

# **IVI Model Scope Major Depressive Disorder**

**May 3, 2021**

**1:00-2:00 PM EDT**

# Speakers



**Jessica Kennedy**

*Chief of Staff*  
Mental Health America



**Mohannad "Ned" Kusti, MD, MPH**

*Corporate Medical Director*  
Pivot Onsite Innovations



**Richard Xie, PhD**

*HEOR Research Manager*  
Innovation and Value Initiative



**Rick Chapman, PhD (Moderator)**

*Chief Science Officer*  
Innovation and Value Initiative

# Objectives of the MDD Model

To build a **flexible**, **open-source**, and **patient-centric** model that will:



Advance the science and practice of health technology assessment (HTA) in the U.S. context



Facilitate multi-stakeholder conversations



Ultimately inform the decision needs of multiple stakeholders in the health care system including employers, payers, and clinicians

# A Path Forward: Improving Value Assessment for Major Depressive Disorder (MDD)



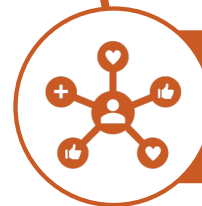
## IVI Open-Source Value Model

- > **IVI prototype model development is a laboratory:** opportunity to improve both the process and mechanics of considering value
- > **Focus on MDD based on:**
  - > Prevalence
  - > Societal burden
  - > Impact on overall health
  - > Evolving treatment landscape (both pharmacologic and non-pharmacologic)
  - > Broad interest from multiple stakeholder groups

## Model Development is a Team Effort



20+ member advisory group contributes to the model design



Insight on patient preference research (input) and decision contexts (outputs)



Allies for public comment periods and use cases (applied research questions)



**Importance of Patient Advocacy in Value Assessment**

**May 2021**

Jessica Kennedy  
Chief of Staff  
Mental Health America

**MHIA**  
Mental Health America

**B4Stage4**



# Apartment hunting: a common consumer value assessment

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- What do I care about?
  - Cost
  - Size
  - Location
  - Needs (dishwasher)
  - Wants (awesome pool)
- How do I make a decision?
  - Shop online
  - Tour the facility
  - Consider past apartments
  - Read reviews



# **What if... we treated apartment hunting like we treated finding MDD treatment?**

- I visit my rentiatrist
- I tell them I'm looking for an apartment
- They say "A lot of people are looking for apartments... we have something that can help"
- They review my housing plan
- They recommend a basic apartment
- I don't know all the research about apartments, but they're a rentiatrist so I trust them
- I move in
- Maybe I like it
- If I don't, I have to go back to the rentiatrist and start the process over again
- I'm not sure how involved I can be

# **Why patient advocacy organizations need to engage on value assessment**

- Value is incredibly complex
- Value does not mean cost
- It's challenging for a layperson to analyze research and assessments
- We don't know what we don't know
- Organizations can represent millions of patients at once
- We can amplify voices of people that aren't always heard

## Why I'm involved in the MDD Advisory Group

“Oh, you feel terrible right now? Here's something that may or may not make you feel better in six to eight weeks. Maybe. I don't know.”

-A colleague at MHA



**Some  
important  
patient  
concerns  
we don't  
always  
consider**

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How fast will this make me feel better?

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Will I still feel like myself?

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Will this help me get out of bed and go hang out with my friends? I'm just so tired, and it's so much energy.

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Will this help me clean my house, which I haven't cleaned in months?

# Contact Us



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# Employer Perspective

*Mohannad Kusti, MD*

*Corporate Medical Director*

## Pivot Onsite Innovations



# Why Do Employers Need to Engage in HTA?



Majority of the people get insurance through their employers



Large employers are typically self-funded or self-insured and are considered the true payer



Employers have a major role in health plan and benefit design including medical, pharmacy plans, and wellness programs



This model would not be complete if it did not engage the employers perspective

# How Does This Topic Impact Employers & Employees?

- > MDD has a significant impact on **productivity**:
  - > Employers are impacted by Absenteeism, Presenteeism, Disability Time, Return to and days away from work.
  - > This could also impact talent retention and acquisition and affect job losses.
  - > Healthcare costs also impact the employer's business bottom line.
  - > Many employers are trying to reach population subgroups and minorities as part of their corporate strategy. There is also that stigma towards workers associated with MDD.
- > MDD has a significant impact on **safety**:
  - > Employees who work in safety sensitive jobs may be impacted by their fitness for duty.

# Model Scope

*Richard Xie, PhD*

*HEOR Research Manager*

*The Innovation and Value Initiative*



## Key Guiding Questions

Some of the specific questions we seek to explore through the modeling include:

- > *For people living with MDD, what key factors define the value of an intervention? What is the relative importance of these value factors?*
- > *What are promising methods to develop value assessment models that reflect patient-defined preferences (e.g., patient preference-based health utilities, multi-criteria decision analysis)?*
- > *How can the model support the decision needs of clinicians, care providers, payers, and employers in comparing the value of various interventions?*

# Health Economic Model Design Snapshot

Dimension	Specification
Target Population	Treatment-naïve adults (18-64 years), diagnosed with MDD by a healthcare provider
Setting and Location	All settings of care (primary, specialty, and telehealth) in the United States
Study Perspective	Societal as base case, flexibility to customize based on specific stakeholder (e.g., employers)
Model Structure	Individual-level simulation
Comparators	Flexibility to model both treatment sequences and treatments, both pharmaceutical and non-pharmaceutical
Time Horizon	Lifetime horizon, flexibility for users to study interim time points (e.g., 1 year)
Outputs	Flexibility to present a range of different economic and clinical outputs
Key Considerations	Including productivity, adherence, delay in starting active treatments for MDD

# Laboratory for Novel Methods

## Health Economic Modeling

Cost-effectiveness analysis (CEA) will compare the incremental cost and benefits of the new treatments to the “standard of care”

## Novel Elements of Value

Inclusion of patient preferences and priorities

Inclusion of productivity

## Real-World Data

Exploration of uses of real-world data sources

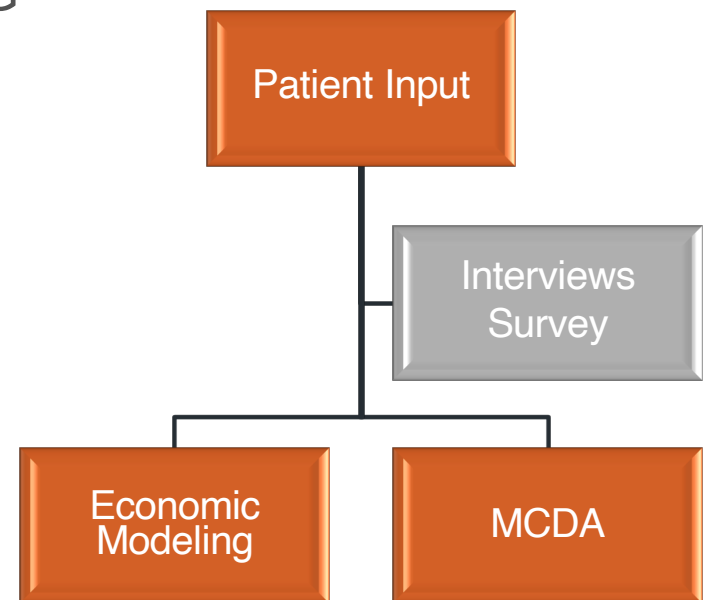
## Multi-Criteria Decision Analysis

MCDA will allow decision-makers to compare value based on their own choices of attributes and preferences

<https://www.thevalueinitiative.org/ivi-mdd-value-model/>

# Incorporating Patient Input

- > Engagement with patient stakeholders in the AG
- > Study in partnership with PAVE researchers
  - > Interviews with people with MDD (N=20)
- > Exploring novel ways to systemically integrate patient input into HTA
  - > Inform utility inputs
  - > Define clinical and economic outcomes
  - > Criteria and weights in MCDA



# Addressing Employer Decision Needs

- > Engagement with employer stakeholders in the AG
- > Consider the impact of adherence on clinical and economic outcomes
- > Enable subgroup analyses
- > Capture the nuances of productivity impacts

Productivity

Absenteeism

Presenteeism

Short- and Long-  
term Disability

Workers'  
Compensation

Fitness for Duty



# Q&A



# Potential Users and Applications

- > All stakeholders affected by MDD or the conduct of HTA are potential users and participants in the modeling process

**Patients**

Comprehensive assessment of impacts on patients

**Clinicians**

Design of treatment pathways

**Employers**

Impact on productivity

**Payers**

Coverage and reimbursement decisions

**Innovators**

Demonstration of social value of novel therapies

**Researchers**

Testing of cutting-edge methods

# MDD Project Timeline



## Model Scope

**Public Comment Period**  
**April 12 – May 14, 2021**

The model scope document describes the model objectives, key assumptions, and early specifications. This document will also describe the specific considerations that will be evaluated and confirmed during the protocol development stage.

## Model Protocol

**Mid-2021**

The model protocol is a technical document that outlines all necessary details for model structure and analyses, including the analytic approaches, assumptions, data inputs, and model output.

## Model Public Release

**Early 2022**

The major depressive disorder (MDD) value assessment model will allow users to use the model's pre-specified inputs or their own data sources to compare treatments for MDD. All model code is open-source, and we invite users to provide feedback and recommendations for improvement.

## Use Case Development and Model Updates

**Ongoing**

IVI and interested stakeholders will use the MDD model to conduct additional research projects. IVI will update the model as new data sources become available.

# Our Ask of You



**Review and Submit  
Comments  
By May 14, 2021**



**Share with Your Colleagues**



**Share the Recorded Webinar  
with your colleagues**

[Available Here](#)

*The Innovation and Value Initiative (IVI) is holding a public comment period on its draft economic model scope on major depressive disorder (MDD) and is seeking feedback from a broad range of stakeholders from April 12-May 14, 2021. This open-source model seeks to incorporate real-world data and multiple perspectives within the model. You can learn more [here](#).*

There are two ways to comment:

Submit via email to [public.comment@thevalueinitiative.org](mailto:public.comment@thevalueinitiative.org)

Respond to survey: <https://www.surveymonkey.com/r/IVIPublicComment>



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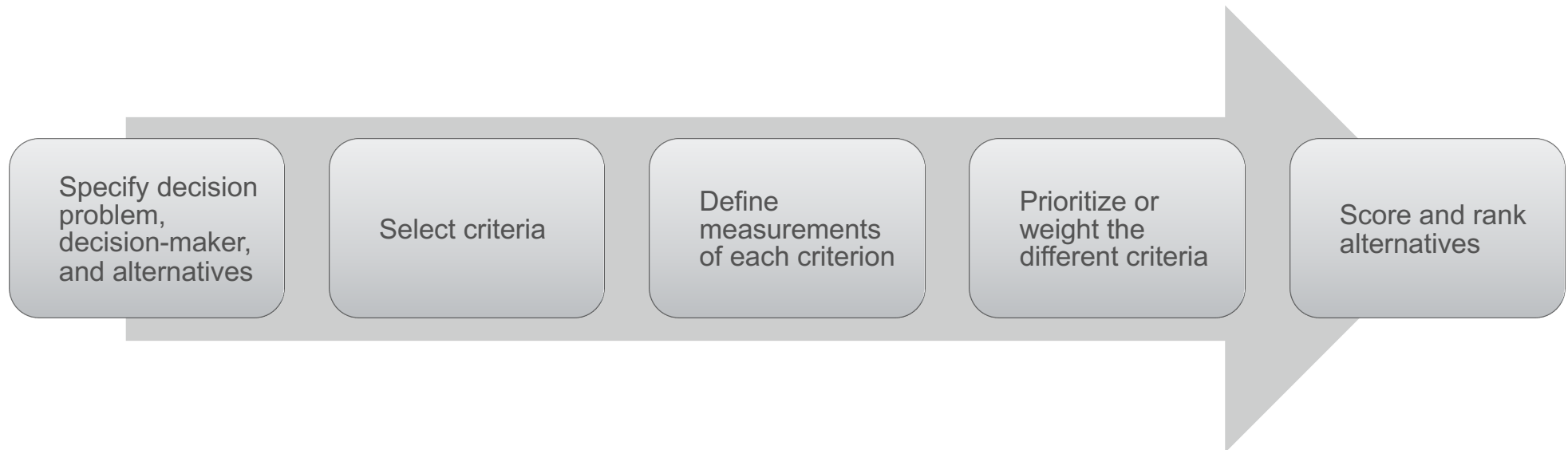


# Appendix



# MCDA Module Development Plan – CAN DELETE

- > Explore and test methods for MCDA
  - > Convening expert working group to guide development of the module
  - > Engaging with decision makers in the development process



# We Want to Hear from You

What elements of the model design are most important to include?

Are there limitations of existing health economic models that the MDD model should aim to address?

What are potential ways that different stakeholder groups could use this model?

What are potential research initiatives or data sources that we should consider?