2022-2023 Annual Report

Medication Death and Incident Review

pennsylvania
DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

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DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

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EXECUTIVE SUMMARY

Overdose continues to be the leading cause of injury-related death in both the United States and in Pennsylvania, most of which involve opioids. Opioid Use Disorder (OUD) is a chronic, treatable illness that requires ongoing, patient-centered care to recover. Buprenorphine, methadone, and extended-release naltrexone are United States Food and Drug Administration (FDA)-approved Medications for Opioid Use Disorder (MOUD) and are the most common medications used to treat OUD. All three medications have been found more successful at reducing illicit opioid use than without the use of medication.

MOUD reduces or removes craving to use opioids, blocks or reduces the effects of illicit opioids, and reduces or eliminates withdrawal symptoms. MOUD is most effective when used as part of a comprehensive treatment plan that utilizes a whole-person approach. Selection of the most appropriate MOUD should be a collaborative process between the individual and the prescriber which considers the various social determinants of health affecting an individual's adherence to their treatment regimen. Methadone is a long-acting opioid agonist medication that is taken daily. Buprenorphine is a partial agonist medication that can be prescribed or dispensed in physicians' offices and is administered orally or by subcutaneous injection or implant with a dosing schedule; this varies based on administration and stabilization of the patient. Finally, extended-release Naltrexone is an opioid blocker that binds and blocks opioid receptors and reduces opioid cravings and is a once-a month injection.

The Medication Death and Incident Review Act of 2020, also known as the "MDAIR Act", was enacted on November 20, 2020, replacing the previous Methadone Death and Incident Review Act of 2012. The updated Act expanded the focus of MDAIR beyond methadone to all FDA-approved MOUD which allows the review and analysis of information related to buprenorphine, extended-release naltrexone, and methadone[1]. The MDAIR Team [2] is responsible for reviewing deaths and incidents in which an FDA-approved Medication to treat Opioid Use Disorder (MOUD) was a primary or secondary cause or contributing factor to the death or incident. In addition, the MDAIR team is tasked with communicating concerns to healthcare and legal systems about issues that could threaten health and public safety, developing best practices to prevent future MOUD-related deaths and incidents, maintain aggregate data, developing appropriate forms for reporting MOUD-related deaths and incidents, developing and implementing strategies to address serious incident cases, preparing an annual MDAIR report, and posting a list of MDAIR meetings on the Department of Drug and Alcohol Programs' (DDAP) website.

In 2021, the MDAIR process was reclassified as part of DDAP's newly created Quality Improvement (QI) Section within the Bureau of Quality Assurance and Administration. A new MDAIR Team was assembled with much of the first year's focus on the re-initiation of discussing a plan to address

[1] Act 126 of 2020

[2] MDAIR Team (pa.gov)

changes to the Act, team duties, review of the data collected, and recommendations going forward. The 2022-2023 report addresses the collaborative processes that have been established by the MDAIR Team and DDAP's QI staff, current and past recommendations made the by the MDAIR Team, and the steps taken to address those recommendations.

Introduction of new legislation originating from the COVID-19 flexibilities and the elimination of the X-Waiver are also discussed, as well as the substances in today's drug supply, such as fentanyl, xylazine, and stimulants, that play a role in many overdose deaths.

NATIONAL DRUG TRENDS

MDAIR drug trends are very similar to what we see on a national scale. MDAIR case reviews during this period rarely involve deaths where MOUD was the only substance involved in someone's death. Nationally, provisional data from the Centers for Disease Control and Prevention (CDC) for 2022 predict all overdose deaths to be close to 110,000, up .5% from 2021. Other predicted increases are overdose deaths involving synthetic opioids, including fentanyl but excluding methadone, methamphetamine, and cocaine[3].

Fentanyl is a powerful synthetic opioid, 50-100 times more potent than morphine, responsible for more than two-thirds of all overdose deaths in 2022. Illicit fentanyl is relatively easy to access because of its low cost to produce and is also being mixed in the drug supply with other drugs, such as heroin, cocaine, and methamphetamine[4].

Xylazine, often called "tranq," is a veterinary tranquilizer that can be life-threatening, especially when combined with opioids. It is known to people who use drugs to extend the effects of opioids, and it is increasingly found in other substances like cocaine and methamphetamine. Its presence is also prevalent in Pennsylvania's MDAIR cases. The Biden-Harris Administration has declared fentanyl adulterated, or mixed, with xylazine as an emerging threat to the United States because of fatal overdoses, negative health consequences, and the interference it has in the reversal of opioid overdoses with naloxone and ability to save lives. Between 2020 and 2021, xylazine-positive overdose deaths increased by 1,127% in the south, 750% in the west, more than 500% in the Midwest, and more than 100% in the northeast[5]. Pennsylvania's Department of Health issued an order that went into effect on June 3, 2023, temporarily scheduling Xylazine as a Schedule III Controlled Substance while proceedings to permanently add it to Pennsylvania's Controlled Substance, Drug, Device, and Cosmetic Act are underway[6].

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[3] Provisional Data Shows U.S. Drug Overdose Deaths Top 100,000 in 2022 | Blogs | CDC

[4] Fentanyl DrugFacts | National Institute on Drug Abuse (NIDA) (nih.gov)

[5] Biden-Harris Administration Designates Fentanyl Combined with Xylazine as an Emerging Threat to the United States | ONDCP | The White House

[6] Pennsylvania Bulletin (pacodeandbulletin.gov)

MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER (MOUD)

Research shows the combination of medication and therapy can successfully treat substance use disorders. For many, medications are a necessary part of sustained recovery. MOUD are also used to prevent or reduce opioid overdose. The goal for individuals is a full recovery, including the ability to live a self-directed life. Medications as a component to treatment and recovery are shown to increase retention in treatment, reduce deaths, decrease illicit substance use and other criminal activity among people who drugs, increase one's employability, and improve birth outcomes among women with opioid use disorders that are pregnant[7]. Length of service varies with all forms of MOUD, depending on the severity of the individual's illness and their response to treatment. Some patients will receive services indefinitely or even a lifetime.

METHADONE

Methadone is a long-acting full opioid agonist, schedule II-controlled medication, used to treat opioid use disorder (OUD). The benefits of methadone are it reduces opioid craving and withdrawal and dulls or blocks the effects of opioids. In Pennsylvania, methadone must be dispensed at a Narcotic Treatment Program (NTP) and closely monitored. NTP's are licensed in Pennsylvania for outpatient, partial, or residential activities. After certain criteria are met, and depending on the stability of a patient, many patients may be given take-home doses between visits (See Proposal to update 42 CFR Part 8). Figure 1 illustrates the availability of NTP's throughout Pennsylvania and the associated geographic challenges.

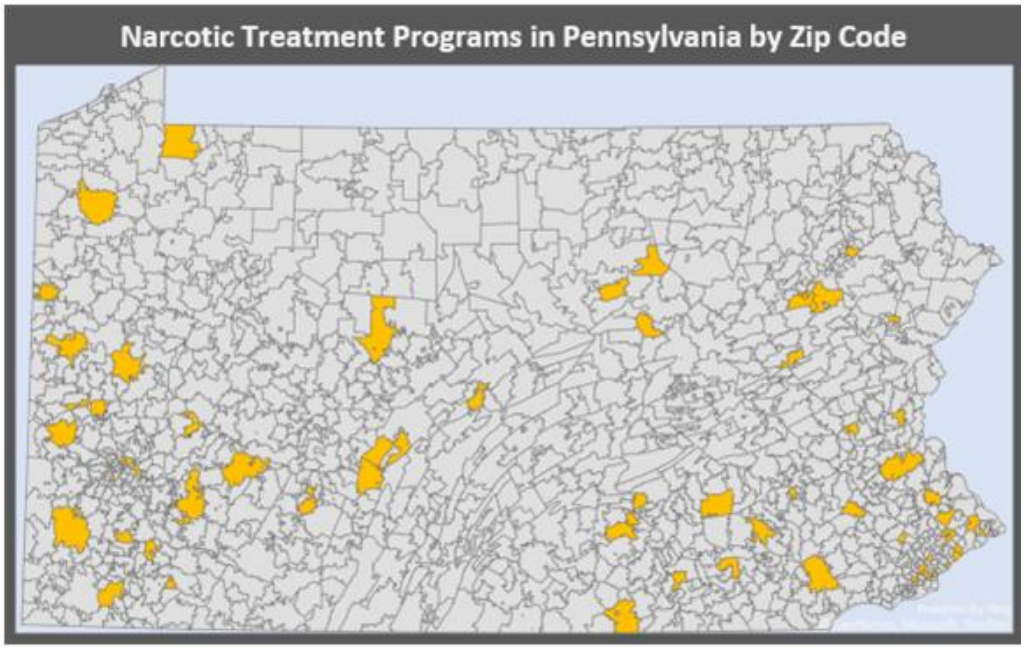

FIGURE 1 NARCOTIC TREATMENT PROGRAMS IN PENNSYLVANIA BY ZIP CODE

[7] Medications for Substance Use Disorders | SAMHSA

BUPRENORPHINE

Buprenorphine is a partial agonist medication, producing euphoric effects and depressing respiration, but not as strong as its MOUD counterpart methadone. Buprenorphine is the first MOUD prescribed or dispensed within a physician's office, considerably increasing access to OUD treatment. Substance use disorder (SUD) programs in Pennsylvania that utilize buprenorphine products either have an "Other Chemotherapy" designation on their license or it uses a prescriber with appropriate DEA registration. Section 1262 of the Consolidated Appropriations Act, 2023 (also known as the Omnibus Bill) removed the waiver requirement to prescribe schedule III, IV, or V medications, like buprenorphine, in the treatment of Opioid Use Disorder (OUD) outside of a NTP setting (see Elimination of the X-Waiver below). Access to OUD treatment with buprenorphine has considerably expanded with the Covid-19 Public Health Emergency (PHE) flexibilities and the proposal to update 42 CFR Part 8 (see below).

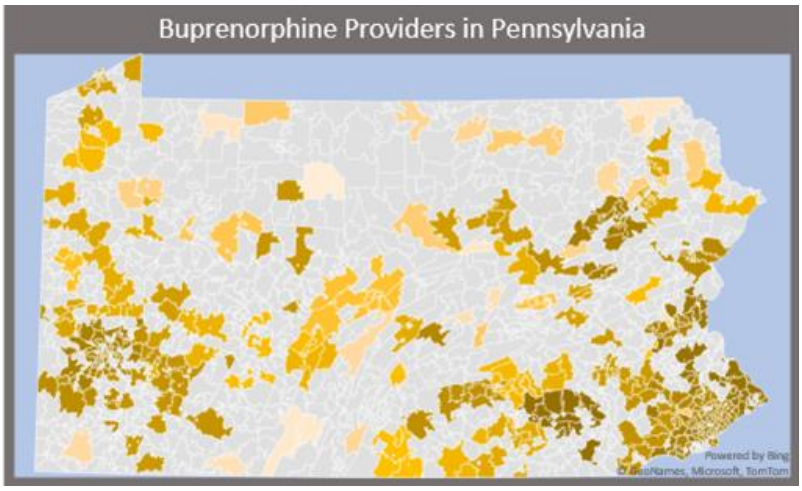

FIGURE 2 REGISTERED BUPRENORPHINE PRESCRIBERS.

NALTREXONE

Naltrexone is an opioid antagonist; it is not an opioid, nor is it addictive, and it does not cause withdrawal symptoms when use is stopped. It works by blocking the euphoric and depressed respiration effects of opioids and suppresses opioid cravings. The extended-release injectable formulation is approved for the treatment of OUD. Unlike methadone and buprenorphine, naltrexone is not a federally scheduled controlled substance, and clinicians do not need to be registered with the DEA to prescribe naltrexone. Patients must be abstinent from opioids for 7-10 days before starting naltrexone, an identified limitation. One study reported patient and provider-identified barriers related to naltrexone because of the necessity to be abstinent from opioids; [8]patients were not ready to stop all opioids as a primary barrier to starting naltrexone as well as other concerns about the inability to manage cravings and manage withdrawal symptoms.

[8] Barriers and Facilitators to the Use of Medications for Opioid Use Disorder: a Rapid Review - PMC (nih.gov)

NATIONAL DEMOGRAPHICS

In the United States, drug overdose death rates increased for each race and Hispanic-origin groups except for non-Hispanic Asian individuals between 2020 and 2021[9]. Non-Hispanic American Indian or Alaska Native individuals had the highest drug overdose death rates in both 2020 and 2021 (42.5 per 100,000 and 56.6, respectively) followed by non-Hispanic Black individuals (35.8 and 44.2, respectively). Data taken from death certificates from the US National Center for Health Statistics between 2007 and 2019 indicate a sharp increase in deaths involving opioids mixed with cocaine and methamphetamine and other stimulants among non-Hispanic Black and Hispanic populations. Cocaine-opioid deaths increased 575% among Black people versus 184% in White people, and methamphetamine and other stimulant-opioid deaths increased 16,200% in Black people versus 3,200% in White people. Black Americans were especially affected in the eastern states, including Pennsylvania[10]. More information regarding cocaine-related deaths will be discussed in the Results and Findings section portion of this report.

NEW AND PROPOSED LEGISLATION

ELIMINATION OF THE X-WAIVER

New legislation opens opportunities for approximately 1.9 million practitioners across the country to provide treatment for those in need of opioid use disorder (OUD) services[11]. Section 1262 of the Consolidated Appropriations Act, 2023 (also known as the Omnibus Bill) removed the waiver requirement to prescribe buprenorphine for the treatment of Opioid Use Disorder (OUD). Practitioners that are registered with the Drug Enforcement Administration (DEA) with a Schedule III authority, may now prescribe buprenorphine if permitted by applicable state law without submitting a waiver (X-waiver). Other federal requirements lifted because of the removal of the waiver include certain discipline restrictions, patient limits, and certification related to provision of counseling.

Additionally, section 1263 of the Consolidated Appropriations Act of 2023, instituted education requirements for all DEA registrants. Starting June 27, 2023, except veterinarians, new or renewing DEA registrants must have at least one of the following as part of their registration:

1. 8 hours of training on opioid or other substance use disorders for renewal or newly applying for a registration to prescribe any Schedule II-V medications;
2. Board certification in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, American Board of Addiction Medication, or the American Osteopathic Association; or

[9] Products - Data Briefs - Number 457 - December 2022 (cdc.gov)

[10] Racial/Ethnic and Geographic Trends in Combined Stimulant/Opioid Overdoses, 2007–2019 - PMC (nih.gov)

[11] Waiver Elimination (MAT Act) | SAMHSA

3. Graduation within five years and status in good standing from medical, advanced practice nursing, or physician assistant school in the United States that included successful completion of an opioid or other substance use disorder curriculum of at least eight hours.

As of this report, The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the DEA were collaborating on the implementation of these changes and working to educate practitioners and the public on what these changes mean and how they will affect them. Educational outreach materials from the two federal agencies are available on the SAMHSA website. SAMHSA will continue to upload additional information and material as it becomes available.

PROPOSED UPDATE TO 42 CFR PART 8

In December 2022, SAMHSA proposed updates to 42 CFR Part 8[12]. A significant part of the proposal is to make the flexibilities under the Covid-19 Public Health Emergency (PHE) permanent. These flexibilities would allow for up to a 28-day of take-home supply of methadone for stable patients and up to a 14-day take-home supply for patients deemed less-than-stable. Initially, the intention of the take-home flexibility was to allow for safe distancing protocols and to reduce the spread of COVID-19. Prior to the PHE, take home privileges were mainly associated with the time patients were in treatment and the absence of positive urine-drug screens, client stability, and provider/physician discretion. Since the flexibilities, SAMHSA reports across the treatment system, patients report feeling respected, and the autonomy allows providers to give more individualized care. A recent survey also found that diversion is low among patients receiving take home doses under the PHE flexibility. Most decedents from the MDAIR cases were not eligible for take-home privileges; however, most were still given a Sunday take-home dose because many programs receive a licensing regulation exception for Sunday and holiday closure.

Pulling from the evidence during the PHE, the proposed rule change includes flexibilities for telehealth for initiation of buprenorphine and encouraging the use of electronic prescriptions.

ACT 30 OF 2022

Under Act 30, DDAP's regulatory suspensions related to the Federal PHE were extended until the last day of the federal exemptions. Pennsylvania suspended regulation 28 Pa. Code § 715.16(e) (prohibiting Narcotic Treatment Programs [NTPs] from permitting a patient to receive more than a two-week take-home supply)[13].

FENTANYL AND XYLAZINE TEST STRIPS

The Pennsylvania Legislature passed Act 111 of 2022. Act 111 of 2022 amended the Controlled Substance, Drug, Device and Cosmetic Act of 1972 to specify products used to identify if a controlled substance contains "chemicals, toxic substances or hazardous compounds in quantities which can cause physical harm or death" is not included in the definition of a "testing product," as mentioned in

[12] Federal Register: Medications for the Treatment of Opioid Use Disorder

[13] 2022 Act 30 - PA General Assembly (state.pa.us)

Section 2(b)(4).[14] This change included, but was not limited to, fentanyl test strips. Additionally, the Test Strip Access Act of 2023[15] has been introduced to the United State House of Representatives in June 2023. This act, if passed, would amend the 21st Century Cures Act to federally allow the use of fentanyl and xylazine test strips.

PROVIDER EXPERIENCES ABOUT RELAXED TAKE-HOME METHADONE

Sparked by the COVID-19 Pandemic PHE and SAMHSA's subsequent proposal to relax federal guidelines for take-home methadone, researchers conducted a qualitative systematic review of providers' experiences with the increased flexibilities[16]. The results were based on a review of 2,518 records across 13 articles, representing 11 studies. According to the review, more than 72,000 people died of opioid-related overdoses in the United States during the first year of the pandemic (March 2020-Febraury 2021), an increase of more than 20,000 deaths from the year before (March 2019-February 2020). Enrollment in methadone treatment is affected because of the daily onsite dosing and the associated stigma. The COVID-19 pandemic and the required physical distancing triggered drastic flexibilities of onsite dosing. Providers were given the authority to use more clinical judgment pertaining to methadone take-homes for patients that meet the criteria for stable or less-than-stable status.

The flexibilities reduce the burden for patients and allows them to take more of a role in decisions around their take-home privileges. According to the review, providers were initially concerned about the safety of patients and potential diversion of the medication, and many providers expressed discomfort with providing additional take-homes. One study suggested a "culture of conservative dosing" that adds to the caution in increased take-homes. Some providers reported suspicion of misuse while others did not see any evidence of misuse, increased overdoses, or adverse change in treatment retention. Some providers described how they kept misuse under control by removing take-home privileges for those patients and providing more supervision. Overall, providers appreciate the autonomy and expressed the ability to provide care that is more tailored to the needs of each patient. Many providers reported the ability to provide better care under the increased flexibilities. Some providers chose to participate in the increased flexibility but, according to the review, there is inconsistent implementation of the flexibilities. One study reported some programs not making any changes to the take-home dosing, and others went back to pre-pandemic protocols once the pandemic started to slow down. Finally, the authors acknowledged client experiences are also an important factor to examine and report a separate review will be conducted on patient experiences.

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[14] 2022 Act 111 - PA General Assembly (state.pa.us)

[15] Text - H.R.4106 - 118th Congress (2023-2024): Test Strip Access Act of 2023 | Congress.gov | Library of Congress

[16] Provider experiences with relaxing restrictions on take-home medications for opioid use disorder during the COVID-19 pandemic: A qualitative systematic review - PMC (nih.gov)

MDAIR LEGISLATION, PROCESSES, AND RESOURCES

The MDAIR Team, established as part of the MDAIR Act, was established to review and examine the circumstances surrounding MOUD-related deaths and incidents in Pennsylvania. Its purpose is to promote safety, reduce MOUD-related deaths and incidents, and improve treatment practices. The MDAIR Team consists of the following representatives:

1. Secretary of DDAP or a designee, serves as chairperson.
2. Director of the Bureau of Administrative Support/Quality Improvement discretionary for Licensing and County Program Oversight (Director of the Bureau of Drug and Alcohol Programs as per legislation).
3. The following individuals appointed by the secretary:
    i. A representative from an opioid-assisted treatment program.
    ii. A representative from a licensed drug and alcohol addiction treatment program that is not defined as an opioid assisted 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.
    ix. A representative from a recovery organization.
    x. An office-based agonist treatment provider.
    xi. A representative of the Department of Health who is affiliated with the Achieving Better Care by Monitoring All Prescription Programs.
    xii. A toxicologist.

Members of the MDAIR team meet at designated times throughout the year to review cases where MOUD was involved in deaths and incidents and work on recommendations for best practices to prevent future MOUD-related deaths. The cases reviewed by the MDAIR Team are prepared in advance by DDAP's Quality Improvement (QI) Section staff.

The MDAIR Team is tasked with the following:

1. Review each medication-related death where a medication approved by the United States Food and Drug Administration for the treatment of opioid use disorder was either the primary or a secondary cause of death and review medication-related incidents.

2. Determine the role that a medication approved by the United States Food and Drug Administration for the treatment of opioid use disorder played in each death and medication-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 medication-related deaths and 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 medication-related deaths and 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 opiate treatment).
6. Develop a form for the submission of medication-related deaths and 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 medication-related deaths to the team. The team and the Statewide association representing county coroners and medical examiners shall collaborate to ensure that all medication-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 the most complete collection of medication-related death and incident 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 Health and Human Services Committee of the Senate, 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 medication-related deaths and incidents.
    ii. Provide aggregate data on five-year trends on medication related deaths and incidents when such is available.

iii. Make recommendations to prevent future medication-related deaths, incidents, and abuse and set forth the department's plan for implementing the recommendations.
iv. Recommend changes to statues and regulations to decrease medication-related deaths and incidents.
v. Provide a report on medication-related deaths and incidents and concerns regarding opioid-assisted treatment programs.

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

The MDAIR Team utilizes the services and expertise of DDAP's QI Staff to fulfill many of its requirements. The QI staff developed a process in collaboration with the MDAIR Team to review and examine MOUD-related deaths and incidents. QI staff have incorporated the following duties as part of their day-to-day tasks to assist in fulfilling the MDAIR Team's legislative obligation:

1. Review reports from various reporting mechanisms for deaths or incidents where MOUD is potentially the primary, secondary, or contributing factor to a death or incident. Reporting mechanisms include, but are not necessarily limited to, Coroner death reports, Incident Reports received by DDAP's Bureau of Licensing, Methadone Death/Incident Case Review Forms filed by Narcotic Treatment Programs, and reports filed by members of the public.
2. Attempt to locate the source of MOUD involved in deaths and incidents.
3. Review applicable documents such as death and birth certificates, law enforcement records when such reviews do not jeopardize ongoing criminal investigations, medical records, opioid-assisted treatment records, children and youth records, records from emergency personnel, traffic fatality reports, and any additional records necessary to conduct the review.
4. Conduct interviews with applicable parties, such as treatment program staff, physicians, coroners, and law enforcement officials.
5. Identify emerging threats and track trends and patterns from the data collected.
6. Document and maintain information associated with each case on the MDAIR Incident/Death Report-Action Form.
    i. Present cases to the MDAIR Team for further review. Cases not presented for direct review by the MDAIR Team are closed, and the notable trends and patterns from those cases are extracted and presented as an overview to the MDAIR Team during MDAIR meetings.
7. Maintain all records that contain personal identifying information (PII) on a designated secure drive, in accordance with 42CFR §2.16.
8. Plan and facilitate MDAIR Meetings.
9. Facilitate logistical tasks to stay on track with action items.
10. Document, track, and follow through with MDAIR Team recommendations.
11. Maintain applicable information on DDAP's Internet Website.

12. Prepare the Annual Report and submit to the MDAIR Team for approval.
13. MDAIR Team Recommendations are documented and DDAP QI staff ensure action items are completed. Action items include, but are not limited to, correspondence to the public or SUD treatment field, development of trainings, licensing alerts, or recommendations for future legislation or regulatory change.

CONFIDENTIALITY OF MDAIR RECORDS

DDAP takes every precaution to ensure all PII is protected against unauthorized use and reasonably anticipated threats or hazards and makes every effort to de-identify all PII prior to presenting cases to the MDAIR Team. In accordance with 42CFR §2.16, DDAP established a Security of Records Policy for the handling, storage, and retention of all records that contain PII. Further, all MDAIR Team members, discretionary members, and DDAP staff participating in MDAIR meetings have signed a confidentiality agreement, agreeing to the confidentiality of any case review and all information pertaining to the name of the deceased individual, guardians, family members or alleged or suspected perpetrators of abuse, neglect, or a criminal act, related to the death or adverse incidents.

NEW MDAIR ELECTRONIC AND FILLABLE FORMS

In May 2023, the MDAIR Team approved a new electronic form created by DDAP's QI staff, for coroners and medical examiners to report MOUD-related deaths, and a separate form for the public, programs, and providers to report MOUD-related deaths and incidents. Along with the respective forms, DDAP QI staff created MDAIR Reporting Helpful tips (pa.gov)for completing the public form. QI staff collaborated with the MDAIR Team to reach out to coroners and medical examiners and requested they begin reporting deaths involving MOUD through the electronic format. The intent for the electronic format was to include information not on the original form and to add naltrexone and buprenorphine as an option for the cause or contributing factor to the death. The electronic form is submitted directly from a link on DDAP's MDAIR webpage. The information is then populated onto an internal spreadsheet, and DDAP QI staff can pull data as needed in real time. DDAP's QI staff also created new fillable forms for parties that may have trouble with the electronic filing; links are posted on the MDAIR webpage, and the fillable forms can be e-mailed to the MDAIR Overdose e-mail account at RA-DAOD@pa.gov. In addition, any party that does not have access to a computer or has trouble with filing a MOUD-related death or incident report can telephone DDAP at 717-783-8200 and ask for a MDAIR form to be printed and mailed to them.

The new electronic filing format has already reduced the number of non-MOUD-related overdose reports that come into the QI section. Previously, DDAP received more than 1,460 coroner death reports between July 1, 2022 and June 30, 2023, many of which did not meet provisional criteria for MDAIR investigation because MOUD was not a primary, secondary, or contributing factor in the death. In June of 2023, the first full month of utilizing the electronic filing, the number of non-MOUD death reports that came into the RA-DAOD account was 22, compared to 71 in June of 2022. The number of non-MOUD death reports are expected to continue to decrease as more coroners utilize the electronic format.

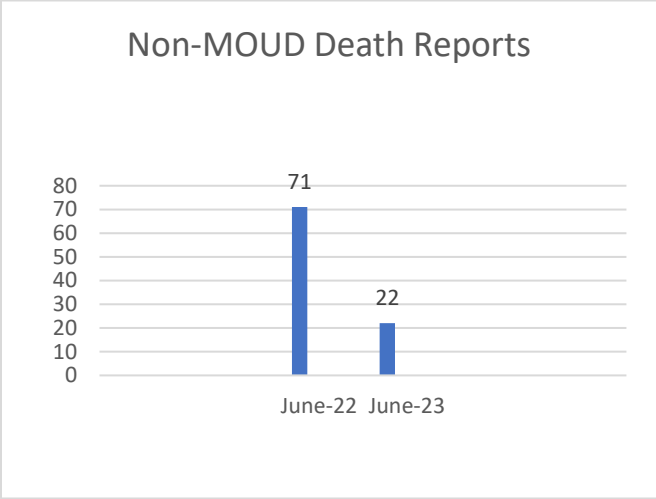

FIGURE 3 COMPARISON OF NON-MOUD REPORTS RECEIVED BEFORE AND AFTER ELECTRONIC FORM.

RESULTS AND FINDINGS

Between July 1, 2022, and June 30, 2023, 219 cases were received that provisionally met MDAIR criteria. 212 cases were by way of coroner death reports representing 26 counties. 7 cases were Unusual Incident Reports referred to the QI Section by DDAP's Bureau of Licensing. Figure 4 reflects the counties in which MOUD-related death reports were received.

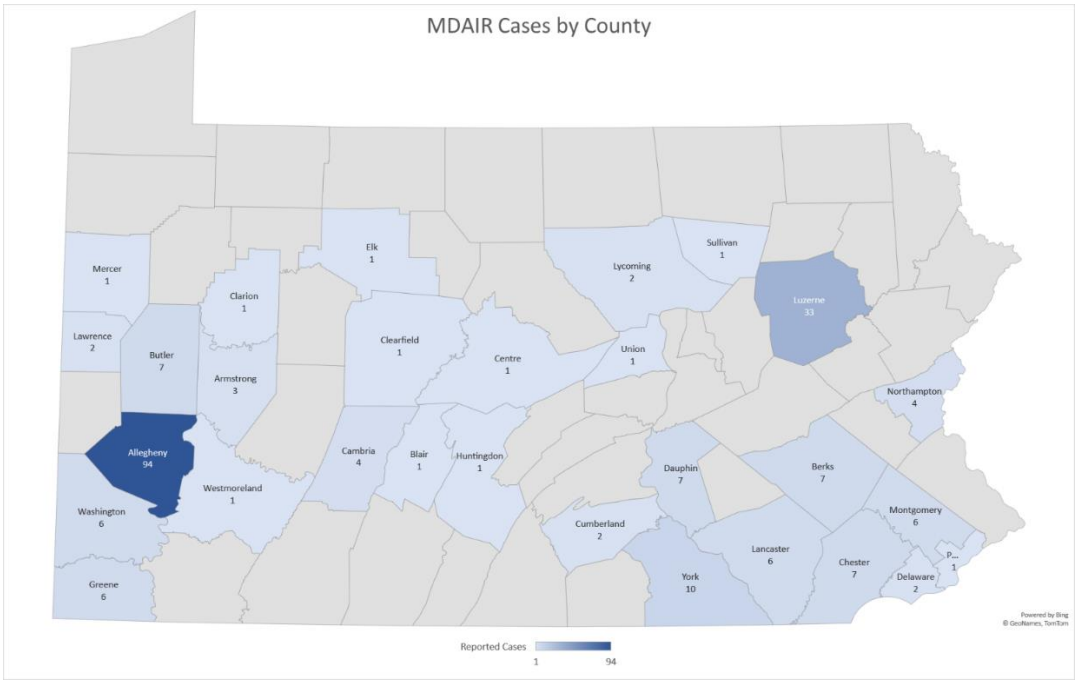

FIGURE 3 MAP OF PENNSYLVANIA SHOWING COUNTIES WITH MOUD DEATH REPORTS – PHILADELPHIA IS INDICATED BY A "P" WITH 1 U/I REPORT.

DDAP received Coroner reports from 26 counties or 39% of the 67 counties in Pennsylvania.

Allegheny	94* (1 UI)	**Cambria**	4	**Cumberland**	2
Armstrong	3	**Centre**	1	**Dauphin**	7
Berks	7	**Chester**	7	**Delaware**	2
Blair	1	**Clarion**	1	**Elk**	1
Butler	7	**Clearfield**	1	**Greene**	6
Huntingdon	1	**Mercer**	1* (1 UI)	**Union**	1
Lancaster	6* (1 UI)	**Montgomery**	6* (1 UI)	**Washington**	6* (1 UI)
Lawrence	2	**Northampton**	4	**Westmoreland**	1* (1 UI)
Luzerne	33	**Philadelphia**	1* (1 UI)	**York**	10
Lycoming	2	**Sullivan**	1		
*** Number includes Unusual Incident Report**					

FIGURE 4 NUMBER OF MOUD DEATH REPORTS RECEIVED BY COUNTY.

DEMOGRAPHICS

Demographic information is limited to the cases submitted for 29 of the 67 counties; 2 cases did not include age or sex. The MDAIR Team and QI staff will continue to engage stakeholders to increase the number of counties reporting MOUD deaths. The data received indicates most overdose deaths are among Caucasian or White males between the ages of 35 and 44. The national demographic data mentioned earlier in this report may be more representative of the overdose demographics in Pennsylvania, because it includes more populous areas.

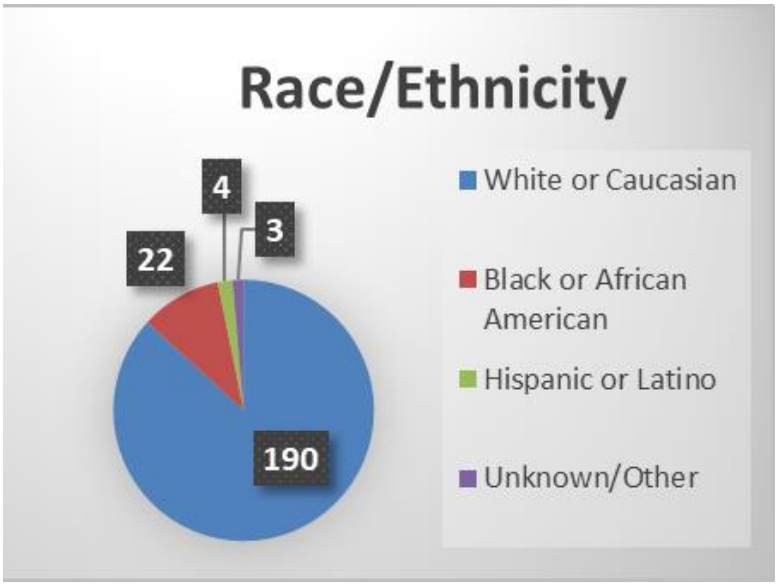

FIGURE 6 RACE AND ETHNIC IDENTITIES OF DECEDENTS.

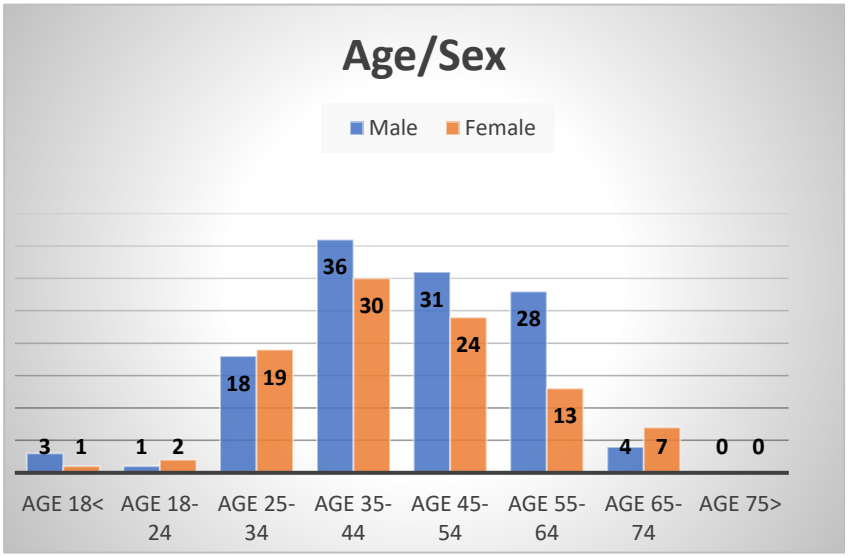

FIGURE 7 AGE AND SEX OF DECEDENTS

ANALYZATION OF SUBSTANCES

219 cases received provisionally met MDAIR criteria for further investigation. 111 cases involved buprenorphine, 103 cases involved methadone, 2 cases involved buprenorphine and methadone. Although 3 cases contained naltrexone, after further analysis, substances in the toxicology reports in addition to the naltrexone are believed to be the cause of death, and naltrexone is not believed to be a factor in those 3 deaths. DDAP continues to reach out to coroners to educate them about what cases meet MDAIR criteria. Cases containing the combination of fentanyl and buprenorphine are counted in the statistical information and then closed by DDAP's QI staff. This process was developed with the guidance of DDAP's former medical director while considering available resources and the comparison of buprenorphine and fentanyl, fentanyl would be the more likely cause of death in these cases.

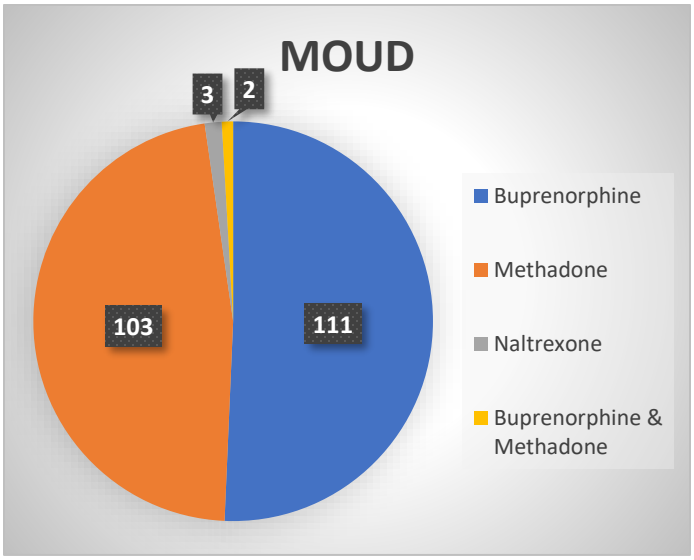

FIGURE 8 CASES MEETING MDAIR CRITERIA FOR FURTHER REVIEW

MOUD PRIMARY CAUSE OF DEATH

MOUD was the only substance present in 11 cases. Interviews were conducted for 3 of those cases; 1 case was also a suicide; 1 case was from a facility that is now closed, and additional information was not obtained; the source of the MOUD could not be located for 5 cases, and 2 cases are still pending.

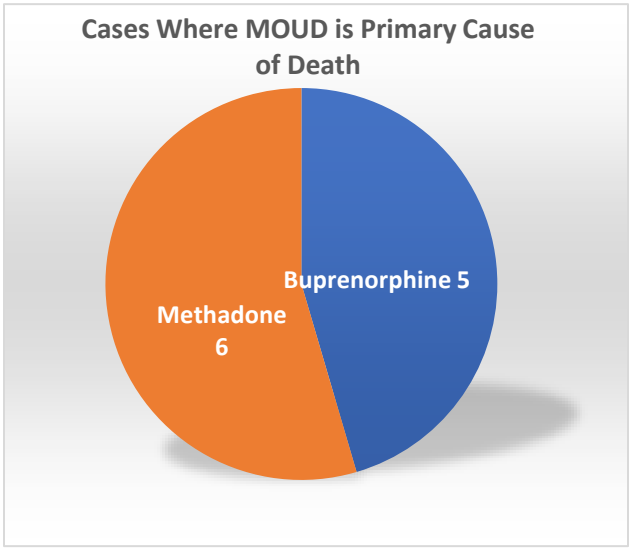

FIGURE 9 CASES WHERE MOUD IS PRIMARY CAUSE OF DEATH

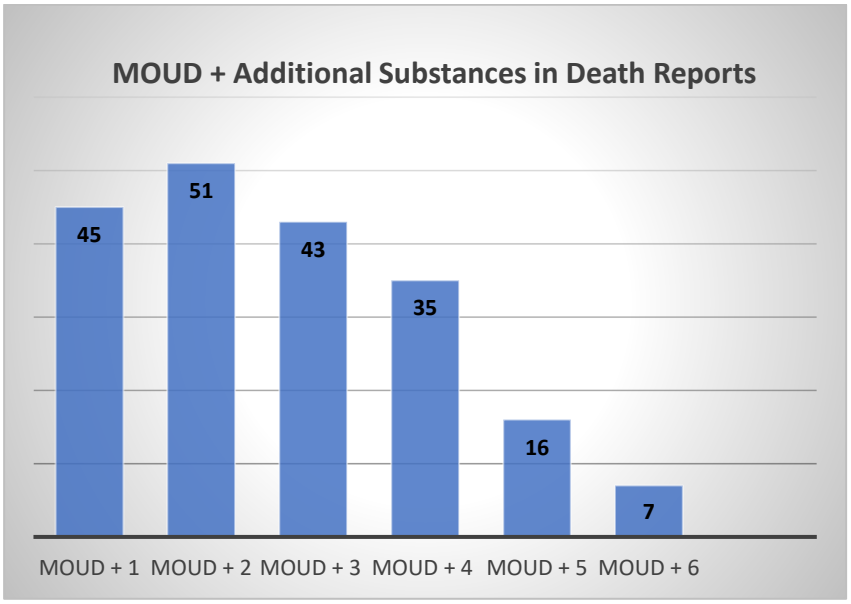

FIGURE 10 ADDITIONAL SUBSTANCES IN DEATH REPORTS FOUND IN CONJUNCTION WITH MOUD

Additional substances were present and contributed to the death in the remaining 208 or 95% of cases.

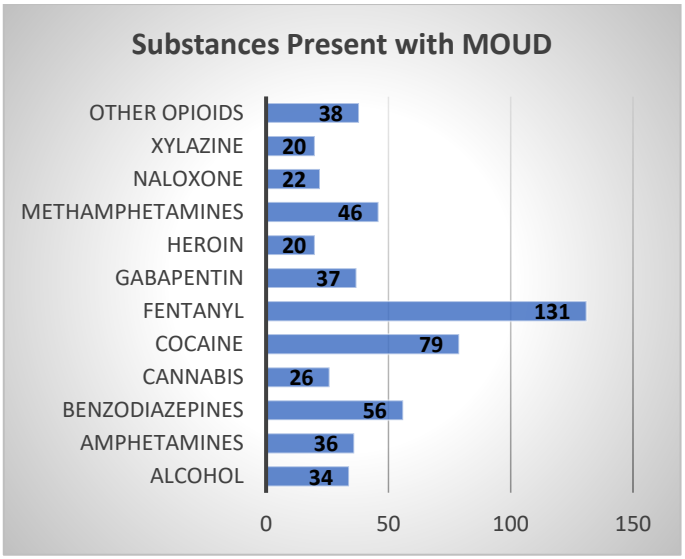

FIGURE 11 ADDITIONAL SUBSTANCES ALONG WITH MOUD CONTRIBUTING TO DEATH

ANALYZATION OF SUBSTANCES (CONT'D)

As fentanyl continues to be an increasing presence among MDAIR cases, the presence of heroin is on a downward trend; Xylazine is also a growing concern. Fentanyl was found in 131 or 60% of all MDAIR cases

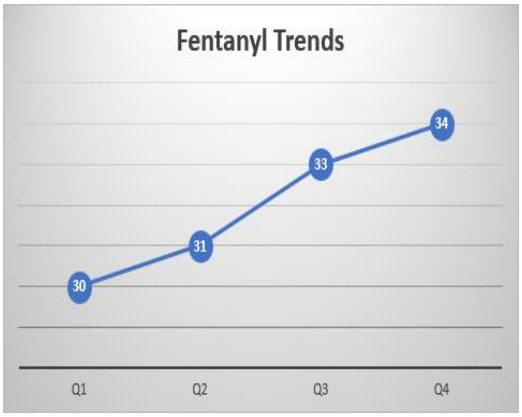

Figure 12 Fentanyl Trends for 2022-23

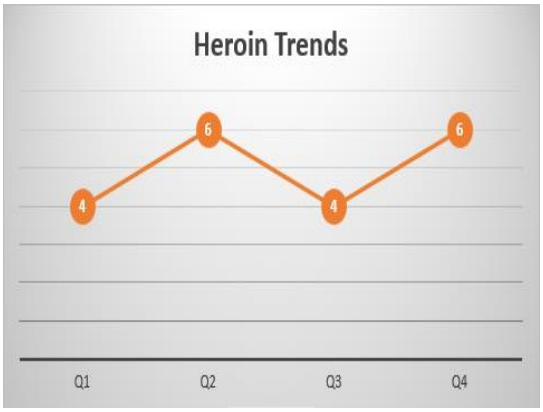

Figure 13 Heroin Trends for 2022-23

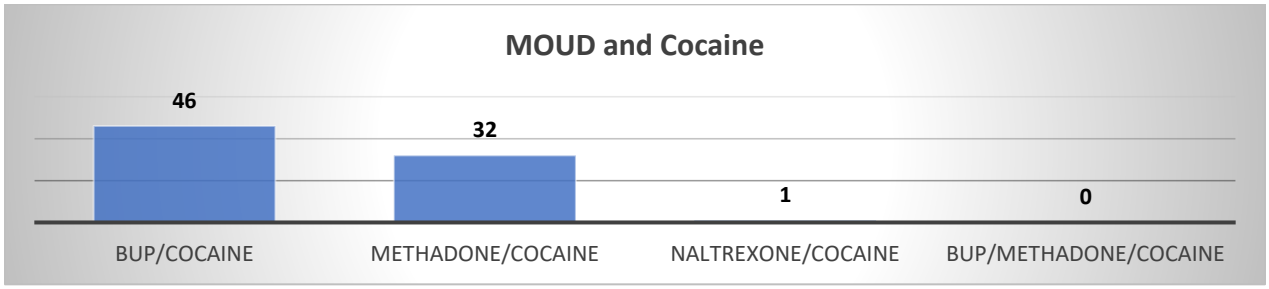

FIGURE 14 CASES WITH COCAINE

Figure 16 shows the increase in Xylazine over the course of the 4 quarters. Figure 17's yellow line demonstrates the total number of cases in each quarter increasing, while the number of cases containing heroin decreases. Xylazine cases are on a slight incline, and fentanyl remains steady.

FIGURE 15 XYLAZINE TRENDS FOR 2022-23

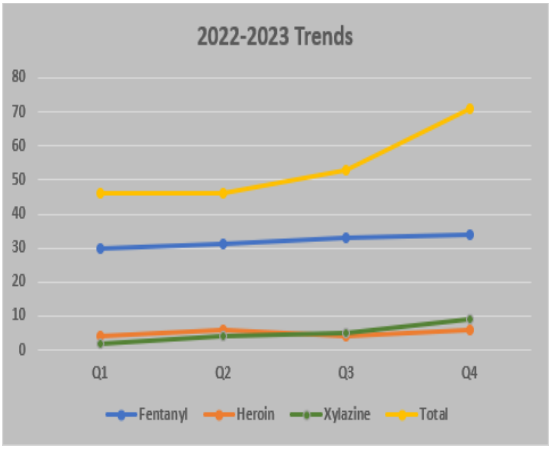

FIGURE 16 2022-23 TREND TOTALS

INTERVIEWS CONDUCTED

DDAP's QI staff conducted 51 interviews. 43 interviews were with NTP providers, 5 interviews were with Office Based Opioid Treatment (OBOT) providers, one pain management doctor, and two primary care physicians. One interview was conducted onsite, the remaining were conducted virtually.

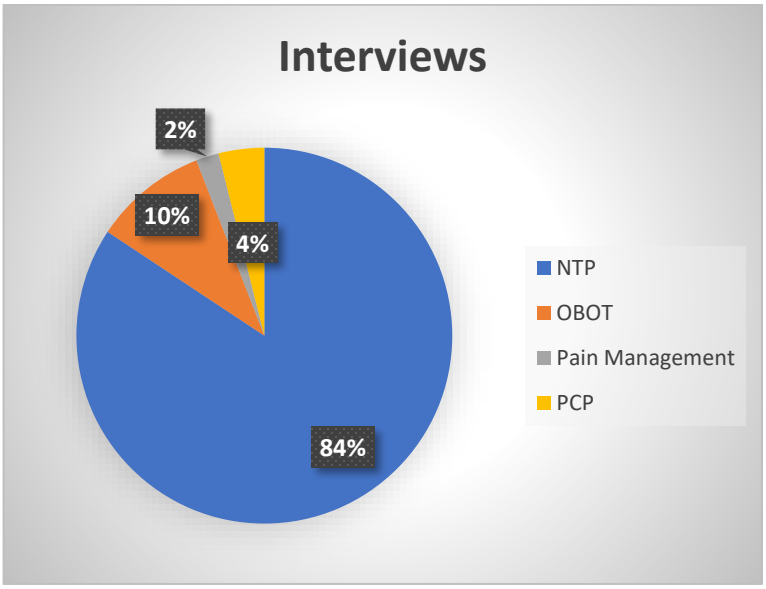

FIGURE 17 TYPE OF INTERVIEW CONDUCTED

IDENTIFIED TRENDS AND BARRIERS

The following trends and barriers were identified from the 51 interviews conducted:

1. Positive UDS: 34 or 67% of decedents had at least 1 positive UDS for illicit substances the month prior to their fatal overdose. Most or all decedents were provided with a Sunday take-home dose of methadone. At the time of this report, fentanyl had not been added to all UDS panels for routine screenings. Some providers tested for fentanyl only if they believed someone was using it.

2. Lack of integrated/coordinated care: Although NTP's have an existing infrastructure to provide ongoing medical care, most of the providers interviewed do not provide services beyond the Chapter 715 regulations. Based on the patient-centered multi-dimensional assessment and the patient's recovery goals, other co-occurring issues, like mental and psychiatric illnesses and conditions, and infectious diseases, were often not addressed.

3. 16 of the 51 or 31% of decedents were not receiving case management or recovery support services, regardless of a Centers of Excellence designation. One provider stated the NTP's purpose is to stabilize patients on methadone, not to treat social determinants of health. It is the MDAIR Team's position however, that in addition to the 715 regulations, Narcotic Treatment Programs should provide services for the activities for which they are licensed and align the services with the ASAM Criteria's 3rd Edition, in accordance with the 1115 Waiver.

4. Transportation continues to present a barrier to patients receiving services.

THE AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM) CRITERIA (3RD EDITION) CHAPTER 715 REGULATIONS

NTP's receive a Certificate of Compliance from DDAP's Division of Licensing. Along with the Certificate of Compliance, providers are licensed for outpatient, partial or residential activities. The majority of NTP's have an outpatient license and follow Chapter 715 regulations. Additionally, in 2017, DDAP began the transition to the ASAM Criteria's 3rd Edition, as required by the Centers for Medicare & Medicaid Services (CMS) in the 1115 waiver application. All service providers should be fully aligned with the ASAM Criteria. NTPs should also be moving in the direction to align with the ASAM Criteria for the level of care for which they are licensed.

RECOMMENDATIONS

The following recommendations were made in earlier reports.

Expand MDAIR to investigate overdose deaths involving all substance, not just MOUD.

Update: Since the initial recommendation, the MDAIR Law has been expanded to include FDA-approved MOUD, including naltrexone and buprenorphine. Interventions beyond Chapter 715 necessary for individuals who demonstrate a need, beyond what is required under the Chapter 715 regulation. Many decedents presented with multiple positive UDS, need for integrated services, transportation barriers, trauma, and other social determinants of health prior to their overdose death. While the focus of the MDAIR Act is MOUD-related deaths, the data show a need for overall improved treatment services within NTP's for those patients in need of additional services. This recommendation will be closed and incorporated into current recommendations that address individuals receiving appropriate service.

DDAP Should prioritize developing relationships with coroners to better understand the roadblocks to reporting MOUD-related deaths. Roughly one-third of Pennsylvania counties submitted overdose reports to DDAP in 2021. For those counties reporting, DDAP has struggled to obtain additional information from coroners beyond the initial overdose death report. When DDAP seeks to gather additional information to better understand the circumstances and the role MOUD played in the death, coroners are often hesitant to release additional information, particularly personal or patient identifying information. DDAP needs to also dialogue with coroners about revising the form currently being used to report overdose deaths to ensure maximum efficiency for reporting of critical data.

Update: DDAP collaborated with the MDAIR Team to create electronic and fillable forms for coroners/medical examiners and the public. DDAP and the MDAIR Team also collaborated to reach out to coroners/medical examiners to provide information about the new reporting format. DDAP's QI staff developed a coroner engagement plan and sent them a letter along with an infographic about the MDAIR process. The MDAIR Team will continue to build and strengthen rapport with coroners.

Partner with other agencies to improve data collection and retrieval of follow up information. DDAP should consider partnering with Department of Health's the Office of Drug Surveillance and Misuse Prevention and Poison Control Centers who are already collecting critical information being sought for the purposes of MDAIR investigations.

Update: DDAP continues to work closely with DOH's Office of Drug Surveillance and Misuse Prevention and Poison Control Centers. A plan to access additional information is pending.

Work with payors to discuss the importance of improving insurance coverage for urine drug screens that test for a variety of substances. Discussions with partners reveal not all substances are included in a urine drug screen due to added cost or lack of insurance coverage.

Update: The MDAIR Team will revisit this recommendation once DDAP discusses this matter internally for potential recommendations.

Gather additional information regarding the safety of a co-prescribing of medications with MOUD. (for example, gabapentin is present in 15% of MDAIR overdose cases)

Update: Gabapentin was present in 37 cases or approximately 17% this reporting period. This medication is not easy to track because it is not a scheduled substance and is not part of the Prescription Drug Monitoring Program (PDMP). The MDAIR Team will investigate this matter and may need to partner with other stakeholders to assist in creating an information sheet or infographic for the medical community, to include medications used in co-prescribing with MOUD.

Recommend and support the implementation of an overdose fatality review (OFRS) in every county across the commonwealth.

Update: House Bill 220 (or Act 101 of 2022) was signed into law on November 3, 2022, authorizing the creation of county suicide or overdose death review teams and outlining the process for establishment of these teams. The first reporting period is calendar year 2023. Counties must submit information to the Department of Health from their OFR's by May 31, 2024. When the reporting information is available, this recommendation will be addressed among the MDAIR Team.

Explore ways to increase access to MOUD Particularly in rural areas of the commonwealth, to reduce overdose deaths. Pennsylvania continues to be a state experiencing vast pockets where MAT is not provided or prescribed. Additional funding opportunities available to the commonwealth coupled with loosened federal requirements tied to the prescribing of MAT provides an opportune time to brainstorm ways to increase access to care in rural areas.

Update: The proposal to update 42 CFR Part 8 to make the flexibilities under the Covid-19 PHE permanent allows for up to 28-days of methadone take-homes for stable patients and up to a 14-day take-home supply of patients deemed less-than-stable. Since the flexibilities, SAMHSA reports increased access across the treatment system, including in rural areas. The flexibilities also allow telehealth for the initiation of buprenorphine, which will also increase access for those in rural areas. Under Act 30, DDAP's regulatory suspensions related to the Federal PHE were extended until the last day of the federal exemptions. Pennsylvania suspended regulation 28 Pa. Code § 715.16(e) (prohibiting Narcotic Treatment Programs [NTPs] from permitting a patient to receive more than a two-week take-home supply.

The elimination of the X-Waiver provides increased access to buprenorphine. All practitioners with Schedule III authority may now prescribe buprenorphine for opioid use disorder in their practice, without submitting a waiver. Other requirements that have been lifted because of the removal of the waiver are certain discipline restrictions, patient limits, and certification related to the provision of counseling.

The lack of transportation is a barrier for many patients on MOUD, especially in rural areas. QI staff now tracks data received pertaining to the lack of transportation. Many facilities are not located directly on a bus route. Facilities that are located on a bus route still report challenges for their patients. Some patients wait up to several hours after their dosing appointment, for the bus to return and take them home.

Through various interviews, QI staff received relevant information regarding how some providers address the transportation barrier. One NTP purchased a van and spends several hours each day transporting patients in rural areas to and from dosing appointments.

This recommendation will be addressed with the MDAIR Team as a transportation prioritization.

Continue to monitor changing guidance for NTPs and buprenorphine initiation at the federal level and update DDAP regulations accordingly. Continue to evaluate the impact of loosened federal requirements tied to the prescribing of MAT on overdose deaths, and champion legislation to make these changes permanent to increase access to care.

Update: The MDAIR Team will continue to monitor MDAIR cases with the relaxation of the federal regulations.

The following are recommendations from the current reporting period:

Integrate/Coordinate and Individualize Care

Services should be delivered in an individualized manner. Patients should continuously be reassessed by their clinical team to ensure the treatment is meeting their needs. Additionally, care that can be integrated for co-occurring conditions, disorders, and morbidities is considered the best practice over sequential care. The MDAIR Team recognizes the integration of care can only occur slowly, over a long period of time. Meanwhile, providers should ensure patients

have a primary care physician (PCP) and, if applicable, a mental health provider, maintain current releases, and correspond with other providers as applicable.
Address stigma as an ongoing initiative. Stigma continues to be subtle, yet pervasive, and often prevents individuals from seeking, getting, and maintaining appropriate services. People living with Opioid Use Disorder (OUD) often have shame within their communities, their families, and within the healthcare system. The MDAIR Team will discuss strategies to address stigma as an ongoing initiative.
Survey NTP's and patients of NTP's. The MDAIR Team is currently developing a survey NTP to get a better understanding of the barriers patients experience from getting services. The Team is working on the logistics with DDAP's QI staff. Based on the results of the survey, the MDAIR Team plans to address recommendations to be included in the next annual report.

The MDAIR Team plans to continue to address action items and develop additional recommendations after the completion of the survey. Meanwhile, the Team will continue its efforts on researching current trends and developing material to educate interested stakeholders about MOUD.

APPENDIX A: APPROVED MEDICATIONS FOR OUD AND PRODUCT

Methadone is a long-acting synthetic opioid agonist that reduces opioid craving and withdrawal and reduces or blocks the effect of opioids.		
FDA-Approved methadone products for the treatment of OUD include:		
Dolophine	methadone hydrochloride	Tablets
Methadose	methadone hydrochloride	Oral concentrate
Buprenorphine is an opioid partial agonist. It works like an opioid but the effect is weaker than full agonists like heroin and methadone. Buprenorphine lowers the effects of opioid withdrawal symptoms and cravings to use opioids without having full opioid potency or effects. This helps people who take the medication abstain from other opioids. Many formulations include buprenorphine and naloxone, an opioid antagonist added to the buprenorphine to reduce the likelihood of an individual injecting or snorting the drug.		
FDA-approved buprenorphine products for the treatment of OUD include:		
Generic	buprenorphine/naloxone	sublingual tables
Brixadi	buprenorphine	injection for subcutaneous use
Bunavail	buprenorphine and naloxone	buccal film
Cassipa	buprenorphine and naloxone	sublingual film
Probuphine	buprenorphine	implant for subdermal administration
Sublocade	buprenorphine extended-release	injection for subcutaneous use
Suboxone	buprenorphine and naloxone	sublingual film for sublingual or buccal use, or sublingual tablet
Subutex	buprenorphine	sublingual tablet
Zubsolv	buprenorphine and naloxone	sublingual tablets
Naltrexone blocks the euphoric and sedative effects of opioids such as heroin, morphine, and codeine. Naltrexone binds and blocks opioid receptors and reduces and suppresses opioid cravings.		
FDA-approved naltrexone products for the treatment of opioid dependence include:		
Vivitrol	naltrexone for extended-release injectable suspension	intramuscular
Source: Information about Medication-Assisted Treatment (MAT) | FDA (current content as of: 5/23/2023)		