

# Public Meeting on Patient-Focused Drug Development for Stimulant Use Disorder

Tuesday, October 6, 2020

FDA will be streaming a live webcast of the meeting with the presentation slides, which is open to the public at: <http://fda.yorkcast.com/webcast/Play/89f7acb8d56e4de8827d1ade8efa42661d>. The webcast recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting.

 #PFDD

# Welcome

**Robyn Bent, RN, MS | CAPT, U.S. Public Health Service**

Director, Patient-Focused Drug Development Program

Office of Center Director

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

# Agenda

- Opening Remarks
- Setting the Context
  - Overview of FDA's Patient-Focused Drug Development Initiative
  - Overview of Stimulant Use Disorder
  - Overview of Discussion Format
- Discussion Topic 1: Health Effects and Daily Impacts
- Break
- Discussion Topic 2: Current Approaches to Management
- Discussion Topic 3: Impact of COVID-19 Pandemic on Stimulant Use Disorder
- Closing Remarks

# Opening Remarks

**Admiral Brett P. Giroir, MD**

Assistant Secretary for Health

United States Department of Health and Human Services

# Overview of FDA's Patient-Focused Drug Development Initiative

**Theresa Mullin, PhD**

Associate Director for Strategic Initiatives

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

# FDA's role in medical product development and evaluation



FDA's mission is to **protect and promote public health** by evaluating the **safety and effectiveness of new drugs**.

While FDA plays a critical oversight role in drug development, it is just one part of the process. **FDA does not develop drugs nor conduct clinical trials.**

Review divisions at FDA (e.g., Division of Neurology, Division of Psychiatry, etc.) provide **regulatory oversight** during drug development, make decisions regarding **marketing approval for new drugs**, and **provide guidance** to regulated industry on clinical, scientific and regulatory matters.

# What is Patient-Focused Drug Development (PFDD)?



PFDD is a systematic approach to help ensure that **patients' experiences, perspectives, needs, and priorities** are captured and meaningfully incorporated into drug development and evaluation.<sup>1</sup>



## Value of FDA's PFDD Meetings

- Patients are uniquely positioned to inform FDA understanding of the clinical context for drug review and regulatory decision making
- Prior to PFDD, available mechanisms for obtaining patient input were limited to discussions related to specific applications under review, such as Advisory Committee meetings and only a few patient representatives
- PFDD meetings provide a more systematic way to obtain patients' perspectives on severity of a condition, and its impact on daily life, and their assessments of available treatment options





# PFDD Meetings Provide Key Stakeholders an Opportunity to Hear the Patient's Voice

The PFDD initiative was **established** by FDA.

2013 – 2017

FDA **values gathering patient input** through PFDD meetings. Hosts FDA meetings and attends Externally Led PFDD meetings



2012

FDA conducted **24 disease-specific PFDD meetings**.  
FDA established **Externally Led PFDD meeting** option



2017 – Present



## PFDD meetings in a wide range of disease areas providing insights

2013	2014	2015	2016	2017
<ul style="list-style-type: none"> <li>Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis</li> <li>HIV</li> <li>Lung Cancer</li> <li>Narcolepsy</li> </ul>	<ul style="list-style-type: none"> <li>Sickle Cell Disease</li> <li>Fibromyalgia</li> <li>Pulmonary Arterial Hypertension</li> <li>Inborn Errors of Metabolism</li> <li>Hemophilia A, B, and other Heritable Bleeding Disorders</li> <li>Idiopathic Pulmonary Fibrosis</li> </ul>	<ul style="list-style-type: none"> <li>Female Sexual Dysfunction</li> <li>Breast Cancer</li> <li>Chagas Disease</li> <li>Functional Gastro-intestinal Disorders</li> <li>Parkinson's Disease and Huntington's Disease</li> <li>Alpha-1 Antitrypsin Deficiency</li> </ul>	<ul style="list-style-type: none"> <li>Non-Tuberculous Mycobacterial Lung infections</li> <li>Psoriasis</li> <li>Neuropathic pain associated with peripheral neuropathy</li> <li>Patients who have received an organ transplant</li> </ul>	<ul style="list-style-type: none"> <li>Sarcopenia</li> <li>Autism</li> <li>Alopecia Areata</li> <li>Hereditary Angioedema</li> </ul> <p style="text-align: center;"><b>2018</b></p> <ul style="list-style-type: none"> <li>Opioid Use Disorder</li> <li>Chronic Severe Pain</li> </ul>

FDA clinical and statistical review staff have also attended over 28 other *Externally-Led PFDD* meetings 2016-19 conducted by patient advocacy groups

# PFDD meetings follow a **town hall style** discussion format



## Overview

Clinical Background and Current Available Treatments



## Symptoms and Daily Impacts

- Panel of patients and caregivers
- Facilitated group discussion



## Current Treatment Options

- Panel of patients and caregivers
- Facilitated group discussion



## Each PFDD meeting is tailored to the needs of the specific disease area

- FDA encourages patient advocates, researchers, drug developers, healthcare providers and other government officials to attend PFDD meetings
- However, our focus is on hearing directly from patients and their caregivers, so we ask that others remain silent in listening mode during the discussions since the meetings are a **platform to hear directly from patients, caregivers and patient representatives.**
- After the PFDD meeting, a **Voice of the Patient report** summarizes the input shared by patients and caregivers.



*Thank you!*

# An Overview of Stimulant Use Disorder

**Maryam Afshar, MD**

Division of Anesthesiology, Addiction Medicine and Pain Medicine

Center for Drug Evaluation and Research

U.S. Food and Drug Administration



## **An Overview of Stimulant Use Disorder**

Maryam Afshar, MD  
Division of Anesthesiology, Addiction Medicine and Pain Medicine  
Office of Neuroscience  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
Patient Focused Drug Development  
October 6, 2020



## Definitions

- Misuse
- Abuse
- Tolerance
- Withdrawal
- Dependence
- Substance Use Disorder





## Definitions

- **Misuse:** the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Misuse is defined in the context of *therapeutic* use, while abuse is defined in the context of *non-therapeutic* use.
- **Drug abuse:** the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect.
- **Tolerance:** a state that develops as a result of physiological adaptation characterized by a reduced response to a specific dose of drug after repeated administration of the drug (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).
- **Withdrawal:** experiencing psychological or physical symptoms in absence of the drug or using the drug to avoid the symptoms.



## Definitions (cont.)

- **Dependence** refers to physical or psychological dependence.
  - *Physical dependence* is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.
  - *Psychological (or psychic) dependence* refers to a state in which individuals have impaired control over drug use based on the rewarding properties of the drug (ability to produce positive sensations that increase the likelihood of drug use) or the psychological distress produced in the absence of the drug.
  - The term “psychological dependence” conveys a similar state to that of “addiction” (American Society for Addiction Medicine (ASAM), 2011) and “substance dependence” (American Society for Addiction Medicine (DSM)-IV-TR, 2000).



## Substance Use Disorder

Based on DSM 5 (2013), SUD is a single diagnosis, with severity determined by the number of symptoms present.

Symptoms can be categorized into:

- Loss of control
- Risky use
- Social problems
- Drug effects

**Stimulant Use Disorder:** Substance use disorder involving any of the class of drugs that include cocaine, methamphetamine and prescription stimulants.



## Stimulant UD Symptoms:

- Loss of control:
  - Stimulants are taken in larger amounts or over a longer period than was intended.
  - Persistent desire or unsuccessful attempts to cut down or control stimulant use.
  - Craving, or a strong desire or urge to use stimulants.
  - A great deal of time is spent in activities to obtain, use, or recover from the effects of stimulants.
- Risky use:
  - Recurrent stimulant use in situations in which it is physically hazardous.
  - Continued stimulant use despite physical or psychological problem that is likely to have been caused or exacerbated by the substance.



## Stimulant UD Symptoms, continued

- Social impairment:
  - Recurrent stimulant use resulting in a failure to fulfill major role obligations at work, school, or home.
  - Continued stimulant use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of stimulants.
  - Important social, occupational, or recreational activities are given up or reduced because of stimulant use.
- Pharmacological effects:
  - Tolerance
  - Withdrawal



## Diagnosis

- Stimulant UD can be diagnosed if at least 2 of 11 symptoms are present in a 12-month period.
- Severity Criteria
  - Mild: 2-3 symptoms\*
  - Moderate: 4-5 symptoms
  - Severe: 6 or more symptoms

\*Patients who are taking stimulant medications as directed can be physically dependent, meaning they can experience tolerance and if the medication is discontinued they can experience withdrawal symptoms, ***but this does not mean that they have SUD.***



## Stimulants

- Stimulants: A class of drugs that include cocaine, methamphetamine and prescription stimulants
- Release of monoamine neurotransmitters (dopamine, norepinephrine, serotonin)
- Increase dopamine in the brain
- Cause euphoria, talkativeness
- Decrease appetite
- Increase activity, restlessness
- Grandiosity
- Cardiovascular symptoms: change in heart rate, BP, arrhythmia
- Chronic or episodic use
- Withdrawal symptoms: dysphoric mood, fatigue, vivid and unpleasant dreams, increased appetite



## Signs of Stimulant Intoxication

- Tachycardia or bradycardia
- Pupillary dilation
- Changes in BP
- Sweating or chills
- Nausea or vomiting
- Agitation or psychomotor retardation
- Chest pain, arrhythmia
- Confusion, seizure, dystonia, coma
- Psychosis





## Are All Stimulant Use Disorders the Same?

- Use of stimulants for different reasons:
  - Enhancement (performing better at job, better cognitive performance, enhanced sexual performance)
  - Coping (help with depressed mood)
  - Social (party, have fun)
  - Conformity (to fit in)
- Is pharmacological intervention expected to have similar results considering the heterogeneity of the population?



## All Stimulants Are Not the Same

Methamphetamine	Cocaine
ADHD, narcolepsy	Local anesthetic in some surgical procedures
Longer duration of effect if smoked	Short duration of high if smoked
Half-life: 12 hours	Half-life: 1 hour
Blocks dopamine reuptake (in low doses) and increases dopamine release.	Blocks dopamine reuptake
Intoxication: aggressive and violent behavior	Intoxication: anxiety, panic, paranoid ideation, psychosis
Neurocognitive impairment is common	



## Methamphetamine

Highly addictive, affects the central nervous system, more potent, longer lasting effects

- Initially desirable effects (euphoria, increase in energy, attention, wakefulness, self-confidence and sexuality, decrease in appetite)
- Risk of infectious diseases such as HIV and Hepatitis B and C (risky sexual behavior, injection practices)
- Long-term MA misuse may cause sexual dysfunction
- Weight loss
- Severe dental problem (due to bruxism, dry mouth, poor oral hygiene)
- Cognitive problems
- Psychosis, violent behavior
- OD: hyperthermia, convulsions, arrhythmia, stroke, death
- In the 1980s, MA use increased due to production in clandestine labs. In 2005, Congress passed the Combat Methamphetamine Epidemic Act, regulating the precursor chemicals (ephedrine and pseudoephedrine) used in the production of MA. Now much of the US MA supply is from the outside.



## Cocaine

- Cocaine is plant based.
- Cocaine preparations vary in potency (e.g. coca leaves, coca paste, cocaine hydrochloride, and cocaine alkaloids such as freebase and crack)
- Is used as an anesthetic in ENT surgeries and to limit bleeding.
- Similar desirable effect as MA (increase in energy and sexuality, decrease in appetite and euphoria)
- Risk of cardiac problems such as MI and arrhythmia
- OD: seizures, cardiac arrhythmias, respiratory failures, stroke
- Common forms:
  - Salt (most commonly hydrochloride salt)
  - Base form (not neutralized by an acid to make salt)



## Prescription Stimulants

- Prescription stimulants include medications such as amphetamine and dextroamphetamine (Adderall and Dexedrine) , and methylphenidate (Ritalin, Concerta).
- All forms of amphetamines were classified as DEA Schedule II drugs. (Schedule II drugs have an accepted medical use and high potential for abuse.)
- Treatment of ADHD, narcolepsy and obesity.
- Can be misused and result in stimulant use disorder, in some cases individuals begin stimulant use to control weight or to improve performance in school, work, or athletics.



## Epidemiology

- Stimulants, including MA, are the world's second most used illicit drug class.
- An estimated 1.1 million people aged >12 had methamphetamine use disorder in 2018, up from 684,000 in 2016. (SAMSHA, 2018 NSDUH)
- Regional variability: highest in the western and midwestern regions
- In 2018, 977,000 people aged >12 had a cocaine use disorder up from 867,000 in 2016. (SAMSHA)
- An estimated 561,000 people aged >12 had a prescription stimulant use disorder similar in the past year. (SAMSHA)
- Between 2012 to 2018, OD deaths involving cocaine increased 3 fold and those involving stimulants, including MA, increased 5 fold. (CDC)



## The Impact of Stimulant Misuse and Abuse

- Health problems including infectious disease (hepatitis and HIV, severe weight loss, dental problems)
- Psychological problems (psychosis, violent behavior)
- Overdose
- Loss of productivity and economic burden for the individual and society
- Legal problems
- Accidents, trauma and premature death
- Disabilities
- Child welfare



## Treatment Options

- Behavioral treatment
  - Motivational enhancement therapy
  - Contingency management
  - Cognitive-behavioral Therapy (CBT)
  - 12-step program and peer support groups
  - Individual and family therapy
  - Matrix Model (16-week behavioral therapy, family education, individual counseling, 12-step support, drug testing, and encouragement for non-drug-related activities)
- Ongoing research to develop
  - Medications
  - Vaccines
  - Noninvasive brain stimulation or other devices





## Some Challenges in Medication Development

- Many unanswered questions:
  - Population to enroll in clinical trials
  - Ways to measure response to treatment
  - How long to measure
- Patient and caregiver perspectives may help us answer these questions



## Population

- Current information suggests that people who use methamphetamine, cocaine, and prescription stimulants are different enough that they can't be combined into a single study
  - May have different responses to the same treatment
  - Different ways of measuring response to treatment (e.g., beyond urine drug testing) may be needed
- Can people who use the same drug by different routes (e.g. smoked, injected, snorted cocaine) be combined in one study?
- Can people who use the same drug for different purpose/in different context of use (e.g., for performance enhancement, to get high) be combined in one study?



## Study Endpoints (How to Measure Treatment Response)

- What problems bring individuals into treatment?
- What do affected individuals, families and clinicians consider treatment success? Just based on drug use, or other parameters?
- What are the best methods of detecting response to treatment?
  - Drug use patterns?
    - No drug use at all? Controlled use? Non-problematic use?
      - Each requires different measures for detection of use
    - What are the best ways to detect drug use? Is self-report enough?
  - Clinical or functional improvement?



## Other Study Design Features

- How long should studies be?
  - How long does it take to see a response to treatment?
  - For patients with sporadic use, can a short-term study show a response?
- What else should we consider that would be important to patients and caregivers?



# Overview of Discussion Format

**Robyn Bent, RN, MS | CAPT, U.S. Public Health Service**

Director, Patient-Focused Drug Development Program

Office of Center Director

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

# Discussion Overview

## **Topic 1: Health Effects and Daily Impacts of Stimulant Use Disorder**

- Health effects of stimulant use disorder that have the most significant impact on your daily life
- How your stimulant use disorder has changed over time
- What drives your use of stimulants
- What worries you most about your condition

## **Topic 2: Current Approaches to Management**

- Your experience with managing your stimulant use disorder
- What approaches you use to manage your stimulant use disorder
- What you have found to be most effective in helping you manage your stimulant use disorder
- What factors you would consider when considering or seeking treatment

## **Topic 3: Impact of COVID-19 Pandemic**

- Impact on substance use or desire to seek treatment

# Discussion Format, continued

## **You'll have a chance to answer polling questions**

- Their purpose is to aid our discussion
- Participants can use the [mentimeter.com](https://www.mentimeter.com) link to answer polling questions
- Individuals with stimulant use disorder or representatives only, please

## **Participants can add comments through the webcast or by telephone**

- Although they may not all be read or summarized today, your comments will be incorporated into our summary report



# Send us your comments!

## You can send us comments through the “public docket”

- The docket will be open until December 7, 2020
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- You can submit as anonymous

Visit: <https://www.regulations.gov/document?D=FDA-2020-N-0259-0005>

Or Search “patient-focused stimulant use disorder” on [www.regulations.gov](http://www.regulations.gov)

And **Click Comment Now!**

The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with links for Home, Help, Resources, and Contact Us. The main heading is "Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments". Below this, there is a section for "Action" with the text "Notice of public meeting; request for comments." and a "Summary" section. A red arrow points from the text "Click Comment Now!" to a "Comment Now!" button located in the top right corner of the page. The button is labeled "Comment Now!" and has a small "Due Dec 7 2020, at 11:59 PM ET" label below it. To the right of the button, there is a "Document Information" section with fields for "ID: FDA-2020-N-0259-0005", "Date Posted: Sep 30, 2020", and "Federal Register Number: 2020-21023".

# Discussion Ground Rules

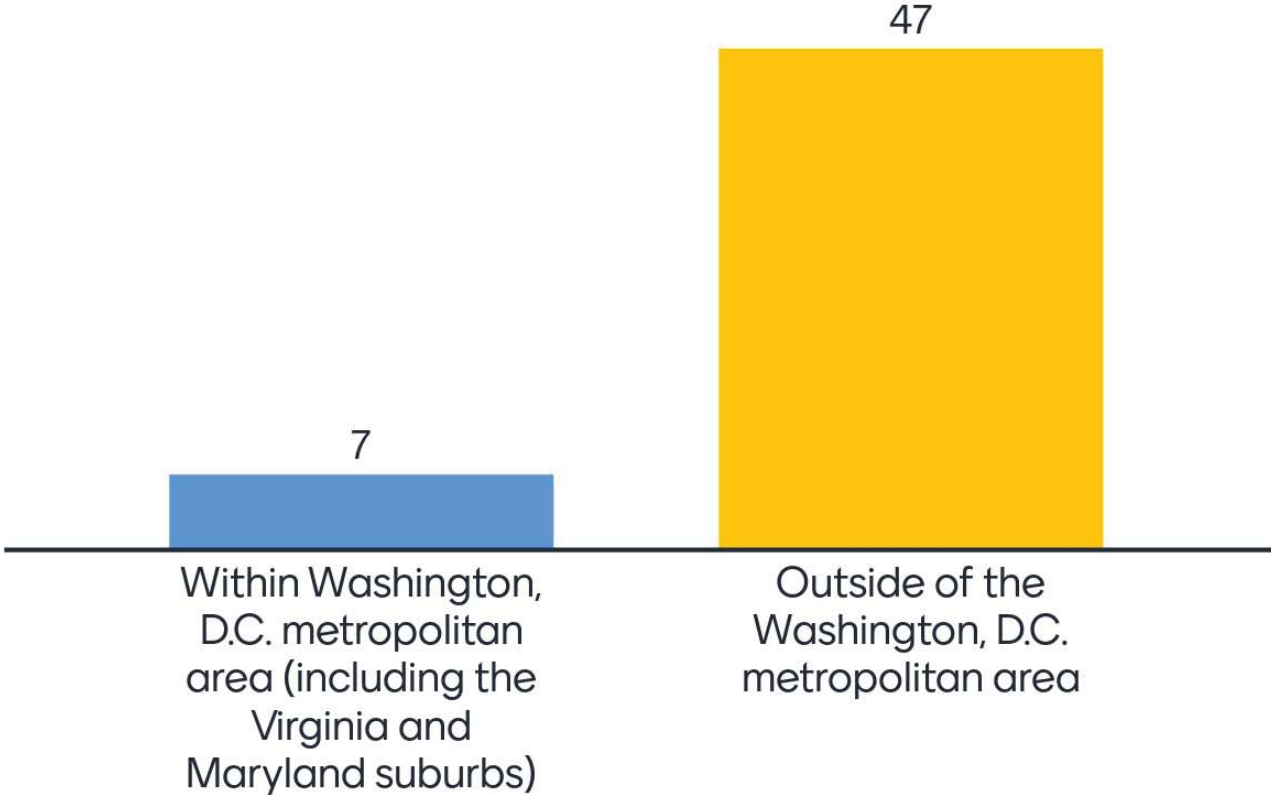
- We encourage all individuals and impacted family members to contribute to the dialogue
- FDA is here to listen
- Discussion will focus on stimulant use disorder health effects and management
- The views expressed today are personal opinions
- Respect for one another is paramount

# Where do you live?

- a. Within Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
- b. Outside of the Washington, D.C. metropolitan area

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

# Where do you live?

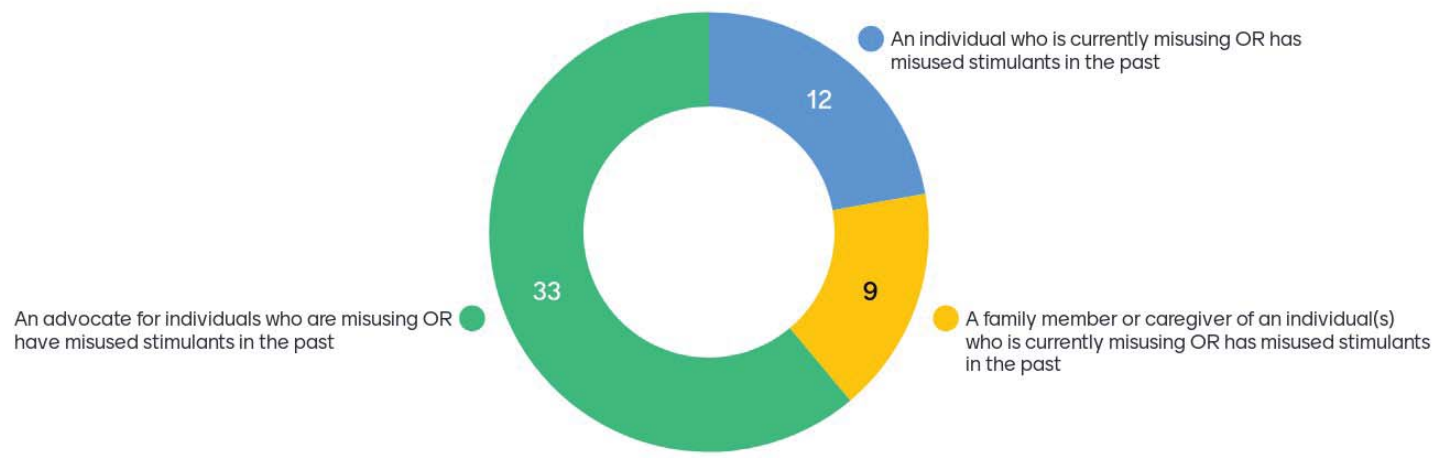


Which statement best describes your experience with stimulant use (e.g., methamphetamine, crystal meth, cocaine, prescription stimulants)?

- a. An individual who is currently misusing OR has misused stimulants in the past
- b. A family member or caregiver of an individual(s) who is currently misusing OR has misused stimulants in the past
- c. An advocate for individuals who are misusing OR have misused stimulants in the past

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

# Which statement best describes your experience with stimulant use (e.g., methamphetamine, crystal meth, cocaine, prescription stimulants)?



We will ask that the remainder of the questions be answered by individuals with stimulant use disorder or a family member or caregiver on behalf of an individual with stimulant use disorder

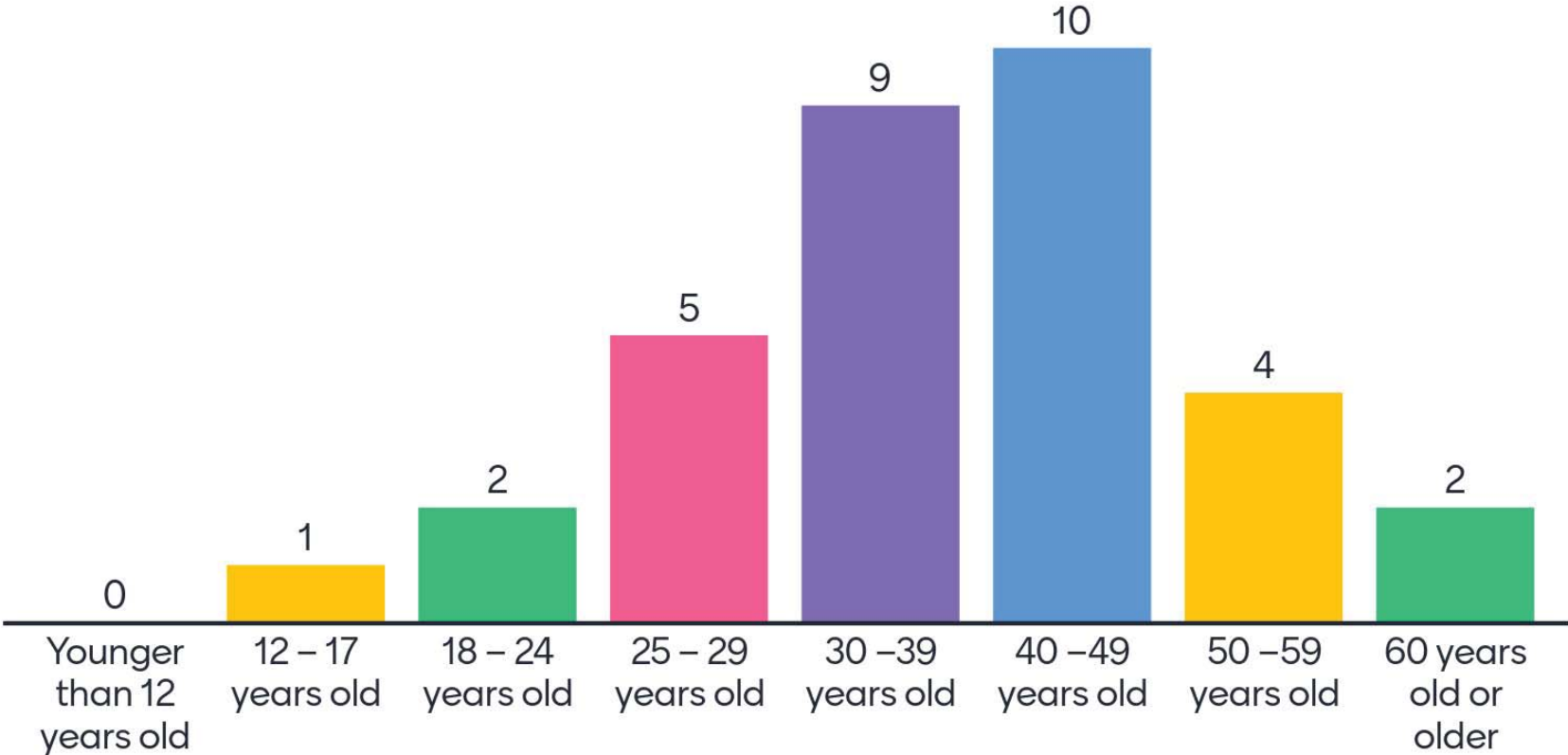
# What is you/your loved one's age?

- a. Younger than 12 years old
- b. 12 – 17 years old
- c. 18 – 24 years old
- d. 25 – 29 years old
- e. 30 –39 years old
- f. 40 –49 years old
- g. 50 –59 years old
- h. 60 years old or older

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# What is you/your loved one's age?

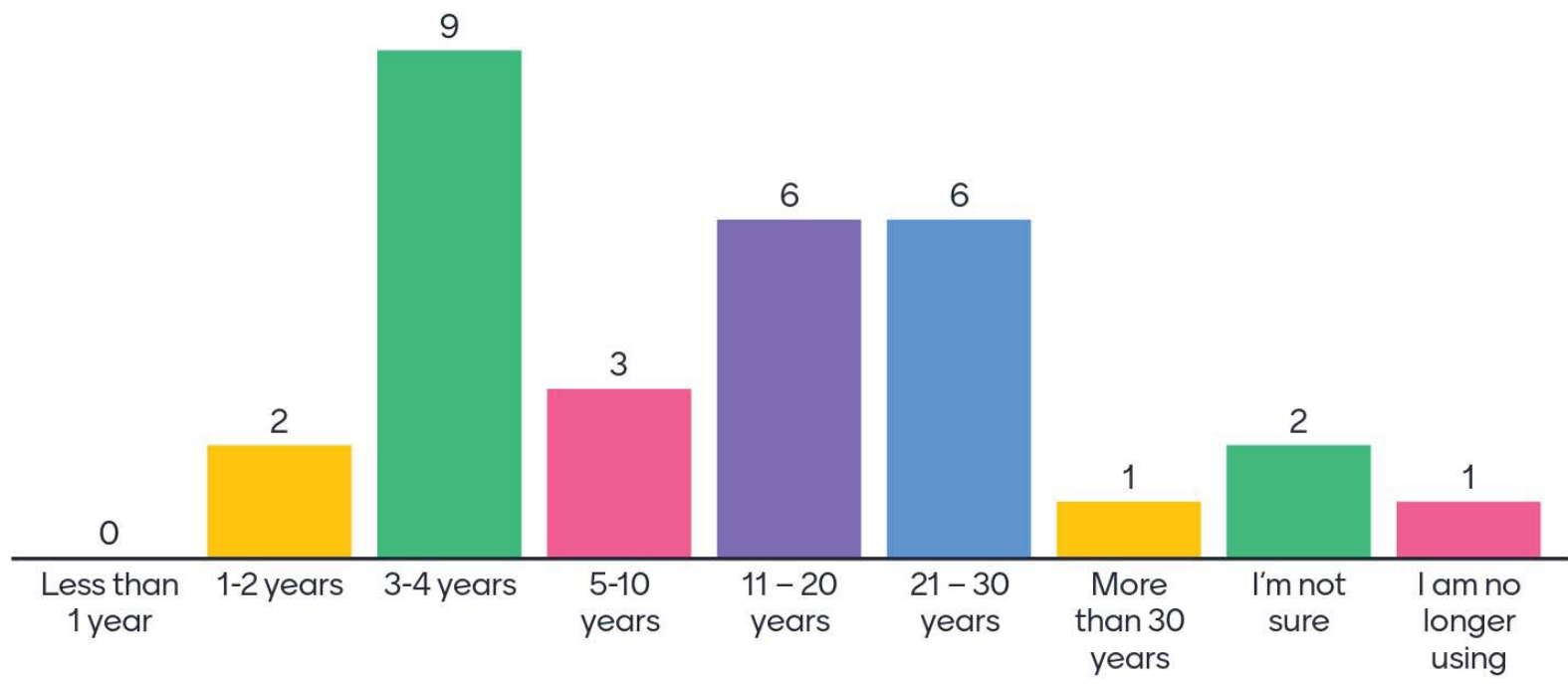


For how long have you/your loved one used stimulants (e.g., methamphetamine, crystal meth, cocaine, prescription stimulants)?

- a. Less than 1 year
- b. 1-2 years
- c. 3-4 years
- d. 5-10 years
- e. 11 – 20 years
- f. 21 – 30 years
- g. More than 30 years
- h. I'm not sure
- i. I am no longer using

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For how long have you/your loved one used stimulants (e.g., methamphetamine, crystal meth, cocaine, prescription stimulants)?

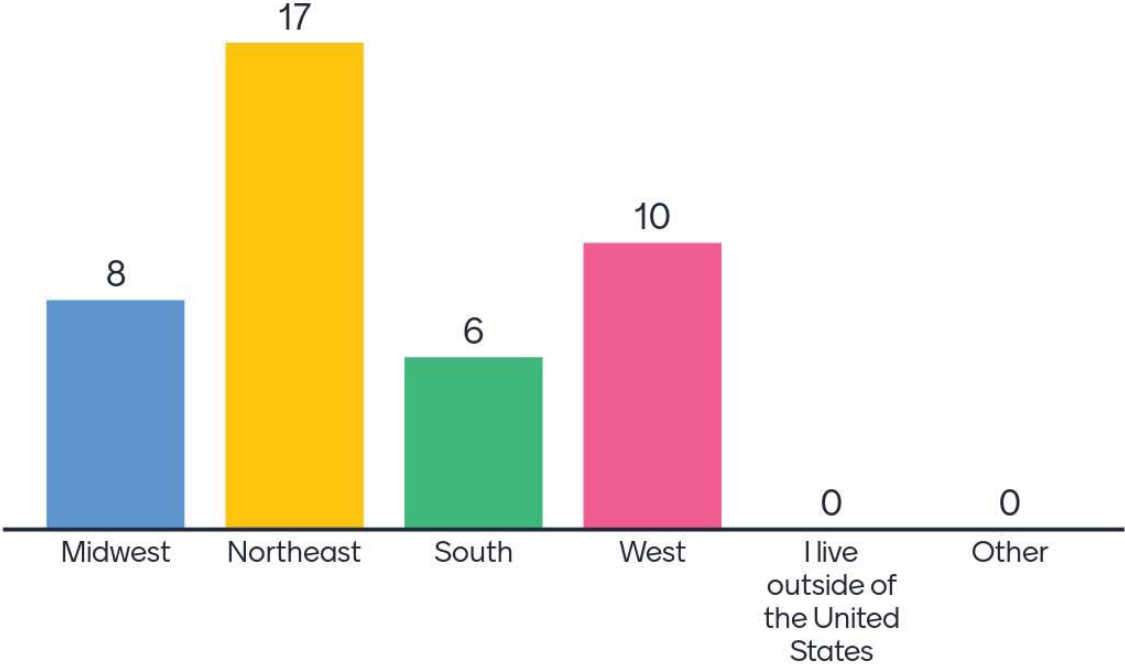


Which region of the United States do you live in?

- a. Midwest
- b. Northeast
- c. South
- d. West
- e. I live outside of the United States
- f. Other

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# Which region of the United States do you live in?



# Topic 1: Health Effects and Daily Impacts

## Health Effects and Daily Impacts of Stimulant Use Disorder

# Topic 1 Discussion Questions

1. How would you describe your journey with stimulant use disorder?
2. Of all the ways that stimulant use disorder impacts your health and well-being, which effects have the most significant impact on your daily life and the daily life of your family and/or friends?

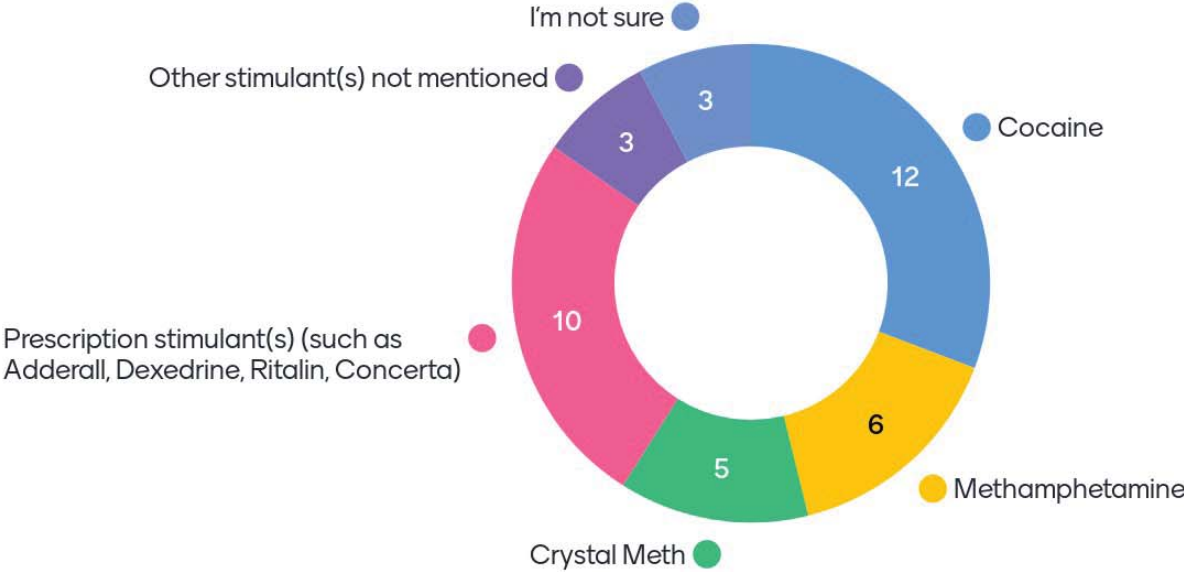
Which stimulant(s) did you/your loved one start using first? **Select all that apply.**

- a. Cocaine
- b. Methamphetamine
- c. Crystal Meth
- d. Prescription stimulant(s)  
(such as Adderall, Dexedrine,  
Ritalin, Concerta)
- e. Other stimulant(s) not  
mentioned
- f. I'm not sure

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.



# Which stimulant(s) did you/your loved one start using first?

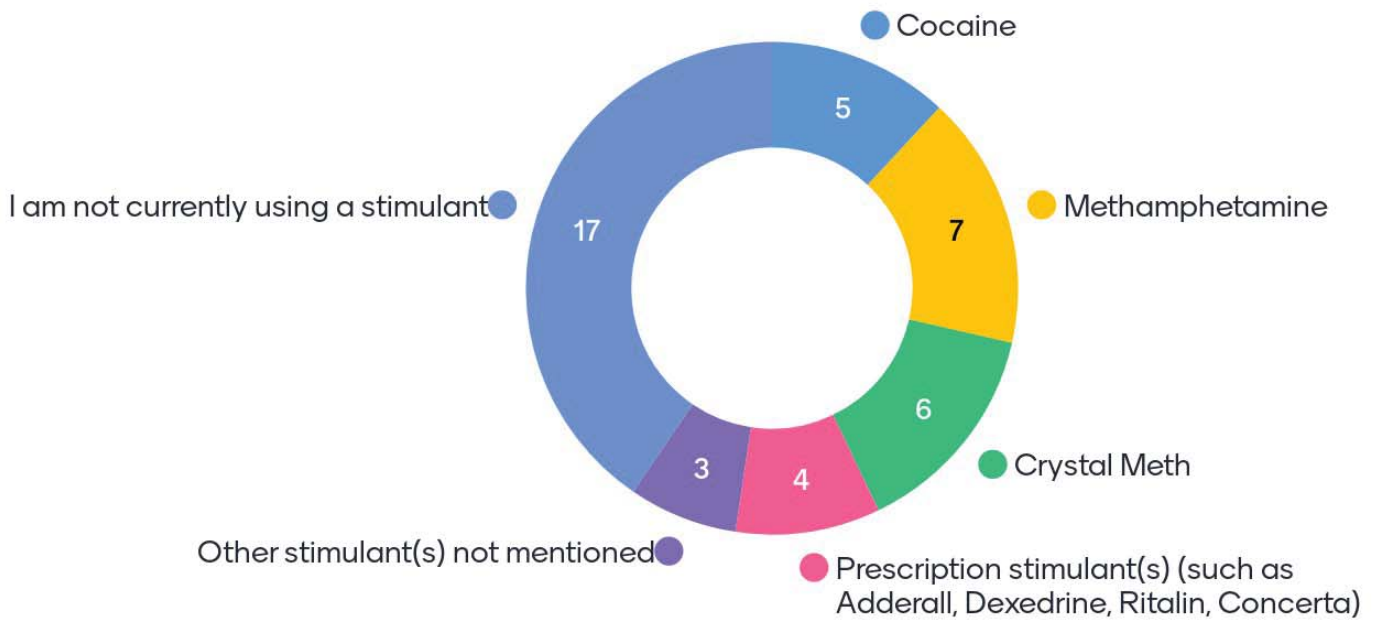


If you/your loved one are currently using a stimulant(s), which stimulant(s) are you/your loved one currently using? **Select all that apply.**

- a. Cocaine
- b. Methamphetamine
- c. Crystal Meth
- d. Prescription stimulant(s) (such as Adderall, Dexedrine, Ritalin, Concerta)
- e. Other stimulant(s) not mentioned
- f. I am not currently using a stimulant

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

# If you/your loved one are currently using a stimulant(s), which stimulant(s) are you/your loved one currently using?

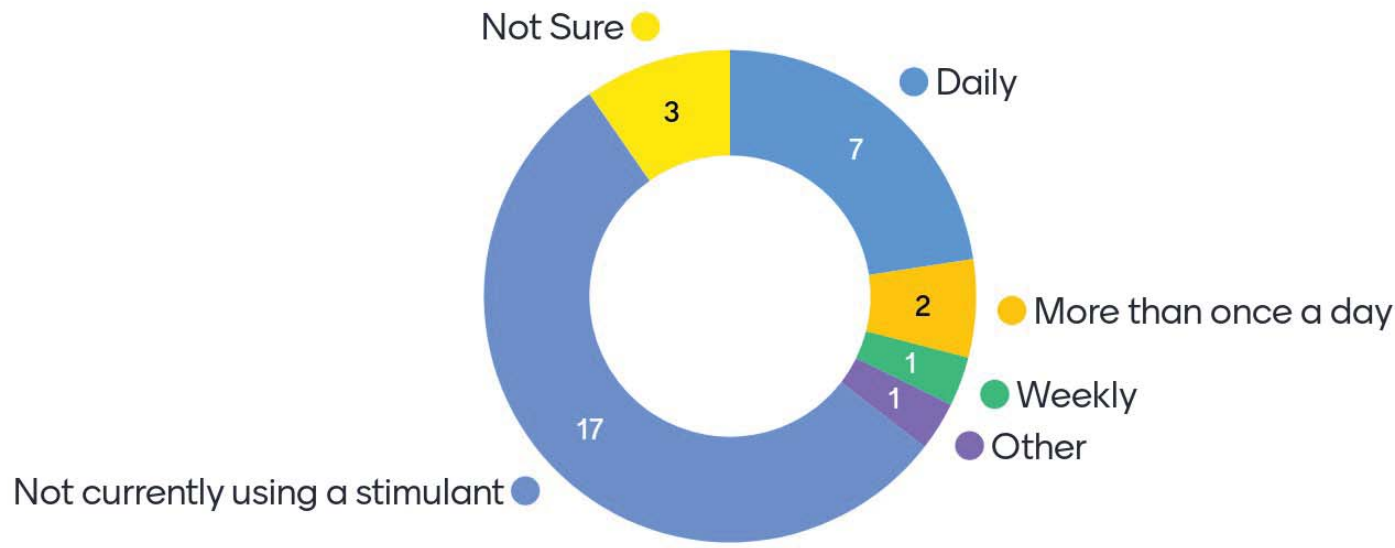


If you/your loved one are currently using a stimulant(s), how frequently do you/your loved one use the stimulant(s)?

- a. Daily
- b. More than once a day
- c. Weekly
- d. Monthly
- e. Other
- f. Not currently using a stimulant
- g. Not sure

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

If you/your loved one are currently using a stimulant(s), how frequently do you/your loved one use the stimulant(s)?

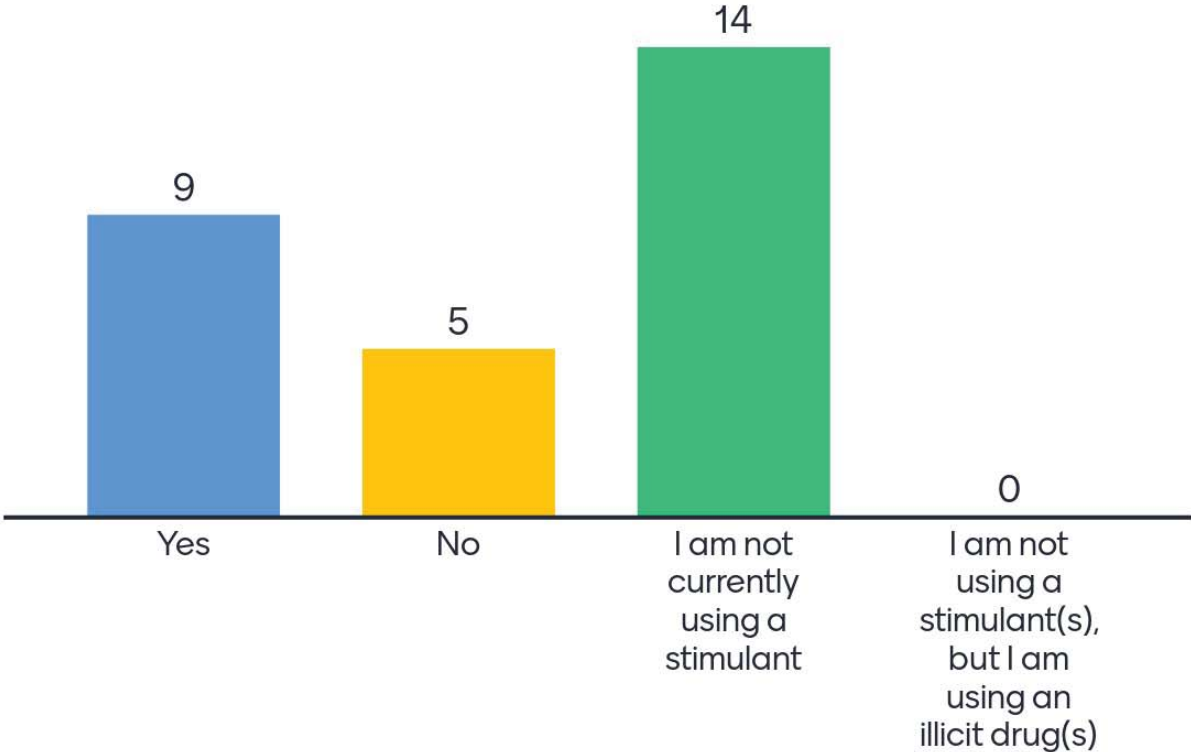


If you/your loved one are currently using a stimulant(s), are you/your loved one also using any other illicit drug(s)?

- a. Yes
- b. No
- c. I am not currently using a stimulant
- d. I am not using a stimulant(s), but I am using an illicit drug(s)

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

If you/your loved one are currently using a stimulant(s), are you/your loved one also using any other illicit drug(s)?



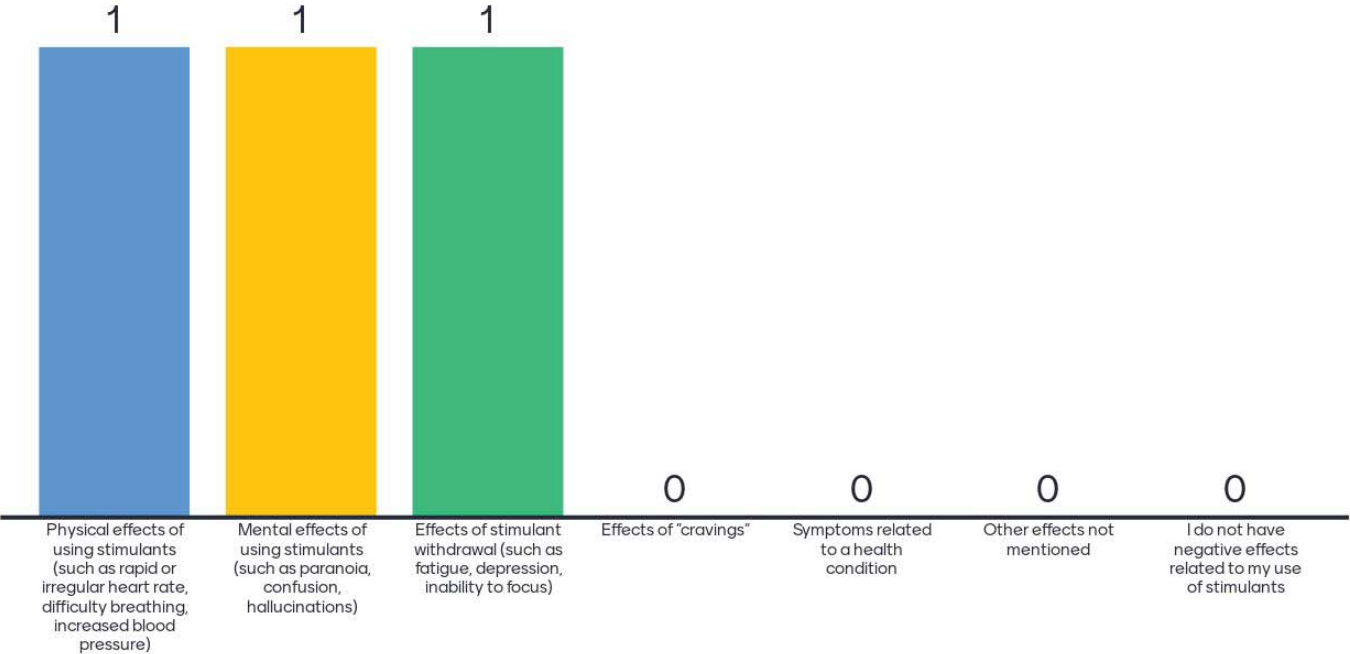
In general, what are the most negative effects related to your/your loved one's use of stimulants? **Please choose up to three answers.**

- a. Physical effects of using stimulants (such as rapid or irregular heart rate, difficulty breathing, increased blood pressure)
- b. Mental effects of using stimulants (such as paranoia, confusion, hallucinations)
- c. Effects of stimulant withdrawal (such as fatigue, depression, inability to focus)
- d. Effects of "cravings"
- e. Symptoms related to a health condition
- f. Other effects not mentioned
- g. I do not have negative effects related to my use of stimulants

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.



# In general, what are the most negative effects related to you/your loved one's use of stimulants?



Thinking specifically of a time when you reduced or abstained from using stimulants, what have been the most negative impacts? **Please choose up to three answers.**

- a. Physical limitations on activities (such as work, school, sports, hobbies)
- b. Cognitive limitations related to work or school activities
- c. Decreased ability to concentrate or stay focused
- d. Fatigue or lack of energy
- e. Insomnia or sleep issues
- f. Impact on relationships
- g. Impact on sexual intimacy
- h. Depression or emotional impacts (such as self-esteem)
- i. Other impacts not mentioned

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# Thinking specifically of a time when you reduced or abstained from using stimulants, what have been the most negative impacts?



- Physical limitations on activities (such as work, school, sports, hobbies)
- Cognitive limitations related to work or school activities
- Ability to concentrate or stay focused
- Fatigue or lack of energy
- Insomnia or sleep issues
- Impact on relationships
- Impact on sexual intimacy
- Depression or emotional impacts (such as self-esteem)
- Other impacts not mentioned



What do you find to be the most significant impacts of your/your loved one's stimulant use on your/your loved one's daily life? **Please choose up to three answers.**

- a. Ability to carry out important activities (such as work, school, sports, hobbies)
- b. Ability to care for myself or family
- c. Ability to concentrate or stay focused
- d. Impact on relationships with family and friends
- e. Risks to safety of self or others
- f. Stigma or discrimination
- g. Worry about the future (such as relapse, overdose)
- h. Emotional impacts (such as self-esteem, self-identify)
- i. Other impacts not mentioned

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

# What do you find to be the most significant impacts of you/your loved one's stimulant use on your/your loved one's daily life?



- Ability to carry out important activities (such as work, school, sports, hobbies)
- Ability to care for myself or family
- Ability to concentrate or stay focused
- Impact on relationships with family and friends
- Risks to safety of self or others
- Stigma or discrimination
- Worry about the future (such as relapse, overdose)
- Emotional impacts (such as self-esteem, self-identify)
- Other impacts not mentioned



Discussion Topic 2  
Current Approaches to Management

## Topic 2 Discussion Questions

1. Have you considered seeking treatment? Why or why not?
2. What are you currently doing to help manage your stimulant use?
3. What are the biggest factors that you consider when making decisions about seeking out or engaging in treatment for stimulant use disorder?
4. What specific things would you look for in an ideal treatment for stimulant use disorder?
5. If you had the opportunity to participate in a clinical study to test an experimental treatment for stimulant use disorder, what factors would you consider when deciding whether you would participate?

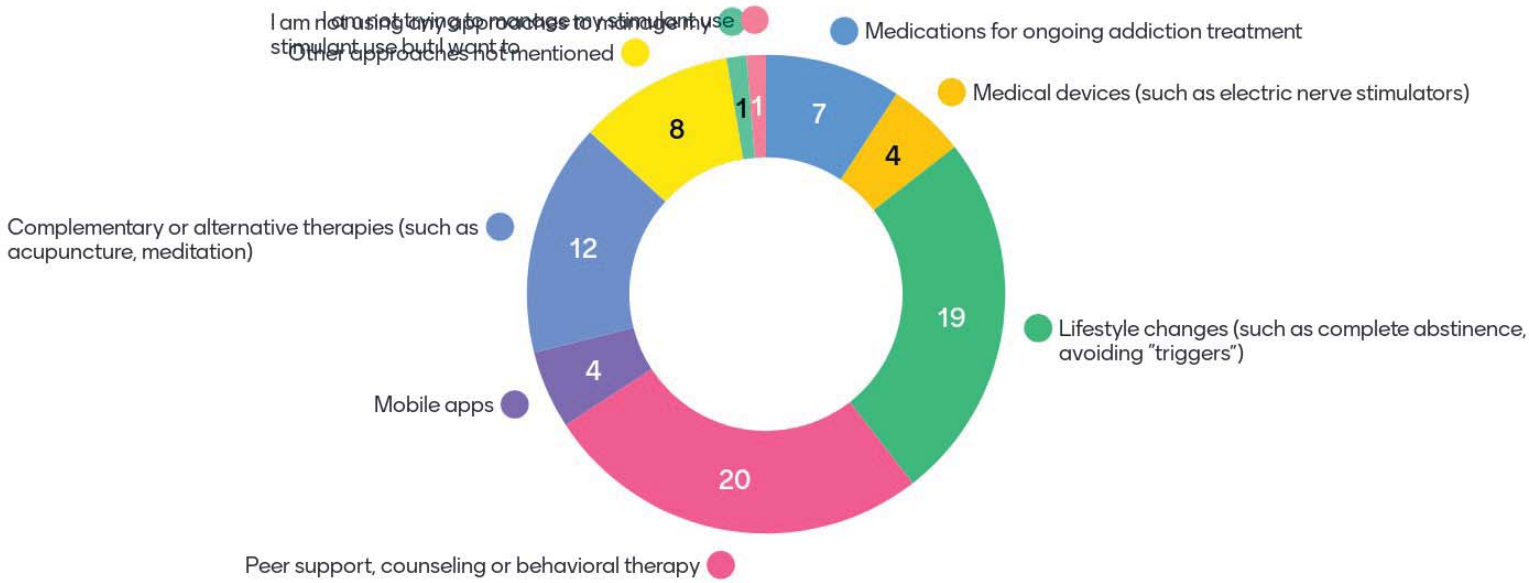
Have you/your loved one ever used any of the following to manage stimulant use? **Check all that apply.**

- a. Medications for ongoing addiction treatment
- b. Medical devices (such as electric nerve stimulators)
- c. Lifestyle changes (such as complete abstinence, avoiding “triggers”)
- d. Peer support, counseling or behavioral therapy
- e. Mobile apps
- f. Complementary or alternative therapies (such as acupuncture, meditation)
- g. Other approaches not mentioned
- h. I am not using any approaches to manage my stimulant use but I want to
- i. I am not trying to manage my stimulant use

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.



# Have you/your loved one ever used any of the following to manage stimulant use?

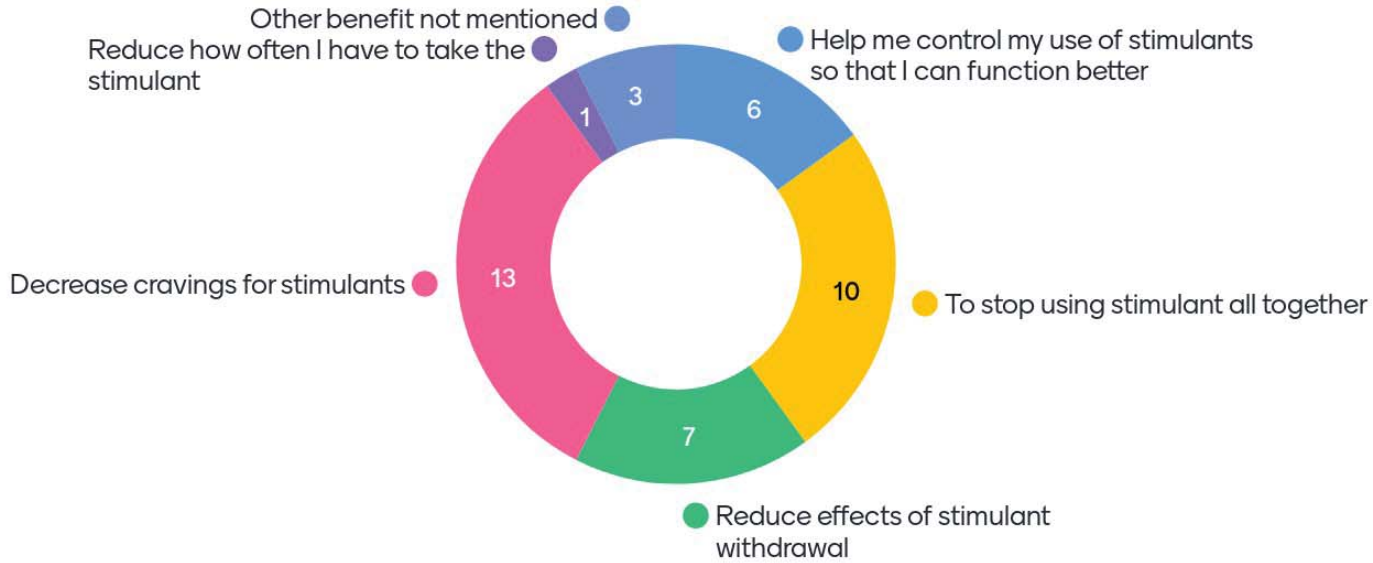


If you are considering a new treatment for stimulant use, which of the following benefits would you consider to be most meaningful? **Please choose up to three answers.**

- a. Help me control my use of stimulants so that I can function better
- b. To stop using stimulants all together
- c. Reduce effects of stimulant withdrawal
- d. Decrease cravings for stimulants
- e. Reduce how often I have to take the stimulant
- f. Other benefit not mentioned

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# If you are considering a new treatment for stimulant use, which of the following benefits would you consider to be most meaningful?

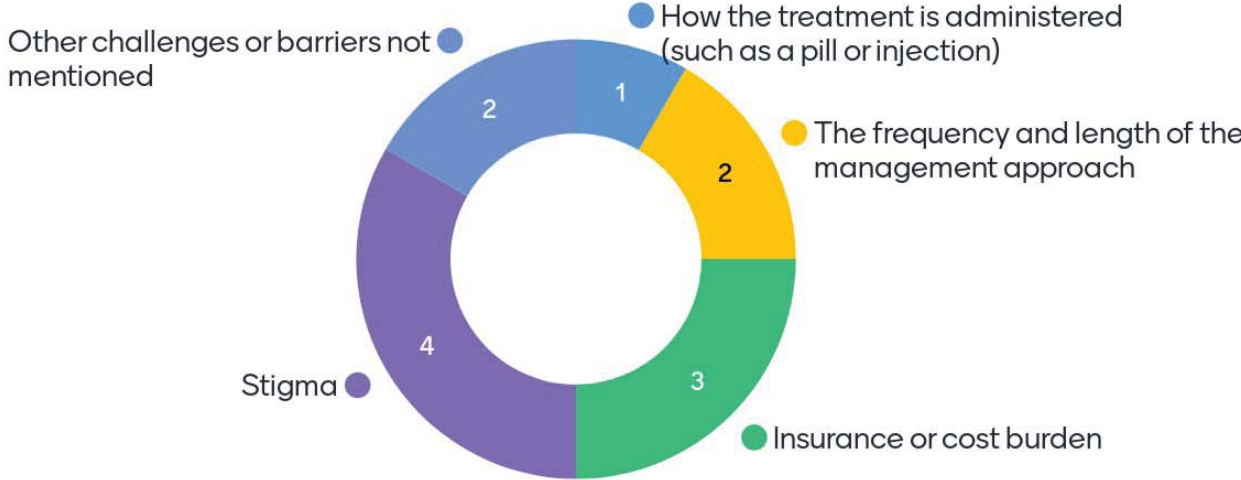


If you are interested in decreasing or stopping stimulant use, what challenges or barriers are keeping you from doing so? **Please choose up to three answers.**

- a. How the treatment is administered (such as a pill or injection)
- b. The frequency and length of the management approach
- c. Insurance or cost burden
- d. Side effects of the treatment
- e. Stigma
- f. Other challenges or barriers not mentioned

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# If you are interested in decreasing or stopping stimulant use, what challenges or barriers are keeping you from doing so?



If there was a clinical trial to study an experimental treatment, would you consider participating?

- a. **Yes:** I would want to know more, but I am generally willing to consider participating
- b. **No:** I would probably not consider participating
- c. **Maybe:** I am not sure whether I would be willing to consider participating or not
- d. I am not interested in decreasing my stimulant use

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

# If there was a clinical trial to study an experimental treatment, would you consider participating?



- Yes: I would want to know more, but I am generally willing to consider participating
- No: I would probably not consider participating
- Maybe: I am not sure whether I would be willing to consider participating or not
- I am not interested in decreasing my stimulant use



# Send us your comments!

## You can send us comments through the “public docket”

- The docket will be open until December 7, 2020
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- You can submit as anonymous

Visit: <https://www.regulations.gov/document?D=FDA-2020-N-0259-0005>

Or Search “patient-focused stimulant use disorder” on [www.regulations.gov](http://www.regulations.gov)

And **Click Comment Now!**

The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with links for Home, Help, Resources, and Contact Us. Below the navigation bar, the main heading reads "Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments". The page content includes sections for Action, Summary, Dates, and Addresses. A red arrow points from the text "Click Comment Now!" to a "Comment Now!" button located in the top right corner of the page. The button is labeled "Comment Now!" and has a small icon of a speech bubble. Below the button, there is a "Document Information" section with fields for ID, Date Posted, and Federal Register Number. The ID is FDA-2020-N-0259-0005, the Date Posted is Sep 30, 2020, and the Federal Register Number is 2020-21023. There is also a "Comments" section at the bottom right of the page.



Discussion Topic 3  
Impact of COVID-19 Pandemic on  
Stimulant Use Disorder

# Topic 3 Discussion Question

1. Has the COVID-19 pandemic impacted your substance use or your desire to seek treatment? If yes, please describe how.

# Closing Remarks

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