

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

Kick-off Meeting

July 30, 2020

11:00 am – 12:00 pm EDT

Welcome and Introductions

Agenda

Meeting Objective: To introduce the Advisory Group to the IVI Open-Source Value Project (OSVP) value assessment model development process and secure feedback on model objectives and initial scoping for major depressive disorder.

Time	Topic	Presenter	Organization
11:00 AM – 11:10 AM	Welcome and Introductions	Jennifer Bright (IVI)	IVI
11:10 AM – 11:20 AM	Review of Preliminary Model Objectives	Richard Xie (IVI)	IVI
11:20 AM – 11:45 AM	Dialogue: Initial Scoping of Major Depressive Disorder	Richard Xie (IVI)	IVI
11:45 AM – 11:55 AM	Introductions to Patient Preference Project (PAVE)	Susan dosReis and Julia Slejko	PAVE
11:55 AM – 12:00 PM	Closing and Target Topics for Upcoming Meetings	Jennifer Bright (IVI)	IVI

Background for OSVP-MDD

- > Novel treatment options (both pharmacological and non-pharmacological) for MDD have emerged in recent years.
- > Given the significant health and economic burden of MDD, it is important to assess the relative value of different treatment strategies to different stakeholders.
- > In our prior OSVP efforts, IVI identified the lack of dialogue and communication among different stakeholders as a key barrier that limited the wider application of value assessment models.
- > To address this challenge, IVI is forming a multi-stakeholder advisory panel and will, from the outset, continuously engage advisors throughout the modeling process
 - A deliberate effort to bring patients and users onboard from the very beginning
 - All sectors of healthcare system will be represented (i.e., *patients, employers, providers, payors and life science companies*)

Source: Ceskova E, Silhan P. Novel treatment options in depression and psychosis. *Neuropsychiatry Dis Treat*. 2018;14:741-747. Published 2018 Mar 13. doi:10.2147/NDT.S157475

OSVP-MDD Advisory Group

The OSVP-MDD Advisory Group

- > The multi-stakeholder Advisory Group will provide expert input and perspective throughout the life of the major depressive disorder value assessment model. Specifically, the Advisory Group will:
 - Review project goals, consider other expert contributors and affirm or share research insight.
 - Give insight to refine the scope of an OSVP model on MDD.
 - Offer feedback on project outlines, preliminary findings and final reports or products.
 - Nominate technical and lived experience experts to participate in patient preference research, panels for review of model protocols.
 - Offer feedback on public comment and dissemination initiatives.

Cadence of Advisory Group Meetings

- > The group will meet approximately 8-12 times over the course of the project.
- > IVI will provide a brief pre-read either as a slide deck or 2- to 3-page document ahead of each meeting.
- > We will aim to keep our discussion as targeted and clear as possible (no whiteboarding!).
- > Our “door” is always open! Please feel free to send ideas, suggestions, and feedback at any point in the process.

Overview of the OSVP-MDD Project

Objectives

The OSVP-MDD project aims to address the following questions:

- > For patients living with MDD, what are the key factors that define the value of a healthcare intervention?
- > What is the relative importance (i.e. priority, tradeoff) of these value factors to their choice of intervention option(s)?
- > What are the decision needs of employers, payers and benefit designers that an assessment of the value of different interventions can support?
- > What methods are optimal to developing value assessment models that better reflect patient-defined preferences (e.g., augmenting health utilities, multi-criteria decision analysis)
- > What real-world data can be incorporated into value assessment models to give insight to factors relevant to patients? To employers? To payers?

Methodology – Initial Thoughts

- > For the OSVP-MDD model, IVI envisions the following two approaches in conducting value assessments for MDD
 - Traditional economic modeling techniques, particularly cost-effectiveness analyses (CEA), will compare the incremental costs and benefits of the new treatments to the “standard of care”
 - Multi-criteria decision analysis (MCDA), which will allow decision-makers to make a choice of alternatives based on a broader set of goals and evaluation criteria
- > Consistent with prior efforts, the OSVP-MDD development will attempt to incorporate and apply novel methods and value elements.

OSVP-MDD Model Development Process

- > IVI envisions the OSVP-MDD endeavor to be a four-phase process

Phase	Task	Time Frame (tentative)
Phase 1	Project initiation, model scoping and feasibility assessment	Q3 to Q4 (2020)
Phase 2	Protocol development, key model input collection	Q1 to Q2 (2021)
Phase 3	Model creation	Q2 to Q3 (2021)
Phase 4	Technical panel review, use case development	Q3 to Q4 (2021)

- > IVI issued an RFP to select research partners and seeks competitive bids. We have received 7 bids and are in the review process.

Key Modeling Consideration

During the first phase of the OSVP-MDD project, IVI will work with the Advisory Group to finalize the scope of the model. In this process, the following key elements will be considered:

- > **Perspective:** Employer, managed care organization/payor, society
- > **Treatment and Comparator:** An antidepressant treatment, a combination of antidepressant and psychotherapy
- > **Time Horizon:** Lifetime, 6 months
- > **Cycle Length:** 3 months, continuous time
- > **Model Structure:** Decision tree, cohort-based Markov models
- > **Data Sources:** Clinical trials, real-world data and evidence, literature, assumptions

Source: Sanders GD, Maciejewski ML, Basu A. Overview of Cost-effectiveness Analysis. *JAMA*. 2019;321(14):1400–1401. doi:10.1001/jama.2019.1265

Ramsey SD, Wilke RJ, Briggs AH, et al. Good research practices for cost-effectiveness analysis alongside clinical trials: the ISPOR RCT-CEA Task Force Report. *Value Health*. 2005; 8(5):521-533.

Discussion Questions for the Kick-off Meeting

- > What are some key decision questions your organization want to address through conducting value assessments of MDD treatments?
 - > What are the key decision factors/criteria/metrics you consider in this process (e.g., costs, outcomes)?
 - > What are the questions you hope the OSVP-MDD can answer for you?
- > What patient population should the value assessment models focus on?
 - > The general MDD population
 - > A subgroup such as the treatment-resistant/difficult-to-treat patients?

Discussion Questions for the Kick-off Meeting

- > Are there any treatments (both pharmacologic and non-pharmacologic) of special interest to you?
- > What are some data sources you would suggest us to reference in building this model?
- > How long do you think the model should simulate? A lifetime, 5 years? And why?
- > Do you think one type of modeling structure is more suitable than another?

Patient-Driven Priorities for the Management of Treatment-Resistant Depression

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



PATIENT-DRIVEN
VALUES *in* HEALTHCARE
EVALUATION

Patient-driven Values in Healthcare Evaluation (PAVE) Center of Excellence in Value Assessment

University of Maryland School of Pharmacy

- *Wendy Camelo Castillo*
- *Susan dosReis*
- *Joey Mattingly*
- *Daniel Mullins*
- *Julia Slejko*

National Health Council

- *Marc Boutin*
- *Eleanor Perfetto*
- *Elisabeth Oehrlein*

In Partnership With
Patient Community Leaders, Payer & Industry
Stakeholders

Funded by
Pharmaceutical Research and Manufacturers of
America (PhRMA) Foundation

PATIENT-DRIVEN VALUE ASSESSMENT

PAVE's fundamental premise is that value in health care must be defined by patients and value assessment must reflect heterogeneity across patients. Our multi-stakeholder collaborations aid us in generating value tools that create opportunities to support patient-centered health care decision-making and support other stakeholders in their engagement of patients.

TRADITIONAL PATH

The traditional path is informed by randomized trial and research data without patient input.

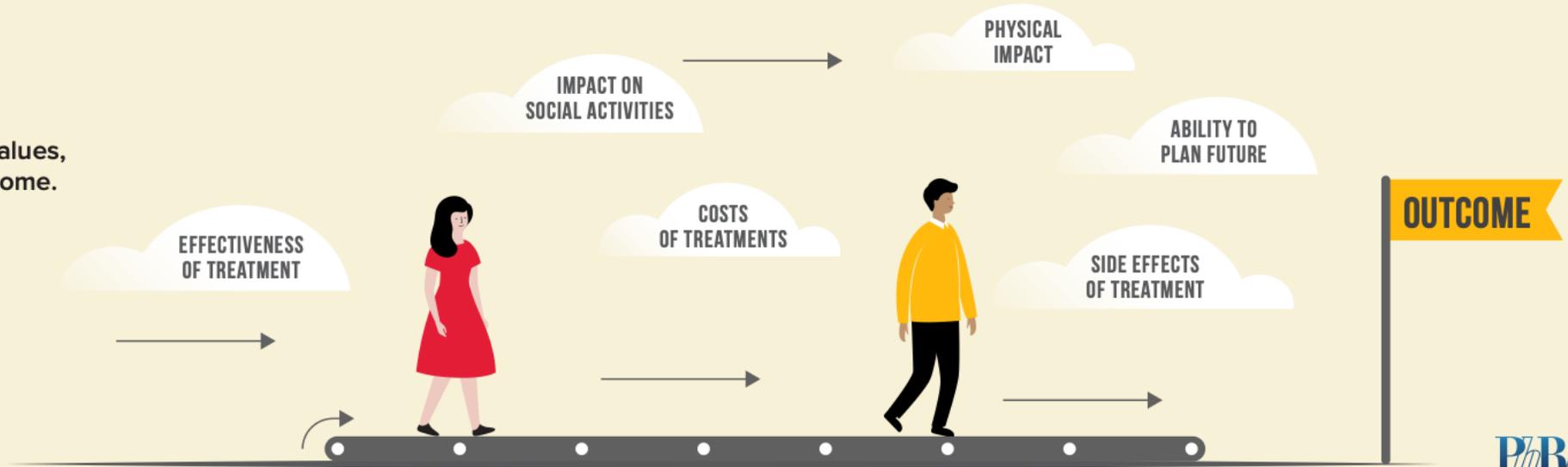


OUTCOME

A PATIENT'S JOURNEY TOWARDS BETTER OUTCOME

✓ PAVE PATH

The PAVE path is informed by patient values, guiding the patient towards better outcome.





Stakeholder-Engaged Derivation of Patient-Informed Value Elements

Susan dosReis¹ · Beverly Butler² · Juan Caicedo³ · Annie Kennedy⁴ · Yoon Duk Hong¹ · Chengchen Zhang¹ · Julia F. Slejko¹

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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 Center developed with patient input a set of condition-agnostic value elements that are important to patients.

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.

<https://rdcu.be/b5Gwg>

- The Major Depressive Disorder (MDD) project builds off this work by
 - Eliciting the importance of the value elements for individuals with treatment-resistant depression (TRD)
 - Assessing the preference utility for these elements
- **Goal:** To identify the PAVE patient-informed value elements that can be incorporated into the value assessment of treatment options for individuals with TRD.

- Aim 1: To identify through a stakeholder-engaged process the PAVE patient-informed value elements that are important to individuals living with TRD.
- Aim 2: To elicit preference utilities for the identified value elements most important in managing TRD.
- Aim 3: To identify the patient-informed treatment attributes that can be incorporated in an economic model for TRD.



- Engage a stakeholder advisory group (SAG) and patient participants in an iterative manner to achieve the study aims.
- Derive, using qualitative research methods, the candidate PAVE value elements most relevant to individuals with TRD.
- Conduct a scoping literature review to place the identified candidate value elements in context with real-world parameters of expected treatment effects and outcomes.

- Commitment
 - 3 meetings for ~60-90 minutes each throughout Phase 1.
- Contribution
 - Provide oversight and direct input on the value elements most important to patients when weighing the benefits, risks, and desired outcomes of treatment options.
 - Provide input that will inform the design and content of the data collection tools to elicit patient priorities for treatment.
 - Advise on the interpretation of the findings.
 - Advise and assist with participant recruitment.

- Develop the survey
- Pre-Test Survey with 20 participants
- Administer Online Survey with 300 participants
- Analyze the survey data
- Review findings with the SAG

- Conduct a scoping review to identify model-based economic evaluations for TRD.
- From published studies:
 - Major cost and outcome model inputs, health utility instruments used.
 - What perspective is used for evaluations, are patient elements considered (e.g. time costs)?
 - Do previous models include novel value elements?
- Determine which patient-informed value elements can be included in an economic evaluation of TRD treatment.

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 for TRD treatment	November 30, 2020
Phase 2: Elicit Preferences for TRD Treatment & Analyze Data	
Design of the Discrete Choice Experiment for Patient-informed TRD Treatment Preferences	December 30, 2020
Pre-test the DCE with 20 Individuals	January 30, 2021
Begin Administration of the Survey/DCE to 300 Individuals	February 10, 2021
Summary of the DCE preference data analysis findings	July 15, 2021
Phase 3: Identify Patient-Informed Value Elements for an Economic Model of TRD	
Summary of TRD economic models	November 30, 2020
Translation of patient informed TRD value elements for an economic model	July 15, 2021

What's Next?

Next Steps for the Advisory Group and for the MDD Model

- > IVI will share minutes from the Advisory Group Meeting in the next two weeks.
- > IVI will publicly announce the launch of the MDD Model, including a separate page on the IVI Website. We will include a list of Advisory Group Members on the Website unless you request us to not include your name or organization (see the registration form).
- > IVI will send all Advisory Group Members a COI form and will send honoraria in the 4th quarter of this year.
- > The next meeting will be held in August 2020 and a final meeting time will be confirmed in the next week.

IVI



**INNOVATION AND
VALUE INITIATIVE**

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Appendix

IVI Purpose: Improving Value Assessment

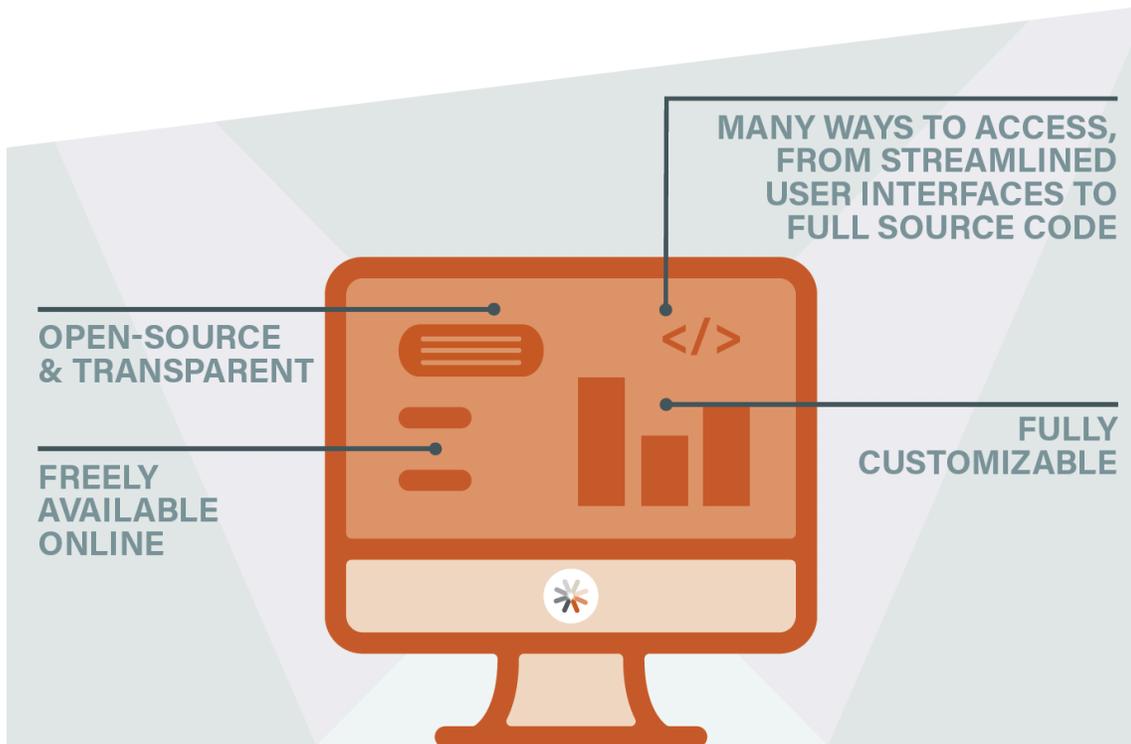
- > Advancing novel methods for research in the field that are **scientifically rigorous** and **credible**
- > Commitment to **transparency** and open-source models
- > Inclusion of **patient factors of value** at the core of value assessment
- > **Engaging all stakeholders** to collaborate
- > Designing solutions for differing **decision contexts**

OUR PRINCIPLES DRIVE ADVANCEMENTS IN VALUE ASSESSMENT



IVI Purpose: Improving Value Assessment

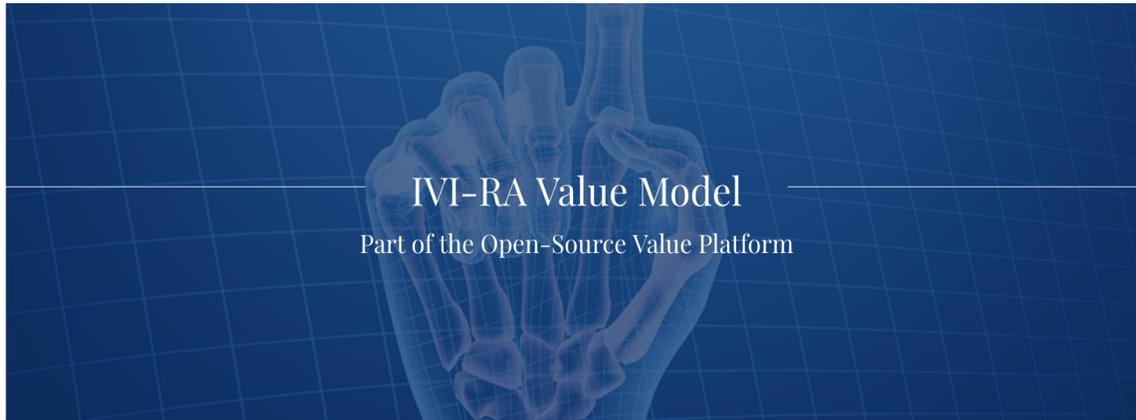
OUR MODELS ARE FLEXIBLE & ACCESSIBLE



- > Building a democratic, open, collaborative platform for:
 - Methods research
 - Exploring patient perspectives on value
 - Disease-focused model development
 - Facilitating localized decision making (for payers, clinicians, patients, and employers)
- > Advancing methods and resources to accelerate value assessment

IVI's Disease-Specific Models

IVI develops models for specific diseases as a laboratory for developing next-generation methods for value assessment



Simulates the lifetime costs and benefits of different strategies for treating patients with moderate to severe rheumatoid arthritis



Examines outcomes and relative value of sequential drug therapies for patients with metastatic EGFR+ non-small cell lung cancer (NSCLC)

Modeling Structure / Techniques

- > According to a recent systematic literature review (Kolovos 2017), the most used modeling structure/techniques in the model-based economic evaluations for MDD included:
 - Decision tree (51%)
 - Cohort-based state-transition Markov model (37%)
 - Individual-based state-transition Markov model (5%)
 - Discrete event simulation (7%)

Source: Kolovos S, Bosmans JE, Riper H, Chevreur K, Coupé VMH, van Tulder MW. Model-Based Economic Evaluation of Treatments for Depression: A Systematic Literature Review. *Pharmacoecon Open*. 2017;1(3):149-165. doi:10.1007/s41669-017-0014-7