

## Real-world Pilot Survey of Clinical Experience Using Dexmedetomidine Sublingual Film for Acute Agitation in Adults with Schizophrenia or Bipolar Disorder

Mae Kwong, PharmD; Michael A. Hooks, PharmD, FCCP, BCPS; Sonja Hokett, PharmD, MS, MSc BioXcel Therapeutics, New Haven, CT, USA

- Agitation is a common symptom in patients with bipolar disorder (BPD) and schizophrenia (SCZ)
- Acute agitation associated with BPD and SCZ may escalate to verbal or physical aggression
- When behavioral de-escalation interventions are unsuccessful, pharmacologic management may be required
- Dexmedetomidine sublingual film (DSF) is approved to treat acute agitation associated with BPD and SCZ in adults

### Objective

To characterize early clinical experience with DSF in the treatment of acute agitation associated with BPD or SCZ

### Methods

- 20 clinicians from 10 institutions who had treated ≥ 3 patients with DSF were invited to participate in an anonymous, 20-question web-based survey
- No incentives were provided to participants
- Closed-ended, multiple choice, ratings, or forced ranked items
- <u>Data included:</u> DSF utilization, institution & patient characteristics; desired and observed treatment outcomes; efficacy and safety; clinical satisfaction; clinician-rated patient satisfaction

- 10 Clinicians responded (50% response rate)
- 80% of respondents do not require a clinical pathway or protocol for the management of acute agitation associated with BPD or
- 90% of respondents reported no formal assessment tool use for rating agitation severity
- 30% reported that 25-50% of patients were impaired or under the influence of alcohol or illicit drugs
- 30% reported that the impaired status was unknown at

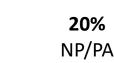
### Respondent Demographics (N=10)







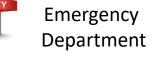




**Psychiatrists** 

### DSF Administration Site of Care<sup>3</sup>





# (Consult-Liaison

\*Responses are forced rank: 1=Most Desirable; 4=Least Desirable

**Prompt and Efficient** 

**Decreased Physical** 

**Decreased Length** 

**Decreased Staff** 

\*Responses are select all that apply

**Restraint Use** 

of Stay

**Observed Outcomes\*** 

Inpatient Psych

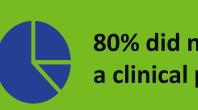
**Desired Outcomes**\*

ettings were prompt and efficient patient treatment and decreased staff injury

op 2 forced ranked desired outcomes for DSF in both inpatient psychiatric and ED

■ED Inpatient Psych





80% did not require or follow a clinical pathway for agitation

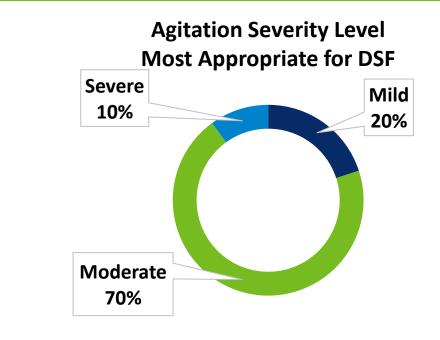


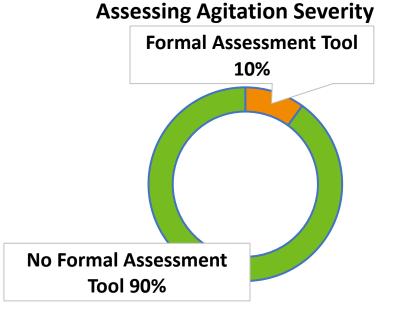
70% identified moderate agitation as the most appropriate patient

**Agitation Severity Level** 



Top three observed outcomes included prompt/efficient treatment, reduced staff injury, and reduced physical restraint use





### **Clinical Experience**

Using a 5-point Likert-type scale, clinicians rated their experience with DSF in 2 areas (Speed of Treatment and Patient Acceptance/Safety) compared to alternative therapies: injectable benzodiazepines (Inj BZD); injectable antipsychotics (Inj AP); combination (Inj BZD + Inj AP); oral benzodiazepine (Oral BZD); oral antipsychotics (Oral AP)

### Efficacy: Speed of Treatment (Time inclusive of prescriber decision to treat, drug acquisition, and through patient response)

- Compared to Oral BZD or Oral AP, DSF was rated <u>somewhat better</u> or <u>much better</u> by **75%** of clinicians surveyed
- Compared to Inj BZD, IM AP, or combination, DSF was rated somewhat better or much better by **57%** of clinicians surveyed

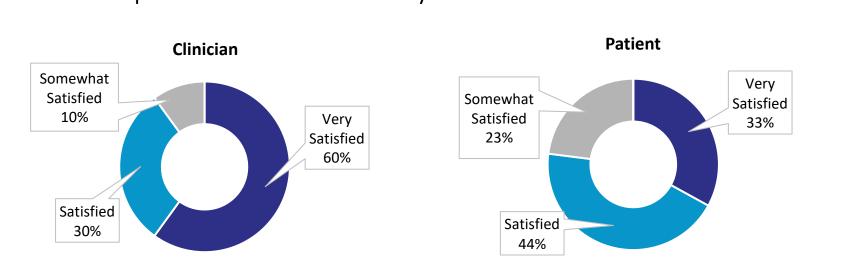
### Patient Acceptance/Safety

- Compared to Oral BZD or Oral AP, 80% of clinicians surveyed rated DSF as somewhat better or much better
- Compared to Inj BZD, Inj AP, or combination injectables, 90% of clinicians surveyed rated DSF as somewhat better or much better

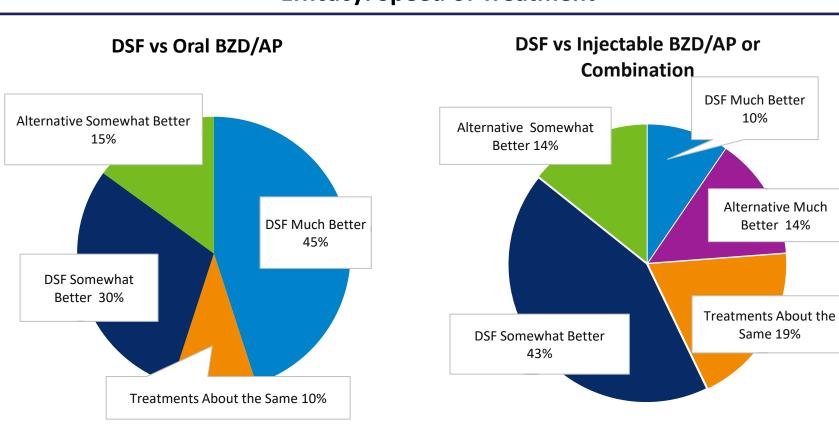
### Satisfaction

29%

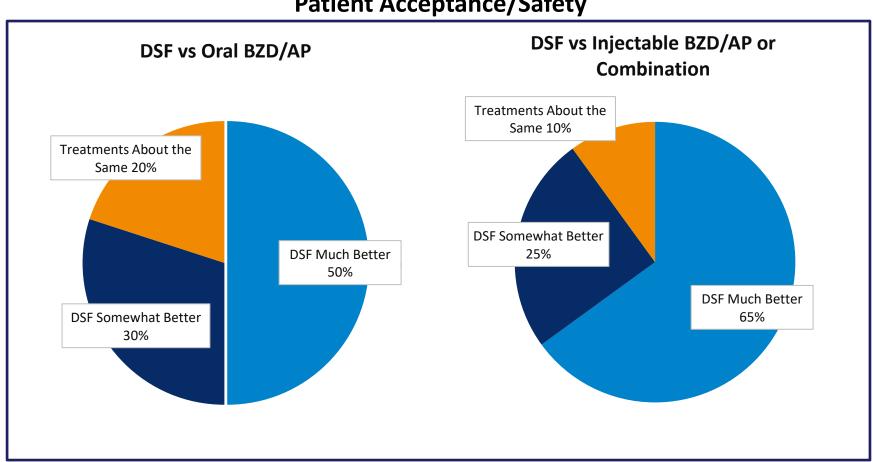
- 90% of clinicians were satisfied to very satisfied with the clinical response to DSF
- 77% of patients were satisfied to very satisfied with DSF



### **Efficacy: Speed of Treatment**







### Conclusions

- This small pilot survey reported early clinical experience with DSF for agitation in adults with schizophrenia and bipolar disorder in inpatient psychiatry and emergency settings
- Most institutions didn't require agitation management protocols (80%) and didn't use agitation severity assessment tools for dose selection (90%)
- Frequently observed DSF treatment outcomes aligned with desired outcomes: prompt and efficient treatment, decreased physical restraint use, and decreased staff injury
- Both DSF speed of treatment and tolerability were rated favorably compared to common oral and injectable treatments
- Early experience using DSF may provide helpful decision-making information to clinicians in similar settings

### Limitations

- Survey results are descriptive in nature and based on a limited number of respondents, so may not be generalizable to other settings
- Because all respondents voluntarily completed the survey, voluntary response bias may exist, and survey results may over-represent organizations with higher interest in implementing strategies to manage acute agitation associated with BPD or SCZ