

Identifying Patient-Driven Value Elements in Major Depressive Disorder

Key Takeaways:

- * Application of the PAVE Patient-Driven Value Element Framework to individuals with major depressive disorder (MDD) is a promising first step of a patient-centric approach to value assessment.
- * Life impact and social impact are elements of importance to individuals living with MDD that often are not incorporated in value assessment.
- * These findings are the first step in this multi-phase study, allowing IVI and PAVE to next quantify the relative importance of the most influential elements identified in this study and, ultimately, explore methods to incorporate the findings into health economic modeling and value assessment.

Research question:

What value elements are most important to people with major depressive disorder (MDD) in evaluating treatment options?

Introduction

As healthcare decisionmakers continue to balance delivery of care against growing cost concerns, the demand for rigorous estimates of the value of both pharmaceutical and non-pharmaceutical health technologies has rapidly increased. Health technology assessments (HTAs) and other value assessment processes serve a growing role in providing needed analyses of the relative value of treatment options.¹ Conventional approaches to value assessment arise from the well-established field of cost-effectiveness

analysis (CEA): health economic models support the comparison of a set of treatments or interventions based on their clinical and economic benefits relative to their net impacts on health system costs.²

Conventional CEA-based value assessment is often conducted from a payer perspective in the United States,³ implicitly intending to maximize clinical and economic benefits while minimizing costs. Value in the healthcare delivery system is complex, however — any decision made at the population level ultimately affects individual patients. There is growing consensus that, even from a payer perspective, such analyses should consider a more comprehensive set of value elements that captures the value of treatments for patients.^{4,5}

To date, broader considerations about patients' perspectives of value have remained largely qualitative and been included as additional contextual information in HTAs. To facilitate rigorous measurement and incorporation of patient-derived value into value assessment, researchers from the Patient-Driven Values in Healthcare Evaluation (PAVE) Center at the University of Maryland developed, in collaboration with patient stakeholders, a framework of condition-agnostic, patient-identified value elements.⁶ These value elements can be tailored to specific conditions in order to facilitate patient-centered value assessment. An initial application of the PAVE value element framework in the context of chronic obstructive pulmonary disease demonstrated its adaptability to condition-specific value assessment.⁷

Building on this work, IVI and PAVE researchers are partnering to apply the PAVE value element framework as part of IVI's next open-source value model in major depressive disorder (MDD).⁸ As the first step in this multi-phase collaboration, a series of interviews with MDD patients was conducted to identify a subset of value elements most important to them.

Study approach

To refine the condition-agnostic set of value elements and identify the most salient elements for MDD patients, interviewers guided 20 respondents individually through a series of structured activities.

Patient respondents were recruited through national patient organizations^b and from referrals by a clinician using an electronic flyer and email invitation. Eligibility requirements were: 1) age 18 or older; 2) diagnosed with MDD; and 3) able to speak and read English. Exclusions were made for those with bipolar disorder or psychotic features, for those living in an institutional setting (e.g., residential treatment facility, group home), and for those with post-partum depression.

The guided activities were conducted over WebEx or Zoom and recorded with respondent consent. Interviews lasted one hour, during which interviewees were asked to evaluate value elements under each of five domains, indicating 1) all value elements they regard as important, and 2) up to five value elements they think are most important. Sociodemographic and disease history information was also collected.

The study design was reviewed and approved by the University of Maryland Institutional Review Board (IRB).

Findings

Twenty people diagnosed with MDD participated in the interviews (see Table 1). Respondents resided in eleven U.S. states, including California, Texas, Illinois, and several southern and northeastern states. The majority of respondents identified as female (n=14); 14 of 20 (70%) identified as White, compared with four and two respondents who identified as African American and Hispanic/Latino, respectively. Age varied from 25 to 65+ years, with 65% (n=13) over age 55.

The aggregate summary of the value elements participants selected as most important within the five domains of treatment effects — short- and long-term treatment effects, treatment access, treatment cost, life impact, and social impact — are presented in Figures 1a-1e. Key novel elements identified as important were provider relationship and trust, emotional status (i.e., well-being), and family relations. Other more traditional elements were symptoms and affordability.

Table 1
Descriptive statistics for interview respondents

Age Group	n	%
25-34	2	10%
35-44	3	15%
45-54	2	10%
55-64	8	40%
65+	5	25%
Sex		
Female	14	70%
Male	6	30%
Race		
African American	4	20%
Caucasian	14	70%
Hispanic/Latino	2	10%
Marital Status		
Married	8	40%
Divorced/Separated	7	35%
Never Married	5	25%
Education		
High School/GED	2	10%
Some College	4	20%
2-Year Degree	1	5%
Bachelor's Degree	7	35%
Graduate Degree	6	30%
Household Income		
Less than \$10,000	3	15%
\$10,000-\$24,999	3	15%
\$25,000-\$49,999	1	5%
\$50,000-\$74,000	5	25%
\$75,000-\$99,999	3	15%
More than \$100,000	5	25%
Employment Status		
Full time	7	35%
Part time	1	5%
Retired	4	20%
Unemployed; not looking for work	2	10%
Disabled	6	30%
Healthcare Insurance Type		
Private Insurance	10	50%
Public Insurance (MA/Medicaid/VA)	4	20%
No Insurance	1	5%
Other Insurance	1	5%
Public Insurance & Private Insurance	4	20%
U.S. Region		
Northeast	6	30%
Midwest	4	20%
South	7	35%
West	2	10%
Mid-Atlantic	1	5%

Implications for Value Assessment in MDD

These results provide important insights for a patient-centric approach to assessing the value of MDD treatment options. Though some results may appear subjectively obvious — that affordability is most important in the treatment cost domain, for example — this exercise's purpose is to provide an objective and comprehensive assessment of the relative importance of various value elements based on direct patient input. Furthermore, applying this method in the context of MDD establishes a set of MDD-specific value elements for use in future research by others in the field.

Establishing this set of MDD-specific value elements is the first phase in our research on integrating patient-driven value elements into value assessments. The results presented here provide a preliminary assessment of the relative importance of a set of elements. In the next phases of the project, we are exploring ways that quantitative estimates can be generated to inform value assessment, such as health economic modeling.

An example of such efforts is determining exactly how patients trade off these elements against one another — both within and across different domains. Using value elements to define attributes of a treatment option, a survey is under development using a discrete choice experiment design that will provide quantitative estimates of how people with MDD make these trade-offs. We hypothesize that the results from this experiment can be used to inform health-state utility inputs for quality-adjusted life-year (QALY) calculation in economic models.

Due to its novelty, applying this approach in value assessment has inherent challenges. Despite their importance, some value elements — Provider Relationship & Trust, for example — are more difficult to conceptualize and measure, making their inclusion in a quantitative study potentially challenging.

In using results such as these to shape understanding of patient-driven value, we must remain aware of and continue to grapple with the implications of excluding important value elements due to measurement difficulties. In addition, particular care must be taken in drawing generalizations about value elements from a limited research sample. Our study employed in-depth interviews with a limited number of respondents, but

further research — administering a survey about value element priorities to a larger sample, for example — would provide valuable insights into our conclusions' generalizability.

Conclusions

This study represents an application of the broader PAVE framework in the specific context of MDD. Translating this research into analyses is still a developing science, however. Developing rigorous approaches to identifying elements that drive value for patients and potential methods for incorporating them into analyses — for example, by using them to adjust health-state utilities for QALY calculation — is an important focus for ongoing research.

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Endnotes

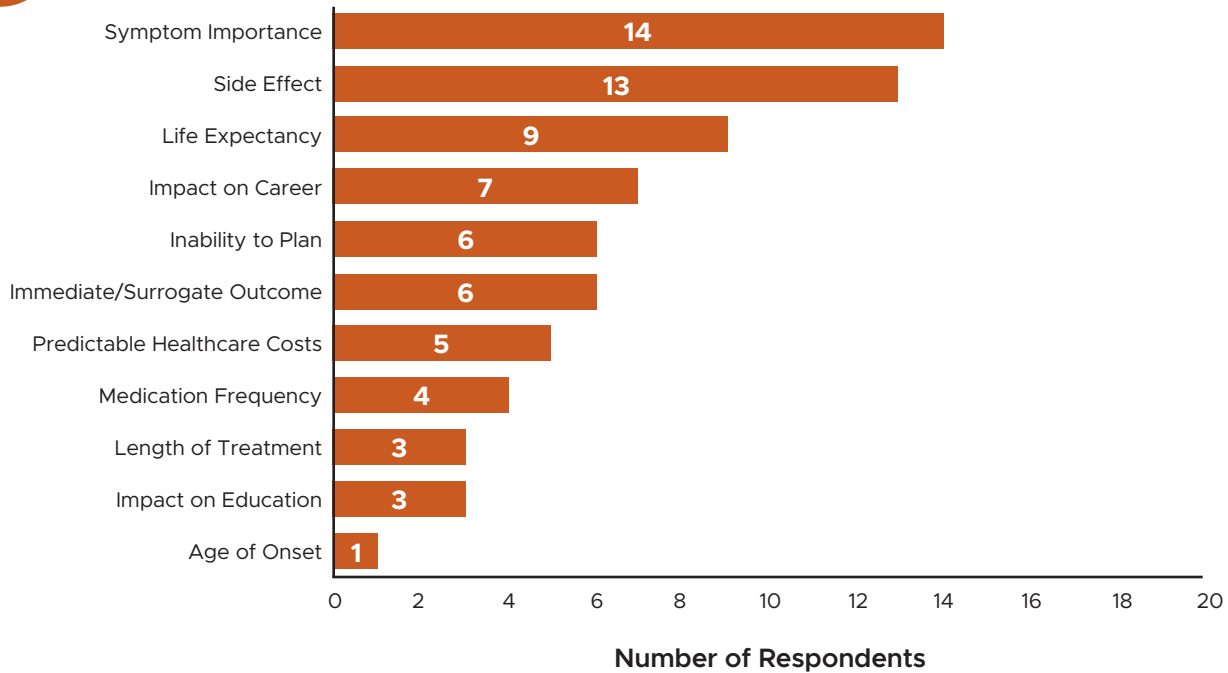
- 7a. The IVI-MDD model is a disease-specific model under development as part of IVI's Open-Source Value Project. For more information, see: <https://www.thevalueinitiative.org/ivi-mdd-value-model/>
- 7b. Advisory Group member organizations from Depression Bipolar Support Alliance (DBSA), Mental Health America, National Alliance on Mental Illness, and a community health center shared information about the project with their networks to recruit potential participants. The majority of participants were identified through DBSA.

FIGURE 1A-E: Most important value elements identified by respondents by domain

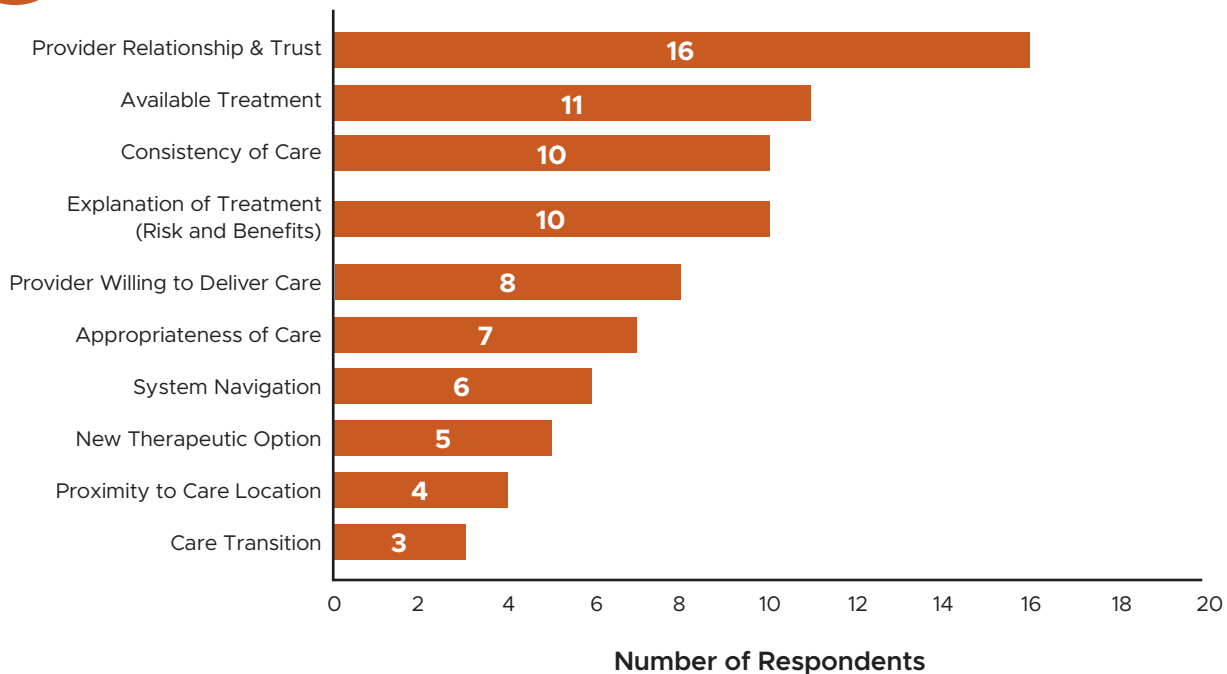
See Appendix for the complete value element descriptions included in the survey.



A. Short- and Long-term Treatment Effects

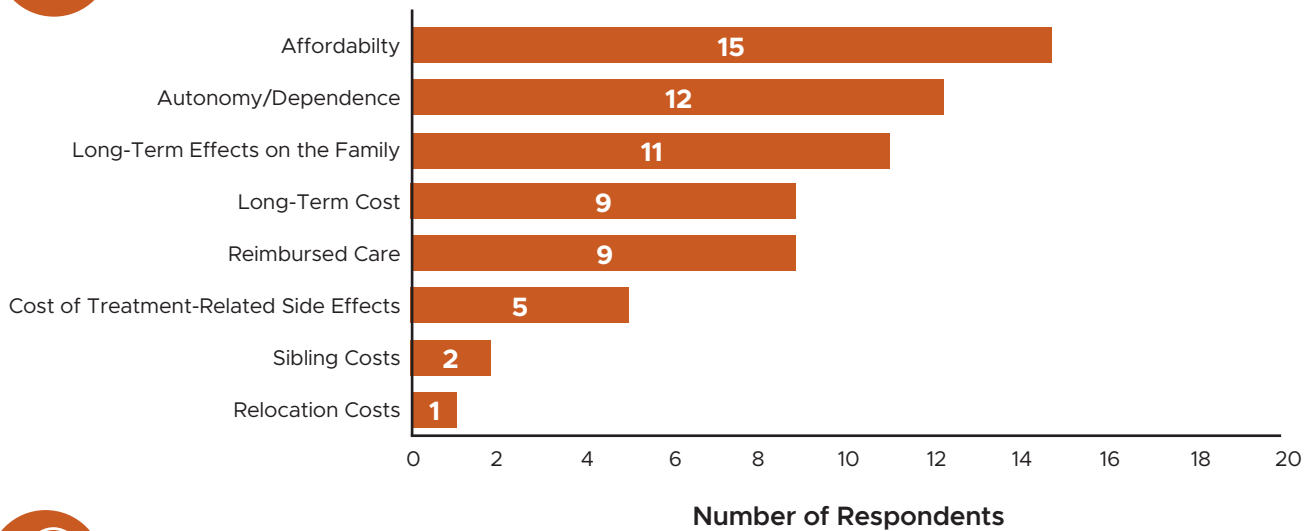


B. Treatment Access

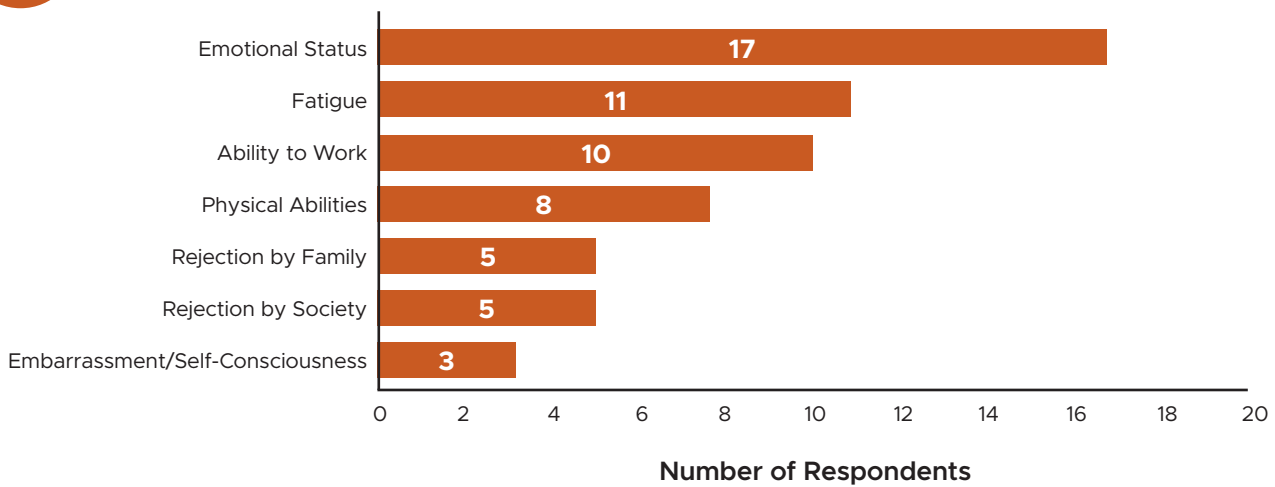




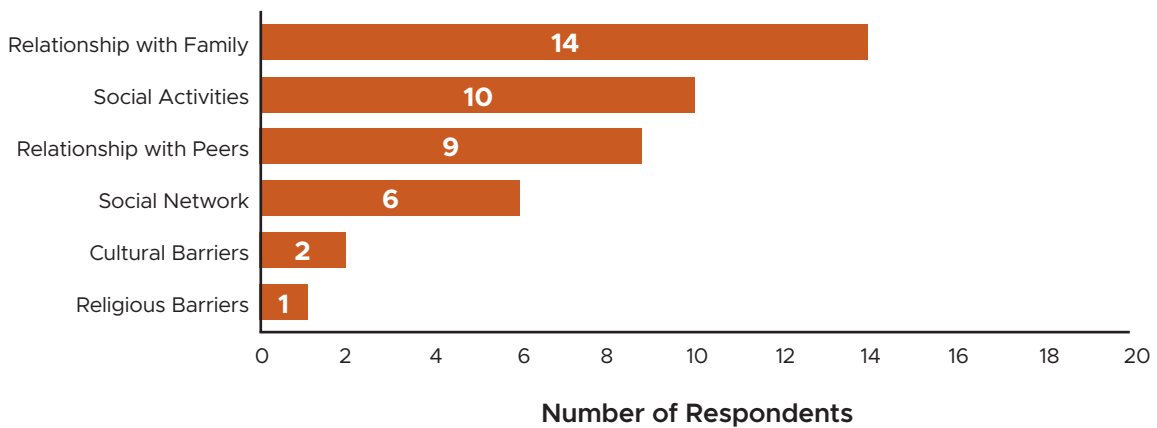
C. Treatment Cost



D. Life Impact



E. Social Impact



About The Innovation and Value Initiative

IVI is a 501(c)(3) nonprofit research organization committed to advancing the science, practice, and use of value assessment in health care to make it more meaningful to those who receive, provide, and pay for care. IVI envisions value assessments founded on the principles of patient-centricity, transparency, and open-source modeling.

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Appendix: Value Element Definitions

Short and Long-term Treatment Effects

Symptom Importance: Preference for some treatments over others, depending on the symptoms that it can alleviate.

Side Effects: The burden that the effects of medication present.

Life Expectancy: The degree to which the symptoms of a particular condition limit one's normal/expected life expectancy.

Medication Impact on Career: The impact of treatment on one's career.

Ability to Plan: The ability to plan for one's future, care needs, treatment, interventions, and/or anything related to therapy.

Intermediate/Surrogate Outcomes: A treatment endpoint that may correlate with a true endpoint but does not always guarantee the true endpoint will be achieved.

Predictable Healthcare Needs: The variability in a condition and ability to predict one's care and treatment needs over the disease trajectory.

Frequency: The number of doses per day; number of times per day one must take a medication.

Length of Treatment: The impact that the duration of treatment/intervention may have on burden in one's daily life.

Impact on Education: For some diseases, the impact of the treatment on one's education/schooling.

Age of Onset: The impact that the age of onset of a health condition plays into the personal benefit/risk assessment in therapeutic decision making.

Treatment Access

Provider Relationship & Trust: The trust one has in the system of care and the health care providers that help one make treatment decisions and/or access care.

Available Treatment: The treatments, interventions, or therapy that are available based on the disease and/or the location of the patient.

Consistency of Care: Consistency with respect to the receipt of treatment.

Explanation of Treatment (Risks & Benefits): The ability of the health care provider to explain to the patient the expectations during the treatment.

Provider Willing to Deliver Care: Having a provider in one's insurance network that is able to deliver or offer the treatment needed.

Appropriateness of Care: The treatment chosen is the right intervention or therapy given the individual's needs and preferences.

System Navigation: A group/person or tools that can help individuals navigate the healthcare system of care more easily.

New Therapeutic Option: New drug option that represents an innovative or breakthrough therapy.

Proximity to Care Location: Treatment that is or is not accessible in or near one's geographic locale.

Care Transitions: A change to a new or different healthcare facility that impacts access to a treatment.

Treatment Cost

Affordability: A treatment, intervention, or anything related to therapy that is/is not within one's ability to pay for.

Autonomy/Dependence: The ability to not be dependent upon others to complete daily life activities.

Long-Term Effects on the Family: The impact of a treatment, intervention, or anything related to therapy that can affect the family as a unit, financially or otherwise, over a 10-year time span and more.

Long-Term Costs: The ongoing costs of treatment and anything related to therapy (i.e., caregiving, etc.) that contributes to financial burden.

Reimbursed Care: The amount of treatment or therapy costs that is covered by insurance or a third-party payer.

Cost of Treatment-Related Side Effects: The cost to an individual and/or society to treat the side effects that arise from the treatment.

Sibling Costs: The burden of disease through the lens of siblings, i.e., sacrifices made, and opportunities lost to siblings of an individual with a disease that may be pediatric- or adult-onset.

Relocation Costs: Costs to a family member or the individual undergoing treatment that is related to relocation in order to be closer to family so that caregiving, transport to appointments, clinical care, and care delivery is possible and/or feasible.

Life Impact

Emotional Status: The effect of the treatment, intervention, or anything related to therapy that impacts one's emotions, like depression or anxiety.

Fatigue: The impact of a treatment, intervention, or anything related to therapy on one's physical and/or mental strength.

Ability to Work: The treatment, intervention, or anything related to therapy that allows or impedes one's ability to work.

Physical Abilities: The ability to take part in physical activities, ability to exercise, early morning activity limitation.

Rejection by Family: The fear of explaining a treatment, intervention, or anything related to therapy to family due to concern about rejection.

Rejection by Society: The fear of explaining a treatment, intervention, or anything related to therapy to people in society due to concern about rejection.

Embarrassment/Self-Consciousness: The treatment, intervention, or anything related to therapy that presents a negative impact on one's self.

Social Impact

Relationship with Family: The extent to which the treatment, intervention, or anything related to therapy impedes one's ability to maintain family relationships.

Relationship with Peers: The extent to which the treatment, intervention, or anything related to therapy impedes one's ability to maintain his/her social relationships.

Support Network: Family, friends and/or a peer group, or community that lends support and encouragement during treatment.

Maintain Social Activities: The ability to continue activities in one's social role during the treatment of a disease.

Cultural Barriers: A treatment, intervention, or anything related to receiving the therapy that presents a conflict with one's cultural practices or beliefs.

Religious Beliefs: A treatment, intervention, or anything related to receiving the therapy that presents a conflict with one's religion.