital Statistics Reports, 67*(9).

[xii] Hedegaard, H., Bastian, B., Trinidad, J., Spencer, M., & Warner, M. (2018). Drugs most frequently involved in drug overdose deaths: United States, 2011-2016. *National Vital Statistics Reports, 67*(9).

[xiii] Controlled Unclassified Information (CUI) is information that requires safeguarding or dissemination controls pursuant to and consistent with applicable law, regulations, and government-wide policies. See 32 CFR §2002

[xiv] From Crime Mapping to Crime Forecasting: The Evolution of Place-Based Policing. National Institute of Justice. Retrieved from http://nij.ojp.gov/topics/articles/crime-mapping-crime-forecasting-evolution-place-based-policing.

[xv] Hudson T.L., Klekamp B.G., & Matthews, S.D. (2017). Local Public Health Surveillance of Heroin-Related Morbidity and Mortality, Orange County, Florida, 2010-2014. *Public Health Reports, 132*(1_suppl), 80S-87S.