

## Evidence for a Patient-Informed Approach to Value Assessment of Major Depressive Disorder Treatments

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## INTRODUCTION

- Major Depressive Disorder (MDD) affects approximately 17.3 million American adults. 1
- Current treatments for MDD include pharmacotherapy (e.g., antidepressants), psychotherapy (e.g., cognitive behavioral therapy), sematic therapies (e.g., electroconvulsive therapy), and combination treatments.
- Historically, economic evaluations of treatments for MDD rely on clinical (response and remission rates) and cost data from scientific evidence, and often do not fully reflect patient priorities.
- Value assessments can be utilized to support treatment value and facilitate patient-centered decision making amongst health care providers, payers, and pharmaceutical companies.
- The lack of patient priorities in evaluations represents the gap that exists between current research agendas and patient priorities in MDD treatments.
- Previous work identified a set of patient-driven value elements and attributes for adults that can be used to make value assessments more patient-centered. This includes treatment effects, access, cost, life impact, and social impact.<sup>2</sup>

#### **STUDY OBJECTIVE**

To identify whether a gap exists between scientific evidence and patient priorities for treatments of MDD.

## **METHODS**

#### Phase 1: Attribute Selection

- One-on-one interviews with 20 adults with MDD were conducted and recorded to learn what matters most when making decisions about their care.
- •Recruitment- Patients were recruited through national patient organizations and referrals by a clinician using an electronic flyer and email invitation.
- Inclusion Criteria- Age 18 and older, MDD diagnosis, ability to speak English.
- Data extraction- interviews elicited the attributes most important in treatment decision-making, which were reflected within five domains: treatment effects, access, cost, life impact, social impact.

## Phase 2: Literature Review

- We conducted a scoping review, using Embase and PubMed, to identify published randomized trials or observational studies of available MDD treatments.
  - Search strategy- Search terms were related to depression/depressive disorders, drug development, and drug comparison.
- Inclusion Criteria- Full-length studies reporting empirical data.
- Data extraction- Treatment type, primary/secondary outcomes, treatment effect estimates, and adverse effect information were extracted.

## Phase 3: Patient-informed Value Elements

• Published scientific evidence of treatment efficacy was compared with the five domains in the PAVE patient-informed value element framework. We identified overlap between the outcomes captured in research studies with patient values as well as where there are gaps between what is important to patients and the evidence about treatment benefits (e.g., treatment effects, quality of life) obtained from Phase 2.

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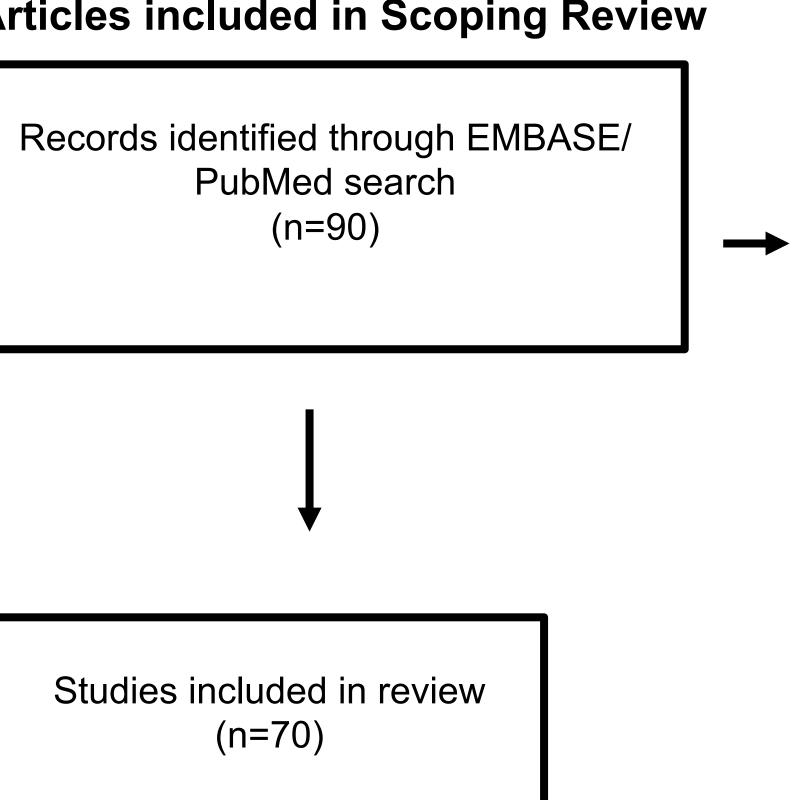
## RESULTS

- Exemplary quotes from the interviews with adults living with MDD were assigned to one of the attributes within the five domains in the patient-informed value element framework (Table 1). The lived experiences identify attributes of MDD treatment that impact individuals who are living with MDD but are not included in research. This demonstrates factors that influence treatment decisions.
- The search resulted in 90 publications, of which 70 were included for abstraction. Figure 1 describes the number of papers excluded and the reasons for exclusion.
- The effect estimates of MDD treatment types in terms of the response and remission rates and other humanistic outcomes were extracted from published clinical trials and observational studies. We summarized percent of studies that reported these outcomes (Figure 2).
- Evidence for MDD treatment efficacy primarily focused on symptoms [response (51%) and remission (44%)] and 30% reported on quality of life and satisfaction outcomes (Figure 2).
- There is a gap between empirical evidence of treatment benefits from published research and what patients valued in managing their MDD. Some key domains/value elements were not consistently measured, some were not measured at all.

## Table 1: Patient- Informed Priorities for MDD treatment Elicited from the Phase 1 Interviews

Value Element Domain	Treatment Attributes	Individual Quotes from the 1:1 Interviews
Treatment Effects	Side Effects	"The last couple of medications I was on gave me bad side effects. I decided I will not ever go on another antidepressant in my life. I don't care how bad I get."
Access	Provider Relations	"this psychiatrist, when I would complain to her, I just felt like she wasn't listening to me.'
Cost	Affordability, Reimbursed Care	"I was able to get security disabilityIt's a major issue. I'm trying to find care that's covered and it's a big problem."
Life Impact	Ability to Work	"I tried to continue work. I was able to get one more year work in and I couldn't do it anymore. I just couldn't do it. I couldn't follow directions."
Social Impact	Relationship with Family	"I did have the depression, I had anxiety and about a year ago I was really in a bad place. My wife has been a bad place and I wasn't there for her. I start[ed] to realize that I was letting her and our son down."

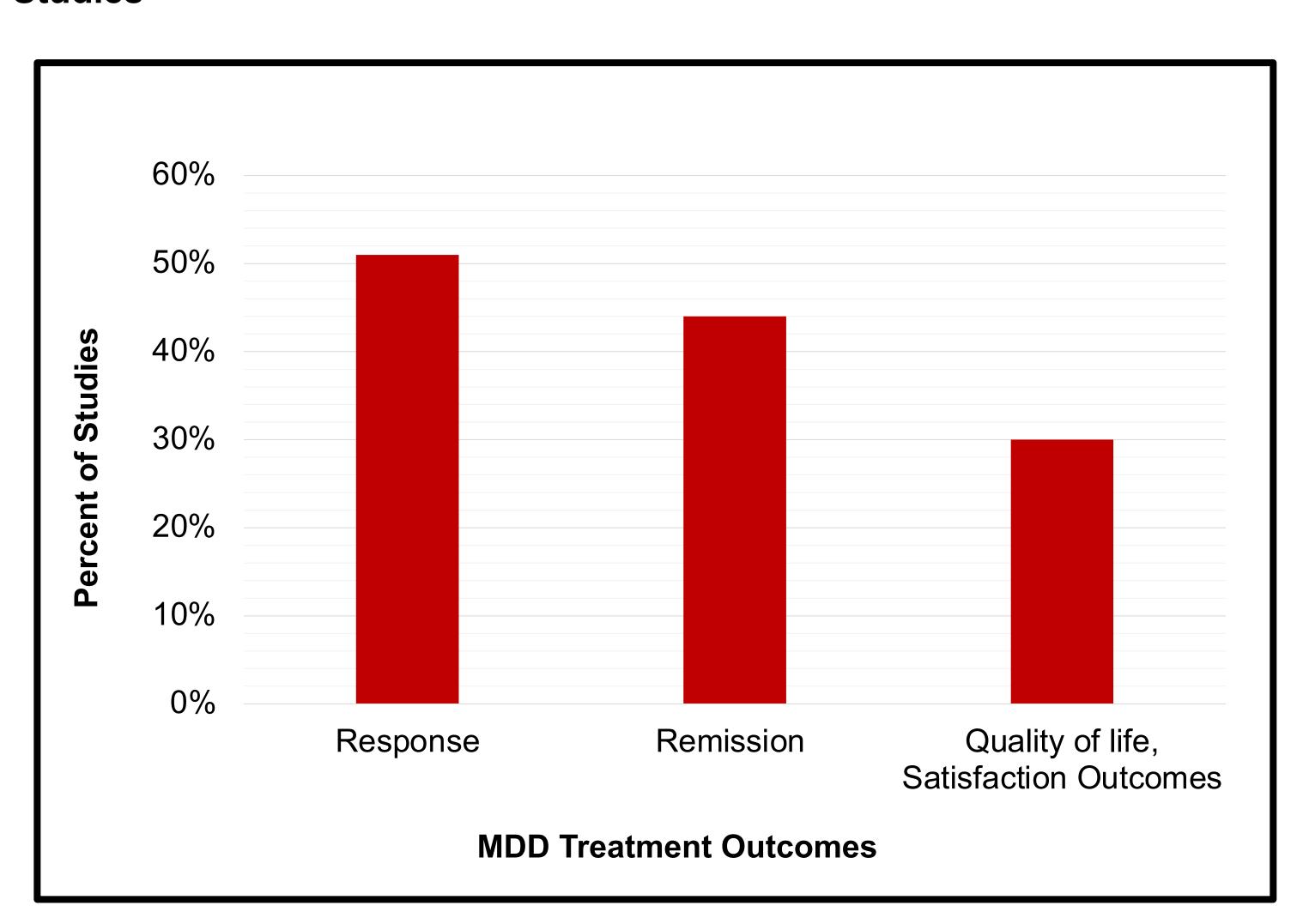
# Figure 1: CONSORT Diagram of Articles included in Scoping Review



Full text articles excluded, with reasons (n=20)

- 5 Pilot study
- 4 Proof of concept study
- 1 Preliminary trial
- 2 Wrong study design
- 6 Did not present minimum data requirements
- 2 Focused on forms of depression other than MDD (i.e., bipolar disorder, childhood trauma)

Figure 2: Primary Outcomes of MDD Treatment Reported in Published Studies



### DISCUSSION

- Empirical research on MDD treatments focuses on response or remission rates, and few address quality of life impacts of treatment.
- Patient-prioritized value elements suggests that functional outcomes, such as ability to work, and the emotional impact, such as personal well-being, are important considerations in treatment decisions.
- This study suggests that patient-informed priorities can complement existing scientific evidence to support a patient-informed value assessment.
- The limited and inconsistently collected information on patient-reported outcomes affecting daily life and social relations is a gap where the PAVE patient-informed value element framework can be used to enhance patient-centered value assessment.
- Future work that engages patients and represents their preferences is needed.

## REFERENCES

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2.dosReis S, Butler B, Caicedo J, et al. Stakeholder-engaged derivation of patient-informed value elements. The Patient - Patient-Centered Outcomes Research. 2020;13(5):611-621. doi:10.1007/s40271-020-00433-8