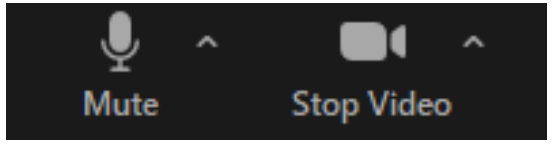
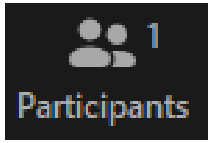
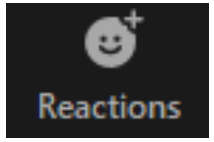
Psychedelic Medicine Task Force

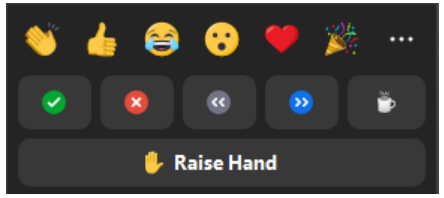
Welcome Psychedelic Medicine Task Force members!

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.

Task Force staff

MDH staff

- **Dana Farley**, Alcohol & Drug Prevention Policy Director, Drug Overdose Prevention Unit Supervisor
- **Dr. Caroline Johnson**, Psychedelic Medicine Scientific Researcher

Task Force chair

- Dr. Jessica Nielson

MAD staff

- Jessica Burke, Senior Management Consultant
- Nick Kor, Senior Management Consultant
- Stacy Sjogren, Senior Management Consultant

Welcome meeting observers

Thank you for your interest in the work of the

Psychedelic Medicine Task Force!

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

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**	**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.

Today’s agenda

- Approve March meeting minutes
- Member-collected feedback
- Decision flowchart and timeline review
- **Break**
- Work group updates
- **Break**
- Research update: LSD
- Guest presentation

Desired meeting outcomes

- Detailed review of decision flow chart/timeline, and discussion to assess as a group whether we are on track
- Work group updates: Members stay abreast of small group work sequencing and have an opportunity to weigh in to keep process moving.
- Research update – LSD results and discussion
- Guest presentation: Right to try and federal exemptions to controlled substances act and Minnesota's decision about cannabis use

Work groups updates

- **Upcoming meetings**
  - **Legal:** Thursday, April 4 at 4:00 p.m.
  - **Regulatory:** Monday, April 8 at 4:00 p.m.
  - **Policy:** Tuesday, April 16 at 4:00 p.m.

Lysergic Acid Diethlyamide (LSD) Literature Review

Dr. Caroline Johnson

DEPARTMENT OF HEALTH

Overview of section

- Health Conditions
- Anxiety Disorders
- Alcohol Use Disorder
- Risks
- Discussion/Mural Activity

Health conditions

- Anxiety (with or without a life-threatening illness)
- Substance Use Disorders
  - Alcohol Use Disorder
  - ~~Opioid Use Disorder~~
- ~~Cluster Headache~~
- ~~Pain~~
- ~~Schizophrenia~~

Anxiety disorders: clinical trials

- Gasser et al., 2014[1]
  - 12-participant phase 2 pilot study
    - With life-threatening illnesses
  - 200µg LSD vs 20µg LSD (active control)
  - Therapy component
  - **Significant reductions in anxiety at 2 months, sustained up to 12 months**

- Holze et al., 2023[2]
  - 42-participant phase 2 crossover study
    - With *and* without life-threatening illnesses
  - 200µg LSD + therapy component
  - **Significant reductions in anxiety up to 16 weeks after treatment**
  - **Significant reductions in depressive symptoms**

1) Gasser et al. (2014). J Nerv Ment Dis; 2) Holze et al. (2023). Biol Psychiatry

Anxiety disorders: unpublished results

- Mind Medicine (MindMed): Recent phase 2b trial, awarded Breakthrough Therapy Designation from FDA
- LSD (MM120) for generalized anxiety disorder[3]
  - 198 participants
  - 25µg, 50µg, 100µg, 200µg, or placebo
  - No psychotherapy
- **One dose (100µg) significantly reduced anxiety and depression measurements up to 12 weeks after treatment**.
  - 48% of participants showed remission

3) Mind Medicine, Inc. (2024). Htpps://mindmed.co/news-events/press-releases

Anxiety disorders: comparison of efficacy

- Current treatments:
  - Psychotherapy (e.g., CBT)
  - Pharmacotherapy (e.g., anti-anxiety, SSRI)
- Meta-analysis…TBA

- Comparing effect size
  - Gasser[1]: d=1.1, d=1.2
  - Holze[2]: d=-0.87
  - MindMed[3]: d=0.81
- Typical treatments
  - CBT: d=0.84[4]; d=1.30[5]
  - Pharmacological: d=2.02[5]; d=0.39[6]
    - Benzodiazepines: d=0.38[6]
    - SSRIs: d=0.36[6]
  - Combination: d=2.12[5]

4) Cuijpers et al. (2014). Clin Psychol Rev; 5) Badelow et al. (2015). Int Clin Psychopharmacol; 6) Hidalog et al. (2007). J Psychopharmacol

Alcohol use disorder

- RCTs from 1960s/1970s
  - Widely variable methodologies
  - Each concluded that treatment with LSD was no more effective than any non-LSD approach
- Current treatments:
  - Naltrexone, Acamprosate, Disulfiram
  - Psychotherapy (CBT)
- Comparison of Efficacy
  - LSD treatment provided significant beneficial outcomes, was comparable to treatment with current medications[7]
- Effect on alcohol misuse, abstinence:
  - LSD: 16%, 15%
  - Naltrexone: 11%, 3%
  - Acamprosate: 1%, 11%
  - Disulfiram: N/A, 11%

7) Krebs & Johansen. (2012). J Psychopharamcol.

Risks

- Mild-to-moderate adverse effects, typically only during treatment
  - Mild anxiety, illusions, headache, nausea
- Significant increase in blood pressure, heart rate, body temperature

- Other things to think about:
  - “Bad trips” unlikely
  - Low abuse potential
- Anxiety treatment risks
- Alcohol use disorder treatment risks

Most adverse effects occur following use outside of the clinical environment

Discussion

- Recommend LSD?
  - If so, in what capacity?
    - Further research?
    - "Medical" vs Non-"Medical"
    - Restricted to certain health conditions, or up to discretion of provider?
    - Etc.

References
1) Gasser et al. (2014). Safety and efficacy of lysergic acid diethylamide-assisted psychotherapy for anxiety associated with life-threatening diseases. The Journal of Nervous and Mental Disease, 202(7), 513.
2) Holze et al. (2023). Lysergic acid diethylamide–assisted therapy in patients with anxiety with and without a life-threatening illness: a randomized, double-blind, placebo-controlled phase II study. Biological Psychiatry, 93(3), 215-223.
3) MindMed receives FDA breakthrough therapy designation and announces positive 12-week durability data from phase 2b study of MM120 for generalized anxiety disorder. (2024, March 7). Mind Medicine (MindMed) Inc. https://ir.mindmed.co/news-events/press-releases/detail/137/mindmed-receives-fda-breakthrough-therapy-designation-and-announces positive-12-week-durability-data-from-phase-2b-study-of-mm120-for-generalized-anxiety-disorder
4) Cuijpers et al. (2014). Psychological treatment of generalized anxiety disorder: a meta-analysis. Clinical psychology review, 34(2), 130-140.
5) Bandelow et al. (2015). Efficacy of treatments for anxiety disorders: a meta-analysis. International clinical psychopharmacology, 30(4), 183-192.
6) Hidalgo et al. (2007). An effect-size analysis of pharmacologic treatments for generalized anxiety disorder. Journal of Psychopharmacology, 21(8), 864-872.
7) Krebs & Johansen (2012). Lysergic acid diethylamide (LSD) for alcoholism: meta-analysis of randomized controlled trials. Journal of Psychopharmacology, 26(7), 994-1002.

Thank You!

Right to try and federal exemptions to the Controlled Substances Act

Shane Pennington, Porter Wright Morris & Arthur LLP

DEPARTMENT OF HEALTH

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, May 6, 2024, 9:30 a.m. – 12:30 p.m.