

Forum on Drug Discovery, Development, and Translation Forum on Neuroscience and Nervous System Disorders

Adult Attention-Deficit/Hyperactivity Disorder: Diagnosis, Treatment, and Implications for Drug Development – A Workshop

December 12, 2023, 9:00 am - 5:00 pm (ET)

December 13, 2023, 8:30 am - 2:00 pm (ET)

Keck Center, Keck 100

500 Fifth St. NW, Washington, DC, 20001

To watch the livestream, please visit the workshop page here.

PURPOSE

A two-day public workshop, convened by the National Academies of Sciences, Engineering, and Medicine's Forum on Drug Discovery, Development, and Translation; and Forum on Neuroscience and Nervous System Disorders; will provide an opportunity for professionals who typically diagnose attention-deficit/hyperactivity disorder (ADHD), drug developers, researchers, regulators, patients, and other stakeholders to examine the diagnosis and treatment of adults with ADHD.

The public workshop will feature invited presentations and discussions to:

- Discuss the criteria for diagnosis and treatment of adults with ADHD, taking into consideration health disparities and perspectives of people with lived experience.
- Consider what is known and unknown about the risks and benefits of ADHD medication use in adult populations.
- Share perspectives on the causes, perceptions, consequences, and health equity implications of non-medical use of prescription stimulants, including misuse potential, overdosage, and toxicity.
- Explore challenges and opportunities for the development of new and improved therapeutics for the treatment of ADHD.
- Consider potential strategies for assessing the risks and benefits of ADHD medication treatment in adult populations, including the intersection with opioid use, that support the public health goal of safely and effectively treating adults with ADHD.

DAY 1: TUESDAY, DECEMBER 12, 2023

9:00 am Welcome, Opening Remarks, and Setting the Stage

CRAIG B.H. SURMAN, Workshop Co-chair
Director, Clinical and Research Program in Adult ADHD
Massachusetts General Hospital
Associate Professor of Psychiatry
Harvard Medical School

9:35 am REGULATORY OVERVIEW

MARTA SOKOLOWSKA
Deputy Center Director
Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

9:55 am SESSION I – DIAGNOSIS OF ADULTS WITH ADHD

Session Objectives:

- Discuss the criteria and available tools for diagnosis of ADHD in adults (including DSM 5 criteria, assessment tools, best practices in diagnosing the condition);
- Explore gaps and barriers when it comes to appropriate diagnosis of ADHD for different adult populations; and
- Consider the long-term public health implications of underdiagnosing, differential diagnosing, and misdiagnosing ADHD in adults and considerations for different populations.

9:55 am Presentation

ANN CHILDRESS

President

Center for Psychiatry and Behavioral Medicine, Inc.

President

The American Professional Society for ADHD and Related Disorders

10:20 am Panel Discussion

Moderator: Steve Lee, University of California, Los Angeles

Clinical Diagnosis Perspective

NAPOLEON HIGGINS

President and Chief Executive Officer

Bay Pointe Behavioral Health

Clinical Screening Perspective

SARA L. WEISENBACH

Associate Professor of Psychology in Psychiatry, Harvard Medical School

President, American Psychological Association, Society for Clinical Neuropsychology (Division 40)

Chief of Neuropsychology

McLean Hospital

Lived Experience Perspective

TAMARA ROSIER Owner, ADHD Center of West Michigan President ADHD Coaches Organization

Research Perspective
MARGARET SIBLEY
Professor of Psychiatry and Behavioral Sciences
University of Washington School of Medicine

Discussion Questions:

- 1. Why do clinicians find it challenging to diagnose ADHD in adults (e.g., co-morbidities, differential diagnosis with other conditions such as depression, anxiety, other psychiatric conditions, and/or COVID-19)?
- 2. What barriers do adults experience when seeking a diagnosis of ADHD, particularly those from minority and medically underserved communities?
- 3. How does an ADHD diagnosis, or the lack of one, impact individuals across adulthood?
- 4. How is ADHD diagnosed under the DSM 5 criteria?

11:20 am COFFEE BREAK

11:50 am SESSION II – MEDICATION OPTIONS FOR ADULTS WITH ADHD: RISKS AND BENEFITS

Session Objectives:

- Consider what is known and unknown about the risks and benefits of ADHD medication use in adult populations;
- Consider the public health implications for potential overprescribing of Schedule II stimulants;
- Discuss the barriers (e.g., legal, regulatory, social, cultural) to access of equitable treatment for adults with ADHD; and
- Explore approaches for alternative treatment options for adults with ADHD (e.g., non-pharmacological interventions, re-tooling of existing medications, new drug development) that may reduce the risk of harm to patients, that take into account social and cultural considerations.

11:50 am Presentation

DAVID W. GOODMAN Assistant Professor of Psychiatry and Behavioral Sciences Johns Hopkins University School of Medicine

12:10 pm Panel Discussion

Moderator: James (Jimmy) Leonard, Maryland Poison Center; University of Maryland School of Pharmacy

Lived Experience Perspective
DUANE GORDON
President
Attention Deficit Disorder Association

ANGELA MAHOME Staff Psychiatrist The University of Chicago

Research/Clinical Perspective (Nonmedication Treatments/CBT)

J. RUSSELL RAMSAY

Independent Practice

Former Co-Founder, Co-Director, Adult ADHD Treatment and Research Program

University of Pennsylvania

Regulatory Perspective TIFFANY FARCHIONE

Director, Division of Psychiatry

Center for Drug Evaluation and Research, FDA

Discussion Questions:

- 1. What is known and unknown about the risks and benefits of medication (stimulant and nonstimulant) use for the treatment of ADHD in adult populations?
- 2. What are the primary barriers (e.g., legal, regulatory, social, cultural) to appropriate treatment for adults with ADHD and how have these barriers been overcome? What are the health equity implications of these approaches?
- 3. How can prescribers, clinicians, and other providers be better informed regarding the treatment options available to their patients?

1:10 pm LUNCH BREAK

2:00 pm **SESSION III – IMPLICATIONS FOR DRUG DEVELOPMENT**

Session Objectives:

- Consider areas of unmet treatment needs for adults with ADHD that could potentially be addressed through new and/or improved therapeutics; and
- Explore challenges and opportunities for the development of new and improved therapeutics for the treatment of ADHD, including options that may reduce the risk of diversion.

2:00 pm Presentation

CRAIG BERRIDGE

The Patricia Goldman-Rakic Professor of Psychology

University of Wisconsin, Madison

2:20 pm **Panel Discussion**

Moderator: Stevin Zorn, MindImmune Therapeutics

Industry Perspective JONATHAN RUBIN

Chief Medical Officer and Senior Vice President of Research & Development

Supernus Pharmaceuticals

AMY ARNSTEN

Albert E. Kent Professor of Neuroscience and Professor of Psychology Yale School of Medicine

Regulatory Perspective

ERIKA LIETZAN

William H. Pittman Professor of Law & Timothy J. Heinsz Professor of Law

University of Missouri School of Law

Discussion Questions:

- 1. How do available therapeutic treatment options meet the needs of adults with ADHD? What are the gaps/unmet medical needs?
- 2. How might alternative treatment options for adults with ADHD reduce the risk of harms, such as misuse potential, overdose, and toxicity?
- 3. What are the barriers and opportunities to the development of new medications for treating adults with ADHD?

3:20 pm COFFEE BREAK

3:50 pm SESSION IV – DAY 1 SYNTHESIS AND DISCUSSION

Session Objective:

- Discuss key themes from previous workshop sessions;
- Lay out questions to be addressed; and
- Consider next step opportunities for improving the diagnosis and treatment of adults with ADHD; implications for drug development.

3:50 pm Panel Discussion

Moderator: Craig B. H. Surman, Massachusetts General Hospital; Harvard Medical School

Pharmacology Perspective

ALMUT WINTERSTEIN

Director, Center for Drug Evaluation and Safety (CoDES) and Consortium for Medical Marijuana Clinical Outcomes Research

Distinguished Professor, Pharmaceutical Outcomes and Policy

University of Florida

Industry Perspective

DAVID BAKER

Former Pharmaceutical Executive – Shire, Alcobra, Vallon Pharmaceuticals

Board Member

Edge Foundation

Lived Experience Perspective

KOFI OBENG

Executive Director

Attention Deficit Disorder Association

Resources and Education Perspective

SUNNY PATEL

Senior Advisor for Children, Youth and Families

SAMHSA

Research Perspective

MARY SOLANTO Professor of Pediatrics and Psychiatry Zucker School of Medicine at Hofstra-Northwell

Discussion Questions:

- 1. Based on the day's sessions, what are the main themes you heard regarding the diagnosis, treatment, and drug development for ADHD in adult populations? What questions remain?
- 2. How can the use of a health equity framework help the those with adult ADHD, health professionals, and others better understand the social, political, economic, and environmental factors impacting the diagnosis and treatment of adult ADHD?
- 3. How do we bridge the gap from where we are now to where we want to be? What is needed and from whom?
- 4. What are some key things from today's sessions we should keep in mind as we move into Day 2?

4:35 pm **Audience Q&A**

4:50 pm **DAY 1 CLOSING REMARKS**

CARLOS BLANCO, Workshop Co-chair Director, Division of Epidemiology, Services, and Prevention Research National Institute on Drug Abuse, NIH

ADJOURN WORKSHOP DAY 1 5:00 pm

5:00 pm **RECEPTION**

DAY 2: WEDNESDAY, DECEMBER 13, 2023

8:30 am OPENING REMARKS

CARLOS BLANCO, Workshop Co-chair

Director, Division of Epidemiology, Services, and Prevention Research

National Institute on Drug Abuse, NIH

8:40 am FIRESIDE CHAT

EVELYN POLK GREEN

Immediate Past President:

Attention Deficit Disorder Association

Past President:

Children & Adults with Attention Deficit/Hyperactivity Disorder

9:20 am SESSION V – ENABLING ACCESS TO RESOURCES AND SHARED DECISION MAKING FOR ADULTS WITH ADHD AND THEIR PROVIDERS

Session Objective:

- Share perspectives and available resources for prescribers, clinicians, and patients on the risks and benefits of ADHD medication use in adults, particularly for underserved populations;
- Discuss practical approaches that have helped overcome barriers (e.g., stigma, misdiagnosis) to appropriate diagnosis and treatment of adults with ADHD; and
- Consider opportunities to enable shared decision making between patients and their providers regarding the diagnosis and treatment of ADHD.

9:20 am Presentation

MARK OLFSON

Professor of Psychiatry, Medicine, and Law;

Professor of Epidemiology

Columbia University

9:40 am Presentation

LARA ROBINSON

Behavioral Scientist

National Center on Birth Defects and Developmental Disabilities, CDC

9:55 am Panel Discussion

Moderator: Andrea Chronis-Tuscano, University of Maryland, Department of Psychology

Lived Experience Perspective

KYLIE BARRON

Clinical Perspective

BRANDI WALKER

Chief Executive Officer

Marie Pauline Consulting, LLC

Psychiatrist Perspective
BENJAMIN CHEYETTE
Psychiatrist
Director of ADHD Programming
Mindful Health Solutions

Telehealth and Social Media Perspective

JESSICA GOLD

Associate Professor, Department of Psychiatry, University of Tennessee Health and Science Center Chief Wellness Officer University of Tennessee (UT) System

(As of 2/1/2024)

Discussion Questions:

- 1. What methods and/or systems are in place to support prescribers, clinicians, and other providers who diagnose and treat adults with ADHD? What else is needed?
- 2. Are there lessons learned from the diagnosis and treatment of pediatric populations that may be applicable for adult populations?
- 3. What approaches have and/or could help support adults with ADHD make informed decisions about the risks and benefits of ADHD medication use?
- 4. How can we best disseminate evidence-based educational materials/content about adult ADHD to patients (including those from diverse backgrounds) so that they can engage in informed discussions around their care?

10:55 am SESSION VI – PUBLIC HEALTH CONSIDERATIONS AND HARM REDUCTION STRATEGIES FOR ADHD MEDICATION USE

Session Objectives:

- Share perspectives on the causes, perceptions, consequences, and health equity implications of non-medical use of prescription stimulants;
- Discuss what is known and unknown about the intersection of ADHD medication use (medical and non-medical) and opioid use; and
- Consider how strategies to reduce the misuse of ADHD medications could impact public health (e.g., limiting patient access to medication, exacerbating existing health inequities).

10:55 am Presentation

BROOKE MOLINA

Professor of Psychiatry, Psychology, Pediatrics, Clinical & Translational Science University of Pittsburgh

11:15 am Panel Discussion

Moderator: Taleed El-Sabawi, Florida International University

Clinical Perspective
ROBIN WEISS
Private Practice of Psychiatry
Past President
Maryland Psychiatric Society

Lived Experience Perspective PATRICK KELLY

Research/Community Health Perspective

RYAN MCNEIL

Associate Professor, Director of Harm Reduction Research

Yale School of Medicine

Research/Clinical Perspective

KEVIN ANTSHEL

Professor of Psychology and Associate Department Chair

Syracuse University

Discussion Questions:

- 1. What is known and unknown about the intersection of ADHD medication use (medical and non-medical) and opioid use?
- 2. What are public health and health equity implications of not appropriately treating adults with ADHD?
- 3. What strategies (e.g., public health efforts, regulatory policies) have been deployed to reduce the misuse of ADHD medications and what was the impact on people with ADHD? What was the impact on public health?

12:15 pm COFFEE BREAK

12:45 pm SESSION VII – DAY 2 SYNTHESIS AND DISCUSSION

Session Objectives:

- Discuss key themes from previous workshop sessions; and
- Consider next step opportunities for improving the diagnosis and treatment of adults with ADHD.

12:45 pm Panel Discussion

Moderator: Carlos Blanco, National Institute on Drug Abuse, NIH

Clinical Perspective- ADHD in underserved populations

JOSEPH SCHATZ

Director, Psychiatric/Mental Health Nurse Practitioner Track

University of Pennsylvania School of Nursing

Lived Experience Perspective

TALEED EL-SABAWI

Assistant Professor of Law

Florida International University

Pharmacology Perspective

MATTHEW RUDORFER

Chief, Psychopharmacology, Somatic, and Integrated Treatment Research Program

National Institute of Mental Health, NIH

Research Perspective AMELIA ARRIA Director, Center on Young Adult Health and Development Professor, Department of Behavioral and Community Health University of Maryland School of Public Health

Family Medicine Perspective LATASHA SELIBY PERKINS Assistant Professor of Medicine Georgetown University School of Medicine

Discussion Questions:

- 1. Based on the day's sessions, what are the main themes you heard regarding enabling access to resources, shared decision making, and strategies to reduce the misuse of ADHD medications for adults with ADHD? What questions remain?
- 2. How can the use of a health equity framework help those with adult ADHD, health professionals, and others better understand the social, political, economic, and environmental factors impacting the health and overall well-being of adults ADHD?
- Considering everything you've heard over the past day and a half, what is important for the FDA to know as it relates to diagnosis, treatment, and drug development for adult ADHD?

1:35 pm **Audience Q&A**

1:50 pm **CLOSING REMARKS**

MARTA SOKOLOWSKA Deputy Center Director Substance Use and Behavioral Health Center for Drug Evaluation and Research U.S. Food and Drug Administration

CRAIG B.H. SURMAN, Workshop Co-chair Director, Clinical and Research Program in Adult ADHD Massachusetts General Hospital Associate Professor of Psychiatry Harvard Medical School

2:00 pm **ADJOURN DAY 2**