



INNOVATION AND VALUE INITIATIVE

MDD Advisory Group Meeting Meeting Summary

June 3, 2021

Attendees:

Kendra Martellow, Neurocrine
Debra Lerner, Tufts University
Nathaniel Counts, Mental Health America
Susan dosReis, PAVE
Julia Slejko, PAVE
Karen Moseley, HERO
Paul Fronstin, Employee Benefit Research
Institute
Mohannad Kusti, Optimal Workplace and
Environmental Wellness Corporation
Julia Slejko, PAVE

Becky Yowell, APA
Iman Nourhussein, Pharmerit
Cheryl Neslusan, Janssen Scientific Affairs
Rahul Dhanda, Neurocrine Biosciences, Inc.
Kevin Ronneberg, Health Partners
Patrick Gillard, AbbVie
Rick Chapman, IVI
Jennifer Bright, IVI
Erica deFur Malik, IVI
Richard Xie, IVI

The Major Depressive Disorder Advisory Group met June 3, 2021. The purpose of the meeting was to review the public comments on the draft scoping document for the major depressive disorder value assessment model. IVI was seeking feedback from the Advisory Group on the comments and recommendations received.

Public Comment Summary

IVI received 19 responses to its request for public comments on its model scope, with comments from individuals and organizations representing industry, individuals and organizations representing people living with MDD, payers, and clinicians.

Overall, comments were supportive of IVI's approach and offered constructive recommendations and feedback to incorporate into the model protocol stage. Since the model scope offered a fair amount of detail, many of the comments will be addressed during the protocol stage, but they provided excellent considerations on how to incorporate the multiple nuances of developing an economic evaluation for MDD. In general, the comments highlighted the importance of addressing the following issues:

- > Patient-centeredness
- > Patient heterogeneity
- > Health inequities

Many comments also applauded IVI's effort to engage in multi-stakeholder engagement to provide a more holistic understanding of value assessment.

IVI clarified that while the "treatment naïve" will be the primary focus, the model will allow for review of an individual's entire treatment trajectory from first treatment through later lines of treatment.

Examples of specific recommendations relevant to the model scope were:

- Include individuals 65 and older in the first version of the model
- Include "peer support services" as a treatment option
- Include sleep quality within the symptom factors
- Include options for multiple types of payers (public and private)

Discussion following the summary of Public Comments

- While IVI has identified different subgroups for the model (older adults, those with partial or no response to treatment, people with suicide attempts), one AG member asked how IVI will navigate the unique treatment pathways for people with MDD. Rather than subgroups, there are multiple unique populations under the MDD umbrella.
- IVI also asked for recommendations for studies or guidance on how to measure peer support services, since it is a newer, and less standardized form of treatment. Several studies were provided in the chat (see below).
- Another AG member asked about how IVI intended to include social determinants of health within the model. IVI has been exploring how to implement this within the model (further discussion below).
- Finally, a member asked about the inclusion of digital condition management tools within the model. While IVI would like to include digital therapies or some of these other tools, there is some question about availability of evidence and how to better conceptualize this within the model.

Public Comment Recommendations: Specific Feedback Areas

Most of the recommendations and suggestions from the comments will be addressed during the protocol development stage or IVI is planning to address in the second edition of the model. There were a few areas where IVI will seek clarification from the organizations or individuals offering comment. IVI identified three primary areas where we would like insight from the Advisory Group.

Prioritization of Subpopulations

In the first version of the MDD model, we are aiming to build capabilities to conduct analyses for the following subgroups: (1) those that have tried a certain number (e.g., 2) of treatments but did not achieve response/remission, and (2) subgroups defined by age, gender, and sociodemographic characteristics (e.g., race/ethnicity, income, education). Below are other subgroups that we plan to explore in future versions of the model:

- > those with a psychiatric comorbidity (e.g., anxiety disorders)
- > those with a non-psychiatric comorbidity (e.g., diabetes)
- > those with suicide attempts
- > those who were previously hospitalized

Discussion

- > *Any important subgroups missing here?*

> *Any subgroups that should be prioritized in the first version of the model?*

Feedback

- Some members asked IVI to explore the concept that the treatment failure population may be a distinct group from the monotherapy MDD patient population. There's going to be complexity there because if they are unique patient populations, it will be very hard to model them longitudinally against one another. In addition, you cannot determine who is going to respond to what treatment, so you can only determine these populations retrospectively.
 - IVI will explore how to triage this within the model.
 - IVI will look for research on predictive risk factors for treatment failure.
- Another member recommended including people who go on disability as an important subgroup for employers.
- Given COVID, IVI may want to consider including people with comorbid anxiety disorders in the first version of the model.
- One thing IVI may want to think about is the inclusion/exclusion criteria of the studies that we would be getting the efficacy data from. If a therapeutic that's focusing on MDD treatment has exclusion criteria for, say, schizophrenia, the data may not be relevant for them. For other comorbidities such as diabetes, given our population, they are likely to be included anyway, so it may be that you do not have to exclude them in the first round.
 - For example, excess weight gain is a side effect of some medications. IVI may want to include some of those features. The model may not answer what's the best treatment for people with diabetes and depression, but you can still include that subpopulation of data.
- Echoing some of the comments, AG members recommended differentiating between episodic treatment pathways and more chronic MDD treatment.

Addressing Health Disparities within the Model

In addition to the subpopulations outlined in the model scope, IVI is seeking novel strategies to address health disparities within the structure of the model. What other suggestions do you have for IVI to consider?

- Insurance coverage (private, public, no coverage)
- Availability of providers within network
- Social network supports (supported employment, training, housing, cash assistance)

Novel Value Elements

Below are three additional novel elements of value IVI plans to evaluate during the protocol development stage:

- Caregiver/Family impacts/burden
 - Financial
 - Health/Quality of Life-related
- Availability of effective MDD treatments now and/or in the future
- Educational/Career disruption

IVI requested feedback on prioritization of these elements and other considerations:

- IVI sees “career disruption” or the “opportunity cost” of lost career opportunities as important concepts but are seeking feedback on how to measure this effectively. By career disruption, IVI does not mean productivity or absenteeism, but the impact of missing promotions, early “retirement,” switching to lower stress jobs, etc.

- For treatment of schizophrenia, there is a “Work Readiness” Questionnaire. Is there something similar for MDD?
- One AG member suggested looking at Bureau of Labor Statistics data to look at disability claims.
- IVI sees caregiver burden both as financial and as less quantifiable such as emotional or social impacts. What are other ways to quantify this issue? There may be studies on family spillover as a result of serious illness.

MCDA Module

IVI is convening a small working group separate from this Advisory Group to develop a MCDA module. This group will work with IVI to ensure that the right decision questions are built into the model from the outset. If you would like to be part of that effort, please contact Rick Chapman at rick.chapman@thevalueinitiative.org.

Research Questions from the Model

We are currently finalizing our research questions to drive the protocol development of the model. Below are some questions that different stakeholders might want to explore using the model:

- What is the societal burden of untreated or under-treated* MDD?
- What is the total productivity gain from improved* treatments/sequences of treatments for MDD?
- What is the impact of lack of access to psychotherapy on patients’ long-term economic and clinical outcomes?
- What are the impacts on caregivers and family members of caring for people with MDD?
- How do key model outcomes vary for certain subgroups (e.g., those with prior treatment experience) compared with the overall population?

IVI asked if members had additional suggestions or questions that we should prioritize:

- Final recommendation: One thing that might be interesting to look at is what's low value care. We usually do cost effectiveness by comparing drug A to drug B. We talked about treatment strategies. It's a tough call to say we're going to pick out the optimal treatment strategy by patient type, but it might be really useful and incremental. What maybe more doable is if we try to identify things that aren't working. And it could be things like lack of continuation with psychotherapy or to try to pick up inefficient ways that our system is not leading to great outcomes for this patient population.

IVI closed the meeting with a brief timeline of next steps and a request to members to respond to the follow-up survey with any additional recommendations.

Record of the Chat:

Erica Malik: As always, thank you so much for joining us today. Please feel free to add comments and questions within the chat.

Jennifer Bright: A question I have is whether there are defined peer support intervention “characteristics” and also a body of research/evidence that demonstrates impact. Any thoughts from our advisors?

Kevin Ronneberg: Curious if there is a need to consider digital condition management tools that are increasingly being adopted by employer groups for their health plan members.

Rahul Dhanda: Is treatment resistance or inadequate response a health state in the model?

Nathaniel Counts: I just hunted around for a second, and I wouldn't live and die by this study, but here's an example: <https://link.springer.com/article/10.1186/s12888-020-02923-3>

Erica Malik: Kevin, I will raise with the larger group. In a short answer, we are going to attempt to include digital therapies but are adequate research.

Nathaniel Counts: The heterogeneity you raised Jennifer makes it so it's hard to demonstrate effectiveness in meta-analyses for peer support.

Erica Malik: Rahul - We are planning to include people whose medicines have failed by a given number of times.

Erica Malik: Rahul - we are also trying to include partial response as well.

Debra Lerner: A suggestion is to change occupational therapy to work interventions.

Nathaniel Counts: Good one on digital interventions:
<https://pure.roehampton.ac.uk/portal/en/publications/digital-interventions-for-anxiety-and-depression-a-systematic-rev>

Nathaniel Counts: In Psychological Medicine

Erica Malik: Thanks Debra - definitions are key.

Debra Lerner: There are systematic reviews of digital interventions that address definitions, though don't necessarily resolve the variations. It is important to differentiate interventions for diagnosed MDD vs wellness, prevention, etc.

Rahul Rhanda: There often is glass ceiling on patients with depression. Evaluating productivity doesn't get at this issue. wondering whether measuring readiness to work would address productivity inclusive of potential objections to giving depressed patients with more responsibility? these data would not be captured in databases but likely if a prospective study is being considered, a CLINRO could be included which evaluates work readiness

Nathaniel Counts: This article just came out on race and depression that's an interesting overview:
https://www.sciencedirect.com/science/article/abs/pii/S0277953621004172?dgcid=raven_sd_aip_email

Karen Moseley: Access to internet for telehealth

Jennifer Bright: We might look at some of the Path Forward sites (employers and providers and patients working together) to see what interventions they might be implementing

Nathaniel Counts: https://www.nber.org/system/files/working_papers/w27157/w27157.pdf

Nathaniel Counts: <https://www.sciencedirect.com/science/article/abs/pii/S0277953621000496>

Nathaniel Counts: Article just came out on family spillover from caregiving for illness:
https://www.sciencedirect.com/science/article/pii/S0277953621003282?dgcid=raven_sd_via_email

Rahul Dhanda: The Cardia study looks at the loss of income due to depressive symptoms. Basically, the created a threshold below which represented a loss of income. Establish a link between threshold and time, to possibly understand implications of MDD on underemployment, etc. Just an additional thought.

Erica Malik: Please email Richard or Rick if you would like to be more involved in the MCDA module - Richard.xie@thevalueinitiative.org or rick.chapman@thevalueinitiative.org

Jennifer Bright: I agree. Incremental and still meaningful. Great suggestion Cheryl.