Psychedelics in the Real World: Using Real World Evidence to Prepare for Approval

Janetta Iwanicki, MD
Rocky Mountain Poison & Drug Safety

May 2022
Roadmap

- Existing Data on Psychedelic Use
- Snapshots of Epidemiology of Psychedelic Use
- Balancing Benefits and Risks of Psychedelics
- Future Considerations in Psychedelic Epidemiologic Research
Existing Data on Psychedelic Use

• Data sources
  • National Survey for Drug Use and Health (NSDUH)
  • National Poison Data System (NPDS)
  • Monitoring the Future (MTF)

• Challenges in data collection
  • Bias toward non-reporting
  • Substance patient is using and substance patient *thinks* they are using may not be the same
    • Lack of specificity
  • Motivations for use poorly captured
  • Delays in data availability
  • No single perfect data system
NSDUH, Lifetime Use, 2019-2020

Thousands of People in US Over Age 12

<table>
<thead>
<tr>
<th>Substance</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCP</td>
<td>5,000</td>
<td>5,000</td>
</tr>
<tr>
<td>LSD</td>
<td>27,000</td>
<td>27,000</td>
</tr>
<tr>
<td>Peyote</td>
<td>6,000</td>
<td>6,000</td>
</tr>
<tr>
<td>Mescaline</td>
<td>10,000</td>
<td>10,000</td>
</tr>
<tr>
<td>Psilocybin</td>
<td>22,000</td>
<td>22,000</td>
</tr>
<tr>
<td>Ecstasy</td>
<td>17,000</td>
<td>17,000</td>
</tr>
<tr>
<td>Ketamine</td>
<td>3,000</td>
<td>3,000</td>
</tr>
<tr>
<td>DMT</td>
<td>2,000</td>
<td>2,000</td>
</tr>
<tr>
<td>Salvia</td>
<td>4,000</td>
<td>4,000</td>
</tr>
</tbody>
</table>
NPDS, Cases by Category, 2020

- Phenylethylamines (incl. Ecstasy)
- LSD
- Psilocybin

Number of Cases

- Total Cases
- Single Substance Cases
- Intentional
- HCF
- Major/Death
MTF, Adolescents 1996-2020, Ecstasy

Use
% who used in last 12 months

Risk
% seeing "great risk" in using once or twice

YEAR

PERCENT

YEAR

PERCENT

8th Grade
10th Grade
12th Grade
MTF, Adolescents 1975-2020, LSD

Use

% who used in last 12 months

Risk

% seeing "great risk" in using once or twice

YEAR

YEAR
Snapshot of 2021
Lifetime Use, RADARS System NMURx Program

<table>
<thead>
<tr>
<th>Substance</th>
<th>Prevalence Among US Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine</td>
<td>1</td>
</tr>
<tr>
<td>LSD</td>
<td>8</td>
</tr>
<tr>
<td>Ecstasy</td>
<td>5</td>
</tr>
<tr>
<td>PCP</td>
<td>2</td>
</tr>
<tr>
<td>Psilocybin</td>
<td>9</td>
</tr>
</tbody>
</table>
Snapshot of 2019-2021 Past Year Use, RADARS System NMURx Program
Developing a Postmarketing Surveillance Strategy: Considerations

**Product Specificity**
- Street vs medical
- High risk of counterfeits

**Molecular Differences**
- Not all psychedelics are the same
- Differential needs for each molecule

**Comparator Development**
- What makes sense for appropriate comparators?
- Rx meds, street drugs, ?
Conceptualizing Comparators

![Graph showing prevalence of use for different drugs over time.](Diagram)
Developing a Postmarketing Surveillance Strategy: Considerations

**Benefit/Risk Balance**
- Measuring unmet needs, benefits, AEs
- Measuring impacts on perceptions and behaviors

**Adverse Event Tracking**
- How to track AEs from multiple sources
- Do we also need to understand “AEs” from non-Rx sources?

**Regulatory Challenges**
- Differential regulations by state
- Range from illegal -> deprioritized -> decriminalized-> legalized
Thank you!

Questions???

Janetta Iwanicki, MD
Chief Scientific Officer
Rocky Mountain Poison & Drug Safety
Janetta.Iwanicki@RMPDS.org