



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

Introduction

- Agitation is a common symptom in patients with bipolar disorder (BPD) and schizophrenia (SCZ)^{1,2}
- 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
- Data included DSF utilization, institution & patient characteristics, desired and observed treatment outcomes, efficacy and safety, clinical satisfaction, and clinician-rated patient satisfaction

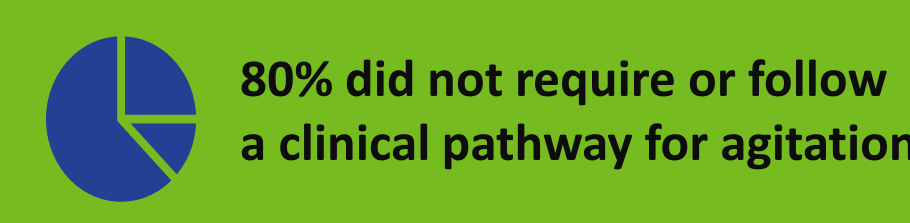
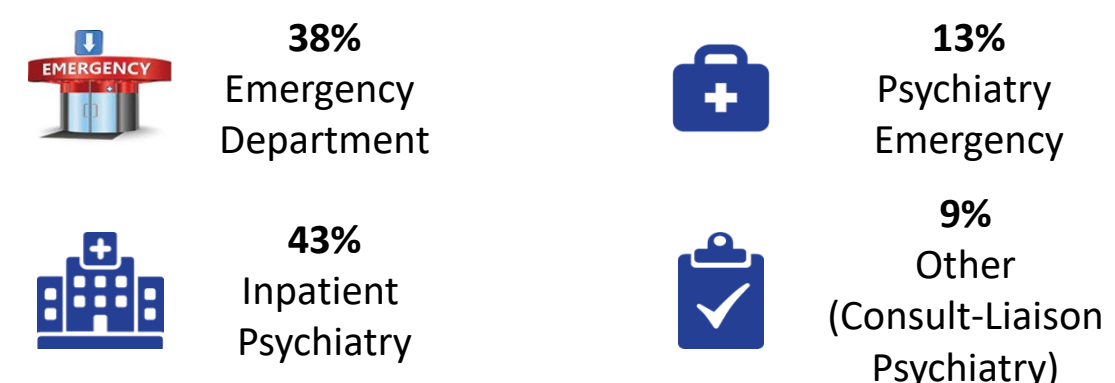
Results

- 10 Clinicians from 10 institutions 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 SCZ
- 90% of respondents reported using no formal assessment tool for rating agitation severity

Respondent Demographics (N=10)

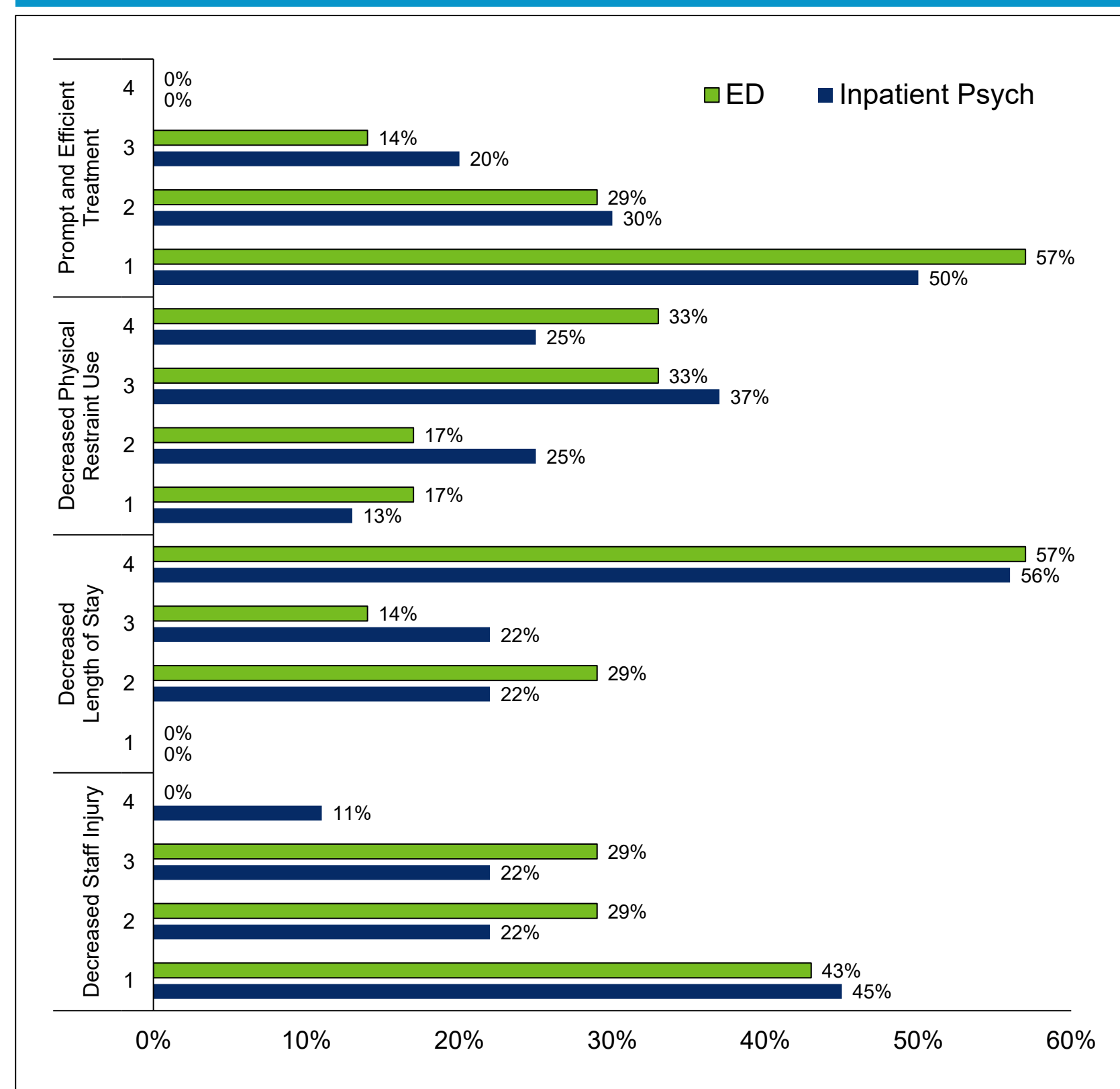


DSF Administration Site of Care (N=10)



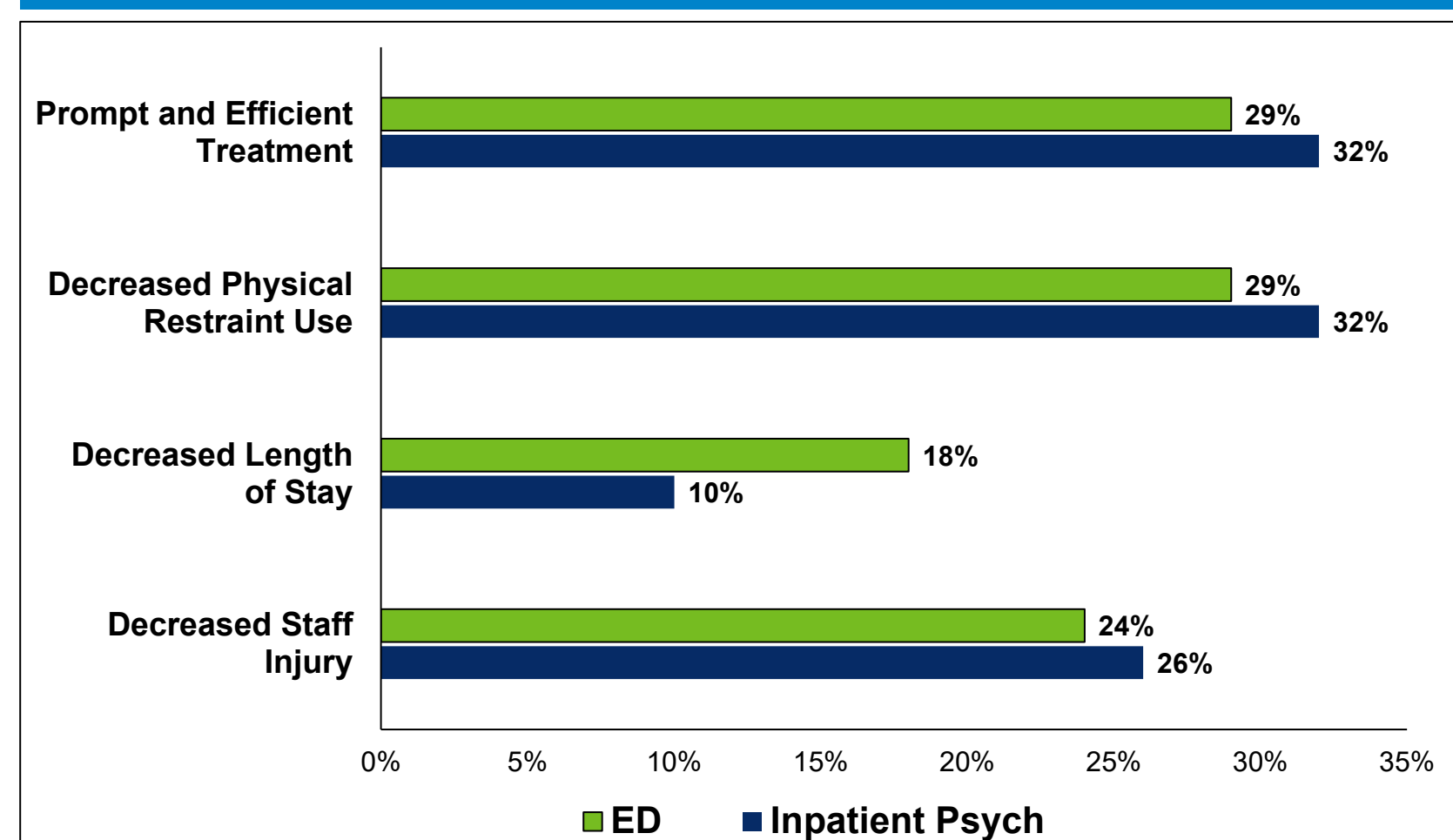
Desired Outcomes*

Top 2 forced ranked desired outcomes for DSF in both inpatient psychiatric and ED settings were prompt and efficient patient treatment and decreased staff injury



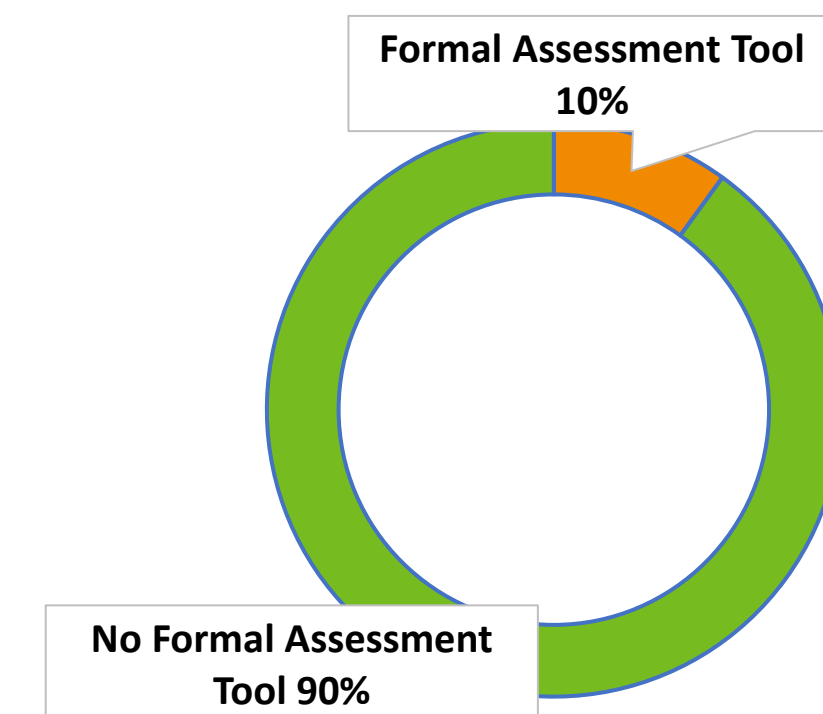
*Responses are forced rank: 1=Most Desirable; 4=Least Desirable

Observed Outcomes*



*Responses are select all that apply

Assessing Agitation Severity



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)

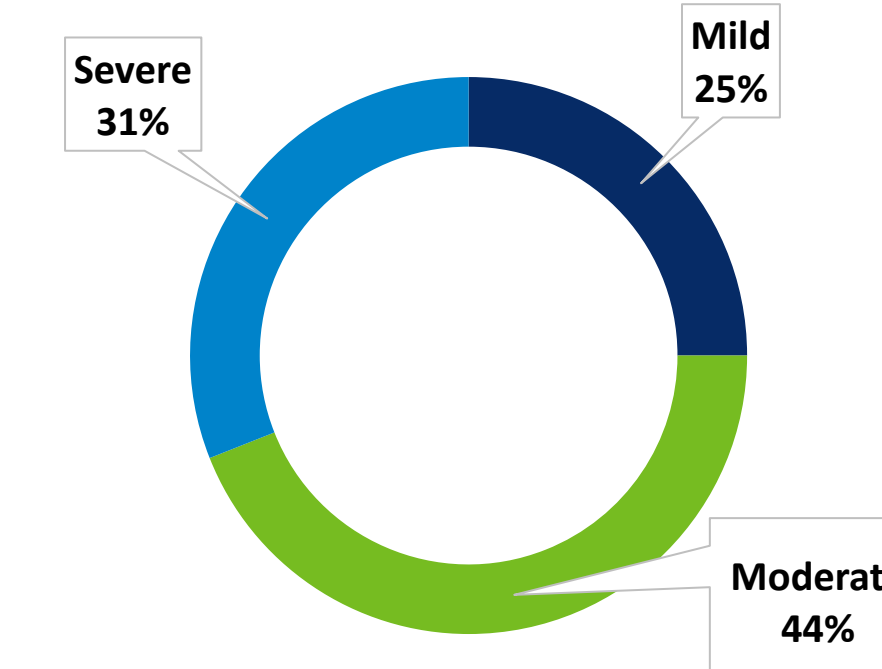
Efficacy: Speed of Treatment (Time inclusive of prescriber decision to treat, drug acquisition, through patient response)

- Compared to Oral BZD or Oral AP, DSF was rated about the same, somewhat better, or much better by **85%** of clinicians surveyed
- Compared to Inj BZD, IM AP, or combination, DSF was rated about the same, somewhat better, or much better by **75%** of clinicians surveyed

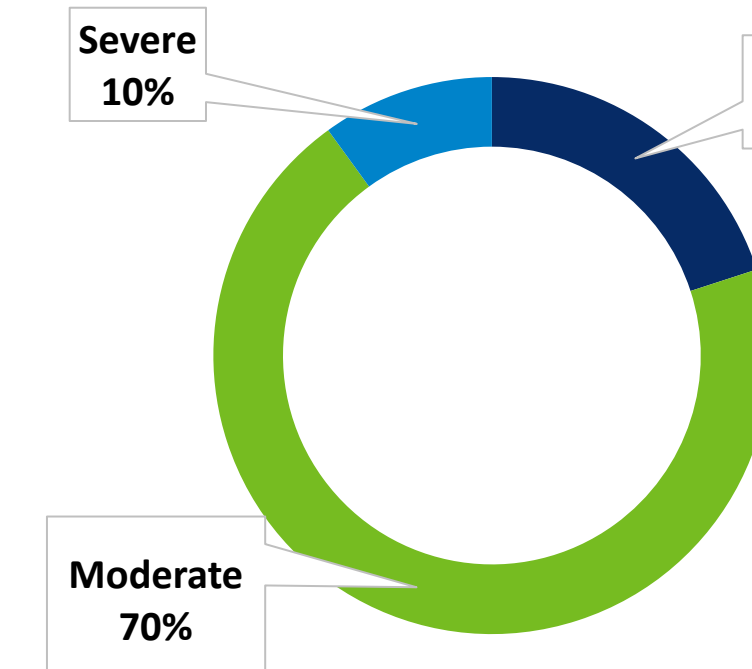
Patient Acceptance/Safety

- Compared to Oral BZD or Oral AP, **100%** of clinicians surveyed rated DSF as the same, somewhat better, or much better
- Compared to Inj BZD, Inj AP, or combination injectables, 100% of clinicians surveyed rated DSF as the same, somewhat better, or much better

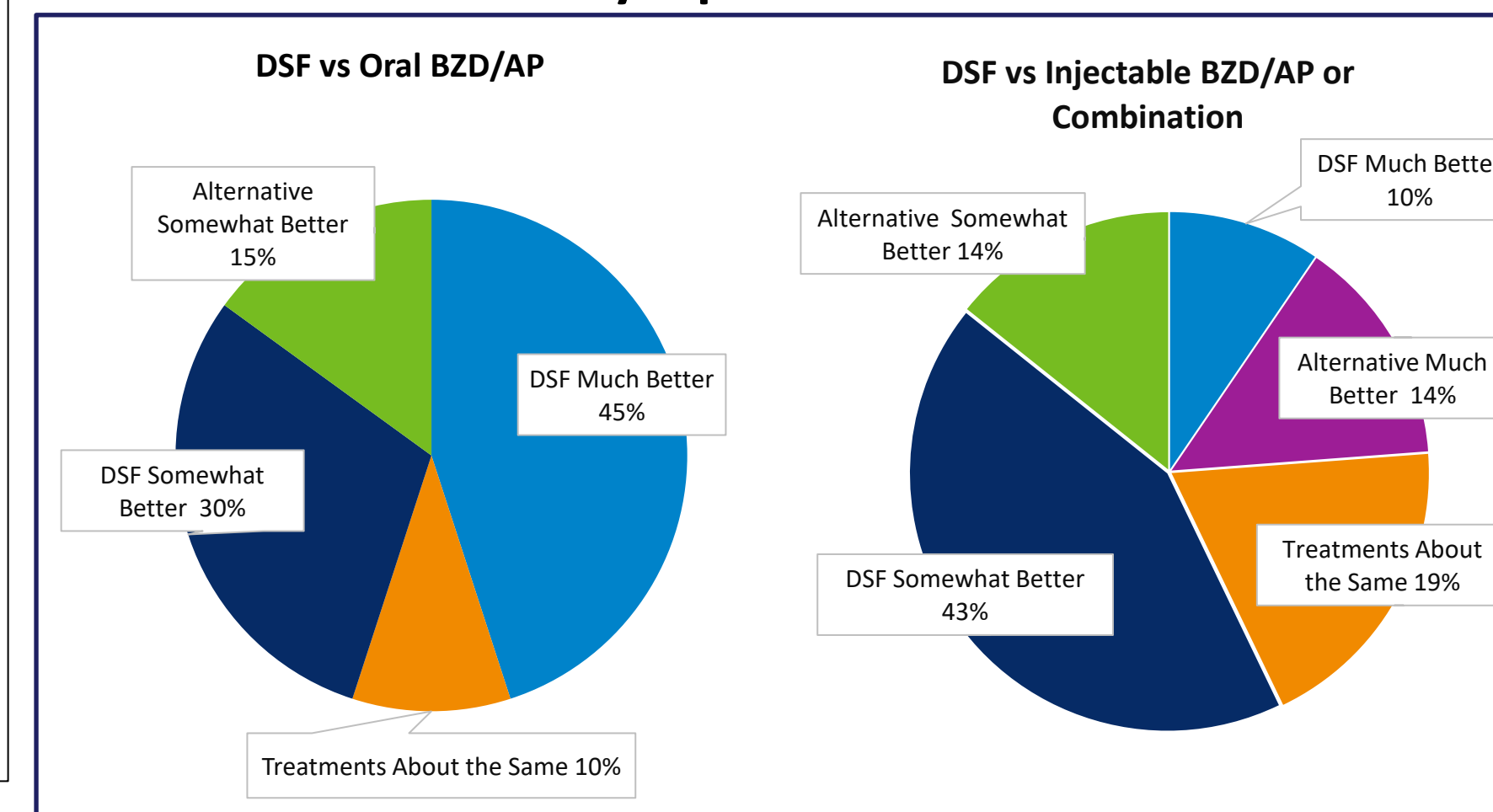
Agitation Severity Level Utilizing DSF



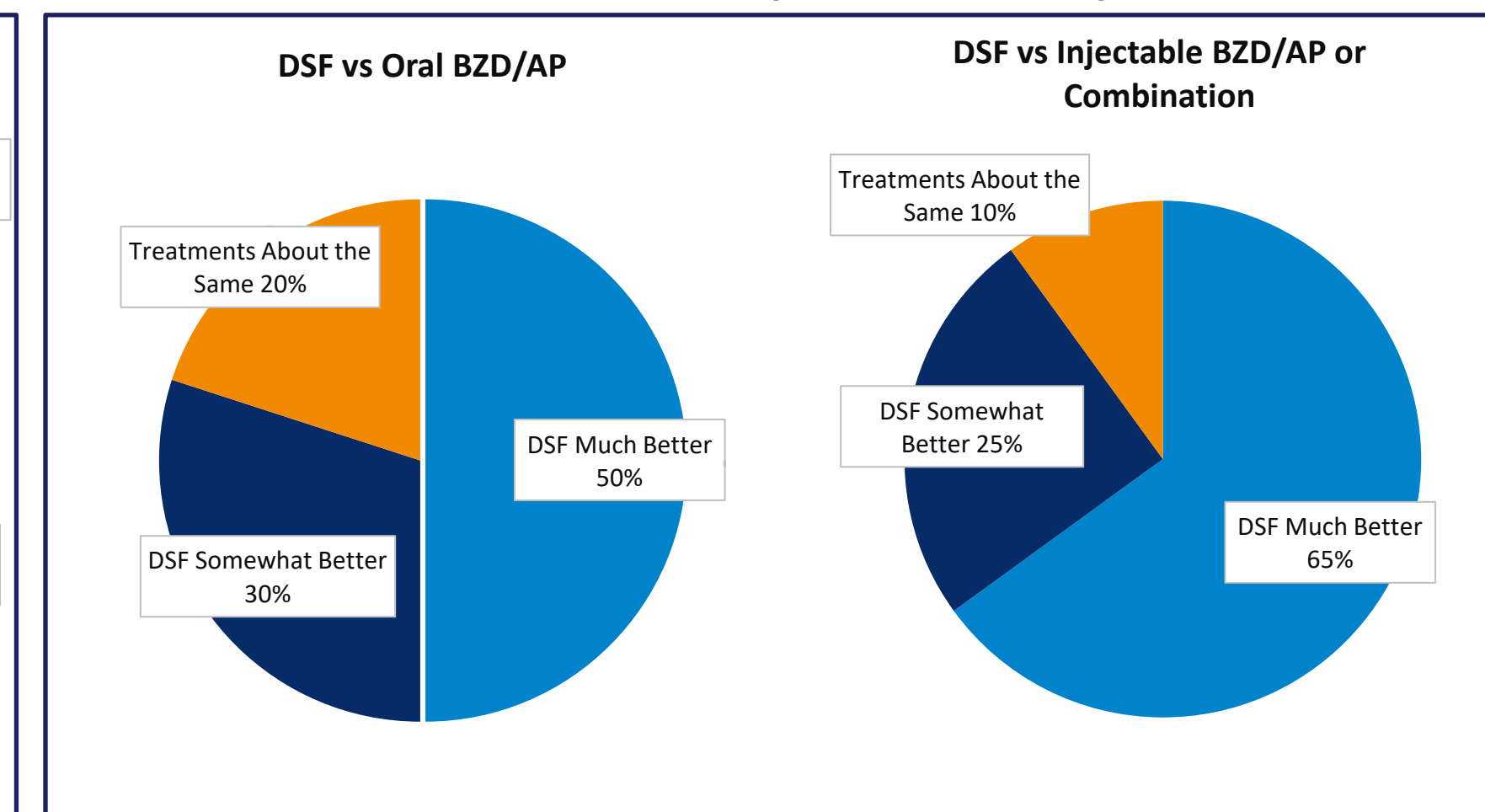
Agitation Severity Level Most Appropriate for DSF



Efficacy: Speed of Treatment



Patient Acceptance/Safety



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