Innovation and Value Initiative Foundation (IVI)
MDD Model Advisory Group Meeting
Minutes
Thursday, July 30, 2020
11:00AM EDT

ATTENDEES

Todd Bledsoe (Neurocrine Biosciences)
Laura Bozzi (PAVE)
Jennifer Bright (IVI)
Rahul Dhanda, PhD (Neurocrine Biosciences)
Susan dosReis, PhD (UMD/PAVE)
Phyllis Foxworth (DBSA)
Paul Fronstin, PhD (Employee Benefits Research Institute)
Patrick Gillard, PharmD (AbbVie)
Michael Grabner (Healthcore)
Raquel Halfond, PhD (American Psychological Association)
Kristin Kroeger (American Psychiatric Association)
Ned Kusti, MD, MPH (National Alliance of Healthcare Purchaser Coalitions)
Debra Lerner, MSc, PhD (Tufts Medical Center)
Erica Malik (IVI)
Kendra Martello (Neurocrine Biosciences)
Karen Moseley (Health Enhancement Research Organization)
Cheryl Neslusan, PhD (Janssen Scientific Affairs)
Theresa Nguyen (Mental Health America)
Gray Norquist, MD, MSPH (Emory University School of Medicine)
Kevin Ronneberg Health Partners
Bruce Sherman, MD (National Alliance of Healthcare Purchaser Coalitions)
Julia Slejko, PhD (UMD/PAVE)
Andrew Smith (DBSA)
Andrew Sperling (NAMI)
Gretchen Wartman (National Minority Quality Forum)
Richard Xie, PhD (IVI)
Becky Yowell (American Psychiatric Association)

APPENDICES

- Appendix A: Transcript of the Video Chat discussion
- Appendix B: Follow-up Written comments

CALL TO ORDER

A meeting of the IVI MDD model Advisory Group was held via teleconference on Thursday, July 30, 2020. Ms. Jennifer Bright calls the meeting to order at 11:00 AM EDT. The purpose of the meeting was to introduce the members of the Advisory Group and gain a better understanding of the background and plan for the development of the MDD model.

WELCOME AND ORGANIZATIONAL UPDATES

Ms. Bright welcomed everyone to the meeting and asked for each member of IVI and the Advisory Group to introduce themselves.

RESEARCH UPDATES

Ms. Bright shared background information on the IVI Open-Source Value Project (OSVP) and discussed how previous OSVP models lacked dialogue and communications among different stakeholder groups, which limited wider applications of IVI's value assessment models. To address this concern, IVI has formed a multi-stakeholder advisory panel and will, from the outset, continuously engage advisors throughout the OSVP-MDD modeling process.

Dr. Richard Xie shared the objectives, proposed methodology, and 4-phase development process for the OSVP-MDD model. The anticipated project completion date is Q4 of 2021. Richard also discussed the key elements that will be considered during the modeling process: perspective, treatment and comparator, time horizon, cycle length, model structure, and data source.

Dr. Susan dosReis introduced the Patient-Driven Values in Healthcare Evaluation (PAVE), a program funded by PhRMA. PAVE's partners include the individuals from the University of Maryland School of Pharmacy and the National Health Council Dr. dosReis discussed how IVI's MDD model build's off of PAVE's work by eliciting the importance of the value elements for individuals with treatment-resistant depression (TRD). The goal of the collaboration is to identify the PAVE patient-informed value elements that can be incorporated into the value assessment of treatment options for individuals with TRD.

DISCUSSION

Dr. Xie opened up the floor for discussion of the development of the MDD model asking the Advisory Group for input on **current gaps in value assessment**, and key points in the discussion included:

- Oftentimes value assessment methods look at Treatment A versus Treatment B, and that is not truly reflective of reality because there is a lot of heterogeneity in treatment patterns and choices. There becomes a need to have a more holistic modeling exercise to look at the whole pathway of MDD treatment.

- Issues with productivity are often not considered in value assessments.
- It would be important and helpful to look at what is best for sub-groups over time, as well as what is best treatment over the course of a lifetime.
- The socio-economic status of the individual impacts access to treatment and types of treatment.
- The type of job is not addressed (e.g., safety concerns).
- The model should focus on or highlight the difference in social determinants of health and access to treatments, especially newer treatments.
- It is important to identify and measure what is important to the patient.
- Healthcare contracts with employers are often for only a short time, which incentivizes a focus on only short-term costs. It would be helpful to consider both short- and long-term measurements of value.
- Cost is often a concern and the model should aim to help determine optimal paths of treatment.
- Another gap is how to evaluate optimal medication selection.
- Another consideration is using a two-step process. The first step would be using a mixture of different models to obtain data, and the second step would be utilizing that data in our models.
- The scoping process for the MDD model should also consider the settings of care (e.g., telehealth services) and the ongoing stigma of mental illness.
- There has been an increasing emphasis on digital therapeutics, and while they make sense, it is difficult to calculate value. The difficulty in sizing the value of digital solutions or compare it to treatment of traditional means should also be considered when developing the model.
- Comorbidity should be addressed.
- The conceptual framework is essential. Taking time to develop this framework is key to developing a successful and useful model.

Participants were also asked to consider the following question: **What patient population should the model focus on?**

- Treatment resistant population are the "most expensive" group in this disease area, and have higher rates of distress and lower functioning.
- However, if we only do treatment resistant depression, we do not actually capture those who have not accessed treatment or those who have positive experiences. It is estimated that at least 30 percent of people with depression do not access treatment.
- If the model starts with a broader depression definition, it needs to ensure that its metrics are sensitive to subgroups.
- Depression also addresses a broader population and may have more impact for more people.

FORTHCOMING BUSINESS

The next meeting will be held at the end of August 2020. The confirmed date and time will be determined in the next week.

ACTION ITEMS

IVI will share the minutes from the Advisory Group meeting in the next two weeks. IVI will publicly announce the launch of the MDD model, including new content on the IVI website. All Advisory Group members and organizations will be listed on the website unless requested not to (included in the previously provided Registration Form). IVI will send honoraria to the Advisory Group members in Q4 of 2020.

ADJOURNMENT

Ms. Bright adjourned the meeting at 12:05 PM EDT.

Appendix A: Transcript of Webinar Chat (Time shown in EDT)

From Jennifer Bright : If you have any questions please feel free to pitch them to me or Erica Malik during this call and we will happily answer live or follow up to clarify. Thank you for being with us!

11:26:35 From Phyllis Foxworth : It's important that we identify and measure what's important to patients. This is a gap

11:27:44 From Phyllis Foxworth : I agree. Modeling needs more real-world data to measure those who are actually in treatment

11:30:45 From Bruce Sherman : Challenges to selecting the right medication for each patient and comparative effectiveness in doing so - and the cost-effectiveness of approaches to ensuring optimal medication selection.

11:31:50 From Theresa Nguyen : what is the cost related to delayed support because of lack of screening and initiation of care in primary care?

11:33:11 From Kendra Martello : Is there a place in this discussion for settings of care where treatment is delivered? As we see the increase in the use of telehealth for primary care and mental health services, do we need to accommodate that setting of care and not just traditional in-office care?

11:35:04 From Karen Moseley : From the perspective of the employer, will there be an opportunity to connect the dots between the value assessments and the value proposition? Also, additional support in a workplace setting include overcoming the stigma barrier through effective communication, training managers at all levels to recognize symptoms.

11:36:11 From Cheryl Neslusan : MDD may also have an impact on the outcomes of other diseases

11:36:59 From Theresa Nguyen : because we are also exploring new medications that offer supports in a shorter period of time than traditional antidepressants it seems important to start exploring the cost of stopping treatment or changing medications due to the 4-6 week efficacy timeline of older antidepressants or 3 fail first requirements?

11:38:54 From Theresa Nguyen : also cost should consider medication treatment exploration and linkage to other treatment options

11:38:54 From Erica Malik : What patient population should the value assessment models focus on? 1. The General Population or 2. Segment

11:39:09 From Theresa Nguyen : both

11:39:11 From Theresa Nguyen : ?

11:41:35 From Theresa Nguyen : if you can't do both, I would say focus on TRD because it's a population that has higher rates of distress and poorer functioning. but general MDD will have larger pop impact. Have fewer groups focused on TRD? maybe you choose which one based on where gaps exist in value models.

11:43:09 From Theresa Nguyen : any model should take a race equity lens into consideration

11:43:59 From Theresa Nguyen : value should also explore savings to public payers because of saved costs due to employment and moving out of disability

11:47:13 From Theresa Nguyen : evaluate cost savings of effective treatment that can prevent poor outcomes (extended inpatient stays, loss of employment/disability leave, or suicide).

Appendix B: Follow-up Written Comments

IVI requested and received several written comments as follow-up from the July 30, 2020 meeting. Transcripts of the written comments are below.

Name of Contributor	Comments
Michael Grabner Healthcore	Additional scientific comments: • I suggest we tackle the TRD population as a subgroup of the main analysis, somewhat similar to how the model could explore patient heterogeneity along lines of gender, SES, or plan line of business (e.g. commercial vs. Medicaid). Having said that, the TRD population will likely need more work than just subsetting the analysis since they have other treatment options (ECT, TMS, esketamine)… • From a user/payer perspective, the ability to populate parameters of the model with RWE generated from populations of interest (e.g. in my case, Anthem members with MDD) would be very useful (e.g. prevalence of comorbidities, direct medical costs, productivity costs). • There is evidence that MDD (specifically TRD) does affect physical conditions; a recent paper quantifies that effect • A wish list item would be to look into the value that telemedicine and apps for MDD bring to the arsenal of treatment options • It would also be of interest to compare "antidepressant + psychotherapy" vs. "antidepressant + antipsychotic (indicated adjunctive therapy)" treatment paths
Cheryl Neslusan, PhD Janssen Scientific Affairs	• Multiple participants highlighted that the model and our approach must not only include perspectives of patients but must also be flexible to capture the nuances of patient differences (e.g., including race, socioeconomic, gender, age, treatment duration). These considerations should apply to treatment responses, access to treatment, and prevalence. There is heterogeneity in the symptoms of depression among patients that needs to be considered. Ideally would like to identify optimal Tx paradigms for different subgroups overtime. • Several participants suggested that the model should be able to account for the impact of treatments over time (short term vs long term and sequence of treatment). Owing to the probability of relapse, need to consider Tx strategies for those that enter this state as well. • Selection and access to the "optimal" treatment, especially for pharmacological agents, remains an ongoing challenge. The model also needs to capture the impact of delayed access to treatment or screenings.

	• Ability to measure productivity and impact on employment-based healthcare vs public health systems. Productivity in non-employment activities also; explore capabilities concept as an outcome (I'm thinking this is what the next bullet point is related to??) Discussion at the meeting on scoping out the conceptual model/refining the scope of the problem we are intending to address will be helpful as value function for an institutional payer is likely to be different than the value function for a patient or employer. • MDD often leads to nontraditional responses other than traditional access to care (e.g., coping mechanisms that might not be measured as treatment) • How does MDD impact the trajectory of other diseases and vice versa? Should medical cost offset be considered in this model? Lifetime models often consider the costs associated with survival, but most often ignore the beneficial impacts of improving conditions like depression that can change the health trajectory of related conditions. **What patient population should the model focus on?** • Treatment resistant population are the "most expensive" group in this disease area, and have higher rates of distress and lower functioning Note Tx resistant may not have become Tx resistant if Tx was optimized initially. Also, definition of Tx resistance is variable. Whatever the definition, it's a small slice of the total MDD population. For policy relevance, important to consider the broader MDD population. • However, if we only do treatment resistant depression, we do not actually capture those who have not accessed treatment or those who have positive experiences. • General depression also addresses a broader population and may have more impact for more people. (would refrain from labeling the broader MDD population as "General" as it may confuse… there are other types of depression that are not MDD. One could incorrectly think that we'd be exploring these subtypes as well)