



Mitigating Risks from Human Xylazine Exposure

MEETING SUMMARY

FEBRUARY 2024

TABLE OF CONTENTS

1. Introduction	3
Background	3
Xylazine Presence in the Overdose Crisis	5
2. Current Landscape and Epidemiological Trends	6
Geographic Distribution & Current Trends in Overdose Morbidity and Mortality Involving Xylazine	6
3. Pharmacology and Toxicology Research	10
Pharmacology and Pharmacokinetics	10
Toxicology	11
4. Clinical Research and Experience	12
Testing	12
Overdose Management & Withdrawal	13
Complications of Chronic Exposure to Xylazine	14
Lived Experience	15
Care Management in a Fragmented Health Care System	15
5. Public Health Responses	17
Public Health Implications of Xylazine in the Illicit Drug Supply	17
Surveillance & Local, Regional, and National Collaborations	17
6. Priorities for Research and Development	19
Knowledge and Data Gaps	19
Product Development	20
7. Actions Needed for Progress/Future Directions	21
8. Conclusion	22
Appendix: Meeting Agenda	23

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1. Introduction

The Reagan-Udall Foundation for the FDA, in partnership with the U.S. Food and Drug Administration (FDA), held a hybrid public meeting titled “Mitigating Risks from Human Xylazine Exposure.” This hybrid public meeting explored real-world experiences and scientific evidence on emerging data trends for human xylazine exposure. The meeting also examined concrete strategies for drug development and clinical research that directly support the mitigation and reduction of risks associated with human exposure to xylazine. Workshop presenters and attendees included clinical and scientific experts, community and harm reduction organizations, persons with lived experience, academic researchers, and federal partners.

BACKGROUND

Xylazine is the active ingredient in an FDA-approved veterinary drug which is used as a sedative and analgesic. It is not currently a controlled substance under the U.S. Controlled Substances Act, although some states have taken action to schedule xylazine.^{1,2,3} No drugs containing xylazine are approved for human use and there are no known benefits of human exposure, only harms. In 2022, the Drug Enforcement Administration (DEA) reported that forensic laboratory identifications of xylazine had risen in all four U.S. Census regions between 2020 and 2021.⁴ Furthermore, due to its impact on the opioid crisis, the White House’s Office of National Drug Control Policy declared fentanyl adulterated or associated with xylazine as an emerging threat.⁵ Given this threat, FDA believes that a better understanding of the landscape of available tools and preventive strategies for reducing the illicit use of xylazine is needed to advance the development of and access to evidence-based treatment for human exposure. The timeline in Figure 1 shows the Federal Government’s actions in response to the overdose crisis and the emergence of xylazine in the illicit drug supply.

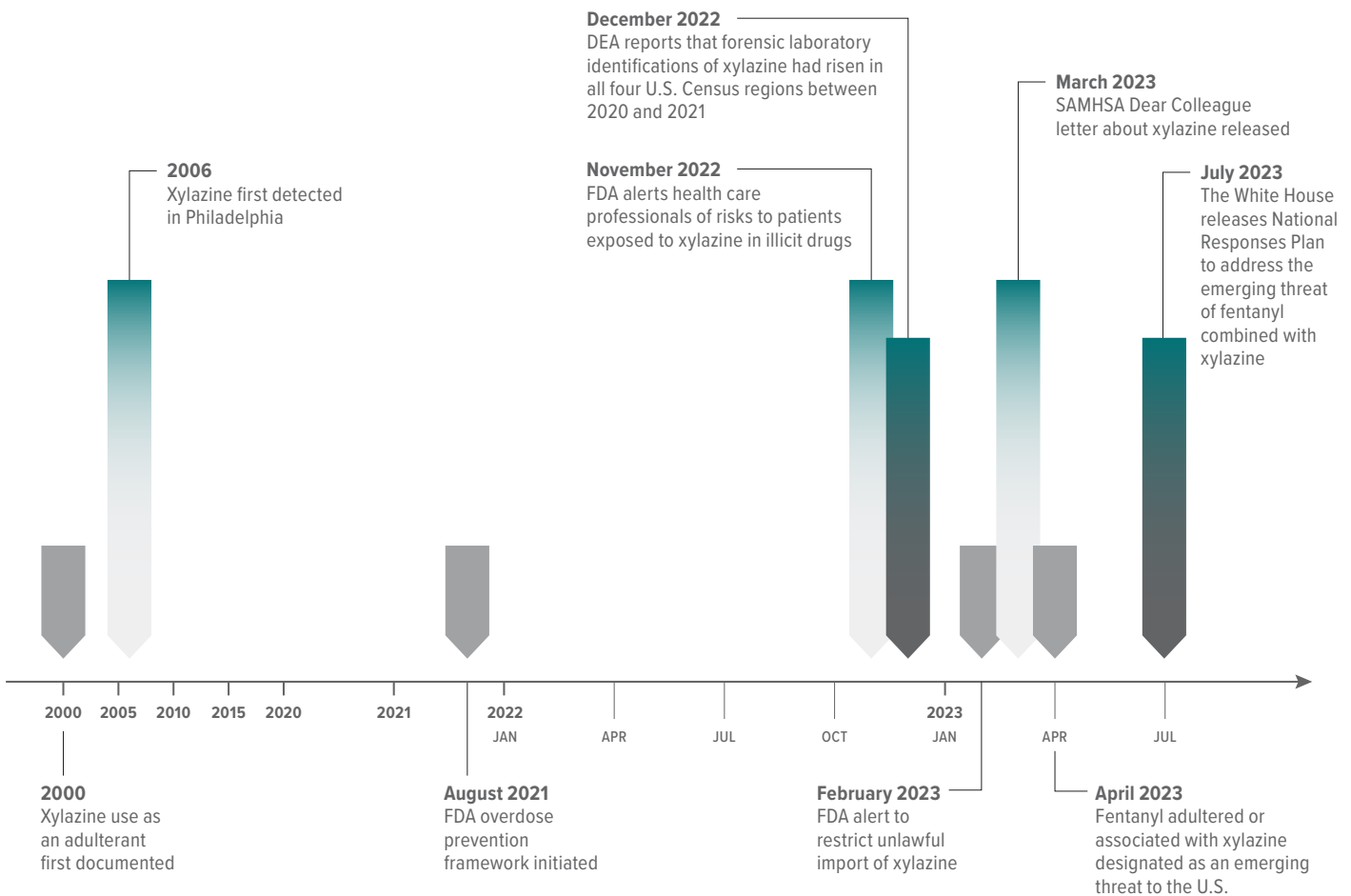
Xylazine Overview

The chemical xylazine was discovered in 1962 in Leverkusen, Germany, with the intended use as an anti-hypertensive agent, but the adverse effects associated with use in people greatly outweighed any benefits.⁶ Drugs containing xylazine are currently only approved for use as a veterinary sedative and analgesic. The use of xylazine as an adulterant⁷ was first documented in the early 2000s, initially in combination with heroin, then combined with other opioids, stimulants, and other substances present in the illicit drug supply. Xylazine is used as a cutting agent⁸ to enhance drug effects or to add weight to a product to increase its street value.⁹

- 1 National Governors Association. State and Federal Actions to Respond to Xylazine. National Governors Association. Published May 9, 2023. <https://www.nga.org/news/commentary/state-and-federal-actions-to-respond-to-xylazine/>
- 2 Detweiler K. Xylazine: What’s Next? *www.dvm360.com*. 2023;54:12–12. Accessed November 26, 2023. <https://www.dvm360.com/view/xylazine-what-s-next->
- 3 Sugarman O, Shah H. Tracking “Tranq” Laws: The State of Policy Responses to the Growing Xylazine Crisis. *Opioid Principles*. Published August 30, 2023. Accessed November 26, 2023. <https://opioidprinciples.jhsph.edu/tracking-tranq-laws-the-state-of-policy-responses-to-the-growing-xylazine-crisis/>
- 4 United States Drug Enforcement Administration. The Growing Threat of Xylazine and its Mixture with Illicit Drugs. DEA. Published 2022. Accessed October 27, 2023. <https://www.dea.gov/documents/2022/2022-12/2022-12-21/growing-threat-xylazine-and-its-mixture-illicit-drugs#:~:text=Xylazine%2C%20reported%20as%20an%20adulterant>
- 5 The White House. Biden-Harris Administration Designates Fentanyl Combined with Xylazine as an Emerging Threat to the United States | ONDCP. The White House. Published April 12, 2023. <https://www.whitehouse.gov/ondcp/briefing-room/2023/04/12/biden-harris-administration-designates-fentanyl-combined-with-xylazine-as-an-emerging-threat-to-the-united-states/>
- 6 Gupta R, Holtgrave DR, Ashburn MA. Xylazine – Medical and Public Health Imperatives. *N Engl J Med* 2023;388:2209–2212. DOI:10.1056/NEJMp2303120
- 7 An adulterant is a pharmacologically active substance that is added to a product intentionally to increase bulk, enhance or mimic a pharmacologic effect, or facilitate drug delivery vs. a diluent that is a substance that adds weight to the sample.
- 8 A substance used to adulterate a drug (also known as a lacing agent).
- 9 Drug Enforcement Administration. *The growing threat of xylazine and its mixture with illicit drugs*. 2022. <https://www.dea.gov/sites/default/files/2022-12/The%20Growing%20Threat%20of%20Xylazine%20and%20its%20Mixture%20with%20Illicit%20Drugs.pdf>

Because no drug containing xylazine is FDA-approved for use in humans, current information about the pharmacokinetic and pharmacodynamic properties of xylazine in humans is extrapolated from case reports, forensic analyses, and animal studies. Physical effects of xylazine in humans may include central nervous system depression, dizziness, respiratory depression, apnea or shallow breathing, and hypotension. Chronic use may lead to severe withdrawal symptoms as well as severe skin ulcerations. Wounds can develop in areas of the body away from the injection site and are thought to be associated with long-term repetitive usage of xylazine by any route of administration.

FIGURE 1. Federal Agency Actions in Response to the Overdose Crisis and Emergence of Xylazine



- FDA overdose prevention framework: <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework>
- FDA health professional alert: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-risks-patients-exposed-xylazine-illicit-drugs>
- DEA alert: <https://www.dea.gov/documents/2022/2022-12/2022-12-21/growing-threat-xylazine-and-its-mixture-illicit-drugs>
- FDA alert to restrict import: <https://www.fda.gov/news-events/press-announcements/fda-takes-action-restrict-unlawful-import-xylazine>
- SAMHSA letter: <https://www.samhsa.gov/sites/default/files/colleague-letter-xylazine.pdf>
- Emerging threat designation: <https://www.whitehouse.gov/ondcp/briefing-room/2023/04/12/biden-harris-administration-designates-fentanyl-combined-with-xylazine-as-an-emerging-threat-to-the-united-states/>
- National response plan: <https://www.whitehouse.gov/ondcp/briefing-room/2023/07/11/in-continued-fight-against-overdose-epidemic-the-white-house-releases-national-response-plan-to-address-the-emerging-threat-of-fentanyl-combined-with-xylazine/>

XYLAZINE PRESENCE IN THE OVERDOSE CRISIS

Increasingly, xylazine is found in the illicit drug supply, primarily in combination with fentanyl, but also mixed with other opioids and stimulants. Overdose deaths involving fentanyl mixed with xylazine have increased since 2019, contributing to the crisis.¹⁰

Aligned with the U.S. Department of Health & Human Services (HHS) Overdose Prevention Strategy,¹¹ the FDA Overdose Prevention Framework identifies four priority areas for FDA to address the crisis: 1) Supporting primary prevention; 2) Encouraging harm reduction through innovation and education; 3) Advancing the development of evidence-based treatments for substance use disorders; and 4) Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.¹²

The National Response Plan to address the emerging threat of fentanyl adulterated with xylazine has set a goal of at least a 15% reduction of xylazine-positive drug poisoning deaths in at least three of four U.S. census regions by 2025.¹³ The following are the six pillars of action included in the response plan:

1. Testing
2. Expand data collection
3. Implementing and expanding evidence-based prevention, harm reduction, and treatment
4. Supply reduction
5. Scheduling
6. Research

This meeting summary highlights activities supporting these pillars of action as well as identifies areas where more research and collaboration are needed.

10 Centers for Disease Control and Prevention. What You Should Know About Xylazine | Drug Overdose | CDC Injury Center. [www.cdc.gov](https://www.cdc.gov/drugoverdose/deaths/other-drugs/xylazine/faq.html). Published May 5, 2023. <https://www.cdc.gov/drugoverdose/deaths/other-drugs/xylazine/faq.html>

11 U.S. Department of Health & Human Services. Overdose Prevention Strategy. Overdose Prevention Strategy. Published September 14, 2021. <https://www.hhs.gov/overdose-prevention/>

12 FDA. Food and Drug Administration Overdose Prevention Framework. Published September 5, 2023. <https://www.fda.gov/drugs/drug-safety-and-availability/food-and-drug-administration-overdose-prevention-framework#:~:text=FDA>

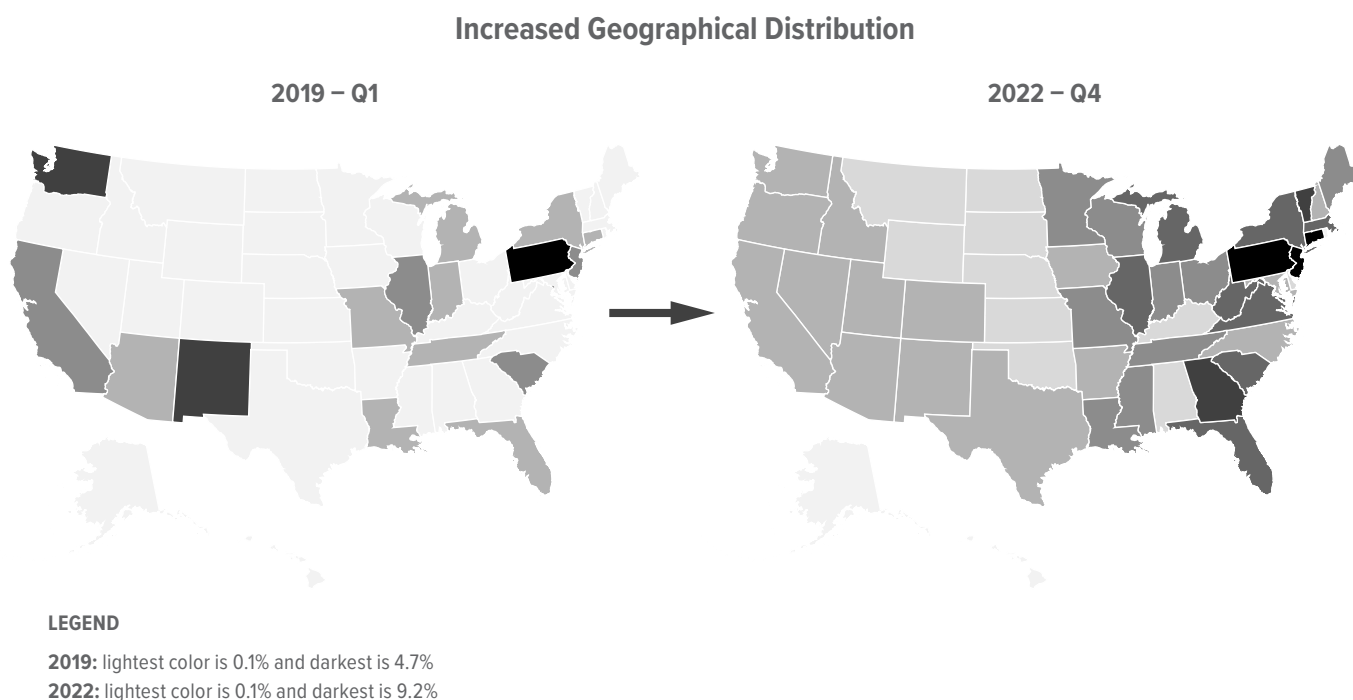
13 The White House Executive Office of the President Office of National Drug Control Policy. Fentanyl Adulterated or Associated with Xylazine Response Plan.; 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/07/FENTANYL-ADULTERATED-OR-ASSOCIATED-WITH-XYLAZINE-EMERGING-THREAT-RESPONSE-PLAN-Report-July-2023.pdf>

2. Current Landscape and Epidemiological Trends

GEOGRAPHIC DISTRIBUTION OF XYLAZINE IN THE ILLICIT DRUG SUPPLY & CURRENT TRENDS IN OVERDOSE MORBIDITY AND MORTALITY INVOLVING XYLAZINE

The use of xylazine as an adulterant in the illicit human drug supply was first documented in the early 2000s in Puerto Rico and subsequently appeared in the contiguous U.S. (in Philadelphia) around the year 2006. Since that time, there has been an expansion of xylazine presence across geographic regions of the U.S. Figure 2 illustrates the change in the geographical distribution of xylazine positivity across the United States from Q1 2019 to Q4 2022, as determined by xylazine detections in forensic samples analyzed by NMS Labs (Horsham, PA) and the Center for Forensic Science Research and Education (Horsham, PA). Xylazine prevalence nationally has increased between 2019 and 2022.

FIGURE 2. Increase in Geographical Distribution of Xylazine from 2019 to 2022¹⁴



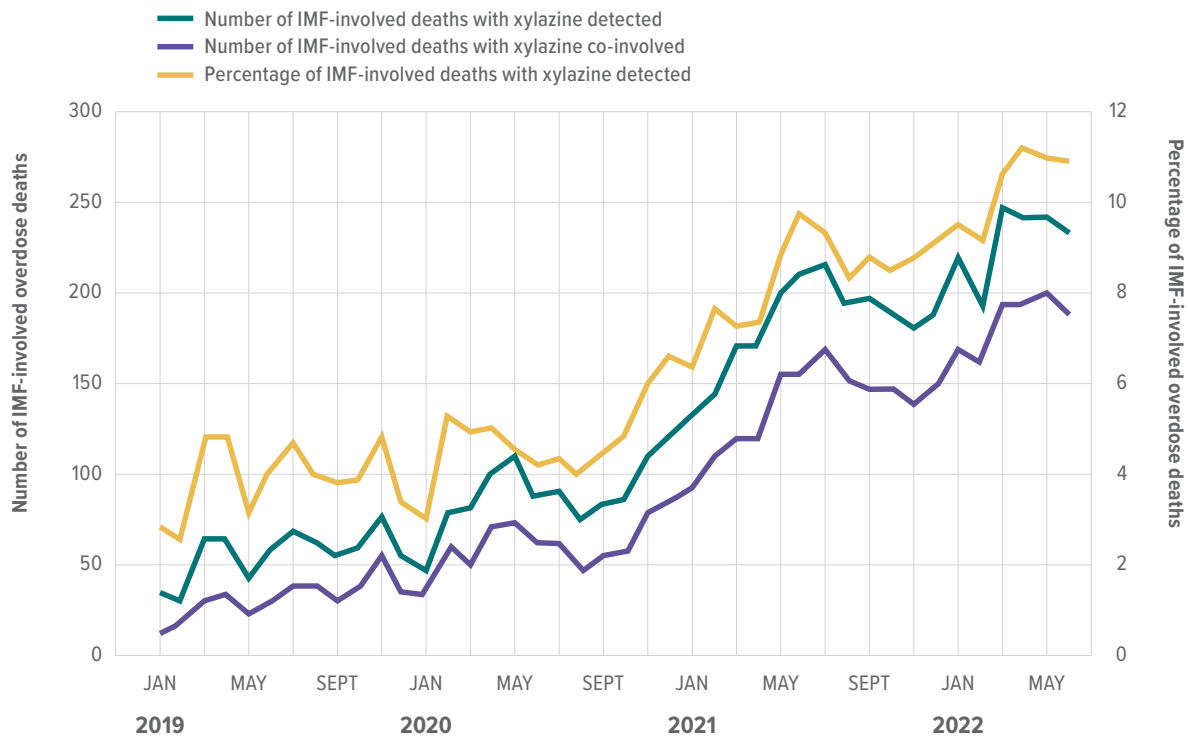
Between April and July 2023, Millenium Health conducted a geographical analysis of urine drug tests containing both fentanyl and xylazine. Xylazine was detected throughout the U.S., with the highest rate of detection occurring in Mid-Atlantic states (i.e., Pennsylvania, Maryland).¹⁵

¹⁴ Krotulski AJ. Xylazine – Perspectives from Forensic and Clinical Toxicology; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

¹⁵ Millennium Health. Zeroing in on Xylazine: The First 100 Days After U.S. Emerging Threat Designation. [Millenniumhealth.com](https://resource.millenniumhealth.com/). Published September 2023. Accessed November 26, 2023. https://resource.millenniumhealth.com//436602/2023-09-13/7n9rzt/436602/1694638062oPgQ9I6K/MLH_058_V07_MH_Signals_Report_Vol_5.1_Xylazine_FINAL.pdf

Provisional data from CDC's State Unintentional Drug Overdose Reporting System (SUDORS)¹⁶ described 107,081 drug overdose deaths in the U.S. in 2022; over two-thirds of these deaths primarily involved illicitly manufactured fentanyl (IMF).¹⁷ These data also showed an increasing trend of xylazine detection within the IMF drug supply. The monthly percentage of IMF-related deaths in which the presence of xylazine was detected increased 276% from January 2019 (2.9%) to June 2022 (10.9%), as illustrated in Figure 3.¹⁸ Xylazine was co-involved in nearly one in nine IMF-involved overdose deaths, with a greater proportion of overdose deaths occurring in those with evidence of injection drug use compared to other routes of administration. The highest rates of overdose including xylazine occurred in the Northeast (Figure 4).¹⁹

FIGURE 3. Xylazine Detection and Co-involvement Among IMF-involved Deaths Increased from January 2019 to June 2022 in 21 Jurisdictions^{20,21}



16 SUDORS is part of CDC's overdose data to action program. SUDORS combines death certificate, medical examiner, core nerve report, and post-mortem toxicology results to include demographic circumstance, overdose risk factors, comorbidities, and contributing drug data. <https://www.cdc.gov/drugoverdose/fatal/sudors.html>

17 Kariisa M, O'Donnell J, Kumar S, Mattson CL, Goldberger BA. Illicitly Manufactured Fentanyl-Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022. *MMWR Morb Mortal Wkly Rep* 2023;72:721–727. <http://dx.doi.org/10.15585/mmwr.mm7226a4>

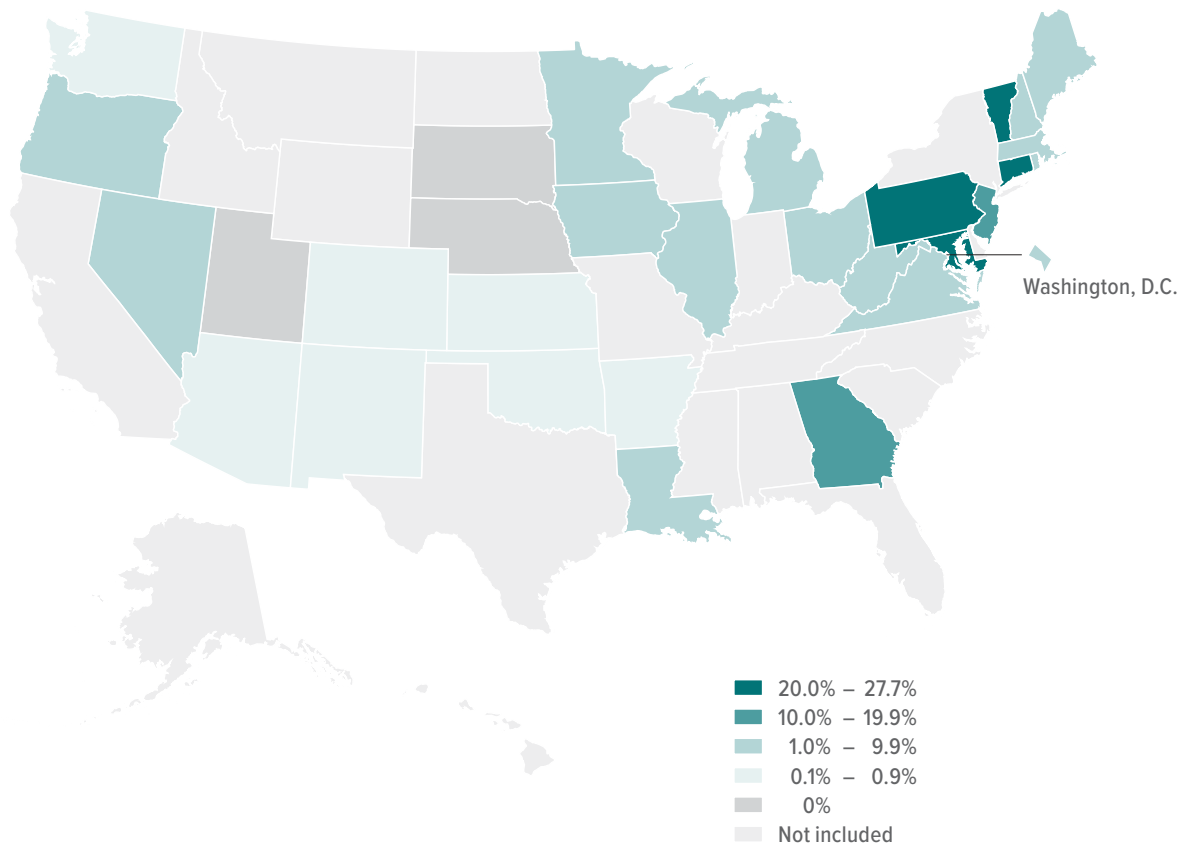
18 Ibid.

19 Ibid.

20 Ibid.

21 21 jurisdictions include Connecticut, Delaware, District of Columbia, Georgia, Illinois, Maine, Massachusetts, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Pennsylvania, Rhode Island, Utah, Vermont, Virginia, Washington, and West Virginia.

FIGURE 4. Percentage of IMF-involved Overdose Deaths with Xylazine Detected, SUDORS, 31 states and District of Columbia, January 2021 to June 2022²²



Xylazine is likely under-detected and under-accounted for in both opioid and polysubstance overdoses since not all jurisdictions or labs test for xylazine as an adulterant. The SUDORS data provide a snapshot of xylazine presence, but the data are not a national representation of the population, and the results may not be generalizable across the country.

Not only is the presence of xylazine expanding in the illicit drug supply, but the purity and amount of xylazine present as an adulterant are also highly variable. Speakers from Pennsylvania and Massachusetts both reported progressively higher proportions of xylazine-positive opioid samples. In 2023, nearly all (99%) surrendered street samples of fentanyl in Philadelphia contained xylazine, up from 91% in 2022 (Figure 5).^{23,24} The average purity of these samples (i.e., the absolute weight of xylazine in the adulterated samples) also increased from 35% to 39% during this same time frame.²⁵

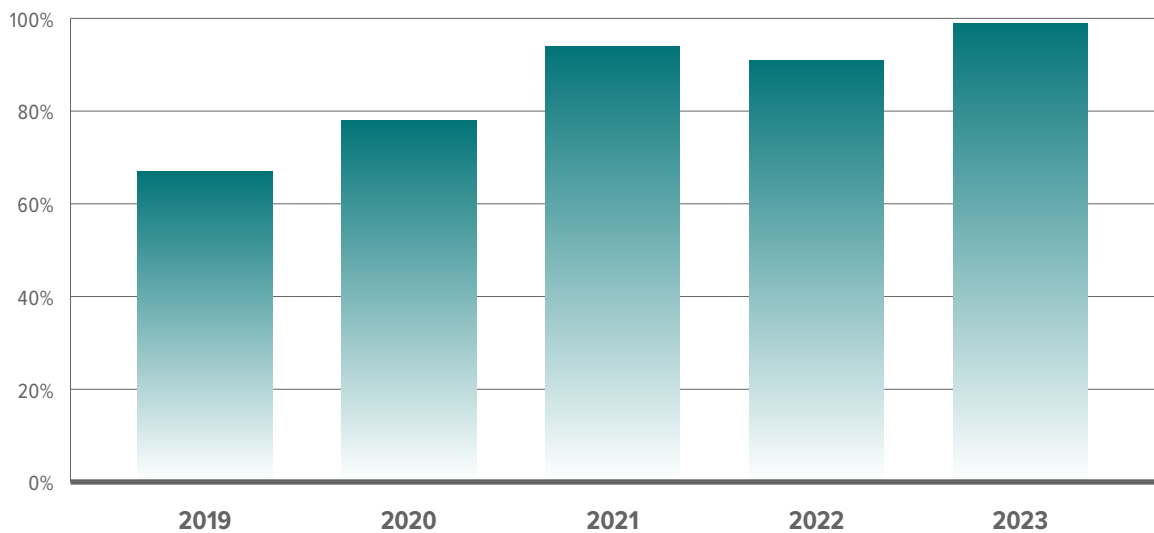
22 Kariisa M, O’Donnell J, Kumar S, Mattson CL, Goldberger BA. Illicitly Manufactured Fentanyl—Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022. *MMWR Morb Mortal Wkly Rep* 2023;72:721–727. <http://dx.doi.org/10.15585/mmwr.mm7226a4>

23 Krotulski AJ. Xylazine – Perspectives from Forensic and Clinical Toxicology; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

24 DiStefano A, Jackson V. Mitigating Risks from Human Xylazine Exposure – The Law Enforcement Perspective; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

25 Ibid.

FIGURE 5. Opioid Samples Containing Xylazine in Philadelphia, PA²⁶



Public health implications of these geographical and epidemiological trends are further discussed in [Section 5](#) of the meeting summary.

²⁶ Krotulski AJ. Xylazine – Perspectives from Forensic and Clinical Toxicology; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

3. Pharmacology and Toxicology Research

PHARMACOLOGY AND PHARMACOKINETICS

Since there are no known benefits or indications for the use of drugs containing xylazine in humans, much of the information surrounding pharmacology and metabolism is extracted from animal data and from human case reports. In silico methods to simulate drug effects in the human body are also used for generating pharmacokinetic and pharmacodynamic predictions. The FDA developed the Public Health Assessment via Structural Evaluation (PHASE) in silico methodology that allows for the rapid assessment of abuse potential and biological effects of emerging drug threats.²⁷

Xylazine is an alpha-2 adrenergic agonist, with pharmacodynamic properties similar to those of clonidine, tizanidine, and dexmedetomidine. Xylazine undergoes extensive phase I (modification) and phase II (conjugation) drug metabolism. Xylazine's secondary pharmacological (off-target) effects include potential activity at imidazoline-1, cholinergic, nicotinic, and serotonergic receptors. Activity at these receptors may contribute to xylazine's adverse effects and the potentiation of fentanyl's effects.²⁸ Xylazine may also affect nitric oxide synthase activity. Nitric oxide is important for wound healing and the process of angiogenesis. In a rat splenocyte model, xylazine showed dose-dependent immunomodulation. Lower doses stimulated the immune system, but higher doses caused inhibition of some immune responses.²⁹ How these actions contribute to the pathophysiology of xylazine-associated wound development remains unclear.

A recent discovery has also identified xylazine as a kappa (**k**) opioid receptor (**kOR**) agonist.³⁰ The findings presented at this meeting have not undergone peer review as of yet. The **kOR** is present throughout the central nervous system and periphery and contributes to the effects of opioid-like compounds. These effects include pain detection, consciousness, motor control, and mood. However, it should be emphasized that the **kOR** has some different effects from the mu opioid receptor, and it is the mu opioid receptor agonists that are thought to be among the most addictive analgesic medications.^{31,32} In addition, differences exist in the kappa receptors of humans and mice.³³ Kappa agonist at the **kOR** may have the potential to reduce substance use disorder potential.³⁴

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- 27 Ellis CR, Racz R, Kruhlak NL, et. al. Assessing the Structural and Pharmacological Similarity of Newly Identified Drugs of Abuse to Controlled Substances Using Public Health Assessment via Structural Evaluation. *Clin Pharmacol Ther*. 2019 Jul;106(1):116–122. <https://doi.org/10.1002/cpt.1418>
- 28 Ball NS, Knable BM, Relich TA, et. al. Xylazine poisoning: a systematic review, *Clinical Toxicology* 2022;60(8):892–901. <https://doi.org/10.1080/15563650.2022.2063135>
- 29 Cupic V, Colic M, Pavicic L, Vucevic D, Varagic VM. Immunomodulatory effect of xylazine, an alpha-2 adrenergic agonist, on rat 2 spleen cells in culture. *Journal of Neuroimmunology* 2001;113:19–29.
- 30 Bedard ML, Murray JG, Huang X, et. al. Xylazine is an agonist at kappa opioid receptors and exhibits sex-specific responses to naloxone administration. *BioRxiv* 2023.09.08.556914; <https://doi.org/10.1101/2023.09.08.556914>
- 31 Valentino, R.J., Volkow, N. Untangling the complexity of opioid receptor function. *Neuropsychopharmacol* 2018;43:2514–2520. <https://doi.org/10.1038/s41386-018-0225-3>
- 32 Dhaliwal A, Gupta M. Physiology, Opioid Receptor. [Updated 2023 Jul 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK546642/>
- 33 Broad, J., Maurel, D., Kung, V. et al. Human native kappa opioid receptor functions not predicted by recombinant receptors: Implications for drug design. *Sci Rep* 2016;6:30797. <https://doi.org/10.1038/srep30797>
- 34 Banks ML. The Rise and Fall of Kappa-Opioid Receptors in Drug Abuse Research. *Handb Exp Pharmacol* 2020;258:147–165. https://doi.org/10.1007/164_2019_268

Dr. Zoé McElligott, from the University of North Carolina Chapel Hill, presented the following research findings:

- Xylazine has full agonist activity at κ -opioid receptors in mice
- Low dose xylazine produces a stimulant response in female mice
- Xylazine exacerbates naloxone precipitated withdrawal in female mice
- Xylazine, and its metabolites, bind additional targets including sigma receptors

In summary, xylazine appears to be a full agonist at the κ OR, at least in mice. In the murine model, naloxone precipitates withdrawal from both xylazine and a fentanyl/xylazine combination in female but only minimal impact on the effects of xylazine alone in male mice. Sex-specific effects exist with female mice demonstrating an enhanced sensitivity to the pharmacological effects of xylazine.³⁵

It is unclear at present as to how these results will translate to humans. The finding of significant sex differences also underscores the uncertainty regarding the interspecies comparability of the potential clinical impact of these findings. These findings also indicate that naloxone may have a role in reversing xylazine overdose. At this point in time, the research has not undergone peer review. Subsequent peer review and replication of these findings will further strengthen the evidence of the opioid properties of xylazine. Most importantly, naloxone should always be administered to a person with a suspected opioid-xylazine overdose.

TOXICOLOGY

Research conducted at the FDA's National Center for Toxicological Research (FDA NCTR) has focused on understanding how xylazine leads to induction of necrotic skin lesions on the body. Potential contributors to wound development include prolonged vasoconstriction leading to hypoxia following xylazine exposure and κ OR agonism. Pentazocine, also a κ OR agonist, leads to formation of similar lesions, illustrating that κ OR agonism itself may be the cause of or predispose a person to wound formation.

Scientists are developing a model for skin lesions induced by parenteral use of xylazine and fentanyl, but acknowledge the existing challenges in translating data from animal studies to humans. Certain aspects of metabolism and toxicological processes translate well between species, but others do not.³⁶ Dr. Gamboa da Costa from the NCTR stated that “a model to investigate the formation of skin lesions needs to reflect receptor activation, potential immune mediated responses, and metabolites formed in humans. The extent to which drugs are metabolized, the nature of the specific metabolites, and the duration of these compounds in circulation can be determinants of their toxicity.”³⁷

Researchers are also working to understand the extent to which the metabolism of fentanyl and xylazine may impact the clearance of one another when taken concomitantly. Understanding this interaction could have significant clinical implications for managing overdose and withdrawal. Equally important is understanding both the activity and toxicity of xylazine metabolites and how and where they function pharmacologically. And their potential interaction with fentanyl pharmacokinetics.

35 Bedard ML, Murray JG, Huang X, et. al. Xylazine is an agonist at kappa opioid receptors and exhibits sex-specific responses to naloxone administration. *BioRxiv* 2023.09.08.556914; <https://doi.org/10.1101/2023.09.08.556914>

36 Gamboa da Costa, G. FDA Research on Xylazine; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

37 Ibid.

4. Clinical Research and Experience

This section provides a synopsis of information pertaining to clinical research and frontline clinical experience with human exposure to xylazine. Areas of focus include xylazine point-of-care and lab testing, overdose management, managing withdrawal, and wound care. Stories of lived experience and how a fragmented health care system impacts care of people exposed to xylazine are also presented.

TESTING

Testing encompasses both qualitative and quantitative evaluation. Qualitative tests determine whether the drug is present or not present whereas quantitative tests determine how much of a substance is present in the sample. Testing may be for the presence of xylazine in a drug sample or for the presence of xylazine and metabolites in the human body. The FDA regulates testing on human samples (e.g., blood, urine).

Community Drug Checking

Table 1 lists and compares the different types of drug checking technology that may be used to test for xylazine. Test strips and Fourier Transform Infrared spectroscopy (FTIR) can provide results in seconds to minutes. More complex and time-intensive technologies (gas chromatography-mass spectrometry, GCMS or liquid chromatography—quadrupole time-of-flight mass spectrometry, LC-QToF) are used to confirm the presence of xylazine in samples from drug products and paraphernalia. Lab testing is used by state drug testing and surveillance programs.

Test strips, for identifying the presence of xylazine in a drug sample, are not regulated by the FDA, so the quality and accuracy of the strips can vary. Strips may also cross-react with other substances to give false positive results, so it is important to understand the limitations of the test strips being used for community drug checking for the presence of xylazine in the illicit drug supply.

TABLE 1. Drug Checking Technology³⁸

	QUALITATIVE	SEMI-QUANTITATIVE	QUANTITATIVE
Devices	Test strips, FTIR, lab testing	FTIR, lab testing	Lab testing, requires weighable sample (5–10 mg)
What is reported?	Absence/presence	Ratios, major/minor/trace	% component breakdown
What can be measured?	Relative prevalence	Relative exposure	Measured exposure
Question	How common is xylazine in the drug supply?	Relative to _____, is there more xylazine in the drug supply?	What percent of a drug sample does xylazine compose? How much xylazine is in a given drug sample?

³⁸ Green T. Mitigating Risks From Human Xylazine Exposure Current Landscape and Epidemiological Trends; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

In Vitro Diagnostic Tests

In vitro diagnostic tests are done on samples collected from the body, such as blood or urine. A clinically useful quantitative assay for xylazine and its metabolites incorporates the following properties:

- Works with the clinical sample obtained
- Has known target concentrations for detection, overdose, and lethality
- Correlates clinical findings with the toxicology results
- Utilizes reference materials for validation

Drug testing can play an important role in informing communities and providing education (see [Section 5](#)) and should be tailored to community needs. Multianalyte rapid tests would be most useful. Implementation of routine standardized toxicology testing will improve surveillance of xylazine and provide further evidence of its role in overdose mortality and morbidity risk.

“...having reliable point of care testing would be particularly helpful as we think about treatment, induction, just understanding what an individual has been exposed to as they are navigating the clinical space. We certainly want to better understand the limitations and appropriate uses of the products that are out there and then any new products that come.”

– CAPT Christopher Jones, PharmD, DrPH, MPH, SAMHSA

OVERDOSE MANAGEMENT & WITHDRAWAL SYMPTOMS

The development of best clinical practices for people presenting to the emergency department (ED) or clinic following xylazine exposure is an evolving process. Frontline clinicians, public health professionals, and clinical researchers from states and counties with high xylazine prevalence shared their experiences and the latest research findings from human exposure to xylazine.

Dr. Perrone from the University of Pennsylvania presented a study evaluating clinical outcomes of people presenting to the ED in which the vital signs of people with opioid overdoses involving xylazine were found not to be statistically significantly different than those exposed to opioids/fentanyl alone. In fact, the need for CPR and the onset of coma within four hours of arrival at the ED were more common in people where xylazine was *not detected*, suggesting that the combination of xylazine and an opioid may be less toxic than an opioid/fentanyl alone.³⁹

“Contribution of the opioid to respiratory depression and death is **substantially more significant** than that from xylazine.”

– Dr. Jeanmarie Perrone, University of Pennsylvania

Speakers and panelists stressed the importance of administering a reversal agent (e.g., naloxone, nalmefene) in any suspected overdose followed by supportive care. In the current landscape, polysubstance overdose is most common and the exact drugs and adulterants ingested will likely be unknown. When sedation continues after opioid overdose reversal with naloxone, it may be due to unreversed sedatives or post-stimulant washout. Reversal of respiratory depression is essential for survival.

³⁹ Love JS, Levine M, Aldy K, et al. Opioid overdoses involving xylazine in emergency department patients: a multicenter study. *Clin Toxicol* 2023;61:173–180. doi:10.1080/15563650.2022.2159427



The endpoint of effectiveness of naloxone isn't arousal, it's breathing."

– Dr. Lewis Nelson, Rutgers New Jersey Medical School

Withdrawal

Xylazine withdrawal shares many of the same symptoms as withdrawal from other substances, as described in Table 2. Since polysubstance overdose is more common, it may be difficult to discern what substances a person is withdrawing from by their symptoms alone. Current withdrawal management focuses on alleviating symptoms that are present. Harm reduction professionals reported that people are very familiar with withdrawal from fentanyl and the persons also using xylazine state that the withdrawal is different from that associated with opioids, and the level of anxiety experienced during xylazine withdrawal can be extreme.

TABLE 2. Overlapping Withdrawal Symptoms

XYLAZINE	OPIOID	BENZODIAZEPINE
<p>Anxiety</p> <p>Dysphoria</p> <p>Restlessness</p>	<p>Tachycardia</p> <p>Diaphoresis</p> <p>Restlessness</p> <p>Mydriasis</p> <p>Body aches</p> <p>Rhinorrhea</p> <p>GI symptoms</p> <p>Tremor</p> <p>Yawning</p> <p>Piloerection</p> <p>Anxiety</p> <p>Dysphoria</p>	<p>Tachycardia</p> <p>Hypertension</p> <p>Diaphoresis</p> <p>Anxiety</p> <p>Tremor</p> <p>Altered mental status</p> <p>Seizures</p> <p>Dysphoria</p>

Reversal Agents

Currently, there is not an FDA-approved agent to reverse the effects of xylazine in humans. Whether or not a reversal agent for humans would be beneficial is questionable, and the corresponding pros and cons associated with reversal agent use must be weighed. Practitioners voiced concern about precipitating withdrawal symptoms with the use of a reversal agent. Since fentanyl is currently driving fatal overdoses, focus should remain on opioid reversal and rescue breathing. Dr. Perrone, from the University of Pennsylvania, expressed, “So if in fact there is a xylazine withdrawal syndrome, having an antidote would probably generally not be able to be utilized in most of these polysubstance overdoses because you would in fact precipitate withdrawal.”

Practically speaking, the time to develop a drug to reverse xylazine effects in humans may surpass the lifespan of xylazine in the illicit drug supply.

COMPLICATIONS OF CHRONIC EXPOSURE TO XYLAZINE

The presence of xylazine in the illicit drug supply would likely remain silent if it wasn't for wound development. Xylazine is associated with deep flesh wounds and, in some people, may require extensive medical intervention. These wounds are often remote to the injection sites, are challenging to treat, and carry a special kind of

stigma. Moreover, there is not one consistent case definition of xylazine-related wounds, thereby complicating its diagnosis, treatment, and management.

Xylazine wounds scar people for life, setting up the potential for long-term discrimination and difficulty obtaining substance use treatment and health care overall. Therefore, there is this potential enduring challenge of further stigmatizing this community with permanent wounds that would be seen.

In addition, some of the physiologic effects seen in humans have already been documented in the veterinary literature when xylazine is administered to large mammals. These effects include heavy sedation, skin wounds, anemia, and glucose dysregulation.⁴⁰ Monitoring for these potential harms in populations with exposure to xylazine is essential to harm reduction strategies around xylazine and for the provision of holistic health care.

LIVED EXPERIENCE

Martín Lin Alcaraz from the Sanos Corporation in Puerto Rico graciously shared his experience with xylazine, providing an on-the-ground viewpoint of how xylazine in the illicit drug supply impacts people's lives. Martín Lin Alcaraz, via a Spanish-to-English translator, shared that he was exposed to xylazine for four to five years of his approximately 30 years of substance use.

“When I started to use this drug I literally lost consciousness. It was very hard for a person to really want to stop using that substance. When you started to use this substance...you couldn't use regular heroin, because you couldn't feel the heroin. You didn't feel the kick. You didn't feel the true legit heroin. You didn't feel it.”

“I started to see a great deal of deterioration in my colleagues, my friends. That picture that you saw about those ulcers, that's nothing compared to the experience. I saw people with maggots in their ulcers, deep ulcers. One thing that was truly repugnant and very painful.”

Presenters shared additional stories and quotations about use experiences with sensations, sedation, withdrawal, and wounds. Dr. Traci Green from Brandeis University, shared the following perspective from a study published in 2022:⁴¹

“You know, I don't like falling asleep and waking up and having no idea how I ended up on the floor or why my arm is sore from, you know, being in an awkward position or why I have cuts and bruises and I don't know how I got them.”

– Shook, 38, male, from Philadelphia

CARE MANAGEMENT IN A FRAGMENTED HEALTH CARE SYSTEM

Fragmentation of the U.S. health care system and institutional stigma hinder holistic care for people afflicted with xylazine-related wounds. If an individual with a substance use disorder also has a wound, they cannot get into inpatient rehabilitation services because the services do not manage wounds. Therefore, the individual is referred to a skilled nursing facility that provides wound care but does not provide treatment for substance use disorder.

40 Zagorski CM, Hosey RA, Moraff, et. al. Reducing the harms of xylazine: clinical approaches, research deficits, and public health context. *Harm Reduction J* 2023;20:141. doi.org/10.1186/s12954-023-00879-7

41 Reed MK, Imperato NS, Bowles JM, Salcedo VJ, Guth A, Rising KL. Perspectives of people in Philadelphia who use fentanyl/heroin adulterated with the animal tranquilizer xylazine; Making a case for xylazine test strips. *Drug Alcohol Depend Reports*. 2022;4:100074. <https://doi.org/10.1016/j.dadr.2022.100074>



Dr. Malik Burnett from the Maryland Department of Health described this issue well:

“And so, it highlights the disconnected nature of our health care system and how each of those parts of the system are unable to work with one another and leave individuals with multifaceted problems... vulnerable and unable to be able to seek care anywhere comprehensively. They have to go from place to place to place... that’s not something that individuals who have strong and deep-seated substance use disorder have the capacity to be able to navigate.”



[The state of Maryland] is trying to put in infrastructure and reform regulations to be able to ensure that some of that care can happen in same space and place, so integrated co-occurring care where individuals can receive wound-based care, substance use disorder care, mental health care, and primary care all in one place. That’s heavy lifting, but it’s that kind of state level-based and federal level-based intervention, particularly as it relates to funding that’s necessary in order for us to be able to really start tackling this problem across all the various dimensions that people are struggling with.”

Links to additional resources to prevent overdose and inform clinical care.

- NeverUseAlone: <https://neverusealone.com/>
- MA Overdose Prevention Hotline: <https://massoverdosehelpline.org/>
- PennCAMP.org Best Practices for Management of Xylazine Withdrawal and Xylazine-related Overdose: <https://penncamp.org/wp-content/uploads/2023/05/CAMP-Xylazine-Best-Practices-1.pdf>

5. Public Health Responses

Presenters and panelists provided different vantage points on mitigating risks from human xylazine exposure.

Substantial variability exists regarding the presence of xylazine in the illicit drug supply, both within and across regions of the country. Because of this variability, it is difficult to quantify exactly how much xylazine people are being exposed to in their community. Understanding the problem at the community level is necessary to be most effective with harm reduction efforts.

PUBLIC HEALTH IMPLICATIONS OF XYLAZINE PRESENCE IN THE ILLICIT DRUG SUPPLY

It is important to educate the public and first responders about the increasing prevalence of xylazine in the illicit drug supply and how this affects responding to an overdose. Already mentioned, but worth repeating, **naloxone or nalmefene should be administered in a suspected or known drug overdose, irrespective of whether or not xylazine is suspected to be present.** The importance of rescue breathing should also be emphasized, along with a reminder that additional doses of naloxone or nalmefene are not needed once a person is breathing.

Wound education is also important, for health care providers, harm reduction professionals, and the public, such as how to identify what could be a xylazine-related wound and the immediate steps to take once a wound has been identified. It is critical that a person notifies their public health professional or seek immediate medical care, rather than waiting until the wound(s) become large and disfiguring. Harm reduction and syringe exchange services are starting to provide wound care kits and information about how to provide proper wound care.

SURVEILLANCE & LOCAL, REGIONAL, AND NATIONAL COLLABORATIONS

Drug checking and surveillance programs provide opportunities to identify and monitor xylazine in the illicit drug supply and estimate the prevalence of xylazine exposure in humans. Patient-centered drug effect surveillance enhances drug testing data with first-person information about the drug experience. This report summarizes three drug-checking and surveillance programs described during the meeting.

Community drug checking in Massachusetts is placed within a harm reduction program where individuals can provide samples for testing. The **Massachusetts Drug Supply Data Stream (MADDS)** team coordinates community drug checking and provides rapid information and alerts to communities about the drug supply. Data are provided on a public website (StreetCheck.org) giving real-time information about the local supply and shifts in the prevalence of xylazine. This allows harm reduction professionals to counsel people based on lab check findings and to collect use experiences associated with the samples collected. Community drug checking refines response capacity and helps to answer questions by public health, harm reduction sites, and people using drugs.

The **Rapid Analysis of Drugs Program** is a statewide drug checking program established in Maryland in partnership with the National Institutes of Standards and Technology for lab testing.⁴² This program is also integrated into a system of care, built upon the existing harm reduction infrastructure present in the state. Harm reduction sites are positioned to collect person-level experiences at the same time the sample is provided. Laboratory analysis complements rapid on-site drug checking for the presence of xylazine in submitted samples from the drug supply or paraphernalia and provides a confirmatory result. This epidemiological drug surveillance program conducted at the state level allows the public health department to understand in real-time what is happening in the illicit drug supply and rapidly share data both state-wide and to individual sites that provided the samples.

Drug early warning systems (EWS) are a multidisciplinary network aiming to exchange information, identify emerging drugs and changes in drug markets, and assess risks.⁴³ **NPS Discovery** is an open access drug EWS launched in 2018 by The Center for Forensic Science Research & Education (CFSRE). Information about drugs and adulterants is obtained from public health, safety, scientific, medical, and legal perspectives with the goal of reducing harm. Aspects of NPS Discovery include:^{44,45}

1. Open-access drug early warning system
2. Combine aspects of surveillance, casework, and research
3. Analyze samples and generate data in-house
4. Develop a panel of high-impact reports
5. Disseminate results and reports widely to stakeholders

The following links provide more information about these programs.

- MADDs: <https://heller.brandeis.edu/opioid-policy/community-resources/madds/index.html>
- Rapid Analysis of Drugs: <https://www.cdc.gov/mmwr/volumes/72/wr/mm7217a2.htm>
- NPS Discovery: <https://www.cfsre.org/nps-discovery/>

42 Russell E, Sisco E, Thomson A, et al. Rapid Analysis of Drugs: A Pilot Surveillance System To Detect Changes in the Illicit Drug Supply To Guide Timely Harm Reduction Responses — Eight Syringe Services Programs, Maryland, November 2021–August 2022. *MMWR Morb Mortal Wkly Rep* 2023;72:458–462. DOI: <http://dx.doi.org/10.15585/mmwr.mm7217a2>

43 Krotulski AJ, Xylazine Perspectives from Forensic and Clinical Toxicology; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

44 Ibid.

45 The Center for Forensic Science Research & Education. NPS Discovery. www.cfsre.org. <https://www.cfsre.org/nps-discovery/>

6. Priorities for Research and Development

Unfortunately, with a volatile and ever-changing illicit drug supply, research seems to lag behind current and emerging threats. Collaboration is essential in order to answer the most important questions and address immediate clinical research needs. Emphasis should also be placed on creating a roadmap for navigating future responses to dangers with the illicit drug supply.

The highest priority areas for research identified were:

- Wound prevention and early identification and treatment in order to prevent permanent disfiguration, amputations, and personal trauma associated with these wounds
- Data collection and data sharing in order to support evidence-based decision making

Table 3 lists the xylazine-related research needs and knowledge gaps presented during the meeting. Well-controlled clinical trials are necessary to answer some of the questions posed, but often strict protocols exclude a large portion of the population being affected by substances present in the illicit drug supply. Real world data, from a broad and inclusive population, is also needed to inform the evidence base. A key consideration when designing clinical trials is generalizability. Will the end results truly inform practice across treatment settings and populations? Incorporating the “practical details of the realities of current substance use practice [will] help us get to treatment interventions faster.”⁴⁶

TABLE 3. Research Needs and Current Knowledge Gaps

EPIDEMIOLOGY & DATA
<ul style="list-style-type: none">• Need comprehensive and systematic data collection from all states and jurisdictions• Is the increased prevalence of xylazine due to increased presence in the drug supply or due to increased testing?• What is happening in areas not routinely testing for xylazine?• What other adulterants are found with fentanyl?
PATHOPHYSIOLOGY, PHARMACOLOGY & PHARMACOKINETICS
<ul style="list-style-type: none">• What is the pharmacokinetic and pharmacodynamic profile (including secondary pharmacology activity) in humans?• What is the significance of xylazine metabolites?• Wound pathophysiology• How does route of administration affect pharmacokinetics, pharmacodynamics, and wound pathophysiology?• How do comorbidities affect these findings?• How do other drugs also found in the nonmedical drug supply affect these findings?

46 Wightman RS. Drug Overdose Testing (DOT): Xylazine; October 4, 2023. <https://reaganudall.org/news-and-events/events/public-meeting-mitigating-risks-human-xylazine-exposure>

HARM REDUCTION, CLINICAL & HEALTH SERVICES

- Development of in vitro diagnostic tests
- How do xylazine and metabolite concentrations correlate with clinical symptoms and outcomes?
- How does xylazine affect pregnant women? the fetus? Neonates?
- What is the best clinical practice for people presenting after xylazine exposure with regard to overdose, dependence, and withdrawal management? How does time from ingestion affect this practice? What aspects of treatment change with polysubstance overdose?
- Does xylazine exposure complicate the transition to medications for opioid use disorder (MOUD)? Which MOUD is most likely to lead to successful induction and retention in treatment?
- What strategies are individuals using to reduce harm?

EDUCATION & COMMUNICATION

- What is the most effective messaging about xylazine for each audience (e.g., substance users, harm reduction programs, health care professionals, public health administrators)?

PRODUCT DEVELOPMENT

Product development must be centered around the people we are trying to serve. It also must be informed by people who use drugs and those on the front lines witnessing the harms brought about by exposure to xylazine. Development considerations should include context of use, acceptability, cost, equity, and accessibility.

7. Actions Needed for Progress/ Future Directions

An important message across sessions was that in order to reduce overdose deaths we can't lose sight of what is driving the overdose crisis. Xylazine is a complicating factor. By focusing on one drug or one adulterant, we risk losing sight of the big picture and will be in the same position, again talking about mitigating the health effects of new substance.

“Because xylazine it's just another substance, and if we could solve all of the problem with xylazine in today, but not dealing with the mental health issues of people and health issues of people, tomorrow we'll just have another problem with another substance. We'll be replacing one problem for another. Because this is not only about xylazine.”

— Martín Lin Alcaraz, Sanos Corporation, Puerto Rico

A coordinated response is essential to prevent overdose deaths not only from fentanyl and adulterants such as xylazine, but from emerging substances such as novel fentanyls, nitazenes, and benzodiazepines. Support is needed from federal, state, and local partners to adequately manage the xylazine and future threats. Communication and information-sharing across all disciplines is critical in order to stay on top of identified and emerging risks and rapidly identify health risks from the ever-changing illicit drug supply.

The following actions are needed to help people already affected by xylazine and to mitigate future risks.

1. Leveraging and improving real-time surveillance and rapid response

A nimble process is needed to track the “fingerprint” of the illicit drug supply that varies greatly over time and geography. A stronger drug checking infrastructure is crucial at the individual, clinical, and community levels to understand emerging substances and combinations of substances.

2. Data collection and information sharing

Data collection, both quantitative and qualitative, is necessary in order to develop evidence-based interventions. Transparency in testing libraries and limitations of testing methods improves knowledge of how results can be interpreted in research and clinical practice. Coordinated, efficient, and multidirectional communication facilitates information sharing so people on the front lines have access to the latest information and researchers and analysts gain insight into what is being seen in day-to-day practice. Information sharing extends to people using substances so individuals are aware of changes occurring in the illicit drug supply and can take steps to protect themselves.

3. Person-centered care

Meet people where they are in order to provide the most effective and efficient services. Expecting people to navigate complicated public health and health care systems is a barrier and adds to the burdens already placed on the people these systems are entrusted to help. The provision of comprehensive services and wound care are top priorities for action.



If we can create spaces and places where you can be able to provide that care, whether it's just simplified housing support initially followed by all the rest of the support from a substance use, wound care, mental health care, and primary care standpoint, and we can get paid for that sort of work, then we can really start to tackle the problem more substantively.”

– Dr. Burnett, Maryland Department of Public Health

8. Conclusion

The most important takeaway from the collective wisdom shared during this meeting is to not lose sight of the bigger picture—the opioid epidemic and overdose crisis. The focus is currently on xylazine, but if we narrow our scope of understanding to only this substance, we will miss intervention opportunities as other substances emerge. If we only address one product at a time, we will never catch up or be proactive in mitigating risk.

A comprehensive, collaborative approach is necessary in developing a strategy to understand and respond to future health and safety hazards arising from the illicit drug supply.

Appendix: Meeting Agenda

MITIGATING RISKS FROM HUMAN XYLAZINE EXPOSURE

Wednesday, October 4, 2023, from 9:15 am – 5 pm ET
Hybrid Public Meeting
In-Person: Marriott Marquis
901 Massachusetts Avenue NW, Washington, DC 20001
Metro Stop: Mount Vernon Square, 7th Street Convention Center

Meeting Description:

The Reagan-Udall Foundation for the FDA, in partnership with the U.S. Food and Drug Administration (FDA), is holding a hybrid public meeting entitled “**Mitigating Risks from Human Xylazine Exposure.**” This hybrid public meeting will explore real-world experiences and scientific evidence on emerging data trends for human xylazine exposure. This meeting also seeks to examine concrete strategies for drug development and clinical research that directly supports the mitigation and reduction of risks associated with human exposure to xylazine. Workshop presentations and discussions will include clinical and scientific experts, community and harm reduction organizations, academic researchers, and federal partners.

Xylazine is a non-opiate sedative, analgesic, and muscle relaxant only authorized in the United States for veterinary use, as approved by the FDA. It is not currently a controlled substance under the U.S. Controlled Substances Act, nor is it approved for human use. However, human exposure to xylazine has emerged as a growing public health issue. Last year, the [Drug Enforcement Administration reported](#) that forensic laboratory identifications of xylazine have risen in all four U.S. Census regions between 2020 and 2021. Furthermore, due to its impact on the opioid crisis, fentanyl mixed (adulterated) with xylazine has also been declared an emerging threat by the [White House’s Office of National Drug Control Policy](#). Given this emerging threat, FDA believes a better understanding of the landscape of available tools and preventive strategies for reducing illicit use of xylazine is needed to advance the development and access to evidence-based treatment for human exposure.

Meeting Goals:

1. Understand the current landscape of xylazine and similar drug compounds in the United States, including changes in patterns of drug use, trends in the illicit drug supply, and real-world experience of overdose.
2. Identify specific areas of exploratory research that can be used to mitigate risks associated with human xylazine exposure.
3. Discuss existing data gaps and specific strategies for improving current surveillance systems.

9:15 am	Welcome
	Speaker: Susan C. Winckler, RPh, Esq, Chief Executive Officer, Reagan-Udall Foundation for the FDA
9:25 am	Opening Remarks: Public Health Strategy
	Speaker: David Holtgrave, PhD, Assistant Director, White House Office of National Drug Control Policy
9:40 am	Opening Remarks: Overview of Xylazine and Addressing Data/Research Gaps
	Speaker: Marta Sokolowska, PhD, Deputy Center Director for Substance Use and Behavioral Health, Center for Drug Evaluation and Research (CDER), FDA
9:55 am	Session 1: Current Landscape and Epidemiological Trends
	<ul style="list-style-type: none"> • CDR Jean Ko, PhD, Deputy Director of Scientific Programs, Division of Overdose Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention • Amanda DiStefano, Intelligence Analyst II, Liberty Mid-Atlantic High Intensity Drug Trafficking Area • Van Jackson, Drug Intelligence Officer, Liberty Mid-Atlantic High Intensity Drug Trafficking Area • Traci Green, PhD, MSc, Professor and Director of Opioid Policy Research Collaborative, Brandeis University • Erin Russell, MPH, Principal, Health Management Associates
11:05 am	Session 2: Pharmacological and Clinical Research Needs
	<ul style="list-style-type: none"> • Keith K. Burkhart, MD, Senior Advisor for Medical Toxicology, Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA • Zoë McElligott, PhD, Associate Professor, Bowles Center for Alcohol Studies, University of North Carolina • Gonçalo Gamboa da Costa, PhD, Senior Science Advisor, National Center for Toxicology Research, FDA • Alex Krotulski, PhD, Associate Director-Toxicology/Chemistry, Center for Forensic Science and Research and Education
12:05 pm	Lunch
	In-person attendees are responsible for their own lunch. Please see handout/event staff for a list of nearby options.

1:10 pm	Session 3: Exploring Product Development Research Needs
	<ul style="list-style-type: none"> • Jeanmarie Perrone, MD, Director, Center for Addiction Medicine and Policy, Perelman School of Medicine, University of Pennsylvania • CAPT Christopher Jones, PharmD, DrPH, Director, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration • Nabarun Dasgupta, PhD, MPH, Co-Founder and Board Chair with Remedy Alliance/For the People • Timothy Stenzel, MD, PhD, Director, Office of In Vitro Diagnostics, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, FDA • Zachary Dezman, MD, MS, Division of Anesthesia, Addiction Medicine, and Pain Medicine, Office of Neuroscience, Office of New Drugs, CDER, FDA
2:20 pm	Session 4: On the Ground Response to Xylazine
	<ul style="list-style-type: none"> • Martin Lina Alcaraz, peer educator, SANOS Corporation, Puerto Rico • Alice Bell, LCSW, Overdose Prevention Project Coordinator, Prevention Point Pittsburgh • Malik Burnett, MD, MBA, MPH, Medical Director, Harm Reduction Services, Maryland Department of Health • Luis Roman, PsyD, Clinical Psychologist, Intercambios, Puerto Rico • Lewis Nelson, MD, MBA, Director, Division of Medical Toxicology and Addiction Medicine, Rutgers New Jersey Medical School • Jennifer Tuerke, Executive Director, Voices of Hope Maryland
3:35 pm	Session 5: Future Directions
	<ul style="list-style-type: none"> • Rachel S. Wightman, MD, Associate Professor of Emergency Medicine and Epidemiology, Alpert Medical School, Brown University • Jane Acri, PhD, Acting Deputy Director, Division of Therapeutics and Medical Consequences, National Institute on Drug Abuse, National Institutes of Health • Elizabeth M. Oliva, PhD, VA National Opioid Overdose Education and Naloxone Distribution (OEND) Coordinator, VA Office of Mental Health and Suicide Prevention, Veterans Health Administration • Laurie Konsella, MPA, Senior Public Health Advisor, Office of Regional Health Operations, Region 8, Office of the Assistant Secretary for Health, US Department of Health and Human Services
4:45 pm	Closing Remarks
	Speaker: Marta Sokolowska, PhD, FDA
5 pm	Adjourn



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