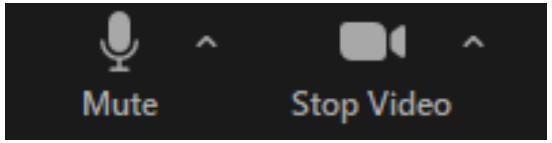
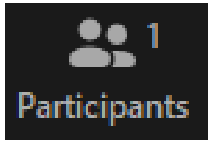
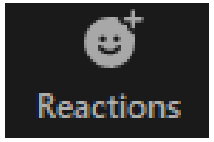
Psychedelic Medicine Task Force

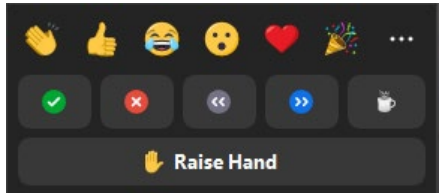
Welcome Psychedelic Medicine Task Force members!

Please use this time to test your Zoom meeting controls located at the bottom of the screen:





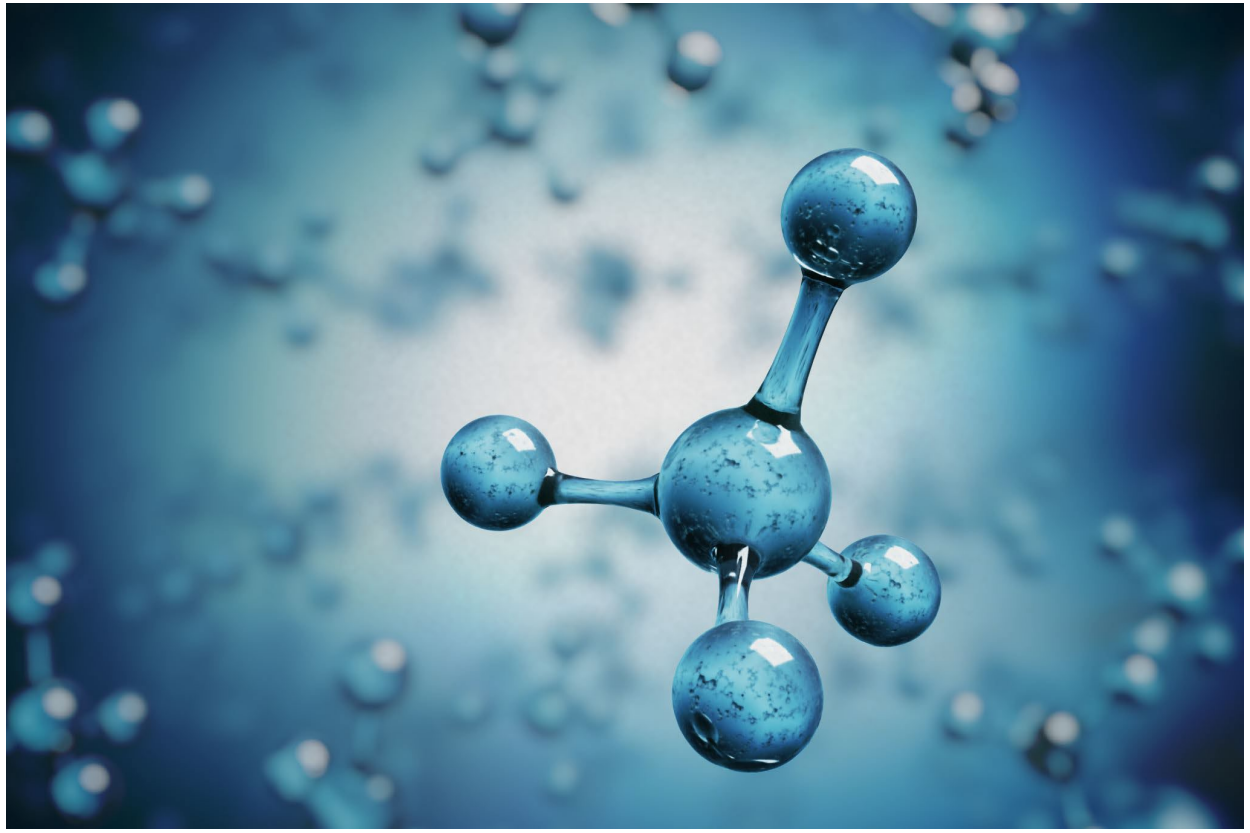




Access **Mural** via the link sent to you in your meeting invitation. Only members have access to this shared workspace. Once on the site, minimize the screen for later use during the meeting.

MDH Staff

- **Dana Farley**, Alcohol & Drug Prevention Policy Director, Drug Overdose Prevention Unit Supervisor
- **Chrissie Deutsch**, Psychedelic Medicine Program Administrator
- **Caroline Johnson**, Psychedelic Medicine Scientific Researcher



MANAGEMENT AND BUDGET
MANAGEMENT ANALYSIS AND DEVELOPMENT

Jessica Burke and Stacy Sjogren,
Senior Consultants providing planning assistance and facilitation

Dr. Jessica Nielson, Task Force Chairperson

Welcome meeting observers

- **Thank you** for your interest in the work of the Psychedelic Medicine Task Force.
- **Today's meeting is primarily organizational**. There are no plans today for taking public comment but, in accordance with Minnesota's Open Meeting Laws, you are welcome to observe this meeting.
- This meeting will not be recorded. **Minutes will be posted on the task force's website** along with other materials for this meeting:

https://www.health.state.mn.us/people/psychmed/index.html

health.psychedelicmemedicine@state.mn.us

Today’s agenda

- Approve December 4, 2023, minutes
- Finalize task force charter
- Work group update
- Legislative report update
- General Q&A
- **Break**
- Review and finalize methodology review
- **Break**
- Legal overview

Legislative charge

The Psychedelic Medicine Task Force was established to advise the legislature on the legal, medical, and **policy issues** associated with the legalization of psychedelic medicine in the state. For purposes of this work, “psychedelic medicine” means MDMA, psilocybin, and LSD.

Task force duties

as outlined in legislation (Subd. 5.)

Scientific Research

1. Survey existing studies in the scientific literature on the therapeutic **efficacy** of psychedelic medicine in the treatment of mental health conditions, including depression, anxiety, post-traumatic stress disorder, bipolar disorder, and **any other mental health conditions and medical conditions** for which a psychedelic medicine may provide an **effective** treatment option.
2. Compare the efficacy of psychedelic medicine in treating the conditions described [above] with the efficacy of treatments currently used for these conditions.

Duties

Develop a comprehensive plan that covers:

1. statutory changes necessary for the legalization of psychedelic medicine.

2. state and local regulation of psychedelic medicine

3. federal law, policy, and regulation of psychedelic medicine, with a focus on retaining state autonomy to act without conflicting with federal law, including methods to resolve conflicts.

    - Such as seeking an administrative exemption to the federal Controlled Substances Act under United States Code, title 21, section 822(d), and Code of Federal Regulations, title 21, part 1307.03; seeking a judicially created exemption to the federal Controlled Substances Act; petitioning the United States Attorney General to establish a research program under United States Code, title 21, section 872(e); using the Food and Drug Administration's expanded access program; and using authority under the federal Right to Try Act

4. Education of the public **on recommendations** made to the legislature and others about necessary and appropriate actions related to the legalization of psychedelic medicine in the state.

Work Cadence

Identify benefits and challenges of legalization Identify policy areas to focus on for work groups *barriers TBD as group work and research continue*		**Plan development + recommendations** *continual review through work group updates, SME presentations, and TF collaborative decision-making*					**Information synthesis, narrowing, and prioritization of report** *research and workgroup(s) continue if needed*		**Drafting of recommendations** *continue information synthesis, narrowing, and prioritization of report as draft takes shape*				**Submit Report Jan 1, 2025**
Dec 12/4/23	**Jan** 1/8/24 **Determine initial subgroups** **Draft initial legislative report due Feb 1** Report will be a basic summary of task force updates, including development, workplan, initial research, etc. No recommendations will be made.	**Feb** 2/5/24	**March** 3/4/24	**April** 4/1/24	**May** 5/6/24	**June** 6/3/24	**July** 7/1/24	**Aug** 8/5/24 **Begin outlining** Determine potential cost of implementation, needed investments, sustainable supports, etc.	**Sept** 9/9/24	**Oct** 10/7/24	**Nov** 11/4/24	**Dec** 12/2/24	**Jan 1 TF ends** Report includes comprehensive plan, scientific research, and any other additional materials members find necessary to share.

First report outline

1. Executive Summary
2. Introduction
3. Task force duties and charge
4. Task force formation
    - Members
    - Missing tribal representation
5. Meeting overview
    - November
    - December
    - January
6. Scientific research methodology
7. Looking ahead
8. Appendices

First report review process

1. MAD Copy editing and accessibility (completed)
2. MAD leadership review (completed)
3. MDH review (ongoing)
4. Task force review (Jan. 8 to Jan. 16)
5. MDH Executive Office approval and submission to Legislature (by Feb. 1)

Finalizing Scientific Research Methods Protocol

DEPARTMENT OF HEALTH

Overview of Section

- Methodology Overview
- Overview of Task Force Input
- Task Force Input Still Needed

Methodology Overview

- Overview
  - Scientific review type
  - Boundaries of research
  - Research question(s)
  - Identify databases
  - Search strategy
  - Apply inclusion/exclusion criteria
  - Levels of Evidence
  - Perform search
  - Appraise the quality of data
  - Analyze results
  - Write & present report on scientific literature

Overview of Task Force Input

1. Scientific Review Type
2. Boundaries of Scientific Research
3. Scientific Questions
4. Databases
5. Criteria
6. Levels of Evidence

1. Scientific Review Type

- Proposed:
  - Meta-analysis
  - Systematic review
  - Rapid review
- Votes for "rapid review"

Subdivision 5, Duties

The task force shall:

1) survey existing studies in the scientific literature on the therapeutic **efficacy** of psychedelic medicine in the treatment of mental health conditions, including depression, anxiety, post-traumatic stress disorder, bipolar disorder, **and any other mental health conditions and medical conditions** for which a psychedelic medicine may provide an **effective** treatment option;

2) compare the **efficacy of psychedelic medicine** in treating the conditions described in clause (1) with the **efficacy of treatments currently used** for these conditions

2. Boundaries of Scientific Research

- **Efficacy:** The performance of the treatment only under ideal and controlled circumstances, such as those in a clinical trial
- **Effectiveness:** How the drug performs in "real world conditions."

- Most votes are for "Efficacy AND Effectiveness"
- Some notes in the "Other" category

3. Research Questions

- Two questions for each drug:
  - Question 1: What are the health conditions that (each drug) shows efficacy/effectiveness in treating?
  - Question 2: What is the efficacy/effectiveness of (each drug) in treating the above-named conditions as compared to the gold-standard treatment?
- Supplementary question: What are the risks associated with (each drug) as a therapeutic treatment?

- Votes indicate these two questions are acceptable

4. Databases

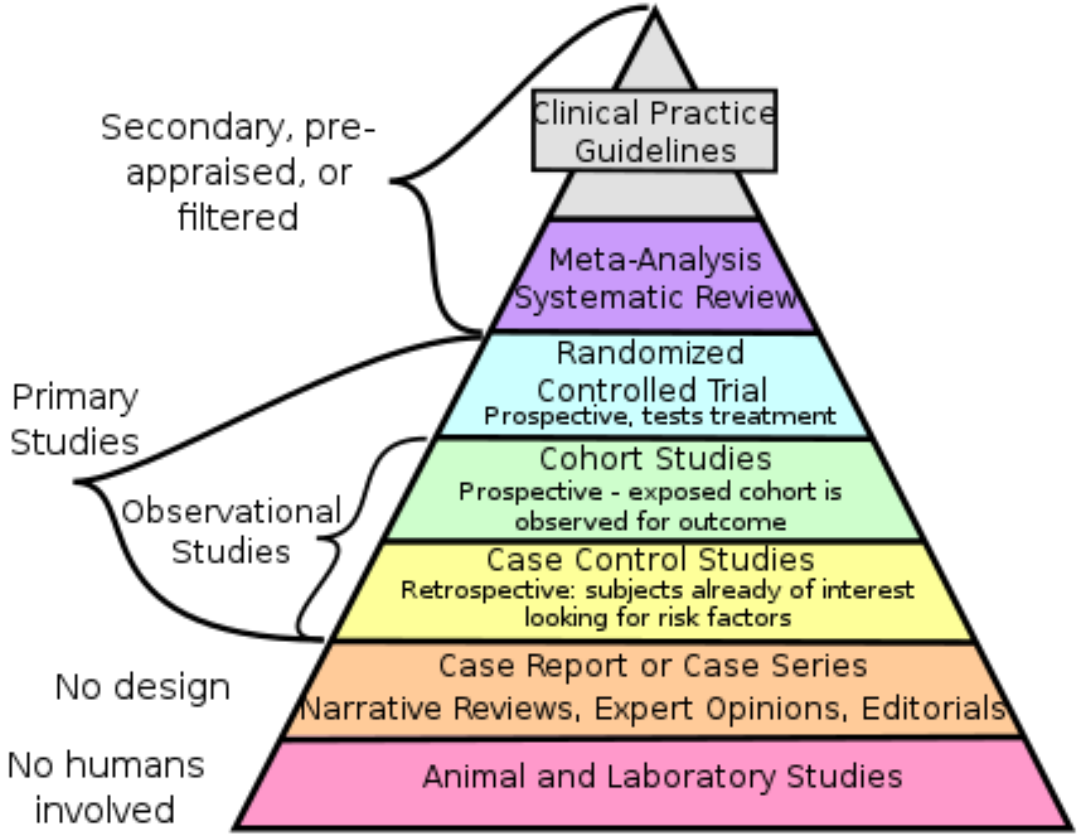
- Academic:
  - Most votes for PubMed
  - Indigenous Research sources
    - Journal of Indigenous Research
  - Other
- Grey Literature
  - ClinicalTrials.gov

5. Criteria

- Date
  - Even split between all vs post-IRB
- Exposure of Interest
  - Most votes for "All"
- Geographic Location
  - "All"
- Language
  - "All"
- Population
  - "All Adult" with notation
- Peer-review only
  - Most votes for "Yes"
- Clinical Outcomes
  - Include Secondary Outcomes
- Therapeutic Setting
  - "All"
- Types of Publication
  - "All"

6. Levels of Evidence

- Most votes are for Randomized Controlled Trials only
- Second-most votes for Observational Studies



Source: The Hierarchy of Evidence – Applied Statistics in Healthcare Research (upei.ca) ; File:Research design and evidence.svg - Wikimedia Commons

Other Considerations

- Three sticky notes on Mural with other considerations

Thank You!

Caroline Johnson, PhD

Caroline.Johnson@state.mn.us

Next steps and adjournment

- **Opportunity for member feedback:** please leave your feedback in Mural.
- **Questions between meetings:** contact Jess Burke (jessica.burke@state.mn.us)
- Next meeting: Monday, February 5, 2024, 9:30 am – 12:30 pm