FENTANYL DRUG CHECKING AND SCREENING:

Roundtable on Clinical Perspectives

Summary Report

REAGAN-UDALL FOUNDATION FOR THE FDA

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Executive Summary

The Reagan-Udall Foundation for the FDA, in partnership with 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.

This document summarizes the discussion from the meeting of clinicians and researchers (n=12) who are knowledgeable about screening for fentanyl and other drugs, primarily in health care settings. The focus of the meeting was to (1) understand clinician/researcher perspectives about clinical fentanyl testing and distribution of fentanyl test strips (FTS) to patients and (2) discuss next steps for technology development, research, and practice.

Key themes included the following:

- Fentanyl screening is valuable in clinical settings, but availability and timeliness of results are limited
- Clinicians who rarely use or lack easy access to fentanyl screening are often hesitant to recommend FTS to patients for drug checking purposes
- Fentanyl screening and drug checking should be included as part of a data-driven harm reduction approach
- Research and data collection to support equity-centered, culturally appropriate approaches to fentanyl screening and drug checking are needed

Key opportunities included the following:

- Invest in research to improve fentanyl screening and drug checking in terms of sensitivity, specificity, and polydrug applicability
- Develop clinical guidance on when, how, and why to use fentanyl screening
- Improve public health surveillance to enable tracking of local overdose information/drug trends and provision of real-time safety alerts
- Adopt a national/state-level approach to recognizing regional variations in drug supply and FTS distribution

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 result in funding and momentum to increase health care and public health responses to substance use. Increasingly, clinicians are providing more screening, early intervention, and treatment opportunities for people who use drugs (PWUD) and those with SUDs. To address the significant increases in overdose deaths attributed to fentanyl combined with various other drugs, clinicians may screen for fentanyl and its analogues. Such screening may be performed to aid clinical decision making, and in some instances, provide an opportunity to connect people to SUD treatment services. Some clinicians are also involved in the distribution of FTS for harm reduction purposes through their health care settings, primarily upon discharge from the emergency department.

As the U.S. Department of Health and Human Services (HHS) considers how to engage with health care providers, it is essential to gather clinicians' perspectives on fentanyl screening and FTS distribution for harm reduction purposes to inform next steps for technology development, research, and practice improvements. Thus, the Reagan-Udall Foundation for the FDA, 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.

Meeting Insights

Participants at the clinician roundtable included 12 individuals representing behavioral health/addiction medicine specialists, emergency medicine specialists, toxicology specialists, primary care specialists, public health practitioners, and researchers.

The roundtable discussion centered on understanding clinicians' perspectives on how they screen for fentanyl, how fentanyl screening impacts health outcomes, and whether other methods of drug screening are being utilized. Additional areas of inquiry included what barriers and opportunities exist regarding the use of fentanyl screening in practice and/or the distribution of FTS at the point of care in clinical settings. 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.

Drug checking in clinical settings

Screening for fentanyl and other substances is used in health care settings for clinical care reasons, and in some instances, it is used for public health efforts to improve surveillance to better understand local drug trends. The use of fentanyl screening in clinical settings raises many of the same concerns expressed by the community group, as well as a distinct set of issues and challenges.

Both groups emphasized the urgent need for better drug checking as part of the response to the overdose crisis. The clinician group expressed particular interest in improving the work occurring in health care settings and pointed to the rapid changes that occurred in diverse health care settings to respond to the COVID-19 pandemic as an example of how quickly mobilization can occur. The group emphasized two primary ways that drug screening for clinical purposes is different from drug checking for harm reduction. In clinical settings, clinicians use drug screening to 1) quickly and accurately identify the substance(s) present in the case of a health emergency where someone is unable to answer questions relevant to their care; and 2) to assist in SUD treatment initiation and/or referral.[1] While harm reduction groups may also assist in treatment referral, the efforts described by the clinicians were typically part of a formal protocol to identify people who are in need of and/or seeking treatment services.

Key theme
Fentanyl screening is valuable in clinical settings, but availability and timeliness of results are limited

The emphasis of the clinician roundtable was on the health care system and how screening for fentanyl fit into the clinical workflow for making health care decisions. For some providers, this also includes a "warm handoff" to SUD treatment services through emergency departments. While there was some discussion about how fentanyl screening can contribute to public health goals of harm reduction and improved surveillance to understand local drug trends, much of the discussion was focused on health care issues. Participants indicated currently available fentanyl screening technology provides limited information and is therefore not ideal for health care purposes. Clinicians involved in harm reduction efforts also discussed concerns about technologies for drug checking, including the rate of false positives, challenges for consumers using FTS for drug checking purposes, and gaps in ability to test for polydrug use.

[1] Early in the roundtable, participants settled on the phrases of "toxicological screening," "drug screening," and "screening for fentanyl" to describe clinical activities of screening individuals' blood or urine for the presence of fentanyl. Throughout this document, "drug screening" will refer to screening for fentanyl presence in individuals' blood or urine. Drug screening was distinguished from "drug checking," the act of using fentanyl test strips or other technologies to assess the content of the substance used (versus the presence of a substance in a person).

In addition to the need for novel or improved technologies that yield better information, participants identified variability in access and cost and lack of standardized clinical guidance as key challenges.

Like harm reduction providers, clinicians in health care settings see value in using screening for fentanyl as part of the SUD "response" system while believing the technology could be improved.

- Fentanyl screening is needed in health care settings, but access is inconsistent for several reasons. Fentanyl has not yet been made part of the standard drug screen in many places. When it is available, screening for fentanyl can be cost prohibitive and, depending on location, may have slow response times that limit its value in clinical decisions. As in the community discussion, various approaches were described for how clinicians conduct screening for fentanyl.[2] Some clinicians indicated they use qualitative drug screening (to detect presence) followed by quantitative drug screening (to detect how much), while others only use qualitative or quantitative screening. Participants reported that while qualitative testing may be sufficient for some health care purposes, for example front line emergency workers, hospital-based providers generally need a quantitative test. However, quantitative screening also has challenges. Some participants stated that results may not be returned for 7 to 10 days, by which time results are moot because the patient may no longer be in their care. There is also ambiguity about how to interpret different quantitative results, leaving some clinicians unsure how to use the information.
- Clinicians shared a need and desire for a "real-time" rapid screen for fentanyl in health care settings. In addition to addressing the concern about time lag with current tests, this would also improve care for patients who are unconscious or otherwise unable to provide information to clinicians to facilitate clinical decision making.
- While some clinicians recommend drug checking, FTS are not distributed in a consistent way in health care settings across the country. In some places, public health departments provide funding and implementation support, and pharmacies may sell and/or distribute them; in others, the health system or provider may need to purchase FTS themselves. This places the onus on health care systems to take the initiative to make the investment.
- Participants raised a particular point affecting Federally Qualified Health Centers (FQHC). In many communities, particularly rural and marginalized communities, FQHCs play an increasing role in providing SUD care as part of their health services. A participant with rural and FQHC expertise expressed a need for a Clinical Laboratory Improvement Amendments (CLIA)-waived test.

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

Key opportunity

Invest in research to improve fentanyl screening and drug checking in terms of sensitivity, specificity, and polydrug applicability

There is an opportunity to improve drug screening (and checking) technology to address clinician concerns about accessibility and cost.

- Investment in research to improve rapid drug screening technologies to address sensitivity, specificity, and polydrug use. Participants expressed need for a "strip" or related technology that has clear indicators such as a "high, medium, low" rubric to provide clearer guidance around the presence of fentanyl both qualitatively and quantitatively.
- Creation of a public-private partnership to invest in technology that lies somewhere between over-the-counter (OTC) FTS and expensive and complicated laboratory technology. Participants indicated such technology could be used in various settings and for various purposes, including for research to examine questions about eligibility and adherence; in clinical settings to facilitate care and referral to SUD treatment; and in SUD treatment programs to have better information about the drugs being used by the client. One participant specifically indicated that rapid FTS would be beneficial for various settings.
- Development of an OTC point-of-care test. Several participants highlighted challenges related to various aspects of needing "CLIA-waived" technology. While it is unclear how this affects specific hospital settings, this issue could be explored further.

Key theme

Clinicians who rarely use or lack easy access to fentanyl screening are often hesitant to recommend FTS to patients for drug checking purposes

Both the clinician and community roundtables highlighted the need for standardized guidance regarding use and implementation of FTS; health care providers indicated a particular need for guidance on drug screening in context of clinical care.

Clinicians described a need for standardized guidance to educate and train medical professionals on how to use drug screening and support utilization of FTS and drug checking. They indicated several areas where assistance would be particularly useful:

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- Assistance in navigating patient education conversations. Some patients may have different levels of interest and/or motivation for receiving information about FTS and drug checking. Participants also underscored the value of having guidance to address patient questions or concerns about fentanyl or FTS, particularly if patients are using FTS on their own.
- Assistance with disseminating and implementing guidance. Participants also mentioned utility in training and technical assistance opportunities, as well as a feedback loop to gather information on real-time implementation issues, challenges, and successes.

Participants asserted that while any guidance would be subject to change as knowledge evolves, it would help serve an interim goal of bringing some level of standardization to the field. The issue of liability was also identified during the roundtable as a possible area where guidance could address clinician concerns, as providing FTS for drug checking may be considered beyond the standard of care.

Opportunity: Develop clinical guidance on when, how, and why to use fentanyl screening

The appropriate federal agency or agencies, potentially in collaboration with public-private partner(s), could facilitate development of educational materials on the use of fentanyl screening technology. Participants in both the clinician and community roundtables suggested guidance be developed in consultation with PWUD, the harm reduction community, addiction medicine specialists, and researchers on the "front lines" to ensure real-world relevance. Educational materials could address:

- How to integrate fentanyl screening into clinical workflow.
- Which types of hospitals and/or health care settings should have fentanyl screening available (e.g., all hospitals, those with clear need, etc.).
- How to interpret results for clinical use and provide support to develop non-punitive, public health-focused responses.

Both groups indicated FTS are not a silver bullet and that fentanyl screening and drug checking should be part of a comprehensive public health framework that includes other harm reduction approaches, addiction treatment, etc.

Key theme
Fentanyl screening and drug checking should be included as part of a data-driven harm reduction approach

Participants expressed a desire to see fentanyl screening incorporated into an overarching public health model network that includes a drug checking surveillance network and follows an infectious disease model. Concerns were noted about variations in what is available across the country for harm reduction, leading to calls for centralized resources and more strategic and coordinated approaches at the federal and state levels. Participants felt this was important to facilitate tracking updates and trends, (e.g., on naloxone availability and polydrug use). Participants also indicated that a more coordinated public health response could address challenges, including lack of accurate data and limitations on data sharing and integration.

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Part of the discussion emphasized ongoing challenges associated with criminalization of drug use and drug checking, with one participant saying criminalization impedes adoption of a "true public health framework." Within the group, there was support for adopting other compelling research-based public health interventions such as safe supply and looking to learn from jurisdictions inside and outside of the United States. Within the United States, cited examples included San Francisco and New York City, where public health has historically been well funded. Outside the United States, Canada's system was identified as a national example where there has been significant investment in infrastructure and collaboration with public health. Participants indicated the federal government could further elevate these examples of partnerships and provide backing to states to support legal and policy changes where drug checking and FTS are still illegal.

Key opportunity
Improve public health surveillance to enable tracking of local overdose information/drug trends and provision of real-time safety alerts

- 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.
- Federal and state agencies could adopt and promote a national and state framework for advancing harm reduction approaches including FTS, OTC naloxone, and syringe services

programs (SSPs). This framework could include review of federal and state legal barriers that prevent uptake of harm reduction approaches, including the use of FTS for drug checking; development of model legislation to repeal or reduce those barriers; and educational campaigns about substance use and harm reduction.

Participants in both clinical and community roundtables expressed a need for better research, data, and evaluation. Of particular concern were racial disparities in overdose rates and the need for tailored approaches to fentanyl screening and drug checking for people of color and others with distinct cultural needs.

Key theme

Research and data collection to support equity-centered, culturally appropriate approaches to fentanyl screening and drug checking are needed

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Roundtable participants indicated there were several areas of research related to outcomes associated with FTS use that, if conducted, may help support broader utilization and inform standardized guidance on best practices. Areas of inquiry that participants suggested prioritizing included:

- Research on outcomes data, such as the impact of FTS interventions on treatment initiation and participation as well as mortality. Several participants mentioned specific interest in understanding how FTS are being used in conjunction with prescribing of medications for opioid use disorder (MOUD).
- Research and evaluation to support equity-informed, culturally appropriate approaches. Participants expressed significant concerns about how the racial composition of who is dying has shifted and how the current disparities may grow, particularly if fentanyl continues to be mixed with stimulants. In general, there was an impression within the group that people from higher socioeconomic classes are "testing all their product," whereas those deemed to be lower income and/or involved in the criminal justice system are not. In addition, they thought that recruiting people through SSPs and other harm reduction services may mean they are reaching a "Whiter" audience, and thus broader outreach to additional settings is needed to potentially diversify the client base.

Key opportunity

Adopt a national/state-level approach to recognizing regional variations in drug supply and FTS distribution

- A research agenda could be developed in consultation with researchers, clinicians, and PWUD and their allies to inform a set of key outcome questions related to broader utilization of drug checking and FTS distribution. This could include questions about how best to track and respond to regional variations in drug supply, who is accessing FTS, and where there are key gaps to address. Federal funding could then be allocated to conduct research and evaluation into the research agenda questions and disseminate the eventual findings.
- The appropriate federal agency or agencies could fund an evaluation to review the impact of the 2021 federal policy change allowing grantees to use federal funds to purchase FTS.[3] This could include exploration of the intersection of clinicians recommending FTS use and prescribing MOUD, as well as how providers are identifying and reaching the most vulnerable groups.
- Harm reduction providers and others engaged in FTS distribution could receive training in cultural humility and providing culturally and linguistically appropriate care, and research could evaluate the effectiveness of this training.

Conclusion

The clinician roundtable hosted by the FDA Foundation in October 2021 brought together behavioral health/addiction medicine specialists, emergency medicine specialists, toxicology specialists, primary care specialists, public health practitioners, and researchers to gather clinical perspectives on fentanyl screening. Participants described their experiences using clinical fentanyl screening and distributing FTS to patients and discussed next steps for technology development, research, and practice. Combined with the feedback collected at the community roundtable, HHS representatives amassed key insights into the real-world challenges and opportunities for fentanyl drug checking and screening.

[3] Federal Grantees May Now Use Funds to Purchase Fentanyl Test Strips. Substance Abuse and Mental Health Services Administration. Released April 7, 2021. https://www.samhsa.gov/newsroom/press-announcements/202104070200