



INNOVATION AND
VALUE INITIATIVE

MDD Advisory Group Meeting
August 3, 2022
1:00-2:15 pm
Meeting Summary

Attendees

Nathaniel Counts, Mental Health America
Rahul Dhanda, Ph.D., Neurocrine
Biosciences, Inc.
Paul Fronstin
Michael Grabner, Ph.D., HealthCore
Karen Moseley, Health Enhancement
Research Organization (HERO)
Cheryl Neslusan, Ph.D. , Janssen
Scientific Affairs,
Kevin Ronneberg, MD, HealthPartners
Gretchen Wartman, NMQF

IVI Staff and Partners

Rick Chapman, IVI
Jennifer Bright, IVI
Richard Xie, IVI
Erica deFur Malik, IVI
Jason Spangler, IVI
Tiffany Huth, IVI
Jessica Brown, IVI
Michelle Cheng, IVI
Michael Mersky, OPEN Health
Julia Slejko, PAVE
Susan Dos Reiss, PAVE

Agenda

Updates on Model Development and Current Work

Discuss Component Research Studies – Early Findings

- MDD Treatment Patterns Retrospective Claims Study (Healthcore)
- Patient-Driven Priorities for Management of MDD (PAVE)

The Major Depressive Disorder (MDD) Advisory Group met on August 3, 2022. The purpose of the meeting was to update the MDD model progress and share the initial results of MDD component research projects. IVI and its research partners were seeking feedback from the Advisory Group (AG) on the treatment sequence simplification, and the incorporation of component research studies to the MDD model.

Updates on Model Development and Current Work

Moving on to phase 3 of the MDD project, IVI is working with our research partner, OPEN Health on the use case development and user interface prototype design in parallel with the finalized model protocol, which will look for the advisory group's review and ensure that the model meets the decision needs of users.

One of the examples is the Treatment Sequence Simplification. As there are more than 476,000 possible treatment pathways for 4 lines, it is necessary that we simplify, combine, and reduce the number of treatments for model tractability. To simplify the treatment sequence, IVI has re-reviewed the clinical guidelines and a real-world treatment patterns study. Seeking strategies to simplify the treatment sequences, IVI will seek feedback from clinician advisors in the advisory group. In the spirit of being flexible and inclusive for this MDD model, IVI will also provide the capability for model users to plug in new treatments, efficacy and safety inputs, etc.

Comments:

- One AG member suggested that the model should not only have the flexibility in terms of changing the time horizon but also where patients start out. The reason is that some people are going to be interested in the newly diagnosed and others might be interested in treatment resistant depression, which is defined as stages 3 and 4 in our draft protocol.
- Another AG member asked how we will accommodate data deficits. IVI is working on a components study that tries to elicit more people from traditionally underrepresented backgrounds. IVI will also be explicit about the limitations of the model and build in the flexibility for people to use their own inputs. IVI asked if there are any data resources from the AG group that can help us populate this model.

Discuss Component Research Studies – Early Findings

MDD Treatment Patterns Retrospective Claims Study (Healthcore) is a retrospective claims study to identify treatment patterns (both pharmaceutical and non-pharmaceutical) in two-year follow-up for commercially-insured individuals newly diagnosed with MDD (age 18 to 64 years). In total, 12,657 patients were included in the study (mean age: 36 years; 60% female; 68% urban); 34% received Rx-only treatments, 25% non-Rx-only, 28% both, and 13% neither. MDD severity at diagnosis (26% mild, 54% moderate, 20% severe) was available for 51% of patients. Following the initial diagnosis of MDD, all-cause inpatient hospitalization rates for those with Rx-only, non-Rx-only, both, and neither were 11%, 10%, 16%, and 29%, respectively, while all-cause mean monthly total costs were \$792, \$633, \$786, and \$1,292, respectively. In multinomial logistic regression, age, sex, patient residence, socioeconomic status, diagnosing provider specialty, and initial diagnosis location were significant predictors ($p < 0.05$) of treatment modality. In multivariable logistic regression among patients with ≥ 2 severity assessments, those who received Rx-only (odds ratio [OR]: 2.03, $p < 0.01$) and both (OR: 3.26, $p < 0.01$) had higher odds of decreasing MDD severity than those who received neither.

Questions/Comments:

- Was a carve-out population included in the study? Healthcore responded that they would go back and check on this.
- Does IVI account for outliers in the study? IVI responded that there were not enough outliers to skew the averages but more detail would come out with the final full set of results.
- IVI shared that the Healthcore study will be used for model specifications and the use cases. The real-world data from the study can help to simplify treatment sequences and inform the cost inputs. As there are many limitations of these costs, IVI would be careful about the nature and the extent to which we can plug into the model.
- One AG member suggested that perhaps IVI can model in adjunctive use of treatments for subjects who are treatment resistant.
- IVI was asked via chat whether IVI would adjust with sampling weights, IVI responded that we would explore this for the final results

Patient-Driven Priorities for Management of MDD (PAVE)

The phase 2 survey recruitment is complete. IVI and PAVE made a deliberate effort to recruit underrepresented subgroups which were defined by race, ethnicity, education and income level. The research team is currently analyzing the full set of sample results. The research team is exploring a few ways to incorporate patient preference estimates into the model and ways patient heterogeneity and preferences will impact model insights. This project will also give us a way to incorporate equity considerations into value assessment. IVI is planning on holding a public webinar to showcase the full set of results in September 2022.

Comments:

- IVI could use the preferences to look at which treatment sequences match patient preferences, to juxtapose that against the quality of which we know is variously deficient, particularly in this disease area.

- Given that some people use the term engagement instead of productivity, which is sometimes considered as an economic term, one AG member suggested that the research team can speak to employers about this and understand the impact on the findings.

Updates on Use Case Development

IVI conducted 16 user interviews with different stakeholders including patients, payers, employers, manufacturers, clinicians, and researchers. Out of 6 potential use cases, IVI identified 3 prioritized themes for use case development based on feasibility and their likely impacts. The three prioritized themes are optimizing real-world treatment pathways, patient preferences and digital health.

Comments:

- Using patient preferences to optimize treatment pathways may lead to better adherence and better outcomes.
- AG is interested in looking at digital health and digital health applications and other ways of delivering care.