IVI INNOVATION AND VALUE INITIATIVE

Open-Source Value Project (OSVP) Major Depressive Disorder Value Assessment Model Advisory Group

Meeting #2

August 27, 2020

3:30 pm – 5:00 pm EST

Patient-Driven Priorities for the Management of Major Depressive Disorder

Susan dosReis, PhD & Julia Slejko, PhD
Co-Directors, PAVE Center
University of Maryland School of Pharmacy

PAVE

PATIENT-DRIVEN
VALUES *in* HEALTHCARE
EVALUATION

Acknowledgements

This project is funded by the IVI Foundation, Inc., a 501c3 nonprofit research organization.

The PAVE Center is funded by the PhRMA Foundation through a Center of Excellence in Value Assessment Initiative.

Objectives

- To clarify priorities for the target population
- To obtain feedback on the set of PAVE value elements that will inform the conceptual framework
- To garner feedback on strategies and considerations when identifying and recruiting participants

Target Population

- Select the target population with consideration of the application of the final product, i.e., open source model
  - Capture the range of heterogeneity among individuals living with major depressive disorder (MDD)
  - Avoid selection bias that will limit inferences
  - Maintain a cohesive and concise focus on the end goal

Target Population

- Advisory Group feedback from prior meeting
  - Individuals who were diagnosed but never treated
  - Individuals who received treatment and had a positive response
  - Individuals who did not respond to first-line treatment (treatment-resistant; difficult-to-treat)
  - Individuals from a range of racial/ethnic and SES subgroups

Target Population

- *Question: Do we want to capture a range of subgroups within MDD?*
- Possible considerations based on AG feedback:
  - Never treated with medication/psychosocial/brain simulation interventions
  - Responder to first-line treatment
  - Responder to second-line treatment
  - Non-responder to 2 or more therapeutic interventions

Patient Preference Framework Development

- **Goal**: To identify the PAVE patient-informed value elements that can be incorporated into the value assessment of treatment options for individuals with MDD

- **Phase 1 Task**: Engage the Advisory Group and patient participants in an iterative manner to derive, using qualitative research methods, the candidate value elements most relevant to the target population.

Proposed Timeline

Deliverable by Study Phase	Anticipated Completion Date
Phase 1: Identify and Refine Proposed PAVE Value Elements	
Conceptual Framework of patient-informed attributes and attribute levels	November 30, 2020
Phase 2: Elicit Preferences for MDD Treatment & Analyze Data	
Design of the Discrete Choice Experiment for Patient-informed MDD Treatment Preferences	December 30, 2020
Pre-test the Discrete Choice Experiment with 20 Individuals	January 30, 2021
Begin Administration of the Survey/Discrete Choice Experiment to 300 Individuals	February 10, 2021
Summary of the Discrete Choice Experiment preference data analysis findings	July 15, 2021
Phase 3: Identify Patient-Informed Value Elements for an Economic Model of MDD	
Summary of MDD economic models	November 30, 2020
Translation of patient informed MDD value elements for an economic model	July 15, 2021

PAVE Value Elements

The Patient - Patient-Centered Outcomes Research
https://doi.org/10.1007/s40271-020-00433-8

ORIGINAL RESEARCH ARTICLE

Stakeholder-Engaged Derivation of Patient-Informed Value Elements

Susan dosReis[1] · Beverly Butler[2] · Juan Caicedo[3] · Annie Kennedy[4] · Yoon Duk Hong[1] · Chengchen Zhang[1] · Julia F. Slejko[1]

© The Author(s) 2020

Abstract

Objectives Our objective was to identify patient-informed value elements that can be used to make value assessment more patient centered.

Methods Mixed methods were used iteratively to collect and integrate qualitative and quantitative data in a four-stage process: identification (stage 1), prioritization (stage 2), refinement (stage 3), and synthesis (stage 4). Qualitative methods involved one-on-one discussions with 14 patient stakeholders from diverse medical communities representing mental health, osteoporosis, blindness, lupus, eczema, oncology, chronic obstructive pulmonary disease, and hypercholesterolemia. Stakeholders completed guided activities to prioritize elements important to patient healthcare decision making. Responses were summarized descriptively as frequencies and proportions.

Results Stakeholders identified 94 value elements in stage 1. Of these, 42 elements remained following the stage 2 prioritization and the stage 3 refinement. During the stage 4 synthesis, the 42 patient-informed value elements comprised the principal set of value elements that were organized by 11 categories: tolerability, disease burden, forecasting, accessibility of care/treatment, healthcare service delivery, cost incurred on the patient, cost incurred on the family, personal well-being, stigma, social well-being, and personal values. The categories fell under five domains: short- and long-term effects of treatment, treatment access, cost, life impact, and social impact.

Conclusions In total, 75% of the value elements in the conceptual model were patient derived and distinct from the elements used in existing value frameworks. Recommendations for tailoring, quantifying, and applying the patient-informed value elements in distinct patient communities are provided. This provides a foundation from which future research may test patient-informed value elements in existing value frameworks and economic evaluations.

- The PAVE Value Elements were developed with patient input and are condition-agnostic.

https://rdcu.be/b5Gwg

Key Points for Decision Makers

Value assessment framework recommendations call for improving value measures to better align with what is important to patients.

This paper presents patient-informed value elements that were developed with continuous patient engagement throughout the process.

The work will advance the field of value assessment because it provides a set of novel and measurable patient-informed value elements that can be incorporated into existing value frameworks and economic evaluations to improve the health technology assessment, data-generation, and decision-making processes.

Process to Select Value Elements

PATIENT-INFORMED VALUE ELEMENTS

Short & Long-term Treatment Effects	Treatment Access	Treatment Costs	Life Impact	Social Impact
Tolerability Medication Frequency Length of Treatment Side effects **Disease Burden** Age of Onset Symptom Importance Intermediate/Surrogate Outcomes **Forecasting** Impact on Education Impact on Career Predictable Healthcare Needs Inability to Plan Life Expectancy	**Accessibility of Care/Treatment** New Therapeutic Option Available Treatment Provider Willing to Deliver Care Proximity to Care Location Appropriateness of Care System Navigation **Healthcare Service Delivery** Provider Relationship & Trust Care Transitions Consistency of Care Explanation of Treatment (Risks & Benefits)	**Cost Incurred by the Patient** Affordability Cost of Treatment-Related Side Effects Long-term Costs Reimbursed Care **Cost Incurred by the Family** Sibling Costs Long-term Effects on the Family Relocation Costs Autonomy/Dependence	**Personal Well-Being** Fatigue Ability to Work Physical Abilities Emotional Status **Stigma** Embarrassment/Self-Consciousness Rejection by Family Rejection by Society	**Social Well-Being** Support Network Relationship with Family Relationship with Peers Maintain Social Activities **Personal Values** Cultural Barriers Religious Beliefs

10-15 VALUE ELEMENTS FROM THE TOP 5 ITEMS IN EACH DOMAIN ELICITED FROM 20 PATIENT PARTICIPANTS

2-3 Commonly Selected Short & Long-term Treatment Effects	2-3 Commonly Selected Treatment Access	2-3 Commonly Selected Treatment Costs	2-3 Commonly Selected Life Impact	2-3 Commonly Selected Social Impact

6-8 VALUE ELEMENTS SELECTED BY SAG

6-8 Value Elements for Patient Preference Instrument

REFINE LANGUAGE WITH PATIENT PARTICIPANTS

Framework for Patient Preference Instrument

Patient Preference Framework Example

Attribute	Description of Attribute	Level
Side Effects	You manage side effects by	Making no changes to your medicines
		Lowering the medicine dose
		Adding another medicine
Reimbursed Care	You pay out-of-pocket	$30 per month
		$90 per month
		$120 per month
Proximity to Care	Your doctor replies within	24 hours
		48 hours
		72 hours
New Therapeutic Option	The medicine is taken	1 time per day
		2 times per day
		3 times per day
Explanation of Benefits and Risks	You learn about treatment options	From your provider or pharmacist
		From a patient support group
		From the media
Physical Abilities	Your CAT symptom score improves by	2 points
		4 points
		6 points

Patient Preference Framework Development

- *Question: Are there concepts missing from the core set of PAVE Value Elements that are pertinent to MDD?*
- *Question: Are there aspects of the data collection documents that could be refined or information added that is not currently captured?*

Participant Recruitment

- *Question: What approaches are possible for identifying and recruiting our target population?*
  - *(For patient stakeholders) do you collect information from your members using clinical instruments (e.g., PHQ-9)? If so, what instruments do you use, and how often?*
- *Question: How can we best target racial/ethnic groups?*
- *Question: What do you anticipate as barriers and how can we potentially avoid this?*