Pennsylvania
Department of Drug and Alcohol Programs

Medication Death and Incident Review

Annual Report 2023 – 2024

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Executive Summary

Opioid Use Disorder (OUD) is a chronic, treatable illness that requires ongoing, individualized care for people to recover. Buprenorphine, methadone, and 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 to be more successful at reducing OUD than without the use of medication.[1]

In accordance with Act 126 of 2020[2] the MDAIR Team[3] is responsible for reviewing cases where MOUD was a cause or contributing factor in a death or incident. These reviews help identify trends, evaluate treatment practices, and develop recommendations to reduce future deaths and improve care.

Recent enhancements in data collection methods, such as Pennsylvania's Department of Health (DOH) File Transfer Protocol and data-sharing agreements, have significantly increased the number of cases reviewed, providing a more comprehensive picture of MOUD-related deaths.

Key Findings from SFY 2023-2024 include the following:

- 435 cases were initially received, with 320 cases meeting criteria for further review based on the presence of MOUD at the time of death and the coroner or medical examiner's determination that the medication contributed to the death[4].
- 61% (194) of cases involved methadone
- 38% (121) of cases involved buprenorphine
- Four cases involved both methadone and buprenorphine
- 89% (285) involved at least one additional substance[5]

1 Treatment of opioid use disorder in primary care - PubMed

2 Act 126 of 2020

3 MDAIR Team | Department of Drug and Alcohol Programs | Commonwealth of Pennsylvania

4 Cases met criteria for further review if medication for opioid use disorder was present and the coroner identified it as a contributing factor to the death, in accordance with Act 126 of 2020.

5 Additional substances refer to substances in addition to the MOUD that were detected in toxicology reports and tracked by DDAP's Quality Improvement staff, including, alcohol, benzodiazepines, cannabis, cocaine, fentanyl, gabapentin, heroin, methamphetamine, naloxone, xylazine, and other opioids.

The most frequently detected additional substances were:

- Fentanyl (200 cases)
- Cocaine (115 cases)
- Xylazine (85 cases)
- Benzodiazepines (65 cases)

There were 44 of the 64 decedents (69%) enrolled in narcotic treatment programs (NTPs) that had a positive drug screen within one month prior to death.

Harm reduction practices for people with OUD are vital. This often includes opioid overdose reversal medications such as naloxone. When looking at harm reduction practices of the providers treating the decedents in this report, naloxone distribution practices differed across treatment settings. Among NTP settings, 40% provided naloxone at both admission and upon request, while among Office Based Opioid Treatment (OBOT) providers, 54% only made naloxone available through prescription.

These findings highlight gaps in overdose prevention strategies, particularly in assessing and mitigating risk among individuals receiving MOUD who continue to use additional substances. Balancing harm reduction approaches with clinical interventions remains a key challenge in improving safety and treatment outcomes for people with OUD and their treating providers.

This report provides data-driven recommendations to enhance treatment practices, strengthen harm reduction efforts, and reduce systemic barriers to care for individuals receiving MOUD in Pennsylvania. These recommendations focus on the following:

- Expand harm reduction strategies across opioid treatment services
- Promote contingency management for stimulant use disorders
- Reinforce cautious methadone take-home practices
- Support individualized care planning
- Educate providers on developing and implementing educational groups focused on medications for individuals receiving services

Introduction

The MDAIR Team is statutorily required under Act 126 of 2020 to review deaths and incidents involving FDA-approved MOUD, including buprenorphine, methadone, and naltrexone. The goal of these reviews is to identify trends, assess treatment practices, and develop recommendations to improve safety among individuals receiving MOUD, as well as reduce overdose deaths.

The MDAIR Team conducted case reviews each quarter of state fiscal year (SFY) 2023-2024 from information gathered from various sources, including:

- The Pennsylvania Department of Health
- County coroners and medical examiners
- The Philadelphia Medical Examiner's Office

Recent improvements in data collection methods, such as enhanced file transfer protocols and data sharing agreements, have expanded the number of cases reviewed, allowing for a more comprehensive understanding of MOUD-related deaths and incidents.

This report presents:

- An analysis of MOUD-related deaths, including toxicology findings and treatment histories
- A review of drug trends among decedents receiving MOUD, including the presence of fentanyl, cocaine, xylazine, and benzodiazepines
- Findings from provider interviews, examining treatment practices, care coordination, harm reduction efforts, and overdose prevention strategies
- Policy recommendations to enhance treatment outcomes and reduce the risk of MOUD-related deaths and incidents in Pennsylvania

By examining these cases and provider practices, the MDAIR Team seeks to inform policy, strengthen clinical interventions, and support harm reduction strategies to improve care for individuals receiving MOUD.

Medications For Opioid Use Disorder (MOUD)

Buprenorphine[6], methadone[7], and naltrexone[8] are FDA-approved medications to treat OUD. Research shows that these medications are effective in reducing opioid use, lowering the risk of overdose death, improving treatment retention, supporting employment stability, and enhancing birth outcomes for pregnant individuals with OUD [9] [10] [11]when combined with behavior therapies and counseling, these medications can successfully treat OUD. Including medications as part of treatment and recovery has been demonstrated to improve retention in treatment, reduce overdose deaths, enhance employability, improve birth outcomes for pregnant women with OUD, and reduce the negative effects of active addiction.

METHADONE/NARCOTIC TREATMENT PROGRAMS/OPIOID TREATMENT PROGRAMS (NTPS/OTPS)

When OUD is the primary diagnosis and is treated with methadone, the medication can only be dispensed from a program that is both state licensed and federally certified. In Pennsylvania, these facilities are referred to as narcotic treatment programs (NTPs), while federal certification uses the term opioid treatment programs (OTPs). For the purposes of this report, the term NTP is used consistently. NTPs are licensed to provide outpatient, partial hospitalization, or residential activities. Based on specific criteria and each person's level of stability, many people are provided with take-home doses of their medication between visits.

OBOT

Section 1262 of the federal Consolidated Appropriations Act, 2023 now allows all practitioners with a current Federal Drug Enforcement Administration registration, including Schedule III authority, to prescribe buprenorphine for OUD. This change encourages practitioners to treat individuals within their own practices. By eliminating the special-waiver requirement that had been in place previously, the policy has expanded access to care, enabling individuals to seek treatment from their primary doctors and reducing barriers to effective OUD management[12].

6 What is Buprenorphine? Side Effects, Uses, Dose & Risk | SAMHSA

7 What is Methadone? Effects, Risks & Addiction | SAMHSA

8 What is Naltrexone? Side Effects, Uses, Dose & Risk | SAMHSA

9 Medications for Substance Use Disorders | SAMHSA

10 Treatment of Opioid Use Disorder Before, During, and After Pregnancy | Opioid Use During Pregnancy | CDC

11 Outcomes associated with the use of medications for opioid use disorder during pregnancy - PMC

12 Waiver Elimination (MAT Act) | SAMHSA

42 CFR PART 8

Making flexibilities initiated by the COVID-19 Public Health Emergency (PHE) permanent and expanding access to care and evidenced-based treatment for OUD, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a final rule amending Part 8 of Title 42 of the Code of Federal Regulations[13], revising several provisions governing NTPs. The revised regulations, which went into effect April 2, 2024, with a compliance date of October 2, 2024, aim to support practitioner autonomy, increase shared decision-making between the practitioner and the individual in services, and reduce barriers to care. Key changes to the final ruling include:

- Updating terminology
- Expanding methadone take-home flexibilities
- Allowing verbal consent to treatment and reducing other barriers to treatment such as one-year documented opioid dependency
- Allowing a wider range of dosages based on physician discretion
- Providing increased access to MOUD for individuals less than 18 years old
- Aligning psychotherapy services and support with each person's unique needs
- Making counseling requirements unique to each person's needs
- Reducing drug testing requirements
- Further defining mobile units and clarifies potential services, interventions, and accreditation processes

DDAP issued Licensing Alert 7-2024 with guidance to providers in Pennsylvania pertaining to some of its Chapter 715 regulations[14].

13 Federal Register :: Medications for the Treatment of Opioid Use Disorder

14 07-2024 42 cfr-part-8-exceptions-licensing-alert.pdf

Limitations

This report and its findings rely on primary source information, including initial death reports from coroners, medical examiners, and information from death certificates. These sources can vary in format, completeness, and quality. Additionally, the data is intended for informational purposes. It is important to note that differences in professional judgement and practices among coroners and medical examiners may result in variations in how the information is reported. Notable limitations include:

- Some coroners and medical examiners may identify cause of death as “mixed drug toxicity”, whereas others may identify specific substances as the cause of death.
- Although DDAP’s QI staff requests toxicology reports associated with these deaths, some coroners and medical examiners do not respond to these inquiries, or the information may not be available.
- Gabapentin and cannabis are not tracked as part of the information received through death certificates.
- Gabapentin may be included as additional information.
- Some coroners and medical examiners include cannabis when reporting directly to DDAP.
- Heroin is reported as “other opioids” on death certificates unless specified as additional information.
- Demographic information listed on death certificates and accompanying information may contain occasional inaccuracies or be incomplete, depending on how the information was collected or reported.
- There is no universally mandated toxicology panel for all cases leading to variability in the substances being tested and reported.

These limitations apply specifically to the death-related data and do not extend to findings based on provider interviews or other contextual information presented later in the report.

Methodology

As part of Act 126 of 2020, the MDAIR Team is responsible for establishing best practices and making recommendations to prevent future MOUD-related deaths and incidents. The MDAIR Team relies on DDAP's Quality Improvement (QI) staff to investigate each reported MOUD-related death or incident. DDAP's QI staff receives reports from county coroners and medical examiners as well as through a collaborative agreement with the PA DOH's Office of Overdose Surveillance and Misuse Prevention. DOH uploads information from all death certificates where MOUD was listed as a cause or contributing factor of death. The information includes the name of the decedent, county of death, decedent's date of birth, date of death, race, cause of death, place of death -- such as residence or home -- and city of death, all of which is reported, if available.

DDAP's QI staff also attempt to locate the source of the MOUD by conducting investigatory reviews, which include interviews with providers, when feasible. These interviews follow a structured format to gather qualitative and quantitative data related to history, treatment access, clinical decision-making, and systemic barriers to care. The data collected includes:

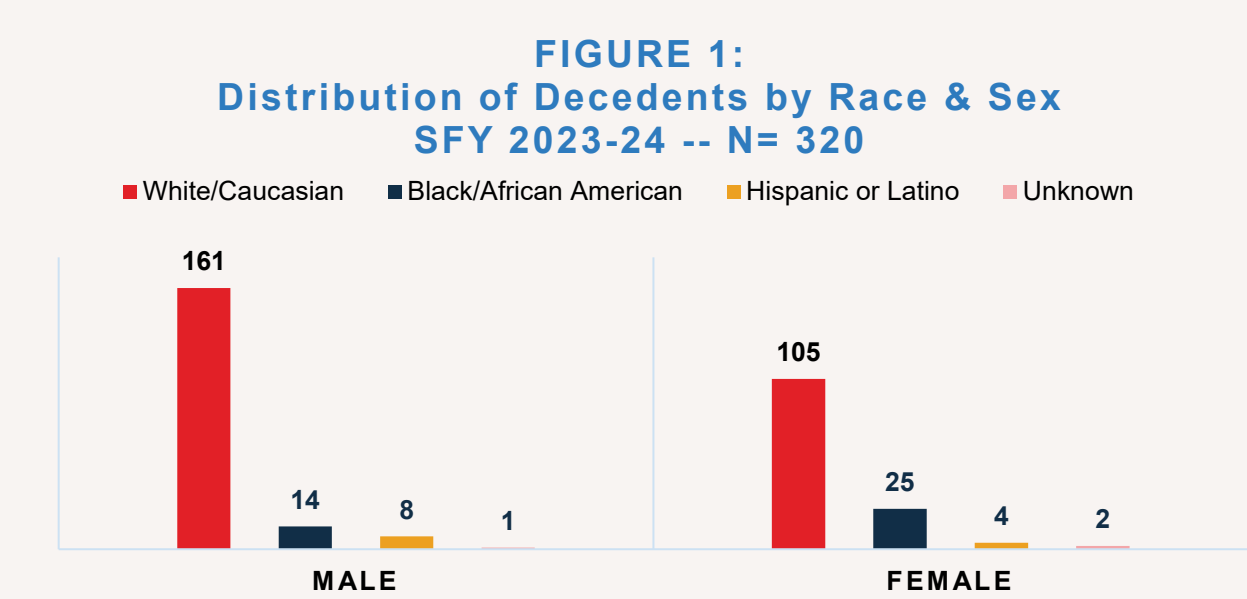
- **Demographic and Admission History:** Date of death, age, gender, county of residence, county of death, date of admission, insurance coverage or funder, and Center of Excellence designation.
- **Treatment and Medication Management:** Medications prescribed, six-month dose history (if available), take-home medication status, availability of split dosing, use of peak and trough testing, and facility closures on weekends.
- **Clinical and Risk Assessments:** Completion of level of care assessments, consideration for higher levels of care, use of motivational interviewing and other evidenced based practices, psychiatric history, medical diagnoses, and concurrent medications.
- **Drug test results and prescription monitoring:** Prescription drug monitoring program (PDMP) report usage and frequency, drug testing results (including substances tested for).
- **Stability and Support:** Overdose history, stability status (as assessed by the provider), housing situation (e.g., living alone), transportation barriers, social support, and whether recovery supports were offered.
- **Coordination of Care:** Releases of information on file, whether communication took place between medical and other providers, extent of coordination between treatment programs and external healthcare or social service providers, and whether case management services were offered.

- **Facility Practices and Provider Reflection:** Use of interdisciplinary teams and provider retrospective analysis.

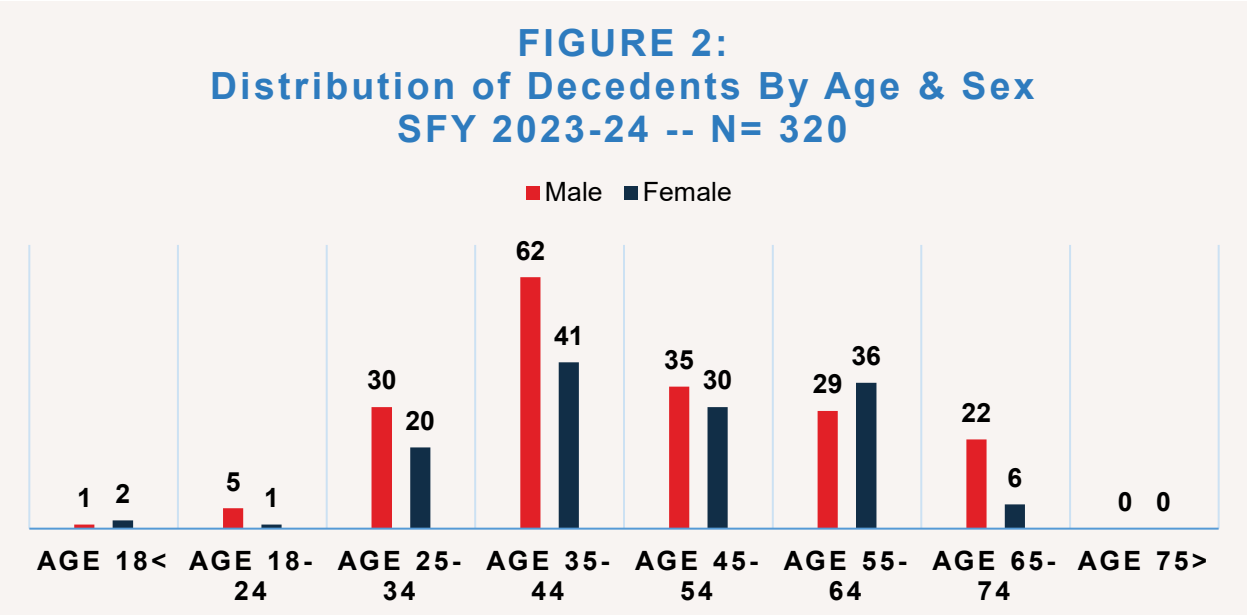
Data collected from these reviews is analyzed to identify trends and patterns across Pennsylvania and presented to the MDAIR Team on a quarterly basis. Due to limited staff resources and the higher likelihood of fentanyl being the main contributor to death compared to buprenorphine, cases containing both substances are counted in the statistical analysis and then closed. Before presenting case information, staff remove all personal identifying information (PII). All data is securely stored in electronic format with access restricted to a limited number of authorized staff and retained in compliance with DDAP's Record Retention policy.

Demographics

For SFY 2023-2024, DDAP received 435 cases of deaths of people being treated with MOUD, with 320 cases flagged for further review. Of those 320 cases, the data showed that 266 decedents were White or Caucasian (161 male & 105 female); 39 decedents were Black or African American (14 male and 25 female), and 12 decedents were Hispanic or Latino (8 male & 4 female). See **FIGURE 1**.



Most male and female decedents were in the 35-44 age range. Due to the limited number of reporting counties in previous years, comparing demographic data to this year has been challenging. However, with the expansion of county data this year, future comparisons should be more accurate and insightful. See **FIGURE 2**.



Geographic Distribution

Information was analyzed across 44 counties; the following is a breakdown of the number of cases reviewed in each county:

TABLE 1: Breakdown of the Number of Cases Reviewed in Each County		
Adams (1)	Dauphin (7)	Mifflin (2)
Beaver (11)	Delaware (5)	Montgomery (14)
Bedford (1)	Erie (7)	Northampton (4)
Berks (2)	Fayette (13)	Northumberland (3)
Blair (6)	Franklin (1)	Philadelphia (56)
Bradford (2)	Greene (4)	Potter (1)
Bucks (11)	Indiana (4)	Schuylkill (1)
Butler (2)	Lackawanna (3)	Somerset (1)
Cambria (6)	Lancaster (4)	Tioga (1)
Carbon (1)	Lawrence (11)	Washington (8)
Centre (1)	Lebanon (2)	Wayne (1)
Chester (3)	Lehigh (3)	Westmoreland (12)
Clearfield (1)	Luzerne (11)	York (9)
Columbia (1)	Lycoming (1)	

Substances Analyzed

DRUG TRENDS IN PENNSYLVANIA AMONG DECEDENTS ON MOUD

A review of the 320 cases revealed that 61% (104) cases involved methadone, while 38% (121 cases) involved buprenorphine. Four cases involved both methadone and buprenorphine, and one case showed traces of naltrexone, though additional substances were also present in that case.

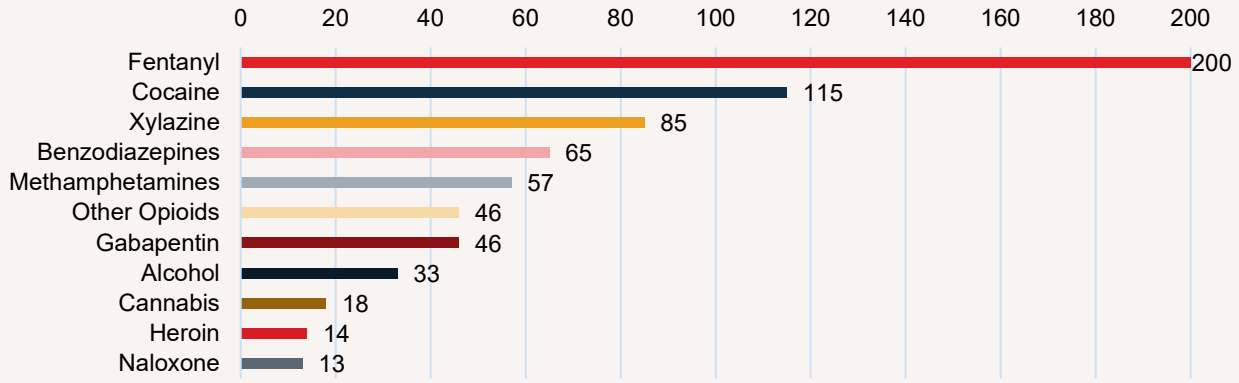
Among the 35 cases where MOUD were the only substances detected, 22 involved methadone, 12 involved buprenorphine, and one contained a combination of methadone and buprenorphine. No cases contained naltrexone alone.

Additional substances were present in 89% (285) of the deaths reviewed. The most frequently detected substances included:

- Fentanyl (200 cases)
- Cocaine (115 cases)
- Xylazine (85 cases)
- Benzodiazepines (65 cases)

The presence of additional substances in the toxicology reports highlights the complexity of polysubstance use among individuals receiving MOUD. This underscores the need for ongoing evaluation of harm reduction strategies, clinical interventions, and systemic barriers to care. See **FIGURE 3.** [15]

FIGURE 3:
Presence of Additional Substances in Cases Involving MOUD[15] SFY 2023-24 -- N= 320



15 "Other opioids" refers to opioid substances detected in toxicology reports excluding fentanyl and heroin, which are tracked separately. This category may include, but is not limited to, prescription opioids such as oxycodone, hydrocodone, and tramadol.

STIMULANT TRENDS IN PENNSYLVANIA AMONG DECEDENTS ON MOUD

Methamphetamines and cocaine together account for 54% of total cases reviewed in SFY 2023 - 2024, reflecting a 20% decrease from the SFY 2022-2023 MDAIR Annual Report. Despite this decline, cocaine remained present in 36% of cases, the second most common additional substance, consistent with the previous Report.

Interviews Conducted

The interview data presented in this report is based on discussions with providers and reflects interpretations of their responses. Additionally, not all providers may have answered every question, which may result in inconsistencies or variability in the data.

DDAP's QI staff conducted 78 interviews; 64 interviews were conducted across a total of 50 NTPs; 14 were with OBOT providers. The data does not show a noteworthy difference in the day of week a death occurred.

NTPS INTERVIEWS AND FINDINGS

A total of 64 interviews were conducted across 50 NTPs, providing insight into factors that may contribute to overdose risk.

- 19 (30%) of decedents were known to live alone, though this statistic does not account for those who may not have been alone at the time of death.
- A review of take-home practices revealed that within one month of a positive drug screen, 11 decedents (17%) were given both Saturday and Sunday take-home doses, and over half (44 decedents) received at least a Sunday take-home dose. These decisions were often due to program closures on Sundays.
- Four decedents died within one month of intake, with only one of the three outpatient programs they attended operating seven days per week.
- Toxicology data indicated that 48 decedents (80%) had a positive drug screen within two months of death, with the majority (44 decedents) testing positive within one month. Despite this, contingency management, a structured approach to reinforcing recovery behaviors, was implemented in only seven programs.
- Fewer than 1% of NTPs had a formal policy for assessing overdose risk.

NALOXONE

Naloxone distribution varied across NTPs. While 40% of programs provided naloxone at both admission and upon request, 25% distributed it only at admission, and 13% made it available solely upon request.

These findings highlight gaps in overdose prevention strategies, particularly in assessing and mitigating risk among individuals receiving take-home methadone and those who are actively or recently using additional substances.

DRUG TEST STRIPS: FENTANYL AND XYLAZINE

Drug test strips are harm reduction tools to determine whether drugs have been mixed or contaminated with other substances[16]. Providing people with drug testing strips can assist them in taking steps to reduce their risk of overdose.

Fentanyl test strips (FTS) are a low-cost harm-reduction tool proven to help reduce overdose risks by enabling individuals to test substances for the presence of fentanyl. Among the providers interviewed, 20 providers (40%) currently offer FTS to individuals receiving services. Sufficient data is not yet available to report on the distribution of xylazine test strips.

OBOT INTERVIEWS

All OBOT providers were treating individuals with buprenorphine products. While the MDAIR Act allows for the review of medical records from healthcare providers, it does not mandate provider participation in interviews. As a result, engagement in these interviews was limited, often due to time constraints and other challenges. Additionally, DDAP regulates only treatment facilities, not OBOT medical practices, which can also limit information obtained from these providers.

Key findings from the interviews DDAP facilitated included the following:

- Fourteen interviews were conducted with OBOT providers
- Eleven cases (79%) contained additional substances that contributed to death; two cases were unavailable; one case contained buprenorphine and buprenorphine metabolite only
- Two providers actively coordinated mental health or substance use counseling
- One decedent had buprenorphine and methadone in their post-mortem toxicology; the source of the methadone is unknown
- None of the OBOT providers utilized contingency management as a behavioral intervention
- One provider reported discussing naloxone at every appointment
- 54% (7 providers) reported making naloxone available through prescription only
    - Two decedents expressly declined naloxone when it was offered

16 Fentanyl and Xylazine Test Strips | SAMHSA

Results & Findings

The MDAIR Team met on August 16, 2023, December 6, 2023, February 21, 2024, and May 15, 2024, to review cases, identify trends and patterns, and develop recommendations and best practices. During these meetings, 320 cases involving MOUD were reviewed, a 46% increase from the 219 cases received during the same timeframe in the previous state fiscal year. The addition of the File Transfer Protocols and data sharing agreements from the Pennsylvania DOH and Philadelphia Medical Examiner's Office has resulted in considerably more cases, allowing a more comprehensive picture of the landscape of overdoses involving FDA-approved MOUD in Pennsylvania.

In 285 (89%) of the cases contained additional reportable substances, with fentanyl (63%), cocaine (36%), and xylazine (27%) being the most common. The presence of xylazine increased dramatically (2,900% from 2022-2023's MDAIR Annual Report), posing unique overdose risks. Xylazine or "tranq" is a veterinary tranquilizer often mixed with fentanyl to prolong the euphoric effects. It can be life-threatening and can complicate efforts to reverse opioid overdoses.

Eighty percent of the decedents from the NTP interviews had positive drug screens for other substances in the two months prior to death. QI staff were unable to determine the number of individuals testing positive for xylazine during NTP interviews as the majority of NTPs do not have xylazine on their standard panel or as an add-on to their standard drug screen panel.

Additionally, 48 of the 50 NTP providers interviewed (96%) reported offering naloxone but distribution methods varied. To improve naloxone access and overdose prevention efforts, providers should assess the effectiveness of their naloxone distribution strategies and expand education on naloxone use to individuals in treatment, their families, and their support networks.

The distribution of FTS highlights a significant but incomplete adoption of harm reduction tools among providers. Forty percent (40%) of the NTP providers reported making FTS strips available to the individuals they serve, however, the concept of distributing xylazine test strips at NTPs is still new, and data is insufficient. Access to these harm reduction tools would empower individuals to make informed decisions, potentially reducing the risk of overdose. Given the widespread presence of fentanyl and xylazine in the Pennsylvania drug supply, expanding the distribution of these test strips across all providers could be a pivotal step in enhancing safety measures and addressing the ongoing overdose crisis.

Despite the persistent use of cocaine during treatment, only seven or 14% of the NTPs interviewed incorporate contingency management as an intervention. Contingency

management is an effective, evidenced based behavioral intervention for stimulant use, both in psychosocial treatment and NTP settings.[17]

Individualized care is essential, as every person has unique needs. Programs may need to offer more intensive services for individuals who are new to treatment or those who continue to use substances that increase their risk for overdose. Preventing overdose remains a central goal, requiring a careful balance of harm reduction strategies and treatment interventions. It is crucial to acknowledge that, despite the best efforts of providers, some individuals may continue to use substances. This reality highlights the importance of harm reduction approaches that emphasize compassionate, nonjudgemental support, prioritize risk reduction, foster trust, and create pathways to safer outcomes.

17 A review of contingency management for the treatment of substance-use disorders: adaptation for underserved populations, use of experimental technologies, and personalized optimization strategies - PMC

Recommendations

Based on the results and findings, DDAP staff suggest the following recommendations to improve the overall treatment, support, and care processes at NTP providers:

1. **Expand Harm Reduction Strategies across Opioid Treatment Services**
   DDAP should develop guidance for providers on promoting naloxone distribution at key points in care – such as program induction, after a positive drug screen, and when take-home medications are dispensed. This guidance should also support the inclusion of family and support networks in naloxone education and access. Additionally, DDAP should explore mechanisms to increase the distribution of fentanyl and xylazine test strips at NTPs and OBOT providers, paired with ongoing education on their use.

2. **Promote Contingency Management for Stimulant Use Disorders**
   DDAP should continue to support the adoption of contingency management as an evidence-based approach to address stimulant use disorders and develop technical assistance to help providers implement this strategy.

3. **Reinforce Cautious Methadone Take-Home Practices**
   DDAP should issue clinical guidance encouraging the use of overdose risk assessments when determining take-home methadone eligibility, particularly during induction and after recent positive drug screens. Guidance should align with SAMHSA definitions of “stable” and “unstable” and encourage documentation of risk-informed decision-making.[18]

4. **Support Individualized Care Planning**
   DDAP should promote person-centered care planning by developing and sharing best practice guidance on aligning psychotherapy and case management with individuals’ goals, needs, and preferences.

   The MDAIR Team should collaborate with DDAP staff to develop a brief provider communication – in the form of an e-mail, bulletin, or memo – to disseminate the message that assessing for physical health, mental health, and substance use disorder needs, and making documented warm handoffs for services not provided onsite, is considered best practice. This message will be distributed through existing Department channels, including provider distribution lists and partner organizations, as well as social media outlets, to reach all NTPs.

5. **Educate providers on developing and implementing educational groups focused on medications for individuals receiving services.**
   DDAP should provide resources to equip providers with harm reduction tools and strategies to empower individuals in substance use disorder treatment programs.

18 Methadone Take-Home Flexibilities Extension Guidance - Find-A-Code Medical Coding and Billing Articles

Included in the resources will be a training to address appropriate medication use, potential side effects, and contraindications.

Areas for Further Exploration

In addition to the recommendations above, DDAP staff identified the following notable areas for additional focus and exploration:

- The intersection of benzodiazepines and MOUD presents a critical area for ongoing research. The combination of benzodiazepines and opioids is known to be potentially fatal, stressing the need for individualized approaches rather than blanket policies precluding benzodiazepine use. Notably, the American Society of Addiction Medicine[19] advises against withholding MOUD based solely on benzodiazepine use, recommending instead for individualized risk-benefit analyses. Research is needed to understand how providers assess risks and benefits when treating individuals for OUD who are using or are prescribed benzodiazepines.
- Additional information pertaining to the co-prescribing of medications which are not currently tracked by the PDMP, such as gabapentin, is necessary. Without this data, it is challenging to determine how these medications are being obtained, making it difficult to develop effective strategies and solutions to address potential risks associated with their use.

19 npg-jam-supplement.pdf