pennsylvania
DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

2016-17 MDAIR REPORT

Contents

Message from the Secretary

February 25, 2019

Fellow Pennsylvanians,

At the Department of Drug and Alcohol Programs, our mission is to engage, coordinate, and lead the commonwealth's effort to prevent and reduce drug, alcohol, and gambling addiction abuse, while promoting recovery. To that end, it is critical that we analyze and understand the complexity of deaths and incidents associated with substance-use.

This report provides a picture of how the Methadone Death and Incident Review team within the department has reviewed and analyzed methadone-related deaths and incidents. The report is also available electronically by visiting http://www.ddap.pa.gov/.

If yourself or a loved one need help, I encourage you to call Pennsylvania's toll-free Get Help Now Helpline at 1-800-662-HELP or the 24-hour internet chat-line found at https://apps.ddap.pa.gov/gethelpnow/.

Sincerely,

Jennifer S. Smith

Jennifer S. Smith Secretary
Pennsylvania Department of Drug and Alcohol Programs

Executive Summary

Methadone is a long-acting synthetic opioid agonist that, when used in combination with therapy, is used for the treatment of opioid use disorder. Since 2012, the Methadone Death and Incident Review (MDAIR) team within the Department of Drug and Alcohol Programs (DDAP) has been tasked with reviewing and analyzing methadone-related deaths and incidents from coroner's reports, emergency medical service and medical records, narcotic treatment program incident reports, and other documents. This report outlines work related to: (1) the most recent review of methadone-related deaths and incidents in Pennsylvania, (2) national data on opioid overdose deaths since 1999, (3) updates on past recommendations by the MDAIR team, and (4) a proposal for expanding the scope of MDAIR team activities moving forward.

In Pennsylvania, from 2013 to 2017, a total of 1,037 cases have been referred to the MDAIR team, of which 370 (35.6%) have been closed. Of these closed cases, approximately half considered methadone to have played a contributing role in the incident or death. An analysis of the toxicology reports of these cases revealed eight deaths in which methadone was the only drug listed as present in the individual's system. Nationally, the methadone death rate peaked in 2006 and has been in steady decline as the rates of heroin, natural, synthetic, and semisynthetic opioids have continued to rise dramatically.

Initially, the annual review of methadone deaths and incidents provided valuable information and informed beneficial recommendations and goals. As time passes and unique incidents are less likely to be encountered, however, the utility of this report has decreased. Furthermore, as trends in drug overdose deaths have changed over time, DDAP has had to balance its limited resources to address more pressing threats, including increasing deaths due to other synthetic opioids (such as fentanyl), as well as anticipated increases in overdoses due to stimulant drug use in the near future.

Thus, DDAP proposes expanding Act 148 of 2012, the enabling statute for MDAIR activities, to allow for annual review of deaths and incidents related to other types of substances based on local and national trends. Furthermore, additional staff resources dedicated to this type of work would assist in reducing backlogs and expanding the overall mission of Act 148. In this way, DDAP can better understand the ever-changing landscape for a variety of drugs of abuse, better equipping the Department to respond with evidence-based prevention, intervention, and treatment strategies for Pennsylvanians in need.

Introduction

In 2012, the Pennsylvania General Assembly established within the Department of Drug and Alcohol Programs (DDAP) a team to review all methadone-related deaths and incidents within the commonwealth.[1] The Assembly tasked this Methadone Death and Incident Review (MDAIR) team with promoting safety, reducing methadone-related deaths and incidents, and improving treatment practices. **Table 1** below displays the members of the MDAIR Team, as well as the statutorily designated roles of each member.[2]

Table 1: MDAIR Team Membership

Name *Organization (if applicable)*	Statutory Role
Jen Smith, Chair *Secretary, DDAP*	Secretary of DDAP or designee
Jodi Skiles *DDAP*	DDAP Director of the Bureau of Treatment, Prevention, and Intervention
William Santoro, MD *New Directions Treatment Services*	Narcotic Treatment Program representative
Stephen B. Roman *Greenbriar Treatment Center*	Licensed Drug and Alcohol Addiction Treatment representative
David Steffan *Northern Lancaster County Regional Police*	Law Enforcement Representative
Thomas Riordan, MD *Addiction Psychiatry & Consultation*	Medical Community Representative
David Freed *Cumberland County*	A District Attorney
Scott M. Grim *Lehigh County Coroner*	A Coroner or Medical Examiner
Bill Stauffer, LSW *PRO-A*	A Member of the Public
Debra Mittura	A Patient or Family Advocate

What is Methadone?

Methadone is a long-acting synthetic opioid agonist that binds to the opioid receptors. Methadone was originally marketed as a pain reliever. The drug is widely used and has been proven to be a successful medication to assist in the treatment of opioid addiction. Methadone does not produce the intense euphoria of shorter acting opioids such as heroin.

"Methadone has been used for decades to treat people who are addicted to heroin and narcotic pain medicines. When taken as prescribed, it is safe and effective. It allows people to recover from their addiction and to reclaim active meaningful lives. For optimal results, patients should also participate in a comprehensive medication-assisted treatment (MAT) program that includes counseling and social support."

- United States Substance Abuse and Mental Health Services Administration

[1] Act 148 of 2012 (71 P.S. § 1691.3(a))
[2] Act 148 of 2012 (71 P.S. § 1691.3(b))

This report outlines work related to the review of methadone-related deaths and incidents from 2016 to 2017. It includes updates on past recommendations, as well as a proposal for next steps.

Methodology

The MDAIR Team reviews information from sources contained in **Figure 1** to determine the role that methadone played in each death and methadone-related incident. During 2016 and 2017, the foremost source of MDAIR data was the reports generated by county coroners or medical examiners. MDAIR review efforts are supported by DDAP staff who prepare cases for review by gathering information and determining if cases meet appropriate statutory criteria for review.[3] Appendix A contains a blank example of a MDAIR report. During its case review, the MDAIR Team determines if methadone was either a primary or secondary cause of death.

Figure 1: Sources of MDAIR Data

- Coroner's reports or postmortem examination records
- Death and birth certificates
- Law enforcement records and interviews
- Emergency medical service records and traffic fatality reports
- Medical records
- Narcotic treatment programs incident reports
- Court and county reports

Confidentiality of MDAIR Records

The MDAIR Team takes every precaution to ensure that the confidentiality of individuals involved in a methadone-related death or incident is maintained as outlined in law. Team members and all participants are required to sign an agreement not to share identifying information outside of Team meetings.[4]

Cases Referred and Reviewed

The far-right column in **Table 2** displays the total cases referred for review from 2013 to 2017. During this period, a total of 1,037 cases were referred. Of cases referred, 370 cases (35.6%) were closed. "Closed" cases are those that either received a final determination from the MDAIR Team or those that did not meet statutory criteria for review. In addition, the table below reveals the time, under current constraints, that it takes to close out all cases referred in a given year.

Table 2: Cases Referred to DDAP for Review by the MDAIR Team, 2013-2017

	Closed in 2013	Closed in 2014	Closed in 2015	Closed in 2016	Closed in 2017	*Open in 2018*	**Total cases per year**
2013 cases	44	72	12	1	0	*9*	**138**
2014 cases	-	53	74	24	4	*87*	**242**
2015 cases	-	-	13	36	13	*160*	**222**
2016 cases	-	-	-	14	7	*252*	**273**
2017 cases	-	-	-	-	3	*160*	**163**
Total closed per year	**44**	**125**	**99**	**75**	**27**	***668***	**1,038**

[3] Act 148 of 2012 (71 P.S. §§ 1691.4-1691.7)

[4] Act 148 of 2012 (71 P.S. § 1691.8)

Results and Findings

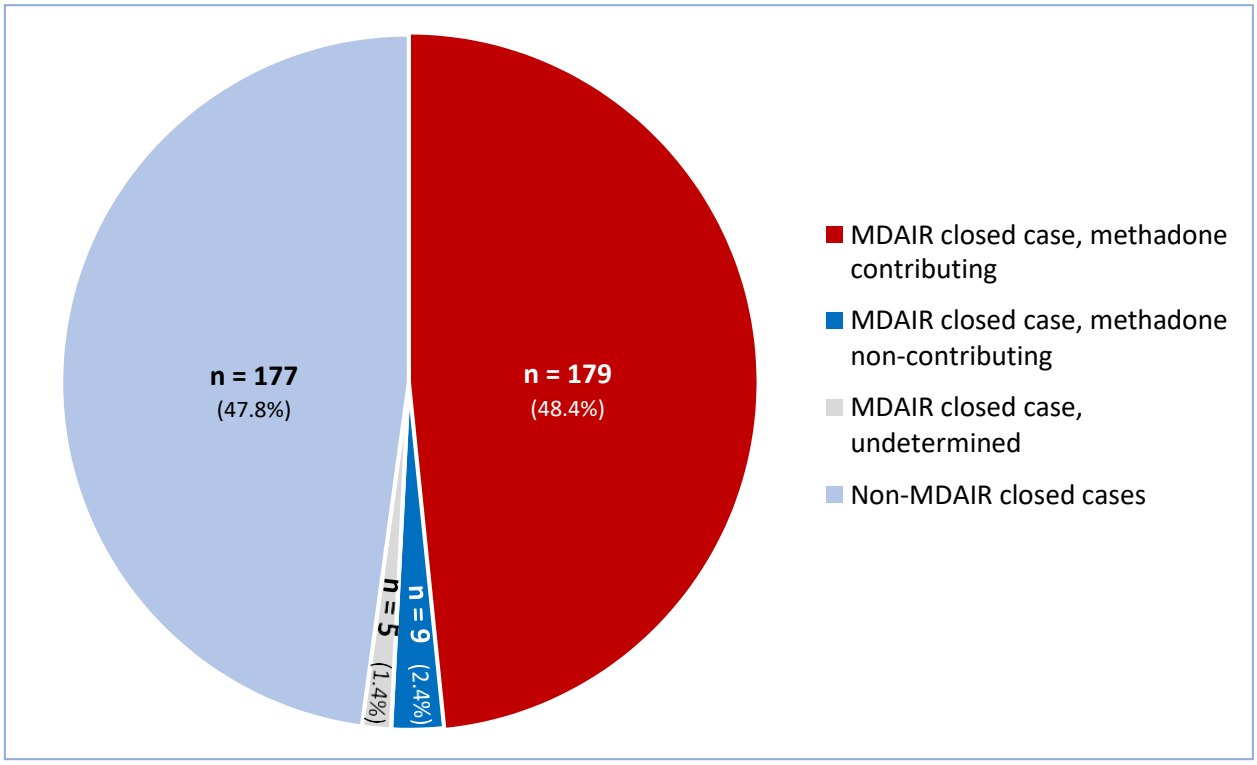
Readers are cautioned that the results presented in the subsequent subsections do not reflect complete methadone death and incident data for Pennsylvania. While coroners and narcotic treatment providers have legal reporting requirements, other sources of MDAIR data report on a voluntary basis.

In addition, the data below represent closed cases and a significant number of cases remain open for review.

Methadone-Related Deaths and Incidents

Of the 370 cases closed between 2013 and 2017 (Table 2), approximately half (n = 177, or 47.8%) were not deemed appropriate for review by the MDAIR team. Of those reviewed by the MDAIR team, 179 cases (48.4% of closed cases) considered methadone to have played a contributing role in the incident or death. The remaining MDAIR closed cases either deemed methadone non-contributing (n = 9) or remained undetermined (n = 5; **Figure 2**).

Figure 2: Breakdown of All Closed Cases



Of the 179 MDAIR closed cases in which methadone was deemed contributing to the incident or death, just over half (n = 98, or 54.7%) were cases in which methadone was prescribed by a narcotic treatment provider (NTP). Other prescribers included pain management specialists (n = 11 cases), primary care providers (n = 5 cases), and private physicians (n = 2 cases). Illicit methadone was the second-most common source (n = 22, or 12.3% of cases), while 41 cases were deemed unknown. Note that NTPs are required by DDAP regulations to report treatment related client deaths and incidents, which include those related to methadone; thus, the MDAIR team has historically received the largest number of incident or death cases in which the primary source of methadone is an NTP.

The sociodemographics of the individuals representing the 179 MDAIR closed cases involving methadone are presented in **Table 3** below.

Table 3: Sociodemographics of MDAIR Closed Cases in which Methadone was a Contributing Factor in Incident or Death

Gender	n	Age Group	n	Race	n
Men	95	< 18 years	3	White	136
Women	84	18-29 years	27	Black/African-American	9
		30-39 years	47	Hispanic or Latino	7
		40-49 years	54	Asian	1
		50-59 years	39	Unknown	26
		60+ years	8		
		Unknown	1		

An analysis of toxicology reports reveals that there were eight deaths in which methadone was the only drug listed as present in the individual's system (**Table 4**). Of these cases, half (n = 4) of the deaths were specifically related to "methadone toxicity/overdose" or "adverse effects of methadone;" one of these four cases included methadone prescribed by an NTP. For the other four cases, it is unclear whether the causes of death were primarily related to methadone based on the descriptions; all of these deaths involved methadone prescribed by an NTP.

Table 4: Cause of Death for Individuals in which Methadone was the Only Drug Present

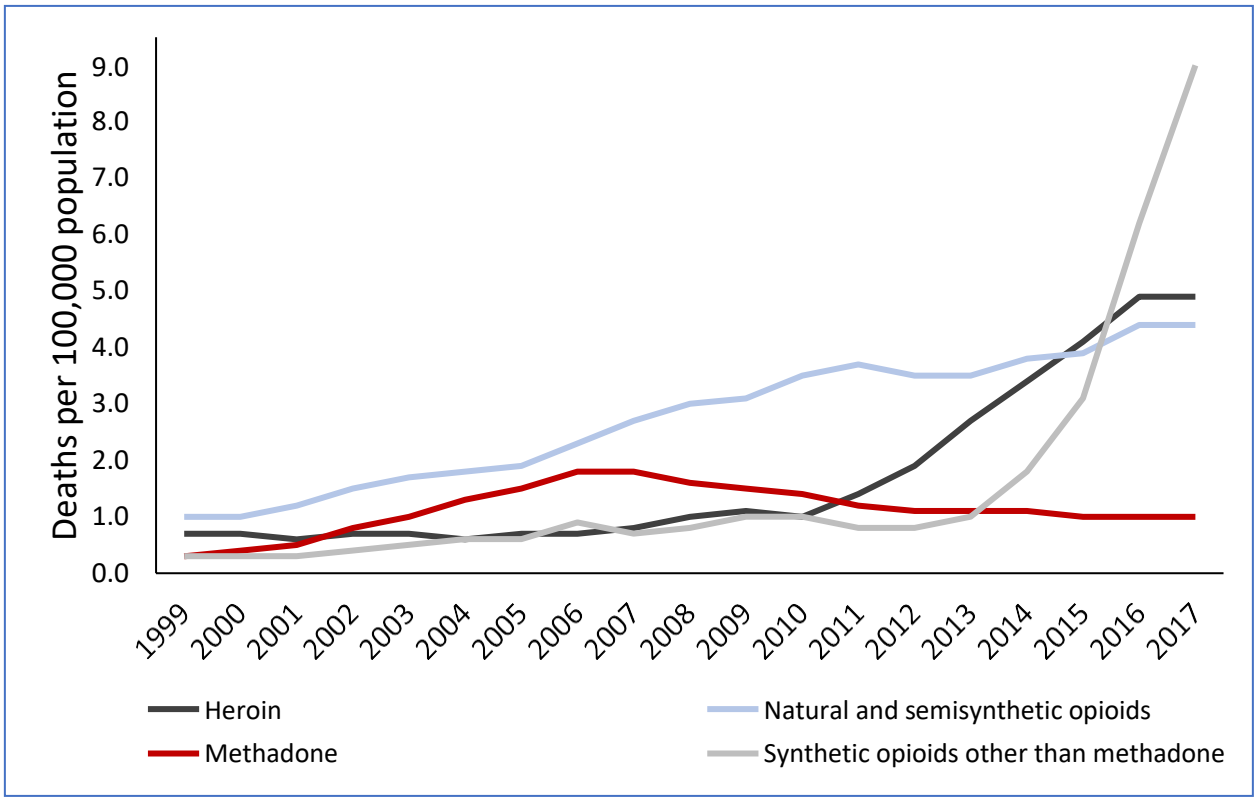
Case	**Cause of death** (per coroner report)	Prescriber	Period on methadone
1	*Methadone toxicity*	Illicit	Unknown
2	*Methadone toxicity*	Illicit	Unknown
3	*Methadone overdose*	NTP	> 2 years
4	*Adverse effects of methadone*	Pain specialist	1-3 months
5	Multi-substance* toxicity	NTP	6- 12 months
6	Subarachnoid hemorrhage – blunt force trauma of the head	NTP	Unknown
7	Hypoxic ischemic encephalopathy; methadone intoxication	NTP	> 2 years
8	Broncho-pneumonitis with sepsis and multi-organ system failure	NTP	> 2 years

* substance(s) not specified in toxicology report; only methadone is listed

National Trends on Methadone-Related Deaths and Incidents

As mentioned in the Introduction, the MDAIR team is limited in their ability to dedicate the time necessary to review and close cases in a timely manner. Thus, a look at national trends may provide a more complete picture of the circumstances surrounding methadone deaths in order to make evidence-based recommendations for potential changes to existing statutes and regulations.

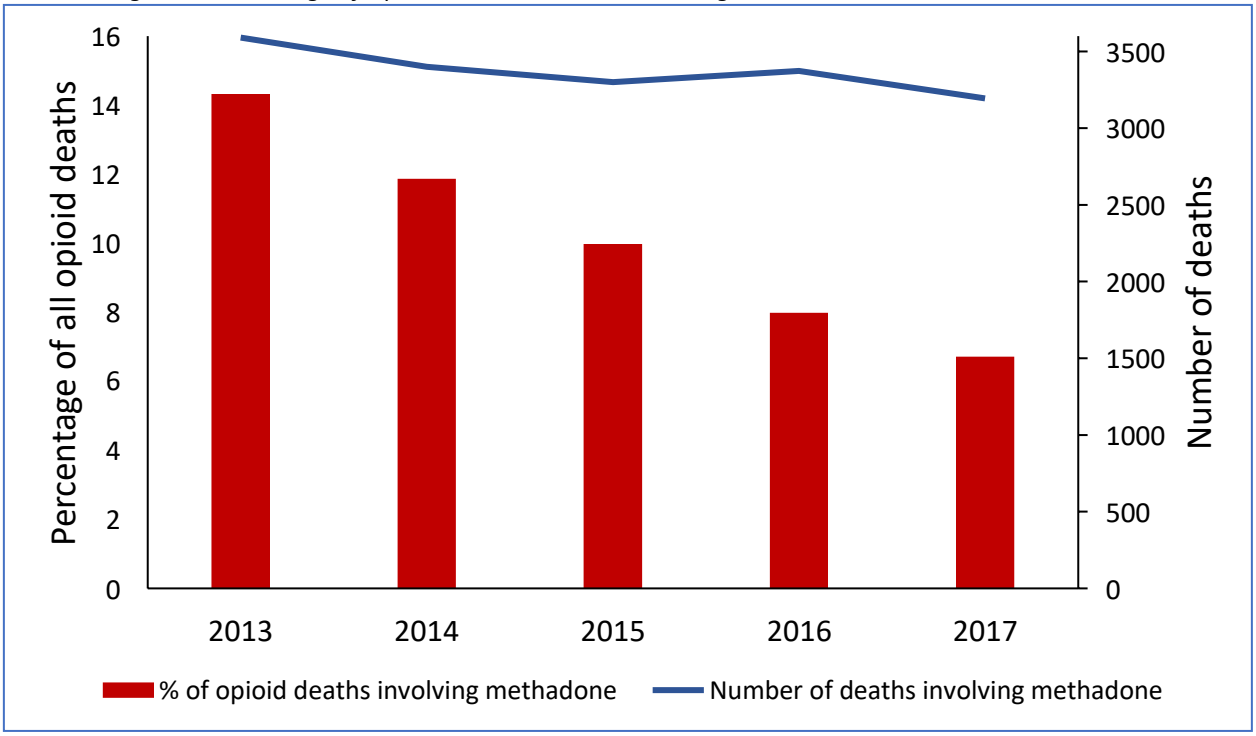
Figure 3: Age-Adjusted Drug Overdose Death Rates by Opioid Category, United States 1999-2017



Data from the National Center for Health Statistics Data Brief No. 329, November 2018.

As shown in **Figure 3**, the nationwide methadone death rate peaked at 1.8 per 100,000 population in 2006; however, as the rates of heroin, natural, synthetic, and semisynthetic opioids have continued to rise over the last decade, and particularly since 2013, methadone deaths have declined and remained steadily at 1.0 per 100,000 for the past two years.

Figure 4: Percentage of Opioid Overdose Deaths involving Methadone, United States 2013-2017



Data from the National Center for Health Statistics Data Brief No. 329, November 2018.

As shown in **Figure 4** – and spanning the dates of cases sent to the MDAIR team for review (2013-2017) – the percentage of nationwide opioid deaths involving methadone has reduced by more than half, from 14.3% in 2013 to 6.7% in 2017. This translates to a decrease from 3,591 overall methadone-related deaths in 2013 to 3,194 deaths in 2017.

Academic Research on Methadone Death Risk

Several recent large studies also offer a perspective on methadone and death risk. A 2017 systematic review and meta-analysis[5] of 19 international longitudinal cohorts – covering 122,885 individuals in methadone treatment – reported rates of death (due to any cause) at 36.1 per 1,000 people for those out of methadone treatment. This figure, however, was reduced to 11.3 per 1,000 people for those in methadone treatment. Overdose as a cause of death, specifically, showed a similar pattern, with rates of 2.6 and 12.7 per 1,000 people in and out of methadone treatment, respectively. Another study[6] of 17,568 adults who had survived an opioid overdose in the past 12 months reported that, compared to those not receiving any form of MAT, opioid overdose deaths decreased by 59% for those receiving methadone, and 38% for those receiving buprenorphine. Together, these data suggest that retention in methadone treatment is associated with substantial reductions in mortality for individuals dependent on opioids.

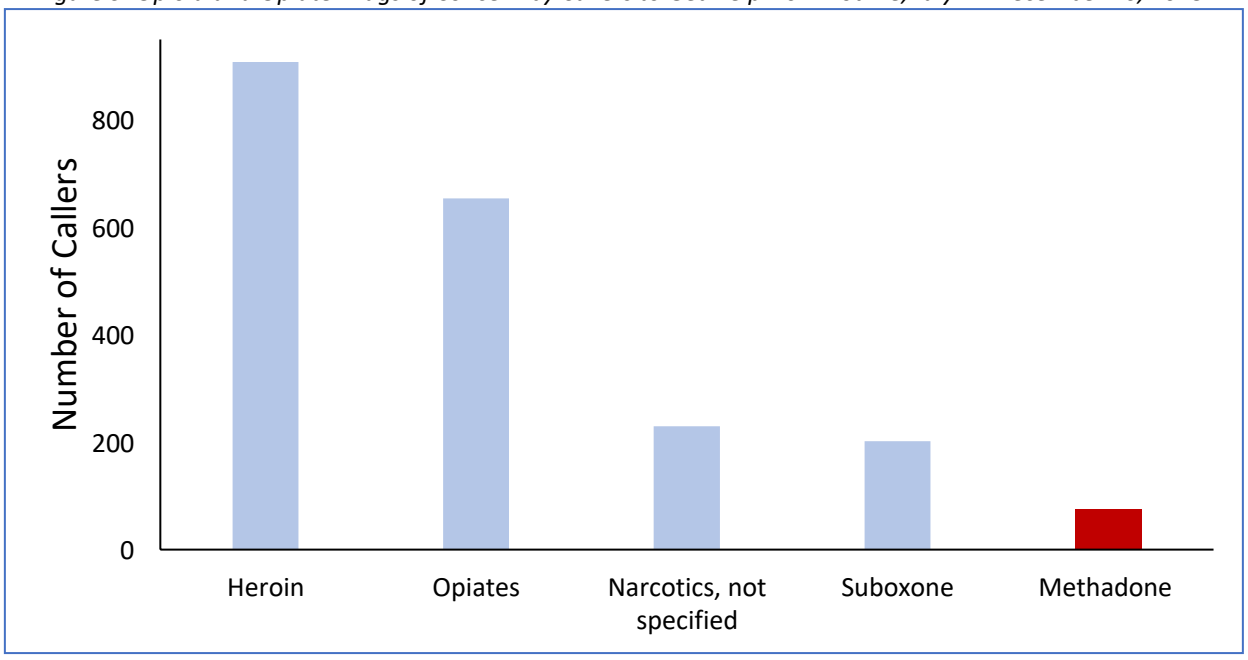
[5] Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ* 2017; 357: j1550.

[6] Larochelle MR, Berson D, Land T, et al. Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: a cohort study. *Ann Intern Med* 2018; 169: 137-45.

Methadone-Related Calls to the Get Help Now Hotline

A unique source of Pennsylvania-specific data that also provides insight into potential concerns surrounding methadone is DDAP's Get Help Now 24/7 hotline. Although the hotline was launched in November 2016, data collection on callers' concerns for their use of methadone and Suboxone, specifically, began in July 2018. According to data from July 2018 until mid-December 2018 (**Figure 5**), 75 callers have expressed concern about their use or potential abuse of methadone. Compared to other opioid and opiate drugs of concern, however, this figure is less than Suboxone (202 callers), narcotic drugs (230 callers), opiates (654 callers), and heroin (908 callers); thus, callers concerned about their use of methadone represent 3.6% of all opioid users. Note that the call data do not capture the exact reason for the call. For example, one call may be about someone who is concerned with methadone abuse, while another may be about someone looking for resources to taper off of methadone.

Figure 5: Opioid and Opiate Drugs of Concern by Callers to Get Help Now Hotline, July 2 - December 16, 2018



Discussion

National data show that methadone overdose deaths have been on the decline since 2007. Likewise, research on methadone indicates that mortality is reduced for individuals in treatment. Medication Assisted Treatment (MAT), including methadone, will continue to be a critical tool in addressing the commonwealth's opioid epidemic. DDAP believes that the benefits associated with methadone treatment outweigh the harm associated with its misuse.

In 2012, the General Assembly tasked the MDAIR Team with reviewing methadone related deaths and incidents to further reduce the harms associated with its misuse. The MDAIR Team's findings led to the series of recommendations outlined in the following section. At the outset, this review provided valuable information, which informed the team's recommendations. However, the utility of this review has decreased over time as novel or unique incidents are less and less likely to be encountered.

Meanwhile, new areas in need of investigation have emerged. Nationally and locally, there continues to be a dramatic rise (**Figure 3**) in deaths due to synthetic opioids (e.g. fentanyl) other than methadone, as well as forthcoming increases in overdoses related to cocaine and methamphetamine use.[7] In addition, as the MDAIR review received no funding, DDAP has had to balance its limited resources considering these new threats. Funding through Federal dollars also presents challenges due to grant limitations and lack of sustainability.

For this reason, DDAP believes that it is time to expand upon the work of the 2012 General Assembly, allowing for the review of incidents and deaths for other substances in addition to methadone. Finally, additional staff resources dedicated to this work would assist in reducing backlogs and expanding MDAIR's mission.

Recommendations

New Recommendation

Recommendation: Expand and Support Act 148
Summary: Act 148 of 2012, the enabling statute for Methadone Death and Incident Review activities, should be expanded to allow the Department of Drug and Alcohol Programs to review deaths and incidents related to other types of substances. The Department of Drug and Alcohol Programs should be authorized to review any substance it deems critical based upon trends in drug and alcohol use, as well as information obtained from past reviews. This work should be supported with personnel resources who would be responsible for program expansion and supporting the reduction of the case review backlog.
Plan: The Department of Drug and Alcohol Programs will work with the legislature to draft and implement an expansion of Act 148.

[7] Hedegaard, Holly, et al. "Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011-2016." www.cdc.gov, 2018, www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf.

Update on Previously-Issued Recommendations

Recommendation #1: Physical and behavioral health specialists should be included as members of a multi-disciplinary team in making treatment decisions regarding patient care, especially with respect to the decision to approve take-home medications. There should also be case management for patients with co-occurring mental health issues or physical health issues.

Update: Pennsylvania has successfully implemented several initiatives designed to enhance the coordination of care between physical and behavioral health. Seven Certified Community Behavioral Health Clinics (CCBHCs), 45 Centers of Excellence (COEs), and eight Pennsylvania Coordinated Medication-Assisted Treatment (PacMAT) sites are "whole person"-focused programs designed to coordinate the continuum of care and keep individuals engaged in physical health, behavioral health, and supportive social services for their opioid use disorder. Each of these sites provide comprehensive case management, care coordination, transitional follow-up care, and patient and family support.

Recommendation #2: Opiate-addicted inmates should complete a drug and alcohol assessment while incarcerated, and upon release should be immediately admitted to the clinically-appropriate level of substance abuse treatment.

Update: Several updates have been made to address this issue:

1. As of April 2018, injectable Vivitrol is available at all state correctional institutions for re-entrants. Under its recent State Opioid Response grant, DDAP will be partnering with the Department of Corrections to expand MAT within the correctional system. This partnership will include a buprenorphine pilot, as well as an expansion of Vivitrol to re-entrants post entry.
2. In January 2017, the inmate general population Therapeutic Community (TC) and the Co-Occurring Disorders TC Curricula began providing evidence-based treatment. In March 2018, six institutions adopted opiate-specific TCs, with the intention of expanding to more.
3. In March 2016, DOC's Bureau of Treatment Services hired a MAT statewide coordinator. This individual provides training and technical assistance to site coordinators, often social workers, and is the liaison between the Bureau of Community Corrections, the Pennsylvania Board of Probation and Parole, Single County Authorities (SCAs), and community-based treatment providers.

Recommendation #3: The Prescription Drug Monitoring Program (PDMP) should automatically populate electronic health records of individual patients so that physicians can easily see a patient's treatment and medication activity. Methadone prescribers should check the PDMP with regard to other controlled substances, including benzodiazepines, prior to prescribing or changing medications.

Update: The Pennsylvania Department of Health (DOH) currently seeks to integrate the PDMP system into electronic health records (EHRs) and pharmacy management systems (PMSes) across the commonwealth. All healthcare entities in Pennsylvania that are legally authorized to prescribe, administer, or dispense controlled substances are eligible to apply for integration. The PDMP Integration Project started late 2017 and significant progress has been made since then. The commonwealth has integrated with 171 health care entities (e.g., health systems, hospitals, private practices, and pharmacies), which represent approximately 33,766 providers and pharmacy stores. Furthermore, as of June 2018, Pennsylvania's PDMP shares data with 17 other states and Washington D.C. to allow prescribers and pharmacists complete information regarding a patient's controlled substance prescription history, regardless of which state they filled their prescription in.

Recommendation #4: DDAP should develop trainings for NTPs to refer and transfer unsuccessful patients to other levels of care more appropriate to the patient's clinical needs, and for other non-medication-assisted treatment programs to refer and transfer unsuccessful patients to clinically appropriate medication-assisted treatment.
Update: As of July 1, 2018, DDAP requires all publicly-funded licensed drug and alcohol facilities to use the nationally-recognized American Society of Addiction Medicine (ASAM) Criteria to place patients in a clinically-appropriate level of care. Statewide training of providers began months before the transition, and continues today. In keeping with the intent of medication being used as an assistance to treatment, the individualized, person-centered ASAM Criteria recognizes the use of MAT in all levels of care across the continuum. It is DDAP's expectation that even providers licensed as "drug-free" ensure that their clients' needs are met, and that a client's use of medication does not preclude admission into their services. Furthermore, under its recent State Opioid Response grant, DDAP will be partnering with the Department of Health to host six regional MAT Training Summits with the objective of increasing the number of qualified professionals treating OUD and breaking down barriers to treatment.

Recommendation #5: Benzodiazepines should not be co-prescribed with methadone. For those seeking admission to an NTP who are taking benzodiazepines, being detoxed off benzodiazepines is preferred prior to admission. Alternatively, a patient may be admitted to an NTP while actively using benzodiazepines as long as a protocol is in place to taper off the benzodiazepines within the first twelve weeks.
Update: The *Safe Prescribing Guidelines for Pennsylvania: Benzodiazepines for Acute Treatment of Anxiety and Insomnia*, updated in 2017, is a comprehensive document that provides guidance and warns against prescribing opioids, including initiating methadone maintenance, while an individual is taking benzodiazepines. Additionally, the guidelines provide resources for how to create dose reduction plans.

Recommendation #6: If a patient has a respiratory issue (e.g. sleep apnea, pulmonary disease, obesity, COPD), there should be coordination of care with their pulmonary/sleep physician that should be noted in the patient's treatment plan. For these types of patients, physicians should consider whether opioid-assisted, naltrexone-assisted, or drug-free treatment would be the most clinically appropriate.
Update: The *Safe Prescribing Guidelines for Pennsylvania: Benzodiazepines for Acute Treatment of Anxiety and Insomnia*, updated in 2017, details how benzodiazepines can worsen the course of conditions, including depression and impulse control disorders (behavioral); hypoxia associated with asthma, sleep apnea, chronic obstructive pulmonary disease, congestive heart failure, and other cardiopulmonary disorders (physical); and fibromyalgia and chronic fatigue syndrome (interface of behavioral and physical health). Using this guidance, physicians should use their best clinical judgment before prescribing an opioid medication such as methadone.

Appendix A: Sample MDAIR Report from Coroner's and Medical Examiners

See attached document

Appendix A

CORONER'S DRUG DEATH REPORT

This form should be submitted within 7 days of the completion of cause and manner of death.

Coroner's Name: **County:**

Date of Death: **Time of Death:**

Coroner's Case #: **County of Residence:**

Decedent's Age: **Gender:**

Race: **Marital Status:**

Manner of Death:

Cause of Death:

Was prescription medication or illicit drug a cause or contributing factor in the death? ☐ **Yes** ☐ **No**

Was methadone a cause or contributing factor in the death? ☐ **Yes** ☐ **No**

Was law enforcement involved? ☐ **Yes** ☐ **No**

If yes, what agency?
Contact Person:
Incident #

Was autopsy performed? ☐ **Yes** ☐ **No**

Was a toxicology test performed? ☐ **Yes** ☐ **No**

Date of Result:

Describe drug(s) evidence found on person/scene (i.e., packing, stampings, markings, etc.:

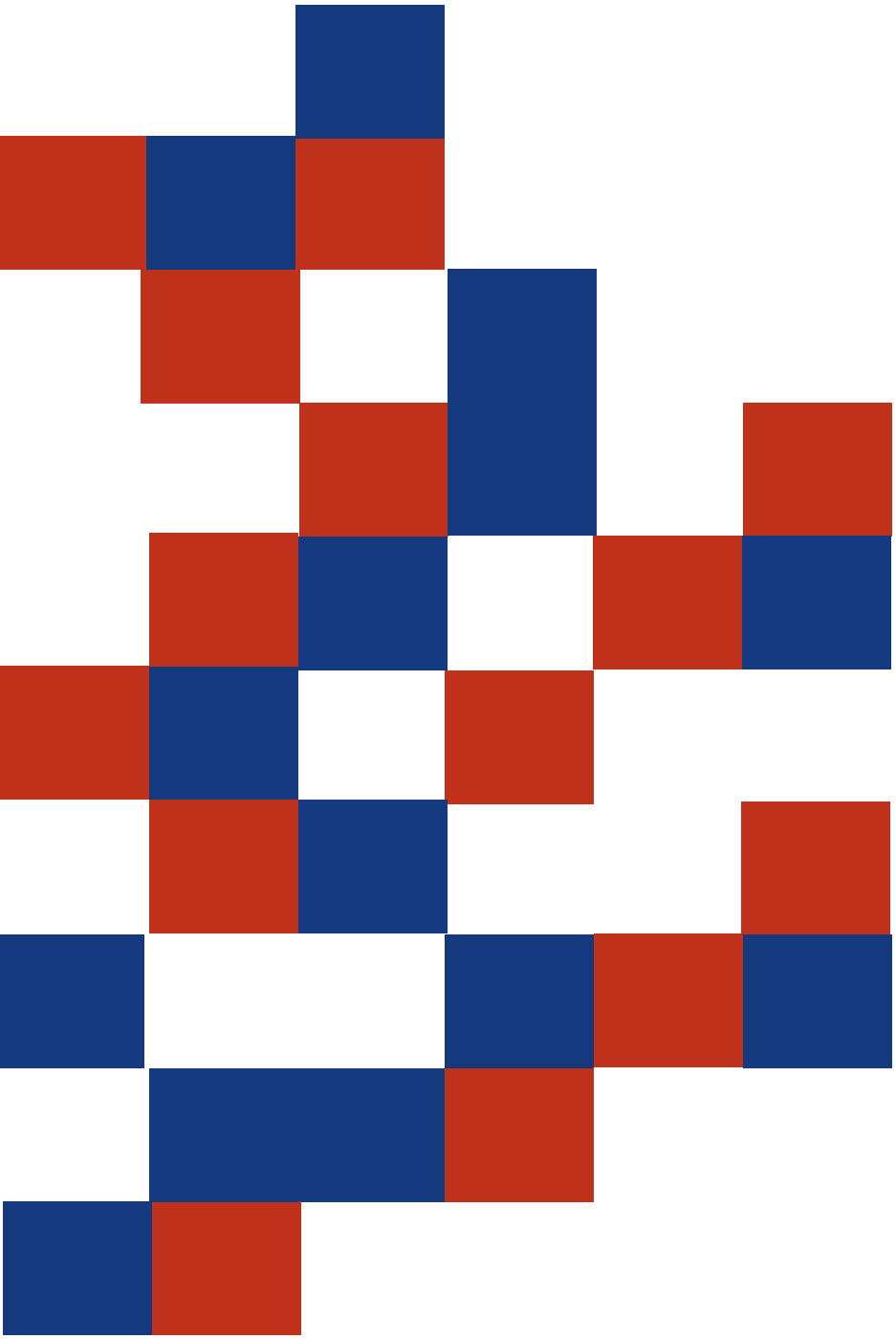
Additional notes/remarks:

If prescription, please provide the following information:

Name & Address of Prescriber:		Name & Address of Pharmacy:	
Medication:		RX Date:	Prescription No.
Amount Prescribed:	Amount Found:	Date Issued:	Dosage:
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			

Name and address of Narcotic Treatment Center:

Substances/Chemicals/Drugs/Alcohol/Poisons	Levels	Name



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