

METHADONE DEATH AND INCIDENT REVIEW

2015 Annual Report

*Reducing Methadone-Related Deaths and Incidents
and Improving Treatment Practices*



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Mission

The mission of the Methadone Death and Incident Review (MDAIR) Team is to reduce methadone-related deaths and incidents that occur as a result of dangerous drug interactions by improving related treatment practices and promoting safe prescribing practices.

Vision

MDAIR'S vision is to identify and promote best practices and policies to ensure access to safe, high quality and cost effective methadone related services.

Legislative Mandates

The MDAIR Team shall:

- Examine the circumstances surrounding methadone-related deaths and methadone-related incidents in the Commonwealth for the purpose of promoting safety, reducing methadone-related deaths and incidents, and improving treatment practices. (Act 148 of 2012, Section 3 (a))
- Review each death where methadone was either the primary or secondary cause of death and review methadone-related incidents. (Section 4 (1))
- Determine the role that methadone played in each death and methadone-related incident. (Section 4 (2))
- Communicate concerns to regulators and facilitate communication within the health care and legal systems about issues that could threaten health and public safety. (Section 4 (3))
- Develop best practices to prevent future methadone-related deaths and methadone-related incidents. The best practices shall be promulgated by the Department of Drug and Alcohol Programs (DDAP) as regulations and posted on its website. (Section 4 (4))
- Collect and store data on the number of methadone-related deaths and methadone-related incidents and provide a brief description of each death and incident. The aggregate statistics shall be posted on DDAP's website. The Team may collect and store data concerning deaths and incidents related to other drugs used in opioid treatment. (Section 4 (5))
- Develop a form for the submission of methadone-related deaths and methadone-related incidents to the Team by any concerned party. (Section 4 (6))
- Develop, in consultation with a statewide association representing county coroners and medical examiners, a model form for county coroners and medical examiners to use to report and transmit information regarding methadone-related deaths to the Team. The Team and the statewide association representing county coroners and medical examiners shall collaborate to ensure that all methadone-related deaths are, to the fullest extent possible, identified by coroners and medical examiners. (Section 4 (7))
- Develop and implement any other strategies that the MDAIR Team identifies to ensure that the most complete collection of methadone-related death and methadone-related serious incident cases is created. (Section 4 (8))
- Prepare an annual report that shall be posted on DDAP's website and distributed to the Majority and Minority Chairs of the House and Senate Judiciary Committees, the Senate Public Health and Welfare Committee, and the House Human Services Committee. Each report shall: (i) provide public information regarding the number of causes of methadone-related deaths and incidents; (ii) provide aggregate data on a five-year trend on methadone-related deaths and incidents, when available; (iii) make recommendations to prevent future methadone-related deaths, methadone-related incidents and abuse and set forth the department's plan for implementing the recommendations; (iv) recommend changes to statutes and regulations to decrease methadone-related deaths and incidents; and, (v) provide a report on methadone-related deaths and methadone-related incidents and concerns regarding narcotic treatment programs. (Section 4 (9))

* Act 148 of 2012 (MDAIR Act) can also be found at 71 P.S. §§ 1691.1-1691.9. However, the references to the MDAIR Act above are consistent with the copy of the Act attached hereto as Appendix A.

Acknowledgements

On behalf of the Department of Drug and Alcohol Programs and the Methadone Death and Incident Review Team, I would like to express heartfelt appreciation and admiration for the tremendous work of the DDAP program representatives and their management team who worked tirelessly to improve the quality of the MDAIR Team's work, both with respect to increasingly thorough information gathering and better analysis of the data gathered.

For their efforts, all the citizens of Pennsylvania owe this team a debt of gratitude. We anticipate that their work will result in better methadone-assisted treatment and fewer deaths and incidents. No acknowledgement or appreciation can replace the knowledge that one has engaged in work that will save the lives of some of our fellow human beings.

We also want to thank both the official and discretionary MDAIR Team members. Uncompensated, these public-spirited citizens volunteered a great deal of their time – as there are six hour meetings held, bi-monthly, in addition to the many hours of travel time and preparation before the meetings. The MDAIR Team members participated in the full review of this annual report and provided input. These volunteers have given Pennsylvania thousands of dollars in time and expertise.

This report provides statistical information where the use of methadone and/or other drugs caused or contributed to the death of an individual. In reviewing this information, we must be mindful that each statistic represents a life of an individual who had hopes, dreams, families, and friends. It is believed that these statistics can assist in developing policies that will help decrease this terrible trend of drug related deaths.

A handwritten signature in cursive script that reads "Jennifer S. Smith". The signature is written in black ink and is positioned in the lower right quadrant of the page.

Letter from the Secretary

On behalf of the Department of Drug and Alcohol Programs and the Methadone Death and Incident Review Team, we are pleased to present our 2015 Annual Report and recommendations for state actions to tackle the public health crisis of heroin and opioid addiction that continues to spread across the Commonwealth.

Thousands of Pennsylvanians are dying each year due to the disease of addiction. “In 2015, 3,383 drug-related overdose deaths were reported in Pennsylvania, an increase of 23.4% from the total number of overdose deaths (2,742) reported in 2014.” (Drug Enforcement Agency Philadelphia Field Division, 2016). Once again, overdoses exceed car crashes as the leading cause of accidental death both in our Commonwealth and our nation.

A comprehensive treatment continuum of services to include prevention and intervention services at the local level, is essential to combating this unnecessary loss of life and damage to our families and communities. One important component of our comprehensive treatment system for those suffering with heroin and other opioid addiction is medication-assisted treatment with methadone. Pennsylvania’s seventy-seven narcotic treatment programs perform a life-saving function for the thousands of patients they serve every day.

For this reason, it is critical that the Department of Drug and Alcohol Programs collaborate with our narcotic treatment programs and their funders to ensure that the safest and most effective methadone practices are implemented and funded. The genesis of Pennsylvania’s Methadone Death and Incident Review Team is described elsewhere in this report, but suffice it to say that the need for safer methadone practices was underscored by the six-fold increase nationally in methadone-related overdose deaths between 1999 and 2009 (reported by the Center for Disease Control).

The dominant theme reoccurring in our work in 2015 is that we need to be placing much more attention on the issue of combined methadone and benzodiazepine use. We know from repeated reports that combining these substances can create an intoxicated state that is directly counter to the work of treatment. We also know that there is a propensity for a non-lethal dose of methadone and a non-lethal dose of benzodiazepines may become lethal when combined. The Team’s 2015 recommendations comprise robust “next steps” toward addressing the dangerous co-use of these medications, but as long as the death rate for methadone-benzodiazepine continues to remain high, the MDAIR Team in future years may well decide to consider additional recommendations and regulations.

On another matter, for a number of years there has been some controversy about how many methadone-related deaths involve methadone that has been prescribed for pain, as opposed to those that involve methadone as a medicine to assist addiction treatment. Unfortunately, the MDAIR Team has not been able to successfully access patient information from physicians who have prescribed methadone for pain and to correlate that to those who have suffered methadone-related deaths and incidents. Accordingly, we cannot determine which system (addiction treatment or pain treatment) is driving most methadone-related deaths. This same limitation has also made it very difficult to determine how many deaths involve methadone that has been illegally diverted to the decedent. But we do anticipate that with the future implementation of the prescription drug monitoring program – to which MDAIR staff statutorily have access – we will be able to shed light on the issue in future years.

I would like to once again thank the General Assembly for its leadership in enacting our Methadone Death and Incident Review Law (Act 148 of 2012) and for its subsequent work in enacting the Prescription Drug Monitoring statute and the Good Samaritan/Access to Naloxone Statute. These laws reflect a steadfast commitment to addressing Pennsylvania’s drug overdose problem.

Pennsylvania is the only state in the entire nation with a Methadone Death and Incident Review Team. As a result, the work of this Team will be useful in guiding policy toward safer and more effective methadone-assisted treatment, not just in Pennsylvania but throughout the nation. To our Team members who volunteer for the sometimes grueling bi-monthly six-hour meetings, they can know that their efforts will be rewarded. While there's little chance they will have the satisfaction of meeting any of those whose lives they are saving, the reality that this is lifesaving work cannot be questioned. The Commonwealth and the nation owe them and our hardworking MDAIR staff a great debt of gratitude.

Jennifer S. Smith

MDAIR INTRODUCTION

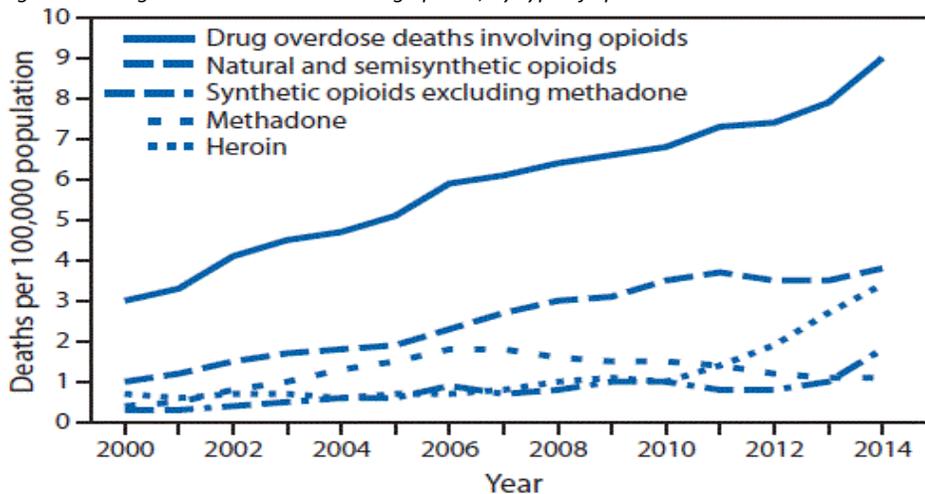
What is Methadone?

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 can suppress opioid withdrawal symptoms for 24 hours or longer” (Center for Substance Abuse Treatment, 2005, p. 18). The other benefits of effective methadone treatment include the elimination of opioid cravings and the blockage of the euphoric effect of opioid drug use. Methadone can be prescribed in either liquid or tablet form. Most of the Narcotic Treatment Providers (NTPs) that are licensed to provide methadone treatment services within the Commonwealth of Pennsylvania are utilizing liquid methadone. The pill form tends to be highly prevalent with pain management prescribers.

Nationwide Opioid Drug Overdose Trends

The nation is in the midst of the deadliest drug epidemic in all recorded history. In 2014, the Center for Disease Control & Prevention (CDC) noted that the rate of opioid overdose deaths was nine per 100,000 people nationwide. Opioids are being prescribed for pain at an excessively high rate throughout the nation from 52 opioid prescriptions per 100 people in Hawaii to 143 opioid prescriptions per 100 people in Alabama. Pennsylvania fell relatively in the middle with 88 opioid prescriptions per 100 people (CDC, 2014). The highly addictive qualities of these opioid painkillers may lead individuals to develop a physiological addiction. Individuals may turn to more affordable substances such as heroin due to the high cost of illicitly attaining prescription opioids when unable to attain a prescription from a legitimate medical provider. Once addicted, many individuals seek medication-assisted treatment for their opioid addiction. Methadone plays a significant role in the treatment of a large number of these individuals. Methadone is also widely used by physicians for the treatment and management of chronic pain.

Figure 1 – Drug overdose deaths involving opioids, by type of opioid – U.S. 2000-2014



Source: CDC, National Vital Statistics System, Mortality file.

MDAIR Background, Team Composition, Review Process & Meetings

The Methadone Death and Incident Review Act (MDAIR Act or Act 148) was signed into law on October 24, 2012 (See Appendix A). The primary intention of this law was to create a Team that is tasked with reviewing and examining the circumstances surrounding both methadone-related deaths and incidents that occur within the Commonwealth of Pennsylvania. Following a thoughtful and careful review process, the Team develops recommendations that will promote safety, reduce methadone-related deaths and incidents, and improve treatment practices as a whole.

The MDAIR Team membership is comprised of:

1. Secretary of DDAP or a designee
2. Director of the Bureau of Treatment, Prevention and Intervention (Act 148 provides that Director of Bureau of Drug and Alcohol Programs is to be on the MDAIR Team. However, that Bureau has been renamed as the Bureau of Treatment, Prevention and Intervention.)
3. A representative from a narcotic treatment program
4. A representative from a licensed drug and alcohol addiction treatment program that is not a narcotic treatment program
5. A representative from law enforcement
6. A representative from the medical community
7. A district attorney
8. A coroner or medical examiner
9. A member of the public
10. A patient or family advocate

The MDAIR Team members meet regularly to review cases involving deaths and incidents that are purported to involve methadone and to work toward appropriate recommendations based on that review. These cases are prepared and presented to the Team by DDAP staff. The information regarding the deaths and incidents is provided by coroners, private citizens, NTPs, medical personnel, police departments and other government agencies. DDAP staff investigates the information submitted, uses all available resources, and provides factual reports to the Team based on the available information. In order to compile information, staff request and review, as appropriate, coroner's reports, death certificates, law enforcement records, medical records, children and youth reports, court records, traffic reports, NTP incident reports, NTP patient records, family records, Department of Human Services information and reports, and multiple media resources.

DDAP conducted seven MDAIR Team meetings in 2015, chaired by either the Secretary of DDAP or his designee. In accordance with Act 148, the meetings are closed to the public. All proceedings, deliberations, and records are confidential. However, any person with information relevant to the review may be invited to attend the meetings and provide information.

Upon completion of the discussion, the Team makes determinations about each case and, when appropriate, makes recommendations regarding steps that can be taken to prevent or reduce the likelihood of similar incidents in the future. Team recommendations are voted upon. Some of the opinions expressed therein may not be the view held by all members of the Team.

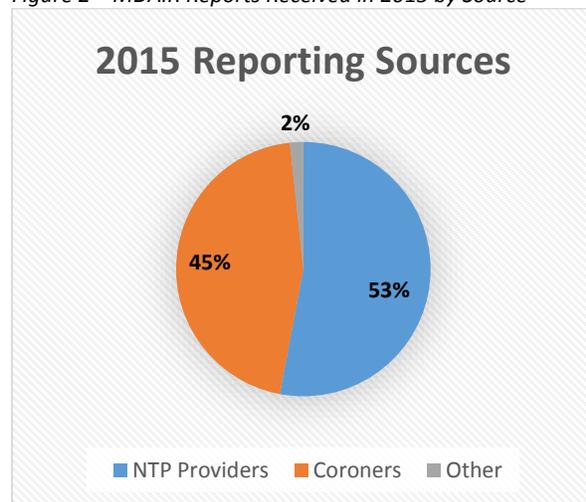
The MDAIR Team takes every precaution to ensure that the confidentiality of individuals involved in a methadone-related death or incident is maintained as outlined in Act 148. Team members and all participants are required to sign an agreement not to share identifying information outside of the Team meeting.

METHODOLOGY

The MDAIR Team was established to promote safety, reduce methadone-related deaths and incidents, and to improve treatment practices. The Act requires DDAP to lead a Team of professionals in the investigation of methadone-related deaths and incidents that occur statewide. This Team is supported by designated departmental MDAIR staff who determine whether a case is appropriate for the MDAIR Team based on the criteria established by Act 148. A methadone-related death, as defined by the act, is “a death where methadone was a primary or secondary cause of death or may have been a contributing factor”. A methadone-related incident is defined “as a situation where methadone may be a contributing factor which does not involve a fatality and involves a serious injury or unreasonable risk of death or serious injury”. This information is presented to the MDAIR Team for review. The data regarding methadone-related deaths and incidents that were presented to the MDAIR Team and analyzed for the purpose of this report were obtained from reporting forms and records that MDAIR staff received from coroners/medical examiners, NTPs, healthcare providers, pain management clinics and law enforcement.

Deaths where methadone may have been a cause or contributing factor are initially identified by the medical examiner/coroner’s office following an autopsy. The medical examiner or coroner complete and submit the coroner drug death report to MDAIR staff for analysis. Cases were eligible for analysis if the coroner drug death report indicated that methadone was a cause or contributing factor of their death. Some cases were also selected if they were certified by physicians. The physicians’ determinations were validated through medical records that verified that methadone was a contributing factor to the death. Blood and/or urine screens were performed to test for licit and illicit substances, such as alcohol, narcotics, benzodiazepines, opioids, marijuana, stimulants and depressants. The results of these screens are also recorded on the coroner drug death report or medical records when available. Furthermore, the coroner drug death report was supplemented by reports from NTPs, physicians, hospitals and law enforcement. These documents were utilized to obtain additional information, regarding the circumstances of the decedent’s death as well as to inform the MDAIR Team of his/her substance abuse and treatment history. The reports were utilized to identify socio-demographic information and to tabulate trends. It should be noted that 30 of the 67 county coroners (45%) reported at least one methadone-related death that occurred in 2015 to MDAIR in accordance with Act 148.

Figure 2 – MDAIR Reports Received in 2015 by Source



Source: MDAIR Database, 2015

Note – Multiple sources report on the same case.

The MDAIR Team notes with extreme interest the difference between the number of methadone related deaths reported to MDAIR by the coroners and the number of deaths reported to the Drug Enforcement Agency (DEA) by the coroners, as illustrated in the DEA’s report, “Analysis of Drug-Related Overdose Deaths in Pennsylvania, 2015” issued in July 2016. Coroners are statutorily required to report methadone related deaths and incidents to the MDAIR Team. The Team is beginning to investigate the disparity of reporting.

A methadone-related incident does not involve a fatality; it captures categories of serious injury or unreasonable risk of serious injury or death. There were thirteen reported and reviewed incidents in 2015. This information was certified by reports received from NTPs, police, or medical personnel. In some instances, blood and/or urine screens were performed to test for licit and illicit substances. These reports

were also utilized to gather socio-demographic information. Once the death and/or incident investigations are completed, they are presented to the MDAIR Team. Subsequent to the presentation, all data elements are recorded in the MDAIR database.

The data categories have remained the same as those noted in 2014. The MDAIR staff has maintained a database designed to track case-related data elements. This database has afforded DDAP the capability of centralizing case information for the purpose of data analysis. All of the charts and graphs included in the report have been created utilizing these data elements. Data is collected and evaluated in the following areas, if applicable or available.

- Type of Occurrence: Death or Incident
- Date of Death or Incident
- Age, Sex, Race and Marital Status
- County of Residence
- County Where the Death or Incident Occurred
- Date the Incident/Death was First Reported to MDAIR Staff
- Methadone Prescriber – Illicit, NTP, Other Private Physician, Pain Management Physician or Veterans Administration
- Receipt of NTP Unusual Incident Report
- Date of NTP Unusual Incident Report
- Receipt of NTP MDAIR Report
- Date of NTP MDAIR Report
- Receipt of Police Report
- Date of Police Report
- Receipt of Coroner’s Report
- Date of Coroner’s Report
- Length of Methadone Treatment
- Determination of the Appropriateness of the Case for MDAIR Team Review
- Date of MDAIR Team Review
- Designation of Whether Methadone was a Contributing Factor to the Death or Incident
- Case Status – Pending Investigation, Active Investigation, Ready for Review, Non-MDAIR Case Closed and Case Closed – MDAIR
- DDAP MDAIR Staff Case Assignment
- Case Specific Recommendations
- Notes
- Cause of Death
- Drugs Present on the Toxicology Report
- Date of Case Closure

The data regarding race, marital status, program name, and length of time on methadone were extracted from the MDAIR Treatment Provider Form. The length of time on methadone was also obtained from medical records. Additional drug information was extracted from the coroner drug death reports and medical records. Pharmacy records were also utilized to verify valid prescriptions. Each of these data elements, along with those previously established, are retained in an electronic MDAIR database.

It is DDAP’s intention that the collection and analysis of this data will drive safer methadone treatment policy and practice within the Commonwealth of Pennsylvania and serve as a model for other states that are committed to reducing methadone-related deaths and incidents.

Rate of Case Completion

The rate of case completion decreased by 20% from 2014 to 2015. This was due to an overall decrease in the number of cases researched by the MDAIR staff from 123 cases in 2014 to 99 cases in 2015.

However, the MDAIR Team was presented with and reviewed a relatively consistent number of cases from 66 cases in 2014 to 63 cases in 2015. At different points of the investigation and/or review process, some cases may be closed due to methadone not being a cause or contributing factor to the death or incident. Additional statistics regarding the rates of completion of MDAIR cases are listed below.

2013 MDAIR Case Rates of Completion

- In 2013, 146 case referrals were received by DDAP staff. At the close of 2013, of the 146 cases received, 46 cases were closed. This represents a 32% completion rate. 100 cases from 2013 remained open into 2014.

2014 MDAIR Case Rates of Completion

- In 2014, of the 100 cases that remained open from 2013, 72 cases were closed. This represents a 72% completion rate for a total of an 81% completion rate for 2013 cases. 28 cases from 2013 remained open into 2015.
- In 2014, 238 case referrals were received by DDAP staff. Of the 238 cases received, 51 cases were closed. This represents a 21% completion rate. 187 cases from 2014 remained open into 2015.

2015 MDAIR Case Rates of Completion

- In 2015, of the 28 cases that remained open from 2013, 28 cases were closed. This represents a 100% completion rate. There are no open 2013 cases.
- In 2015, of the 187 cases that remained open from 2014, 74 cases were closed. This represents a 36% completion rate for a total of a 53% completion rate for 2014 cases. 113 cases from 2014 remained open into 2016.
- In 2015, 239 cases were received by DDAP staff. Of the 239 cases received, 13 cases were completed. This represents a 5% completion rate. 226 cases from 2015 remained open into 2016.

The rate of case completion verifies that it takes MDAIR about two years to completely review all of the cases received in any given year. The reasons for this are the sheer number of cases received, the reluctance of some of the involved parties to provide the relevant, confidential records, and the expansive amount of information needed to accurately review a case. The MDAIR staff anticipates that the rate of case completion will increase given a newly implemented review process and improved cooperation by all involved parties.

FINDINGS

MDAIR staff presented 63 cases to the MDAIR Team in 2015. These cases involved methadone-related deaths and incidents that occurred between 2013 – 2015. Of the 63 cases presented to the MDAIR Team, four were determined not to be methadone-related deaths (2) or incidents (2) after further review. The MDAIR Team reviewed a total of 59 cases of methadone-related deaths and incidents in 2015. These cases consisted of 56 deaths and 3 incidents.



Figure 3 – MDAIR Death Cases Reviewed in 2015 by County
Source: MDAIR Database, 2015

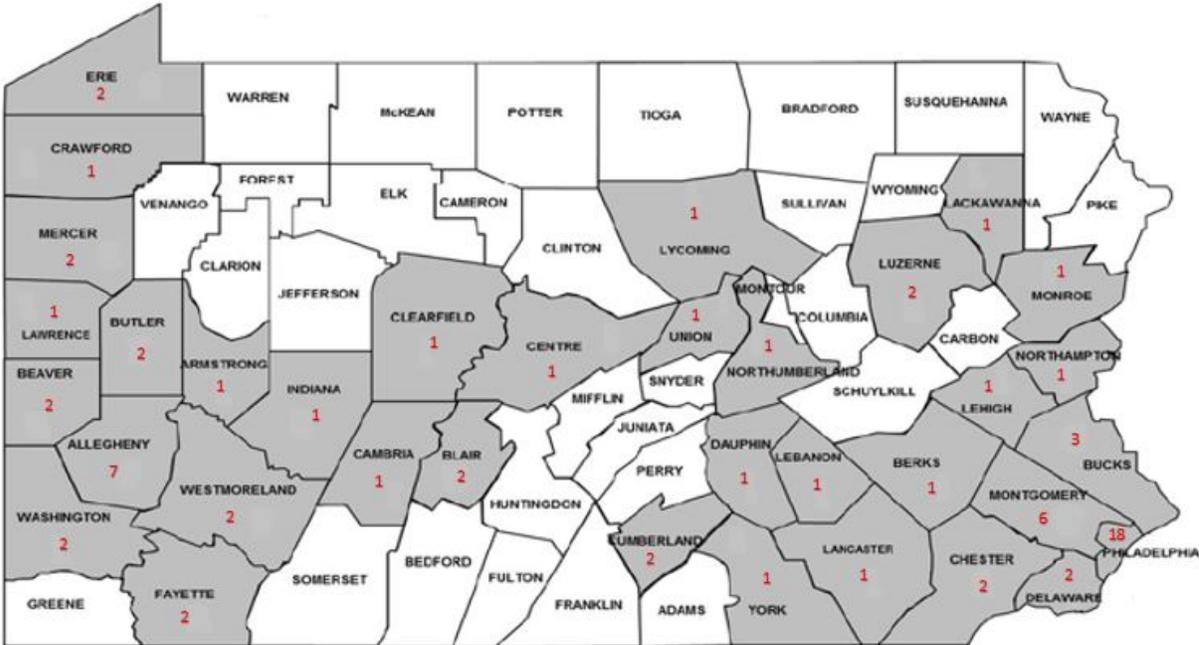


Figure 4 – Narcotic Treatment Providers by County (77 NTPs Statewide; Total Capacity-26,087 patients)
Source: DDAF Licensing Division, 2015

A study by Jones and McAninch (2015) found that opioid involvement occurred in 75% of benzodiazepine overdose deaths in 2011. Furthermore, a Canadian study revealed that 60% of those with an opioid-related death, whom were prescribed an opioid for non-malignant pain, were found to have benzodiazepines in their system at the time of death (Gomes, Mamdani, Dhalla, Paterson & Juurlink, 2011). Although both of these studies analyzed data that pertained to deaths involving various opioids – not just methadone, the significance of the findings are relevant to methadone providers given that the data analyzed for the cases that were reviewed by the MDAIR Team in 2015 revealed a consistency with regards to methadone-related deaths that involved benzodiazepines and the results of the previously noted studies.

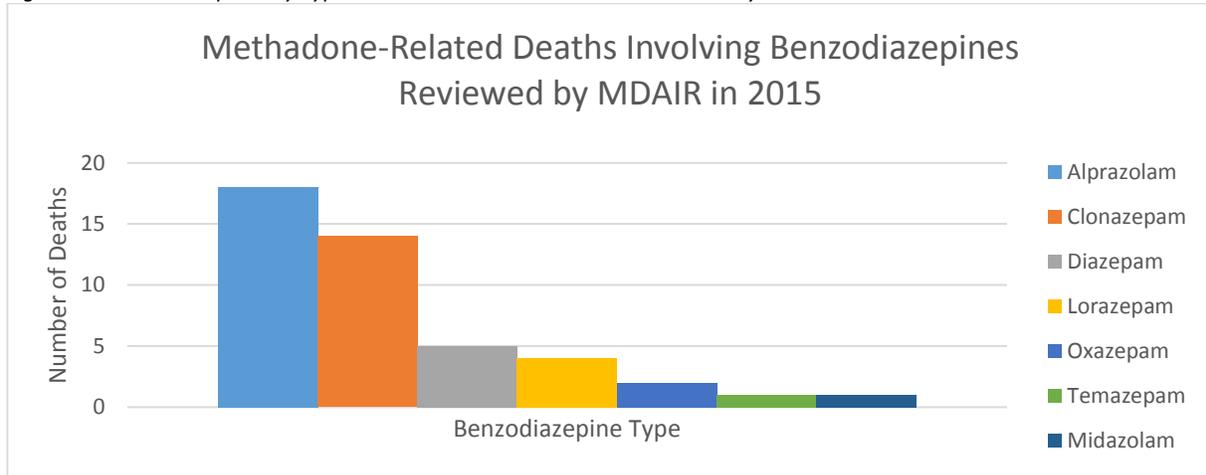
Table 1 – Methadone-Related Deaths Involving other Drugs

Total Methadone-Related Deaths	56
1 ≥ Benzodiazepines	34
1 ≥ Prescription Opioids	20
1 ≥ Benzodiazepine & Prescription Opioid	12
Methadone & Other Drugs	7
Methadone Only	5

Source: Coroner/Medical Examiners and Medical Personnel, 2015.

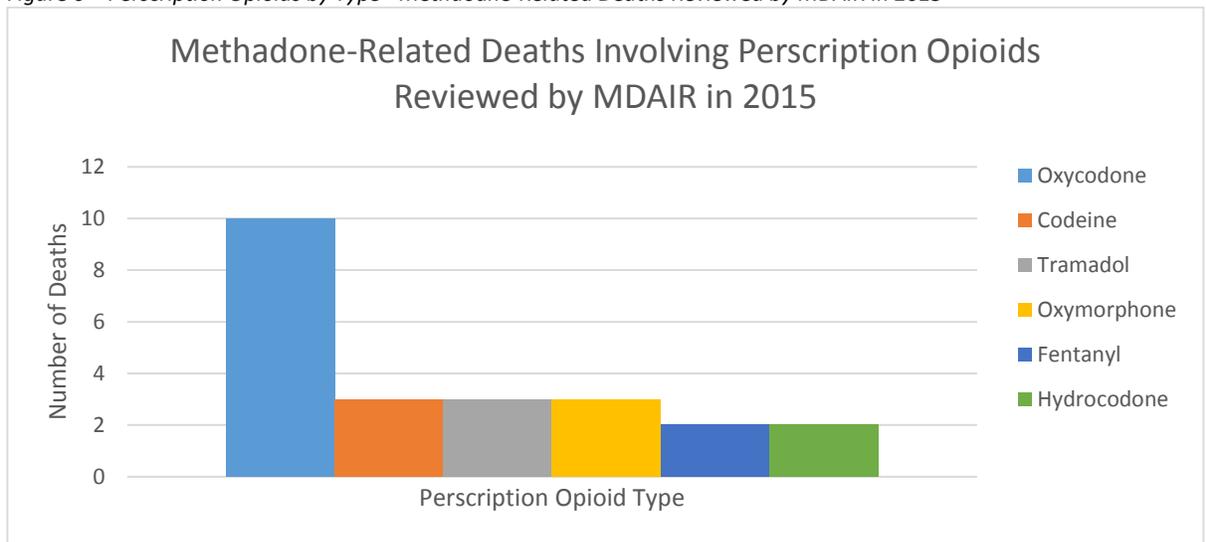
Of the 56 methadone-related deaths reviewed by the MDAIR Team in 2015, 61% involved the use of both methadone and at least one benzodiazepine in their blood or urine at the time of death. Although other various medications were revealed on the toxicology results for many of these cases, the data suggests that the use of just one benzodiazepine in conjunction with methadone can be lethal.

Figure 5 – Benzodiazepines by Type - Methadone-Related Deaths Reviewed by MDAIR in 2015



Source: MDAIR Database, 2015

Figure 6 – Perscription Opioids by Type - Methadone-Related Deaths Reviewed by MDAIR in 2015



Source: MDAIR Database, 2015

Furthermore, 36% of the methadone-related deaths involved methadone and other opioids; 21% of the methadone-related deaths involved the combination of benzodiazepines and other opioids; and 12% of the methadone-related deaths involved no use of opioids nor benzodiazepines. The next section of this report will focus on a longitudinal analysis of benzodiazepine and opioids regarding all of the MDAIR cases that have been reviewed by the MDAIR Team since 2013.

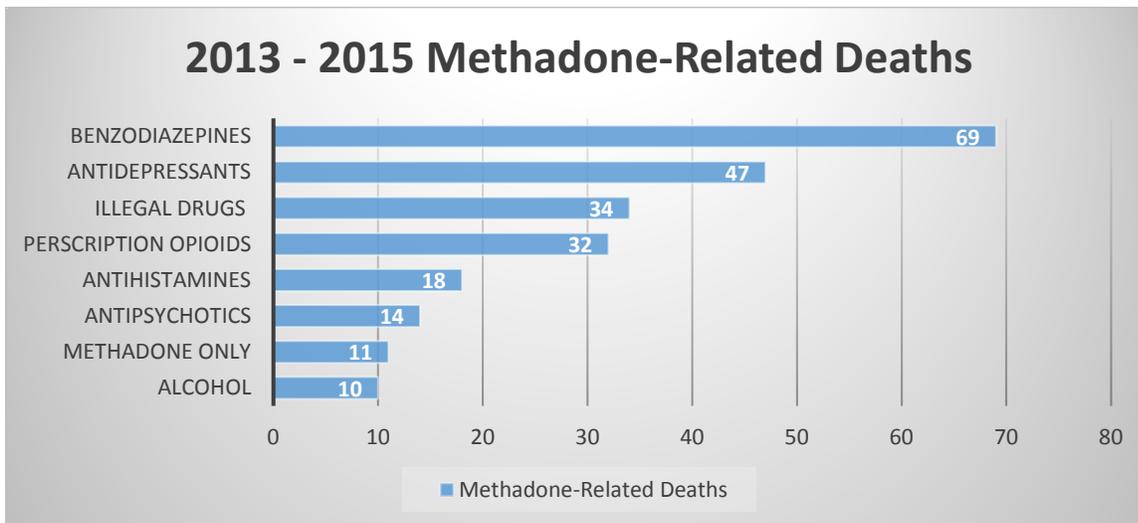


Figure 7 – Drugs Involved in All Methadone-Related Deaths Reviewed by the MDAIR Team Since 2013
 Source: Coroner/Medical Examiners and Medical Personnel, 2013 – 2015.

The MDAIR Team reviewed a total of 123 cases that were determined to be methadone-related deaths since the Team’s inception in 2013. The chart listed above provides the data regarding the number of methadone-related deaths that involved other notable drugs. In many cases, there were various drugs identified on the toxicology results, which included 22 cases that involved both benzodiazepines and opioids. Of the 123 methadone-related deaths reviewed by the MDAIR Team from 2013 - 2015, 69 cases (56%) involved the use of both methadone and at least one benzodiazepine.

Table 2 – Methadone-Related Deaths Involving Benzodiazepines

Prevalence of Benzodiazepines in Methadone-Related Deaths	
Alprazolam (Xanax)	35 %
Clonazepam (Klonopin)	21 %
Lorazepam (Ativan)	8 %
Diazepam (Valium)	8 %
Temazepam (Restoril)	3 %
Oxazepam (Serax)	3 %
Midazolam (Versed)	1 %

Source: Coroner/Medical Examiners and Medical Personnel, 2013 - 2015.

Table 3 – Methadone-Related Deaths Involving Perscription Opioids

Prevalence of Perscription Opioids in Methadone-Related Deaths	
Oxycodone	13 %
Codiene	5 %
Oxymorphone	4 %
Fentanyl	3 %
Hydrocodone	3 %
Tramadol	2 %
Buprenorphine	1 %

Source: Coroner/Medical Examiners and Medical Personnel, 2013 - 2015.

The tables listed above address the specific types of benzodiazepines and prescription opioids that were identified on the toxicology results. The benzodiazepines that were the most prevalent in the 123 methadone-related deaths were Alprazolam & Clonazepam. The prevalence of Alprazolam & Clonazepam in the 69 methadone-related deaths that involved the use of one or more benzodiazepine were 58% and 38%, respectively. Additionally, the prescription opioid that was the most prevalent in methadone-related deaths was Oxycodone at 13%. The prevalence of Oxycodone in the 32 methadone-related deaths that involved the use of one or more prescription opioids was 50%.

Table 4 – Methadone-Related Deaths Involving Illegal Drugs

Prevalence of Illegal Drugs in Methadone-Related Deaths	
Heroin	15 %
Cocaine	13 %
Marijuana	7 %
Methamphetamine	2 %
PCP	1 %

Source: Coroner/Medical Examiners and Medical Personnel, 2013 - 2015.

Table 5 – Methadone-Related Deaths Involving Antihistamines

Prevalence of Antihistamines in Methadone-Related Deaths	
Diphenhydramine	12 %
Hydroxyzine	2 %
Promethazine	1 %
Meclizine	1 %

Source: Coroner/Medical Examiners and Medical Personnel, 2013 - 2015.

*Table 6 – Methadone-Related Deaths Involving Antipsychotics **

Prevalence of Antipsychotics in Methadone-Related Deaths	
Quetiapine	8 %
Olanzapine	2 %
Chlorpromazine	2 %

Source: Coroner/Medical Examiners and Medical Personnel, 2013 - 2015.

The data analysis of methadone-related deaths reviewed by the Team from 2013 – 2015 revealed that 38% involved at least one antidepressant, 28% involved at least one illegal drug, 15% involved at least one antihistamine, 11% involved at least one antipsychotic, and 8% involved alcohol. Only 9 % involved methadone and no other drugs. The most prevalent antidepressants were Citalopram and Sertraline. The most prevalent illegal drugs were heroin and cocaine. Furthermore, the most prevalent antihistamine and antipsychotic were Diphenhydramine (Benadryl) and Quetiapine (Seroquel), respectively.

Please note that any charts or tables in the report that compare the presence of one drug to another is not meant to suggest that any one of the drugs is more dangerous than the other. Rather, the intent was solely to reflect the prevalence of the drug in the cases reviewed.

*Table 7 – Methadone-Related Deaths Involving Antidepressants **

Prevalence of Antidepressants in Methadone-Related Deaths	
Citalopram (Celexa)	8 %
Sertraline (Zoloft)	8 %
Bupropion (Wellbutrin)	5 %
Doxepin (Silenor)	5 %
Amitriptyline (Elavil)	4 %
Trazadone (Olepro)	4 %
Venlafaxine (Effexor)	4 %
Fluoxetine (Prozac)	3 %
Mirtazapine (Remeron)	3 %
Nortriptyline (Pamelor)	2 %
Paroxetine (Paxil)	2 %
Duloxetine (Cymbalta)	1 %
Fluvoxamine (Luvox)	1 %

Source: Coroner/Medical Examiners and Medical Personnel, 2013 - 2015.

Longitudinal Analysis of NTP Involvement:

The table listed below addresses the total number of case referrals analyzed by date of death that involved a Narcotic Treatment Provider (NTP) from 2013 – 2015. The data indicates that the percentage of case referrals that are deaths that involve an NTP have steadily declined from 2013 – 2015.

Table 8 – MDAIR Case Referrals by Date of Death from 2013 - 2015

NTP METHADONE DEATH REFERRALS - YEAR TO YEAR ANALYSIS		
YEAR	NTP DEATH REFERRALS	TOTAL # OF REFERRALS REGARDLESS OF REFERRAL SOURCE
2013	95 (71%)	146
2014	129 (53%)	238
2015	111 (48%)	239

Source: Coroner/Medical Examiners and NTP Reports, 2013 - 2015.

* Keep in mind a confounding variable may be that the concomitant use of antidepressants and/or antipsychotics could be necessary because of co-occurring disorders and not due to the abuse of these medications.

Age & Gender:

The average age of those involved in cases reviewed by the MDAIR Team in 2015 and determined to have been impacted by a methadone-related death or incident was 40 years old. Data collected via the coroner's drug death report, MDAIR treatment provider form, and unusual incident report indicated that deaths occurred more frequently amongst those who were age 40 to 49 years old.

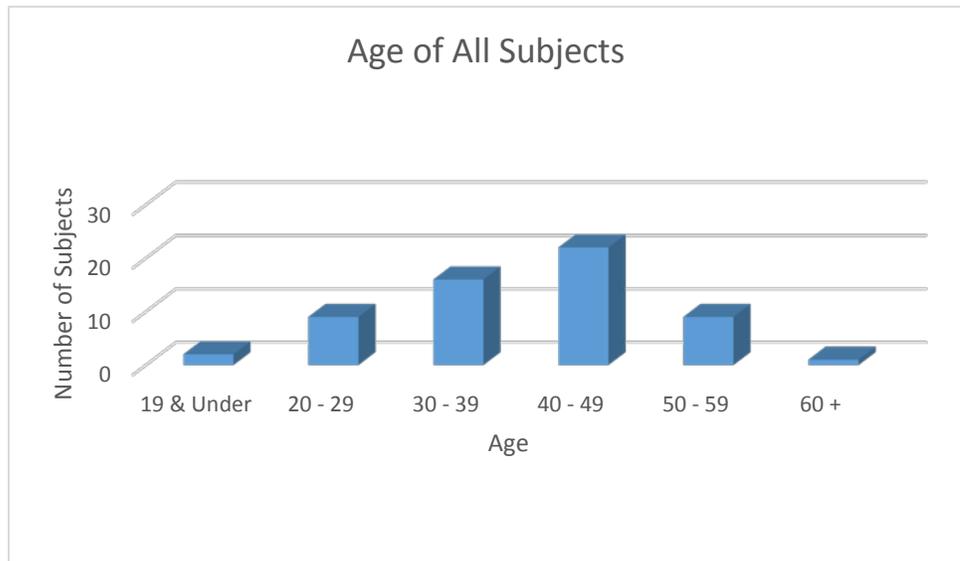
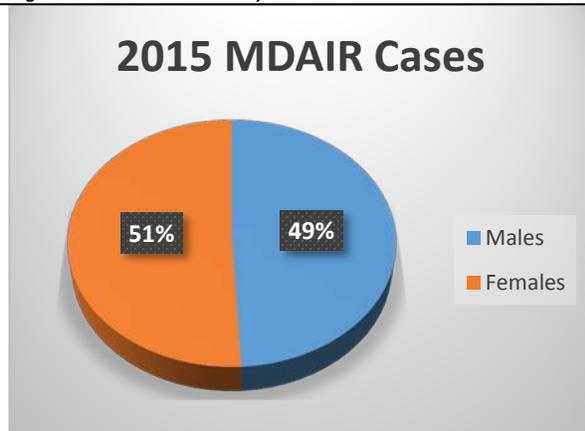


Figure 8 – MDAIR Case Subjects by Age Group
Source: Coroner/Medical Examiners, NTPs and Medical Personnel, 2015.

Figure 9 – MDAIR Cases by Gender



Source: Coroner/Medical Examiners, NTPs and Medical Personnel, 2015.

Table 9 – MDAIR Cases by Age Group for Male & Females

Age of Subjects	Male	Female	Total	%
≤ 19	1	1	2	3%
20 – 29	4	5	9	15.5%
30 – 39	7	9	16	27%
40 – 49	12	10	22	37%
50 – 59	4	5	9	15.5%
60 +	1	0	1	2%
Total	29	30	59	

Source: Coroner/Medical Examiners, NTPs and Medical Personnel, 2015.

The age group for both men and women that were more likely to experience a methadone-related death or incident was 40 – 49 years old. This data is consistent and reflective of the nationwide data regarding all opioid overdose deaths. To date, the data also revealed that men and women were equally impacted by methadone-related deaths or incidents. In addition, 29 cases reviewed (49%) involved men and 30 cases reviewed (51%) involved women. The age group of 35 – 54 years old comprised 53% of all opioid overdose deaths nationwide in 2014 (Rudd, Aleshire, Zibbell & Gladden, 2016).

Race/Ethnicity:

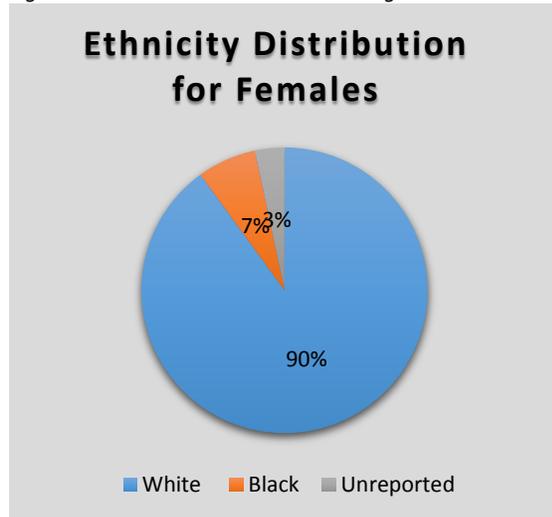
Table 10 – MDAIR Cases by Ethnicity & Marital Status

Race/Ethnicity	Count of Race	%	Marital Status	Single	Married	Divorced	Separated	Widowed	Unknown
Black/African American	3	5%		1		2			
Hispanic/Latino	1	2%			1				
White	50	85%		17	8	7	2	2	14
Unreported	5	8%		1					4

Source – Coroner/Medical Examiners, NTPs and Medical Personnel, 2015.

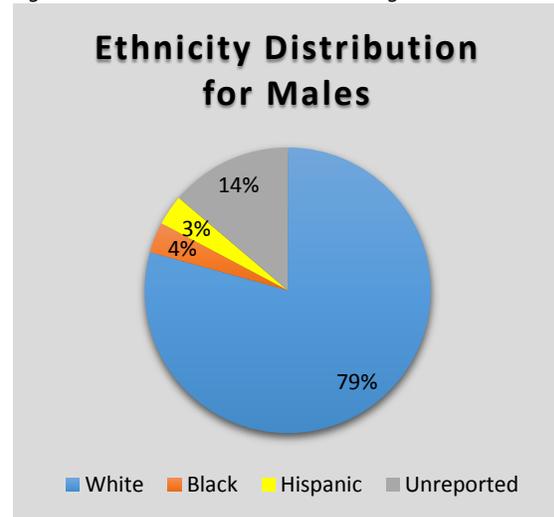
To date, of the 59 methadone-related cases of either deaths or incidents that were presented and reviewed by the MDAIR Team in 2015, 85% of the cases involved white case subjects.

Figure 10 – 2015 MDAIR Cases Involving Females



Source: Coroner/Medical Examiners, NTPs and Medical Personnel, 2015.

Figure 11 – 2015 MDAIR Cases Involving Males



Source: Coroner/Medical Examiners, NTPs and Medical Personnel, 2015.

The data was further analyzed to identify any notable trends with regards to ethnicity of male and female case subjects. The data revealed that 90% of the case subjects were white females and 79% were white males. Additionally, 37% of all case subjects were married at one point in their life. The case subjects that were reported as single accounted for 32% of all cases. The MDAIR staff was unable to obtain the marital status for 31% of the cases that were presented to the MDAIR Team in 2015.

Analysis of the Source:

The MDAIR Team is tasked with reviewing the methadone-related deaths and incidents that are referred to MDAIR staff. Statutorily, NTPs are required to report methadone-related deaths and incidents. Other potential sources of methadone that were identified in the cases reviewed by the MDAIR Team are not required by law to report a methadone-related death or incident. As such, MDAIR receives a larger number of cases where the primary source of methadone is an NTP. However, through our analysis, we have also been able to identify cases where the primary source of methadone was pain management, illicit use, primary care physicians and unknown. We are hopeful that the use of the Prescription Drug Monitoring Program (PDMP) will allow us to further determine the source of the methadone for future cases.

Length of Treatment & Risk:

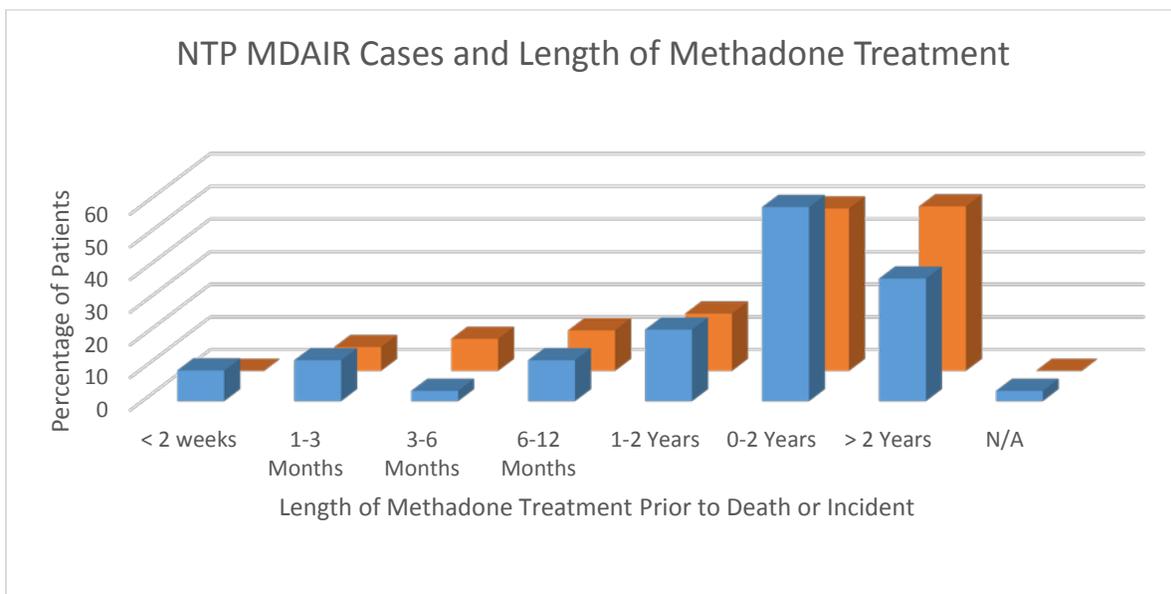


Figure 12: Number of Methadone-Related Deaths & Length of Treatment

Source: Coroner/Medical Examiners, NTPs, Medical Personnel & PATOD, 2015.

- PATOD's sample of NTP patients currently in treatment include 2341 patients from 5 licensed NTPs in Pennsylvania.
- The notation for N/A pertained to a case that involved the death of an infant that accessed and ingested his/her parent's take-home bottles. This was listed as "N/A" because the infant was not an NTP patient.

According to the data, there is a heightened safety risk of a methadone-related death or incident for patients that have been receiving methadone treatment from an NTP for more than 2 years. The data suggested that the safest period of time regarding the risk of a methadone-related death or incident for an NTP patient is within the first 3 – 6 months of treatment.

Based on the findings and case information that was presented to the Team in 2015, the Team developed 30 new recommendations for stakeholders. These recommendations are listed in the next section of this report.

MDAIR Team's 2015 Recommendations

General Recommendations:

1. All practitioners prescribing opioids, semi-synthetic opioids, and synthetic opioids should be ordering urine drug screenings (UDS) for their patients. The UDS should screen for the prescribed product along with at least the following: methadone, benzodiazepines, opiates and oxycodone.
2. The Department of Human Services (DHS) and Department of Drug and Alcohol Programs (DDAP) should work together to allow Behavioral Health Managed Care Organizations to fund multiple services where there are concurrent levels of treatment occurring when clinically necessary. This should be reviewed by the Clinical Standards Committee. For example, payment should be made for a patient on methadone maintenance who is appropriately admitted to a detox facility for methamphetamine abuse (heroin, alcohol, or benzodiazepines could be substituted for methamphetamine).
3. There should be case management for patients with co-occurring mental health issues or physical health issues.
4. 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.
5. The PDMP should automatically populate electronic health records of individual patients so that physicians can easily see a patient's treatment/medication activity.
6. Primary care physicians, in complex cases, should consult with a pain management physician to determine the safest mode of patient treatment for pain.
7. Where it is known that a hospital/emergency department patient is an NTP patient, the hospital shall inform and coordinate care with the NTP after obtaining appropriate releases and prior to discharge.

Recommendations for Narcotic Treatment Providers:

1. If a treatment facility becomes aware of a household member or acquaintance of a patient receiving take-homes, who has died from illicit methadone use, the provider will call back the patient and inquire about the status of their methadone take-homes.
2. In a case where a patient is transferred from one NTP to another, the receiving provider shall obtain all clinically pertinent information from the referring provider.
3. Where take-home doses are being prescribed, the prescriber should co-prescribe and train the patient in the use of Naloxone; and, where possible, train family members in the use of Naloxone.
4. Physical and behavioral health specialists should be included as members of the multi-disciplinary team in making treatment decisions regarding patient care, especially with respect to the decision to approve take-home medications.
5. The amount of funding to a provider should be increased if the level of counseling is intensified.

6. As a condition of admission, NTPs shall obtain from the patient consents to release information deemed necessary by the NTP to properly coordinate the patient's care.
7. 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.
8. 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. For these patients, the NTP will not raise the dose of methadone above 60 mg until the patient is completely detoxed from benzodiazepines. For the patient who has been on methadone maintenance and in the past prescribed benzodiazepines from a physician, the NTP and the prescribing physician will arrange for the patient to be tapered off of benzodiazepines within 12 weeks or have the patient enter a detoxification program for the expressed purpose of discontinuing the benzodiazepines. For the patient who is already on methadone maintenance and begins using benzodiazepines, licit or illicit, that patient needs to have this issue addressed immediately. If the patient is receiving a legitimate prescription from another physician, this physician needs to be contacted and an alternative treatment discussed and provided. If the patient is consuming illicit benzodiazepines, this will be treated as any other positive urine drug screen. If the patient continues to use illicit benzodiazepines, that patient risks being tapered off and discharged from the NTP or may be referred to an inpatient program for benzodiazepine detoxification. Regardless of the case presentation, all methadone take-home medications will be denied in all of these situations.
9. DDAP's Clinical Standards Committee should develop a protocol for benzodiazepine detoxification for an individual who is on benzodiazepines that presents to an NTP, either at the beginning or during the course of methadone treatment with the aim of detoxing the individual off of benzodiazepines in a clinically sound manner.

Recommendations for Methadone Prescribers:

1. Any methadone prescriber should be familiar with and have working knowledge of the principles of SAMHSA's Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs Treatment Improvement Protocol Series 43 (pp. 65-68) to assist with determining a standard for methadone dosage increases.
2. Patients who are receiving long term methadone treatment for pain should have regular quantitative testing to see if the levels of methadone are consistent with what has been prescribed. Appropriate referrals, including referrals for psychiatric, psychological, or substance use evaluation and treatment, should be made for patients who appear to be at risk of having a substance use disorder. For patients who appear to be diverting, but do not appear to have a substance use disorder, they should be immediately discharged.
3. If a patient has a respiratory issue (e.g. sleep apnea, pulmonary disease, obesity, COPD), there should be coordination of care with his/her 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.
4. There should be an ongoing conversation between medical staff and the patient about adjusting the patient's dose of methadone to the lowest therapeutic dose.

5. Benzodiazepines should not be co-prescribed with methadone.
6. For those prescribing methadone, initiation of a benzodiazepine prescription is contraindicated due to the serious risk of death by overdose/respiratory depression.
7. Prescribers of methadone are to check the PDMP with regard to other controlled substances including benzodiazepine use prior to prescribing, changing medication, and introducing any new medication.
8. Any and all benzodiazepine use by patients taking methadone should be clearly addressed in the treatment plan with the goal of discontinuation.
9. When treating a patient with a history of substance use disorder, extreme caution should be used with the prescription of any potentially addictive medication.
10. If a patient is unable or unwilling to provide a requested urine sample, then it should be treated as a positive result, unless the patient agrees to provide an oral swab test.
11. For methadone pain prescribing patients, there should be a UDS at each appointment.
12. Pain management physicians treating methadone patients with mental health (MH) or substance use disorders (SUD) should integrate and coordinate care with the patients' MH and/or SUD provider(s). In addition, the provider payer systems should support such integration and coordination. DDAP, DOH, DHS and Department of State shall collaborate to ensure such integration and coordination.
13. At the time of a positive UDS, there should be a substance use disorder screening and, if needed, an evaluation and referral to substance use disorder treatment.
14. Methadone prescribers should develop strong protocols for educating patients about methadone and its risks.

Conclusion

Methadone is highly effective in treating opioid dependence and alleviating chronic pain. Methadone maintenance treatment for opioid dependence reduces crime, HIV seroconversion, and heroin deaths. Methadone treatment for chronic pain is effective because of its long half-life, affordability, and efficacy among patients intolerant or unresponsive to other opioid painkillers (Brooks, D., Modesto-Lowe, V., & Petry, N., 2010).

Despite these benefits, there are substantial risks associated with methadone especially when combined with polysubstance use. Patients receiving methadone often present with symptoms of anxiety and believe that benzodiazepines are the only medication that can alleviate those symptoms. The combination of methadone and benzodiazepines can present significant individual risk of illness and death (Brooks, D., Modesto-Lowe, V., & Petry, N., 2010). Our findings indicated that a significant number of methadone-related deaths reviewed by the Team from the span of 2013 – 2015 involved the use of benzodiazepines (56%), antidepressants (38%), illegal drugs (28%), antihistamines (15%) and antipsychotics (11%).

Since methadone and benzodiazepines are both central nervous system depressants; serious, life-threatening, or fatal respiratory depression may occur. Combining the two depressants can slow the heart rate and breathing until death. Generally when someone overdoses from a combination of methadone and benzodiazepines, he/she may fall asleep, stop breathing, and pass away in his/her sleep (Deeds, 2016). Our findings indicated that 69 of 123 cases reviewed by the Team from the span of 2013 – 2015 involved at least one benzodiazepine.

The MDAIR Team continues to work diligently to address the dangers of the co-prescription and polysubstance use of methadone and benzodiazepines. In addition, the MDAIR Team continues its efforts on researching current trends, educating and training prescribing physicians, and influencing regulation reform.

APPENDIX A – MDAIR ACT

(Act 148 of 2012)

METHADONE DEATH AND INCIDENT REVIEW ACT - ENACTMENT

Act of Oct. 24, 2012, P.L. 1198, No. 148 Cl. 35

An Act

Establishing the Methadone Death and Incident Review Team and providing for its powers and duties; and imposing a penalty.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Methadone Death and Incident Review Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Department." The Department of Drug and Alcohol Programs of the Commonwealth.

"Methadone-related death." A death where methadone was:

- (1) A primary or secondary cause of death; or
- (2) May have been a contributing factor.

"Methadone-related incident." A situation where methadone may be a contributing factor which:

- (1) Does not involve a fatality; and
- (2) Involves:
 - (i) A serious injury; or
 - (ii) Unreasonable risk of death or serious injury.

"Narcotic treatment program." A program licensed and approved by the Department of Drug and Alcohol Programs for chronic opioid drug users that administers or dispenses agents under a narcotic treatment physician's order, either for detoxification purposes or for maintenance.

"Secretary." The Secretary of Drug and Alcohol Programs of the Commonwealth.

"Team." The Methadone Death and Incident Review Team established under section 3.

Section 3. Establishment of Methadone Death and Incident Review Team.

(a) Team established.--The department shall establish a Methadone Death and Incident Review Team and conduct a review and shall examine the circumstances surrounding methadone-related deaths and methadone-related incidents in this Commonwealth for the purpose of promoting safety, reducing methadone-related deaths and methadone-related incidents and improving treatment practices.

(b) Composition.--The team shall consist of the following individuals:

- (1) The secretary or a designee, who shall serve as the chairperson of the team.
- (2) The Director of the Bureau of Drug and Alcohol Programs.
- (3) The following individuals appointed by the secretary:
 - (i) A representative from narcotic treatment programs as defined in 28 Pa. Code § 701.1 (relating to definitions).
 - (ii) A representative from a licensed drug and alcohol addiction treatment program that is not defined as a narcotic treatment program.

- (iii) A representative from law enforcement recommended by a statewide association representing members of law enforcement.
- (iv) A representative from the medical community recommended by a statewide association representing physicians.
- (v) A district attorney recommended by a statewide association representing district attorneys.
- (vi) A coroner or medical examiner recommended by a statewide association representing county coroners and medical examiners.
- (vii) A member of the public.
- (viii) A patient or family advocate.

(c) Initial meeting.--The initial meeting of the team shall take place within 90 days of the effective date of this section. During this initial meeting, the team shall develop a schedule for its work and reports.

(d) Expenses.--Members of the team shall not receive compensation but shall be reimbursed for necessary travel and other reasonable expenses incurred in connection with the performance of their duties as members. If possible, the team shall utilize the services and expertise of existing personnel and staff of State government.

Section 4. Team duties.

The team shall:

(1) Review each death where methadone was either the primary or a secondary cause of death and review methadone-related incidents.

(2) Determine the role that methadone played in each death and methadone-related incident.

(3) Communicate concerns to regulators and facilitate communication within the health care and legal systems about issues that could threaten health and public safety.

(4) Develop best practices to prevent future methadone-related deaths and methadone-related incidents. The best practices shall be:

(i) Promulgated by the department as regulations.

(ii) Posted on the department's Internet website.

(5) Collect and store data on the number of methadone-related deaths and methadone-related incidents and provide a brief description of each death and incident. The aggregate statistics shall be posted on the department's Internet website. The team may collect and store data concerning deaths and incidents related to other drugs used in opioid treatment.

(6) Develop a form for the submission of methadone-related deaths and methadone-related incidents to the team by any concerned party.

(7) Develop, in consultation with a statewide association representing county coroners and medical examiners, a model form for county coroners and medical examiners to use to report and transmit information regarding methadone-related deaths to the team. The team and the statewide association representing county coroners and medical examiners shall collaborate to ensure that all methadone-related deaths are, to the fullest extent possible, identified by coroners and medical examiners.

(8) Develop and implement any other strategies that the team identifies to ensure that the most complete collection of methadone-related death and methadone-related serious incident cases reasonably possible is created.

(9) Prepare an annual report that shall be posted on the department's Internet website and distributed to the chairman and minority chairman of the Judiciary Committee of the Senate, the chairman and minority chairman of the Public Health and Welfare Committee of the Senate, the chairman and minority chairman of the Judiciary Committee of the House of Representatives and the chairman and minority chairman of the Human Services Committee of the House of Representatives. Each report shall:

(i) Provide public information regarding the number and causes of methadone-related deaths and methadone-related incidents.

(ii) Provide aggregate data on five-year trends on methadone-related deaths and methadone-related incidents when such information is available.

(iii) Make recommendations to prevent future methadone-related deaths, methadone-related incidents and abuse and set forth the department's plan for implementing the recommendations.

(iv) Recommend changes to statutes and regulations to decrease methadone-related deaths and methadone-related incidents.

(v) Provide a report on methadone-related deaths and methadone-related incidents and concerns regarding narcotic treatment programs.

(10) Develop and publish on the department's Internet website a list of meetings for each year.

Section 5. Duties of coroner and medical examiner.

A county coroner or medical examiner shall forward all methadone-related death cases to the team for review. The county coroner and medical examiner shall use the model form developed by the team to transmit the data.

Section 6. Review procedures.

The team may review the following information:

(1) Coroner's reports or postmortem examination records unless otherwise prohibited by Federal or State laws, regulations or court decisions.

(2) Death certificates and birth certificates.

(3) Law enforcement records and interviews with law enforcement officials as long as the release of such records will not jeopardize an ongoing criminal investigation or proceeding.

(4) Medical records from hospitals, other health care providers and narcotic treatment programs.

(5) Information and reports made available by the county children and youth agency in accordance with 23 Pa.C.S. Ch. 63 (relating to child protective services).

(6) Information made available by firefighters or emergency services personnel.

(7) Reports and records made available by the court to the extent permitted by law or court rule.

(8) EMS records.

(9) Traffic fatality reports.

(10) Narcotic treatment program incident reports.

(11) Narcotic treatment program licensure surveys from the program licensure division.

(12) Any other records necessary to conduct the review.

Section 7. Access to records.

(a) Juvenile records.--When deemed necessary for its review, the team may review and inspect all files and records of the court relating to a child pursuant to a proceeding under 42 Pa.C.S. Ch. 63 (relating to juvenile matters) in accordance with 42 Pa.C.S. § 6307 (relating to inspection of court files and records). This subsection shall not apply to files and records of the court subject to a child fatality or near fatality review pursuant to 23 Pa.C.S. Ch. 63 (relating to child protective services).

(b) Medical records.--Notwithstanding any other provision of law and consistent with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936) and 42 CFR Pt. 2 (relating to confidentiality of alcohol and drug abuse patient records), health care facilities and health care providers shall provide medical records of an individual under review without the authorization of a person of interest to the team for purposes of review under this act.

(c) Other records.--Other records pertaining to the individual under review for the purposes of this act shall be open to inspection as permitted by law.

Section 8. Confidentiality.

(a) Maintenance.--The team shall maintain the confidentiality of any identifying information obtained relating to the death of an individual or adverse incidents regarding methadone, including the name of the individual, guardians, family members, caretakers or alleged or suspected perpetrators of abuse, neglect or a criminal act.

(b) Agreement.--Each member of the team and any person appearing before the team shall sign a confidentiality agreement applicable to all proceedings and reviews conducted by the team.

(c) Liability.--An individual or agency that in good faith provides information or records to the team shall not be subject to civil or criminal liability as a result of providing the information or record.

(d) Discovery.--The proceedings, deliberations and records of the team are privileged and confidential and shall not be subject to the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law, discovery, subpoena or introduction into evidence in any civil or criminal action.

(e) Meetings.--Meetings of the team at which a specific death is discussed shall be closed to the public and shall not be subject to the provisions of 65 Pa.C.S. Ch. 7 (relating to open meetings).

(f) Attendance.--Nothing in this act shall prevent the team from allowing the attendance of a person with information relevant to a review at a methadone death and incident team review meeting.

(g) Penalty.--A person who violates the provisions of this section commits a misdemeanor of the third degree.

Section 9. Regulations.

The department shall promulgate regulations as necessary to carry out the purposes of this act.

Section 20. Effective date.

This act shall take effect in 90 days.

APPENDIX B – References

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