Artificial Intelligence-Based Estimation of the CGI-I to Address Gaps in Real-World Data and Increase Study Sample Size

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Background

The Clinical Global Impression Scale - Improvement (CGI-I) is a clinician-reported measure for global assessment of change in patients with psychiatric conditions.[1] The CGI-I is widely used in clinical trials for conditions such as major depressive disorder (MDD), bipolar I disorder, schizophrenia, and anxiety disorders due to its clinical relevance for capturing treatment response.

The brevity and ease of use of the CGI-I also make it suitable for use in routine clinical practice for monitoring treatment response and patient outcomes over time,[2] yet documentation of the CGI-I is inconsistent in real-world data sources such as electronic medical records (EMRs). This limits the utility of these data for supporting large, heterogeneous real-world studies. To address this gap, a previous effort applied artificial intelligence (AI) methods to estimate CGI-I scores for patients using routinely-recorded clinical notes data with very good performance.

Objective

This effort assessed the feasibility of using the CGI-I estimation model to increase the sample size for RWD studies of treatment response in different classes of medications prescribed for psychiatric conditions.

Methods

The CGI-I model was developed and validated using data from the OM1 Mental Health Specialty Network (**Table 1**). The model was applied to the OM1 MDD PremiOM Dataset, a RWD source containing data on over 490,000 MDD patients with a diagnosis of depression and receiving treatment from a mental health professional. Patients were included in this feasibility assessment if they met the following inclusion criteria:

- Diagnosis of MDD
- New drug initiation (index date) for a drug indicated for depression treatment
- Baseline observation within 90 days prior to 14 days after the index day and follow-up observation between 45-273 days post-index date.

Results

The cohort included 182,750 patients (**Figure 1, 2**). Of these, 38,252 had at least one observed CGI-I score in the study timeframe. The remaining 144,498 patients had estimated CGI-I (eCGI-I) scores generated by the AI model.

Increases of 4.3x to 6.0x in available study sample size were observed across drug classes (**Figure 3**). Specifically, sample sizes increased for:

- Serotonin-specific modulators (6.0x)
- Serotonin-norepinephrine reuptake inhibitors (5.1x)
- Norepinephrine dopamine reuptake inhibitors (5.0x)
- Serotonin antagonists and reuptake inhibitors (5.0x)
- Atypical antipsychotics (4.9x)
- Tetracyclic antidepressants (4.5x)
- Tricyclic antidepressants (4.4x)
- Selective serotonin reuptake inhibitors (4.3x)

Conclusions

- Use of an AI-based model to estimate CGI-I scores for patients with depression increased the number of patients available for RWD studies across drug classes.
- This novel approach to addressing missing data in studies using RWD could lead to a better understanding of MDD treatment response and patient outcomes over time.

Table 1. eCGI-I Model Performance

PPV	NPV	AUC	Spearman's R	Pearson's R
0.46	0.82	0.71	0.40	0.38

Figure 1. Age of Patients with Observed CGI-I Scores vs. Patients with Observed and Estimated eCGI-Scores

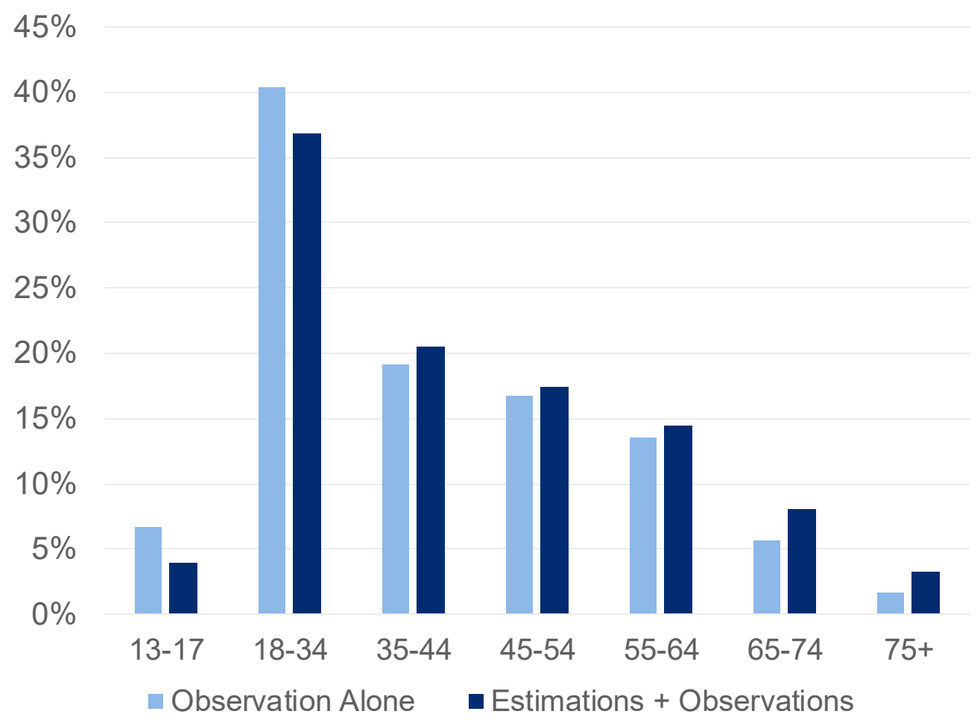


Figure 2. Sex of Patients with Observed CGI-I Scores vs. Patients with Observed and Estimated eCGI-Scores

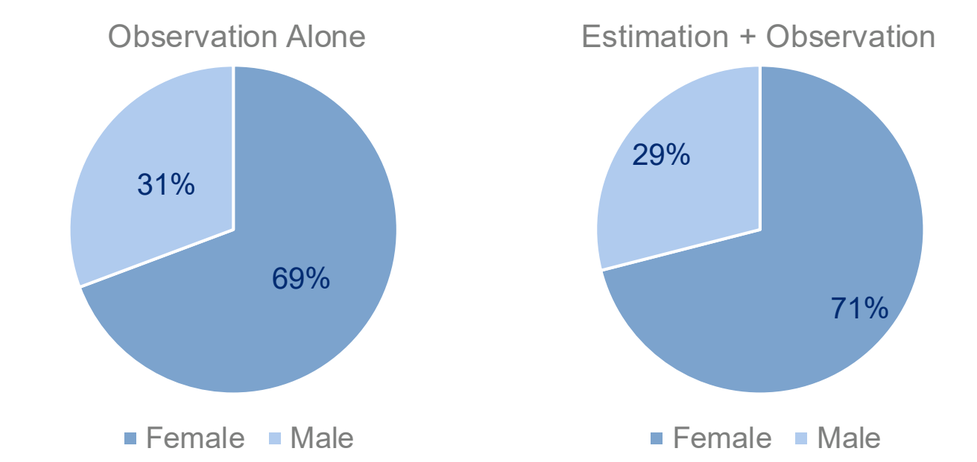
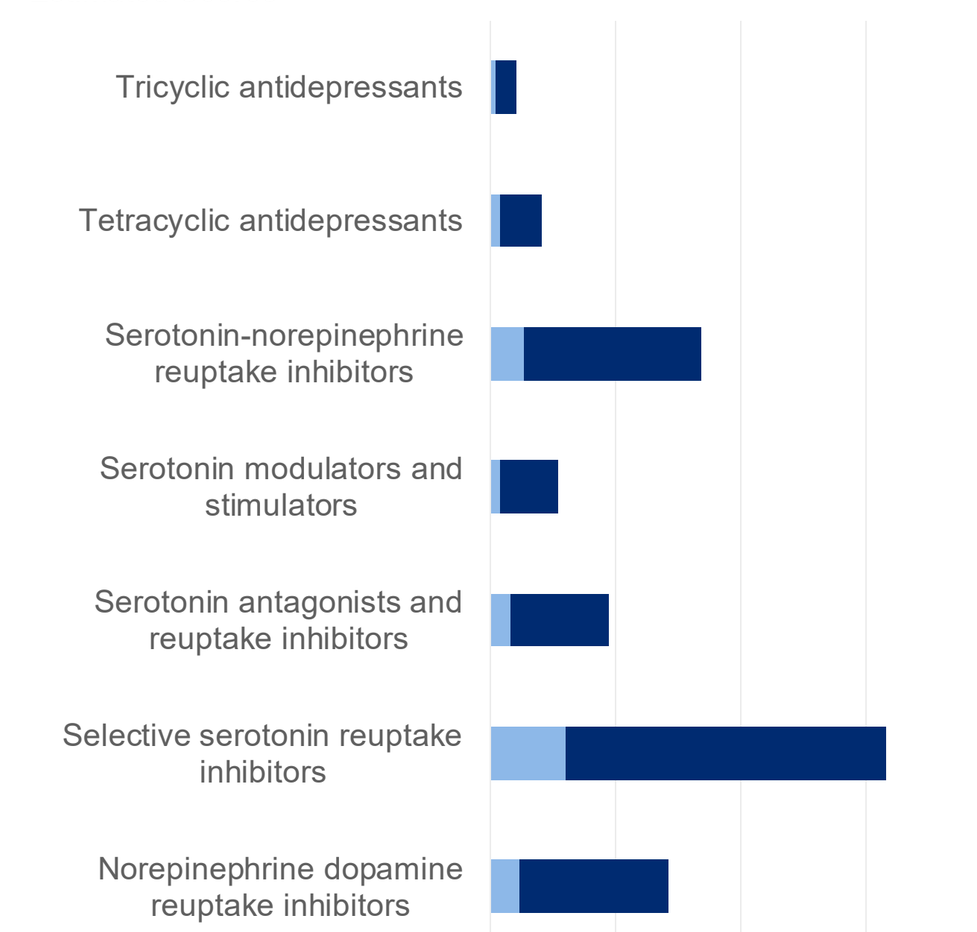


Figure 3. Available Patients for Inclusion in RWD Studies with Recorded CGI-I Scores Only vs. Patients with Recorded and Estimated Scores



Conference

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References

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