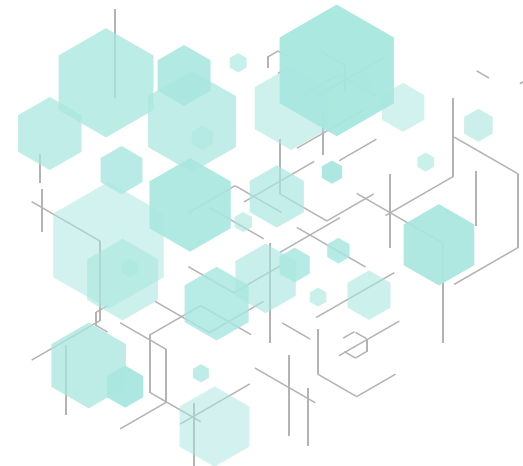
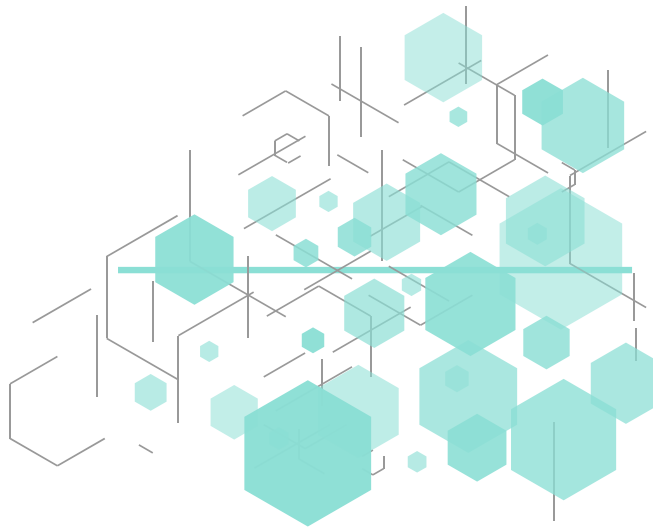


# FENTANYL DRUG CHECKING AND SCREENING:

## Roundtable on Community Perspectives Summary Report



## Contents

Executive Summary.....	2
Introduction .....	3
Roundtable Insights .....	4
Conclusion.....	13

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## Executive Summary

The Reagan-Udall Foundation for the FDA (FDA Foundation), in partnership with several operating divisions within the Department of Health and Human Services (HHS), convened two roundtable meetings to understand the perspectives of the harm reduction community, clinicians, and researchers about using fentanyl drug checking and screening as harm reduction and clinical strategies.

These proceedings summarize the discussion from the harm reduction community roundtable (n=16) and supplemental individual interviews (n=6), inclusive of representatives from national and local harm reduction organizations, state and local government agencies, tribal organizations, and researchers who have experience distributing fentanyl test strips (FTS) or are knowledgeable about FTS specifically or drug checking more generally. The focus of the harm reduction community roundtable was to: (1) gather community perspectives on using FTS and other drug checking methods and (2) discuss next steps for technology development, research, and practice.



### Key themes included the following:

- FTS are a valuable community drug checking tool, but additional research/improvements and greater access are needed
- Standardized information about best practices for FTS use is needed
- Drug checking strategies should be implemented using equity-centered and culturally appropriate approaches
- FTS require integration into broad, locally tailored harm reduction programs
- Legal, policy, and funding barriers prevent more widespread adoption of FTS



### Key opportunities included the following:

- Invest in research to enhance technical capabilities, knowledge of best practices, and evaluation of outcomes
- Provide information on how to use FTS and how to interpret results
- Target outreach to people not traditionally served by SSPs and groups who generally experience health disparities
- Wrap FTS and other drug checking methods into a broader harm reduction framework that includes naloxone, SSPs, and other tools
- Identify which federal agencies have jurisdiction over FTS and pursue appropriate external partnerships to address barriers to FTS adoption

## Introduction

Policy and practice changes are creating an evolution in how communities and the substance use and health care fields respond to substance use and substance use disorders (SUDs). These changes are providing funding and momentum to increase health care and public health responses to substance use; increasingly, this includes harm reduction approaches aimed at reducing negative consequences associated with drug use. To address the significant increases in overdose deaths attributed to fentanyl combined with various other drugs, more community-based organizations have started to distribute fentanyl test strips (FTS) as a strategy to identify illicitly manufactured fentanyl and its analogues.

As HHS considers how to engage with such programs, it is essential to gather community perspectives on FTS and other drug checking methods to inform next steps for technology development, research, and practice improvements. The FDA Foundation, in partnership with several HHS operating divisions, convened two roundtable meetings to understand the perspectives of the harm reduction community, clinicians, and researchers about using fentanyl drug checking and screening as harm reduction and clinical strategies.

### Background on drug checking as a harm reduction strategy

Many U.S. harm reduction programs now include drug checking initiatives, as well as syringe exchange access, counseling, and support services.<sup>i</sup> Drug checking services allow people to better understand the contents and dose/strength of the substance they intend on taking and mitigate harms associated with consuming an unknown substance.<sup>ii</sup> Drug checking encompasses a range of interventions, such as color-spot testing, gas or liquid chromatography, and various methods of spectroscopy. Testing may be performed independently by consumers or sent to a centralized lab for analysis.<sup>iii</sup> While locations in the United States are beginning to expand drug checking for harm reduction purposes, these types of services have long been used in music festival and community settings in Canada, Australia, and many European countries.<sup>iv</sup> Drug checking approaches are inclusive of laboratory-based and point-of-care models, and in the U.S., historically have been limited to music festivals, some syringe services programs (SSP), and community-based organizations.<sup>v</sup>

Drug checking technology is also used for purposes outside of the harm reduction framework, including by law enforcement, toxicology labs, and health care settings to determine the presence of illicit drugs.<sup>vi</sup> Under these circumstances, the information may be used for clinical decision making as well as for the broader public health need of creating a type of surveillance system to improve understanding about local drug supplies.

As FTS were originally developed as a field test to screen for the presence of fentanyl in urine, harm reduction organizations are using FTS “off label” to inform people who use drugs (PWUD) of the composition (and potential contaminants) present in their drugs.<sup>vii</sup> This use has raised questions about the feasibility of FTS for harm reduction purposes because the technology is being used in ways and settings for which it was not designed. As a result, harm reduction providers, researchers, and others have identified challenges with the technology and other implementation concerns that should be addressed as part of any comprehensive effort to scale up FTS distribution and use.

## Roundtable Insights

Participants at the harm reduction community roundtable included 16 individuals, with six supplemental individual interviews conducted to capture additional insights. Participants included PWUD, local and national harm reduction leaders, researchers, state government public health representatives, federal grantees who use harm reduction strategies, rural technical assistance providers, Native American harm reduction leaders, and toxicology specialists. A clinician meeting was also held and summarized in a separate paper.<sup>1</sup>

*Both community providers and clinicians shared concerns about the technology and desires for improvements to provide more accurate information.*

The roundtable discussions were centered on gaining a basic understanding of how participants are using FTS, what challenges and barriers they are experiencing, and where there are opportunities to improve learning and practice in future efforts. Additional areas of inquiry included whether there are methods other than FTS that participants are using or would like to use, and what related challenges and opportunities there are for their application to front-line harm reduction and surveillance use. While some themes were consistent across the two roundtables, others were more nuanced based on the setting and purpose, (e.g., use for clinical health care decisions, use for harm reduction, and use for surveillance). Shared themes and key distinctions between the roundtable discussions are highlighted in this summary. The themes are organized around an ecological framework that starts with those that most directly impact individuals’ experiences and progresses to those that indirectly impact the individual through the larger contextual environment.

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<sup>1</sup> A report that summarizes themes from the roundtable with community representatives can be found in *Fentanyl Drug Checking and Screening: Roundtable on Clinician Perspectives* on the FDA Foundation website: <https://reaganudall.org/programs/substance-use-disorders>



**Key theme**

FTS are a valuable community drug checking tool, but additional research/improvements and greater access are needed

During the discussion, participants explained that they are distributing FTS via a range of harm reduction settings and in a variety of ways, often subject to funding limitations. In some communities, FTS are distributed in partnership with community-based SUD treatment providers. In others, they are being included in overdose prevention “tool kits” that are disseminated through emergency departments, harm reduction groups, and recovery organizations. The group identified one specific dissemination strategy used to reach beyond traditional harm reduction organizations: conducting outreach to organizations and settings that serve the general public. Participants indicated that focusing on non-traditional, non-clinical sites like barbershops, the Salvation Army, bars and clubs, and other community-facing entities could increase reach, particularly to people who may not identify as needing harm reduction services because they do not think they are at risk for an overdose.

*Both community providers and clinicians shared concerns about the technology and desires for improvements to provide more accurate information.*

While participants were generally supportive of the use of FTS as a drug-checking strategy, they expressed concerns about the technology and the implications of its use as an overdose prevention strategy. As one participant said, “The technology is easy – FTS just weren’t designed with real-world drug use in mind.” Participants explained FTS may be hard to use and interpret for individuals checking drugs on their own. FTS use requires access to clean water and good lighting to read results accurately; these requirements may be particularly challenging for vulnerable individuals like those experiencing homelessness, who may lack access to bathrooms or other venues with adequate lighting.

The pros and cons of current FTS technology and other available drug-checking methods were also a significant topic of discussion. While participants indicated that current FTS have value, there is a desire to have more sophisticated technology that can provide more precise data about the contents of drugs. However, they acknowledged that more advanced technology like spectrometry is in scarce supply in the U.S. and has shortcomings, like cost and complexity, that may be challenging for harm reduction organizations. Participants cited what they see as promising research advances to move beyond the use of disposable test strips alone to an “idealized practice” of using FTS, then Fourier-transform infrared (FTIR) spectroscopy, with follow-up confirmatory testing. They described how FTIR can miss fentanyl in low concentrations and has low power to discriminate between closely related fentanyl analogues, so accuracy requires confirmatory testing (e.g., with liquid chromatography).<sup>viii</sup> Another

technology of interest was portable spectroscopy (infrared, near-infrared, and Raman), which is valued because of the sensitivity to the presence of different cutting agents.

Additional insights included the following:

- There are numerous questions about who is accessing FTS, who is most likely to benefit, and where there are gaps. Participants discussed who they see as most “at risk” and in need of targeted outreach for receiving FTS. Subpopulations mentioned included:
  - People who lack basic resources, e.g., clean water and housing.
  - People who may not be connected to harm reduction services or regularly receive information about safer use because their use is occasional/casual.
  - People who are younger, middle class, and more educated who can afford tests and avoid using when results are positive.
  - People who are seeking to use fentanyl intentionally.
- Participants identified several core technological challenges with FTS that affect the usability and reliability of FTS for individuals and organizations:
  - FTS are non-quantitative testing devices that do not provide information on quantity, purity, or presence of adulterants or fillers.<sup>ix</sup> A few harm reduction providers expressed some skepticism about the value of FTS in fentanyl-saturated drug markets for this reason. Others indicated that for surveillance purposes, there is a significant need for both qualitative information about which fentanyl derivatives are present and a reference standard to check drugs against.
  - FTS produce false positives with MDMA and methamphetamine.
  - There is a lack of uniformity in test strips. Analysis shows batch-to-batch sensitivity for some fentanyl analogues varies greatly.
  - FTS check for a relatively small number of analogues.



**Key opportunity**

Invest in research to enhance technical capabilities, knowledge of best practices, and evaluation of outcomes

The discussion suggested there is room to invest in research on optimal use of FTS, implementation of FTS as a harm reduction strategy, and outcomes associated with wide adoption of FTS.

- Federal agencies could invest in research to improve understanding about whether there are certain populations of PWUD for whom FTS are most beneficial.

- Participants indicated federal agencies could play a role in addressing concerns about the need to improve FTS technology and create more uniformity in FTS. Specific suggestions included:
  - Developing technology to provide quantitative information about which fentanyl analogues are present, and whether the amount of fentanyl present is within a “danger zone” that is potentially lethal.
  - Supporting FTS technology with an indication for testing drugs for presence of fentanyl for harm reduction purposes, not for clinical or forensic purposes.
  - Working directly with manufacturers as part of product development, supporting cross-lab validation studies and/or the development of shared methodology for use by communities to access, interpret, and share results across sites.



**Key theme**  
Standardized information about best practices for FTS use is needed

Participants identified a need for the development and dissemination of standardized educational materials including appropriate testing guidelines, general “how to use” information, limitations of FTS, and other applicable harm reduction best practices. However, the group cautioned against any sort of standardized guidance that would stifle innovation or

*Information about drug checking rationales and the role of FTS should be part of a public health-focused harm reduction effort, and best practices for implementation and use need to be standardized and disseminated to various audiences.*

flexibility typically needed with community-based interventions. Several participants raised concerns about the education and marketing materials being used by FTS manufacturers to advertise their use for harm

reduction purposes. As one participant said, “The commercial expansion into this space is really warping the intervention.” Several participants raised concerns that the fentanyl messaging being used by some law enforcement entities is contributing to misinformation and fearmongering about fentanyl “spread” and mixture with other drugs. Several core messages were identified by the group as important to incorporate in clear guidance, including:

- FTS have value as an overdose prevention tool as well as an outreach and engagement tool that may help initiate meaningful conversations with PWUD around harm reduction, even in markets where fentanyl presence/contamination is widespread.
- FTS should be one component of a broader harm reduction and overdose prevention framework, and they should be accessible through settings and services that reach the full continuum of PWUD.



- FTS can be used for drug checking for harm reduction purposes, but there are technology and subpopulation-specific limitations that need to be considered.
- FTS should be framed as a public health intervention that is part of a broader set of multitiered public health resources and responses, not law enforcement responses.



### Key opportunity

Provide information on how to use FTS and how to interpret results

- The appropriate federal agency or agencies could take the lead in developing useful tools (e.g., a consumer report) for state and local agencies, harm reduction programs, clinical providers, and others distributing FTS. Consistent with harm reduction best practices, participants suggested guidance be developed in consultation with PWUD, harm reduction providers, and other key stakeholders to ensure real-world relevance.
- The appropriate federal agency or agencies could assist in the dissemination of standardized guidance and other education materials, provide training and technical assistance resources, and support learning discussions to address misinformation being shared about FTS.



### Key theme

Drug checking strategies should be implemented using equity-centered and culturally appropriate approaches

Participants emphasized the importance of tailoring services to various subgroups of PWUD, including those who are more vulnerable to overdose because of various aspects of marginalization by society and existing systems. In addition, participants indicated that there are many people vulnerable to overdose who would benefit from FTS and drug checking but are not being served by traditional harm reduction programs. Thus, there is a gap in understanding

*Shared concerns were expressed about the need for equity-focused approaches and those that target broader social and health needs: “This isn’t a fentanyl crisis; this is a crisis of criminalization, poverty, and racism. Addressing equity and broader social determinants is vital.”*

what alternatives to traditional harm reduction services may work better for engaging different groups of PWUD regarding drug checking.

While there was consensus on the importance of prioritizing vulnerable populations, varying perspectives on who is most vulnerable and why underscored the need to better understand various subgroups of PWUD.

Participants identified the following populations as having distinct needs for culturally appropriate and equity-centered approaches:

- Given persistent racial disparities in overdose rates, treatment access, criminal justice involvement, and health services in general, participants indicated it is important to strengthen culturally and linguistically appropriate drug checking services for Black and Indigenous people across all age groups and geographic locations.
- Youth and young adults between the ages of 18 and 35 were identified as an additional vulnerable group requiring culturally and developmentally appropriate services. Participants explained that the age of people they are seeing overdose in their communities has shifted dramatically younger in recent years. They reported the highest rates of use and overdose were among this group, who are also the least likely to be engaged in harm reduction services.
- Rural communities were also identified as places with greater health disparities and less access to FTS and related harm reduction services. Participants thought expanding telehealth strategies, which some states have begun to implement, may particularly benefit this group.



**Key opportunity**

Target outreach to people not traditionally served by SSPs and groups who generally experience health disparities

- Specific investments could be made to support strategies to serve people experiencing homelessness, as well as other groups for whom there are fewer resources. Potential investments could include leadership development, capacity building, infrastructure support, and workforce strategies. Priority could be given to organizations that are led by people of color and/or those that serve Black, Indigenous, and people of color (BIPOC) communities with culturally and linguistically appropriate harm reduction, treatment, peer supports, and other critical services.
- Specific investments could be made to tailor developmentally and culturally appropriate outreach for older youth and young adults between the ages of 18 and 35. This could include outreach and engagement strategies for young people of color, as well as those who may not see themselves as vulnerable to overdose due to their drug use being occasional/casual.
- Federal agencies could collect and analyze data aggregated by race, income, gender, and other demographics to understand who is benefiting from FTS and other drug checking services and where there are disparities and gaps in access.



**Key theme**

FTS require integration into broad, locally tailored harm reduction programs

During the discussion, participants emphasized the importance of applying lessons learned from previous investments into harm reduction research, best practices, and community-informed approaches. As one participant said, “We are not starting from scratch.” Participants highlighted the following lessons as potentially applicable to the utilization of FTS:

- Ongoing need to address stigma and reduce barriers that limit access to FTS. Participants indicated that stigma related to substance use continues to create barriers for harm reduction activities, including the use of FTS and broader drug checking. These barriers underscore the need for trust building and community education to improve understanding and acceptance of harm reduction activities as part of broader overdose prevention efforts. Participants also shared the observation that not all PWUD understand the benefits of using drug checking and other harm reduction services because they don’t see themselves as having SUDs and therefore don’t think they are at risk for overdose. While this dynamic is not well understood, participants suggested that the tendency of some people who engage in occasional/casual drug use to distinguish themselves from people with SUDs and thus decline harm reduction services may be rooted in stigma.
- FTS should be delivered as part of a comprehensive harm reduction framework that reaches the full continuum of PWUD.
  - FTS distribution provides an opportunity to engage PWUD in broader conversations about safer use, availability of other services, interest in treatment services, etc. As one participant said, when delivered in the context of a broader services framework, FTS provide an opportunity to talk about something other than “death and naloxone.”
  - A broader harm reduction framework can help address concerns about the larger issue of a contaminated drug supply and the presence of fentanyl in a range of substances, not just opioids. Participants expressed concern about the current focus on fentanyl and feared losing sight of other existing and emerging drug trends that may be more dominant in certain regions, such as stimulants. FTS could be used to look at data more broadly around overdoses to improve understanding of how the drug supply and (poly)drug use may be changing.
- A more systematic, community-level approach to drug checking is needed.

*Participants cited the importance of localized strategies that increase access to broader harm reduction services (e.g., naloxone and safe consumption sites) that are known to prevent adverse outcomes.*

- Participants stated that using different methods to create a sequential testing approach could make the drug checking process more informative. According to participants, ideally FTS are combined with other testing methodologies to determine what other contaminants are present. They indicated FTS can be used as a “first step” to determine the presence of fentanyl, and then a technology like spectrometry can be used as a “second step” to understand what other contaminant(s) may be present. Finally, they suggested a “third step” to analyze broader drug seizure data to understand how prevalent a drug is at the community level. One participant described a need for confirmatory testing steps, stating that understanding community prevalence was required to determine the “ground truths” of positive and negative predictive value.
- Participants emphasized the critical importance of having locally informed efforts because drug supplies are locally and geographically defined. They described community drug checking as an essential component to understanding local trends and nuances. Several broader, non-FTS examples of drug checking that arose in discussion included the Drug Information and Monitoring System, a distributed network of drop-in centers providing low-barrier access to presumptive testing in the Netherlands; and Energy Control’s Drug Testing Service, which allows identification and quantification of drug samples destined for personal use in Spain. The latter facilitates a continual follow-up of trends in the illegal drug market and provides warnings in case of incidents that involve significant health risks. The South Carolina Department of Health and Environmental Control also has a program that collects and tests drug samples from hospitals from patients who have overdosed; South Carolina hospitals are increasingly participating, making the analysis more statewide.
- One participant suggested that if each state could permit forensic or academic labs to receive samples from the public, it would greatly enhance capacity for community drug checking. They highlighted the impediment of forensic labs only testing criminal case samples. According to another participant, “There are labs with capacity, talent, technology and ‘social will’ to perform tests that are held back by [state] policy...willing labs ‘can’t do it, won’t do it’ because of controls around their ability to perform analytical services.” A participant further stated that one lab in California provides mail-in services for most of the country.



**Key opportunity**

Wrap FTS and other drug checking methods into a broader harm reduction framework that includes naloxone, SSPs, and other tools

Participants indicated a need for a unifying framework for advancing harm reduction approaches that addresses national, state, and local issues and needs. They further specified the following:

- The framework could emphasize public health responses and include FTS and other drug checking technologies, OTC naloxone, and SSPs. The framework could include review of legal barriers that prevent uptake of harm reduction approaches, development of recommendations at the national and state level to reduce those barriers, and educational campaigns about substance use as a public health issue and the specific role of harm reduction in saving lives.
- Investments could be made in a public health surveillance system to track overdose information and drug trends more accurately at the local level, as well as offer real-time safety alerts to community-based organizations working with PWUD and/or people in treatment and recovery programs.



#### Key theme

Legal, policy, and funding barriers prevent more widespread adoption of FTS

Participants indicated there are various barriers that prevent more widespread adoption and uptake of FTS, most of which stem from criminalization of drug use, drug checking, and harm reduction. They stated that criminalization leads to law enforcement activities that may play a role in disrupting the supply chain, which creates fluctuations in the drug supply that are often linked to overdose risk. Several participants said that criminalization inherently yields an

unregulated drug supply, which is an underlying factor in the overdose crisis.

*Participants expressed concerns about the impact of criminalization of drugs, PWUD, and drug checking and emphasized the need for policy changes to facilitate adoption and use of FTS.*

- Legal barriers, such as drug paraphernalia laws, limit FTS use. According to participants, there is

ongoing “weariness and caution” about the role of law enforcement in responding to substance use and overdoses. They shared that even in contexts where there are amnesty agreements like music festivals, people are scared by the presence of law enforcement and may not want to use drug checking services. Participants explained that while some states are taking steps to address these challenges, e.g., by passing laws to decriminalize various aspects of drug use like paraphernalia possession, more work is needed to mitigate legal barriers.

- One participant described a different, more positive relationship with a law enforcement entity that resulted in law enforcement and a local harm reduction group partnering to distribute FTS.
- Criminalization has also created barriers to funding. Participants thought the lack of federal and state funding for harm reduction approaches may explain the limited reach of harm reduction groups.
- Use of FTS for drug checking purposes may create specific funding challenges for some states. At least one participant mentioned state-level procurement processes that legally prevent states from purchasing FTS for drug checking purposes.



**Key opportunity**

Identify which federal agencies have jurisdiction over FTS and pursue appropriate external partnerships to address barriers to FTS adoption

- Federal agencies could review, as appropriate, federal policies that prevent adoption of FTS and other harm reduction approaches, and Congress could make changes to enact policies that would eliminate those barriers. In addition, although much of criminal justice and health care policy is locally determined, federal agencies and leadership could set a new national tone for drug policy that encourages decriminalization of policies and practices that prevent access to FTS, efforts to support the use of FTS for harm reduction, and other harm reduction approaches. They could encourage states to do a similar review to identify policies, e.g., those regarding state procurement, that could be changed. Federal agencies could also offer incentives in the form of grants, training and technical assistance, capacity and infrastructure support, and other learning opportunities to advance use of FTS and other harm reduction approaches.

## Conclusion

The community roundtable hosted by the FDA Foundation in October 2021 brought together PWUD, harm reduction leaders, researchers, government public health representatives, federal grantees, rural technical assistance providers, Native American harm reduction leaders, and toxicology specialists to gather community perspectives on using FTS and other drug checking methods. Participants described their experiences using and distributing FTS and discussed next steps for technology development, research, and practice. Combined with the feedback collected at the clinician roundtable, HHS representatives amassed key insights into the real-world challenges and opportunities for fentanyl drug checking and screening.

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