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# Essential data dimensions for prospective international data collection in older age bipolar disorder (OABD): Recommendations from the GAGE-BD group

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#### Abstract

**Background:** By 2030, over 50% of individuals living with bipolar disorder (BD) are expected to be aged  $\geq 50$  years. However, older age bipolar disorder (OABD) remains understudied. There are limited large-scale prospectively collected data organized in key dimensions capable of addressing several fundamental questions about BD affecting this subgroup of patients.

**Methods:** We developed initial recommendations for the essential dimensions for OABD data collection, based on (1) a systematic review of measures used in OABD studies, (2) a Delphi consensus of international OABD experts, (3) experience with harmonizing OABD data in the Global Aging & Geriatric Experiments in Bipolar Disorder Database (GAGE-BD,  $n \geq 4500$  participants), and (4) critical feedback from 34 global experts in geriatric mental health.

**Results:** We identified 15 key dimensions and variables within each that are relevant for the investigation of OABD: (1) demographics, (2) core symptoms of depression and (3) mania, (4) cognition screening and subjective cognitive function, (5) elements for BD diagnosis, (6) descriptors of course of illness, (7) treatment, (8) suicidality, (9) current medication, (10) psychiatric comorbidity, (11) psychotic symptoms, (12) general medical comorbidities, (13) functioning, (14) family history, and (15) other. We also recommend particular instruments for capturing some of the dimensions and variables.

**Conclusion:** The essential data dimensions we present should be of use to guide future international data collection in OABD and clinical practice. In the longer term, we aim to establish a prospective consortium using this core set of dimensions and associated variables to answer research questions relevant to OABD.

#### KEYWORDS

international collaboration, older age bipolar disorder, prospective studies

## 1 | INTRODUCTION

Older age bipolar disorder (OABD), defined as BD in individuals aged  $\geq 50$  years, represents as much as 25% of the population with BD.<sup>1</sup> The lifetime prevalence of OABD is about 1%-2% with a 1-year prevalence of 0.1%-0.7% in the general population.<sup>2</sup> Approximately, 6% of geriatric psychiatry outpatients and 10% of inpatients have BD<sup>3</sup> and compared to other older adults with mental health conditions, people with OABD are among the highest users of general medical services.<sup>4</sup>

There are several critical limitations in the current OABD literature, mainly a lack of robust conclusions derived from clinical trials that utilize large, and diverse samples with standardized high-quality

data. Thus, clinical course and treatment trajectories are poorly understood in OABD.<sup>5</sup> Findings are primarily based upon studies with a relatively limited number of participants (usually  $< 50$ -100) with a narrow geographic and age representation. Additionally, data collection is not standardized between studies, with different sites using very different scales. Thus, findings about the changes that occur during the second half of life in BD have been inadequately addressed to date.<sup>6-8</sup> There are many important gaps, with little evidence about, (1) mood symptom trajectory, (2) general medical comorbidities, (3) long-term effects of medications on general health, and (4) cognitive function evolution over time. In sum, the data on OABD are too scattered to draw firm conclusions. In recognition of the need to better understand how BD presents and evolves

across the lifespan, the International Society for Bipolar Disorders (ISBD) constituted a global expert panel: the Global Aging & Geriatric Experiments in Bipolar Disorder Database (GAGE-BD). The GAGE-BD has generated many high-powered analyses so far,<sup>6,9-16</sup> but is still limited by differences in study design and measures between contributing sites that necessitate harmonization and loss of fine-grained data.

To promote an even more complete understanding of OABD, prospective multi-site studies are needed. To facilitate this, we propose a list of recommendations for essential data dimensions and associated variables for prospective data collection among OABD. This set of variables will enable clinical trialists who want to contribute data to collect large-scale, coordinated, prospective cohorts and clinical trials focused on OABD, as well as clinicians who are interested in monitoring single patients or cohorts to have an approximate idea of how their OABD patients are doing and their prognosis. The current recommendations aim to standardize OABD data dimensions which would render higher quality, and more systematic data collection than even the recent GAGE-BD initiative. Moreover, it will enable the development of prospective clinical trials tailored to OABD. Multi-site integrated datasets represent an opportunity to better understand how aging may impact the presentation and evolution of BD across the lifespan, enhancing research and clinical practice regarding OABD.

## 2 | METHODS

The following is a summary of the process of how we established the initial recommendations for the essential data dimensions and associated variables for prospective data collection in OABD.

1. A systematic review of measures used in OABD studies: In 2017, an international group of experts performed a systematic review to identify studies examining OABD. Relevant articles were assessed to categorize the types of clinical, cognitive, biomarker, and neuroimaging OABD tools routinely used in OABD studies from the preceding 5 years.<sup>17</sup>
2. As a strategy to overcome the challenge of interpreting findings from existing limited OABD research studies, we reached out to 26 international OABD experts through the ISBD-OABD Task Force and their networks and performed two iterations of initial Delphi consensus.<sup>18</sup> The consensus was reached through a systematic, interactive, and iterative process which was conducted among a panel of experts to move toward agreement.

During the Delphi consensus, we followed 11 steps: (1) stated our research problem which is the challenge to collect heterogenic global OABD data, (2) outlined the rationale of the topic and methods used, (3) clearly explained the purpose and process of Delphi survey to the team, (4) scheduled rounds (2 iterations with a larger team and a core team to coordinate the final iteration), (5) experts selection process defined (GAGE-BD members and other international OABD

researchers were invited), (6) reliability and validity issues identified, (7) literature data interpretation shared (initial interpretation from the systematic review and secondary searches from 2018 to 2022), (8) defined ethical responsibilities toward expert sample and research community (consideration of access, costs, translations, etc.), (9) collected data on response rate for each round (first round presented the number of issues generated and second round the strength of support), (10) presented and interpreted results: >80% defined as consensus and 59-79% indicative of further consensus evaluation, and <50% consensus for excluded the item proposed, and (11) made recommendations based on conclusions.

3. Experience with harmonizing archival OABD data in the GAGE-BD Database: As we integrated international data collected from previous studies on >4500 OABD patients as of 2021, we gained insight into a) which data were being frequently collected by OABD researchers, and b) the challenging experience of harmonizing data when different measurement tools were used to evaluate similar construct dimensions (e.g., re-coding MADRS and HAM-D scores to "high/moderate", "mild", and "no" depression symptom severity categories).
4. A core GAGE-BD Essential Data Dimensions working group of OABD experts (PL, LE, SR, AO, and AT) then met on five occasions. Based on the experience with GAGE-BD, the initial Delphi, and the systematic review, the consensus was reached through a systematic, interactive, and iterative process with this working group of experts to move toward 100% agreement. During these meetings, a comprehensive list of scales used in mental health assessments was discussed and compiled. As well, the rationale for choosing an Essential Data Dimension and associated variables, as well as their recommended, supplemental, and second-line instruments over other options were also tabulated.
5. We then distributed a draft to the GAGE-BD steering committee and ISBD Task Force. Critical feedback from 34 global experts in geriatric mental health, including experts by experience, was then integrated to create the final version of the essential OABD dimensions.

## 3 | RESULTS

We developed recommendations for the essential dimensions for prospective data collection in OABD (Table 1). The proposal includes 14 dimensions, including a total of 56 recommended elements for prospective data collection in OABD and two dimensions for healthy controls (Table 2). The main dimensions identified were as follows: (1) demographics, core symptoms of (2) depression and (3) mania, (4) cognition, (5) elements for BD diagnosis (SCID or MINI based), (6) descriptors of course of illness, (7) suicidality, (8) course of treatment, (9) current medication, (10) psychiatric comorbidity (SCID or MINI based), (11) general medical comorbidities, (12) functioning, (13) family history, and (14) other. An essential set of seven scales are recommended: Montgomery-Asberg Depression Rating Scale

TABLE 1 Recommendations on the essential data dimensions for prospective data collection in OABD.

Essential data dimensions	Recommended instruments/questions	Second-line and supplemental instruments
Demographics	1. What is your age (at initial assessment, in years): 2. Sex you were born with: M/F 3. What is your gender identity: a) man, b) woman, c) trans person, d) non-binary e) fluid f) other___ 4. Do you identify as a racial, ethnic, or cultural minority in your country? Y/N 4.1. If Yes, please name it_____ 5. Are you an immigrant to your current country? Y/N. 5.1. If yes, how long ago did you arrive in this country? (years) 6. Number of significant social contacts (e.g., friends, family members)___ 7. Relationship status: a) never had a long-term relationship b) married/common law/couple/partnered, c) divorced, d) widow 8. Current living situation: a. Live alone in a house or apartment b. Live with a roommate or family member c. Live in a nursing home or group home d. Homeless or living in a homeless shelter 9. How many years of education have you completed, not counting preschool?____ 10. Highest completed education: a. Middle school or lower b. High school or equivalent c. Technical degree/community college d. University Bachelor's degree e. Postgraduate degree: (e.g., Masters, PhD) 11. Are you currently employed? a) Yes, paid part-time or full-time job b) Full-time student, volunteer, or homemaker b) Unemployed, but I want to work c) No, retired because of disease d) No, I am retired or do not want to work 12. When you have worked, has it been at your educational level? (Y/N) 13. How long do or did you have a paid job? a) <1 year, b) 1-5 years, c) >5 years	
Depression	14. MADRS with individual MADRS items (e.g., reduced sleep, reduced appetite)	
Mania	15. YMRS with individual items (e.g., sexual interest, irritability)	
Cognition	16. Screening: MOCA with individual MoCA items and sub-domain scores (e.g., Visuospatial/ Executive) 17. Subjective cognitive function: COBRA	MMSE (especially for people with dementia or low educational level)
Bipolar Disorder diagnosis	SCID or MINI 18. Bipolar subtype (Bipolar I or II or NOS) 19. BD diagnostic code (ICD) 20. BD diagnosis description 21. Rapid cycling (Y/N) 22. Current episode type (e.g., manic/depressed/euthymic/mixed/remitted) 23. Most recent affective episode type 24. History of psychosis (Y/N) 25. History of seasonal pattern (Y/N)	Clinical diagnosis based on DSM5 Time in euthymia (months) when applies
Course of BD illness	26. Age at BD diagnosis 27. Age of first mania/hypomania 28.-Age of first depressive episode 29. Age at first psychiatric hospitalization (admission or overnight stay at ER) 30. Number of psychiatric hospitalizations (admission or overnight stay at ER) 30.1. Number of psychiatric hospitalizations due to manic episodes 30.2. Number of psychiatric hospitalizations due to depressive episodes	
Suicidality	31. History of suicidal attempt (Y/N) 31.1. Number of suicidal attempts 31.2. Age at first suicidal attempt 31.3. Age at most recent attempt 31.4. Number of admission(s) for suicidal attempts? ?	

(Continues)

TABLE 1 (Continued)

Essential data dimensions	Recommended instruments/questions	Second-line and supplemental instruments
Course of Treatment	32. Age at first treatment for BD 33. Ever used lithium: Y/N 33.1. Ever used lithium in monotherapy? Y/N 33.2. Total duration of lithium use in years 34. Ever engaged in psycho/social therapy, e.g., structured program or multi-session approach (Y/N) 35. Ever had ECT series (Y/N) 35.1. Number of series/courses 36. Ever had TMS series (Y/N) 36.1. Number of series/courses 37. Treatment-resistant (>2 adequate pharmacological trials of a BD treatment that failed) (Y/N)	
Current Medication	Medications that are taken REGULARLY and not "as needed" or "prn" (see Appendix S1 in supplementary table) 38. Number of current antipsychotics 39. Number of current anticonvulsants/mood stabilizers 40. Number of current antidepressants 41. Number of current sedative-hypnotics 42. Lithium (Y/N) 42.1. Current lithium total daily dose (e.g., 150 mg BID = 300 mg daily dose) 43. Number of current stimulants 44. Number of non-psychiatric medications	Names of medication(s) and dose(s) for each category (1–4, 6) Examples (see Appendix S1) 1.2.- Current total dose of antipsychotics in units of chlorpromazine 5.2.- Current lithium blood level (e.g., -0.6 mmol/L) 5.3.- occurrence of lithium toxicity events.
Comorbid Psychiatric Diagnoses	45. MINI- or SCID-based diagnosis (Y/N) 46. Anxiety disorders (Y/N) 47. Substance use disorder (Y/N) 47.1 Alcohol use disorder (Y/N) a) current b) history of disorder 47.2 Cannabis use disorder (Y/N) a) current b) history of disorder	Clinical diagnosis based on DSM5, by psychiatrist or mental health provider with expertise in OABD Specify (Y/N) Panic Disorder Agoraphobia Social Anxiety Disorder PTSD OCD Alcohol use disorder Substance use disorder Generalized Anxiety Disorder Personality disorder
Psychotic symptoms	48. History of psychotic symptoms (Y/N)	BPRS-18-item, including individual items
General Medical comorbidities	49. CIRS-G (current, including all subcategories, total score, severity score)	List of general medical diagnoses and age of onset of each.
Functioning	50. FAST-O, including individual items	GAF: Global Assessment of Functioning Global deterioration scale (for assessment of primary degenerative dementia and delineation of its stages)
Family History	51. Total number of first-degree relatives with known information Total number of those with <ul style="list-style-type: none"> <li>• bipolar disorder</li> <li>• major depression</li> <li>• schizoaffective disorder</li> <li>• schizophrenia or other psychotic disorders</li> </ul>	
Other	52. Quality of Life in BD (QoL-BD) 53. BMI 54. Frequency of physical exercise: a) never, b) 1-3 times per week c) > 3 times/week 55. Smoking status: current, former, never 56. History of moderate/severe TBI (that included loss of consciousness >30 min)	

Abbreviations: BMI, body mass index kg/m<sup>2</sup>; BPRS, brief psychiatric rating scale; CIRS-G, cumulative illness rating scale; DSM5, diagnostic and statistical manual for mental health 5; ECT, electroconvulsive therapy; FAST-O, functional assessment short test for older adults; MADRS, Montgomery-Aberg depression rating scale; MINI, mini international neuropsychiatry interview; MOCA, Montreal Cognitive Assessment; QoL-BD, quality of life in bipolar disorders; SCID, structured clinical interview; TMS, trans magnetic stimulation; YMRS, young mania rating scale.



**TABLE 2** Recommendations on the essential data dimensions for prospective data collection in (1) healthy controls or (2) non-BD patients (e.g., unipolar depression).

Essential elements for	Demographics: Same as above	Any other additional data
1.-Healthy controls or	Clinical Measures – Healthy Controls:	
2.-Non-BD patients	1. BMI	
	2. CIRS-G	
	3. History of moderate/severe TBI (that included loss of consciousness >30 min)	
	4. Use of any psychotropic medication (Y/N), If yes, please indicate in the medication list (see Appendix S1 at the end)	
	Clinical Measures – Non-BD patients (e.g., unipolar depression):	
	All the same as BD but substitute this diagnosis for BD in all BD-specific variables	

Abbreviations: BMI, body mass index kg/m<sup>2</sup>; BPRS, brief psychiatric rating scale; CIRS-G, cumulative illness rating scale; DSM5, diagnostic and statistical manual for mental health 5; ECT, electroconvulsive therapy; FAST-O, functional assessment short test for older adults; MADRS, Montgomery-Asberg depression rating scale; MINI, mini international neuropsychiatry interview; MOCA, Montreal Cognitive Assessment; QoL-BD, quality of life in bipolar disorders; SCID, structured clinical interview; TMS, trans magnetic stimulation; YMRS, young mania rating scale.

(MADRS), the Young Mania Rating Scale (YMRS), the Montreal Cognitive Assessment (MoCA), Cumulative Illness Rating Scale-Geriatric (CIRS-G), Functional Assessment Short Test for Older Adults (FAST-O), Subjective Cognitive deficits in bipolar disorder (COBRA), and Quality of Life in Bipolar Disorder (QoL-BD), from which the first five include individualized items. An additional set of optional data were defined as supplemental elements, such as Brief Psychiatric Rating Scale (BPRS-18). The estimated time for collection of the essential data dimensions for prospective data collection in OABD is about 3 h and can be completed by a mental health professional or research staff with training in these scales

## 4 | DISCUSSION

These recommended essential data dimensions from the GAGE-BD consortium build upon the past decade of work by the ISBD-OABD Task Force and subsequent research to build an integrated archival dataset specifically focused on OABD outcomes. The essential data dimensions, which represent a step toward collaborative OABD research worldwide, were created through the following processes: (1) a systematic review of measures used in OABD studies by the ISBD Task Force, (2) experience with harmonizing archival OABD data in GAGE-BD, (3) a Delphi consensus of international OABD experts, and (4) critical feedback from 34 global experts in geriatric mental health.

Intentionally, this set of essential data dimensions does not include certain dimensions such as tolerability or adverse effects, since different types of treatment will have different side effects and these data will be collected as per individual trial's needs.

Below is a summary of the rationale for how we decided on some of the major essential elements for prospective data collection in OABD:

- a. Depression—Montgomery-Asberg Depression Rating Scale (MADRS).<sup>19</sup> The two most common and validated outcome measures for depressive symptoms in reports focused on late-life depression and depression in OABD are the Montgomery-Asberg Depression Rating Scale (MADRS)<sup>17,20</sup> and the Hamilton

Depression Scale (HAM-D).<sup>17,21</sup> Although the HAM-D is a commonly used, reliable, and valid measure of depression severity, many problems with the scale have been described, including overrepresentation of vegetative symptoms and underrepresentation of atypical symptoms.<sup>20</sup> Furthermore, some items of the HAM-D have low interrater and retest coefficients. Compared to the HAM-D, the MADRS has more precision in estimating depression and a greater capacity to differentiate between responders and non-responders to antidepressants.<sup>22–25</sup>

The members of the working group identified the MADRS as easier to use. Also, the MADRS is more sensitive to the changes brought by treatment (compared to the HAM-D) and less sensitive to comorbidities,<sup>26</sup> which is advantageous in OABD, which often has general medical and cognitive comorbidity. We also found, in harmonizing depression severity data across cohorts in the GAGE-BD integrated dataset, that the MADRS had the highest effect sizes in relation to daily functioning, an important outcome measure for OABD.<sup>15</sup> As well, the MADRS is widely known and used in the late-life depression literature, which would allow easier comparison of data from prospective studies of OABD with other older age mood/unipolar depression datasets. *Characteristics:* time to administer: 15 minutes; availability: free access and validation in > 14 languages, including English, Spanish, French, German, and Portuguese. Alternatives considered: We carefully considered the HAM-D. In fact, between 2011 and 2016, more studies in OABD used the HAM-D ( $n = 22$ ) compared to the MADRS ( $n = 9$ ). However, from the accumulated studies from the GAGE-BD group, MADRS has been used a similar number of times ( $n = 6$ ), compared to HAM-D ( $n = 7$ ). Also, we considered whether to use 'options'—e.g., for investigators to have the MADRS or the HAM-D. However, our experience with GAGE-BD made it very clear that it is challenging to harmonize data across more than one scale, which forced us to translate a continuous scale into discrete categories (e.g., no, mild, moderate/severe depression severity)—limiting the ability to have a sensitive continuous measure. We also explored the idea of using a Z-score with multiple scales, but ultimately decided that a single scale should be used in the essential elements for prospective data collection in OABD and the consensus favored the MADRS.

**Mania - Young Mania Rating Scale (YMRS):**<sup>27</sup> Strengths of the YMRS include its brevity, widely accepted use, and ease of administration. The updated GAGE-BD dataset includes many ( $n = 17$ ) studies using YMRS. Our experience with GAGE-BD made it clear that there was already a consensus on the use of this scale for rating mania symptoms among OABD researchers. *Characteristics:* time to administer: 10 minutes; availability: free access and validation in a minimum of six languages, including English, Spanish, French, Turkish, German, and Portuguese.

**Cognition screening - Montreal Cognitive Assessment (MoCA)**<sup>28</sup> and **subjective cognitive function - COBRA:**<sup>29</sup> The updated GAGE-BD dataset includes  $n = 0$  studies using MoCA, while  $n = 9$  used the MMSE. Although some argue that it is not as sensitive to each domain as a full neuropsychological battery, it is highlighted that a core strength of MoCA is that it assesses different cognitive dimensions: attention and concentration, executive functions, memory, language, visuo-constructional skills, conceptual thinking, calculations, and orientation. Additionally, MoCA is able to provide appropriate age and education-adjusted norms.<sup>30</sup> The discriminant potential of MoCA between subjective cognitive decline (SCD) and mild cognitive impairment (MCI) is good, while the discrimination of SCD from dementia is excellent.<sup>28</sup> A systematic review on measurement tools for assessment of OABD<sup>17</sup> reported that less than two-thirds of papers used measures of cognitive performance, with about half using screening instruments of limited sensitivity. In clinical practice, instruments that also assess executive function which is common in BD (e.g., MoCA) could be used for annual screening for cognitive dysfunction. *Characteristics:* time to administer: 10 minutes; availability: validation in >15 languages, including English, German, Spanish, French, Portuguese, Chinese, Arabic, etc. Interestingly, a version for older adults with visual or auditory impairment has been developed.<sup>31</sup> Alternatives considered: MMSE. In a study<sup>32</sup> assessing the relationship between the Montreal Cognitive Assessment and Mini-mental State Examination for assessment of mild cognitive impairment in older adults, MoCA and MMSE were more similar for dementia cases, but MoCA distributed mild cognitive impairment (MCI) cases across a broader score range with less ceiling effect. A cutoff of  $\geq 17$  on the MoCA helped to capture early and late MCI cases. Additionally, MMSE lacks tasks targeting a wider variety of cognitive dimensions and is no longer in the public domain which may be too costly for some settings.

The assessment of subjective cognitive function would appear to be a relevant domain to assess in OABD, given the demonstration that this is a predictor of cognitive decline in older age and dementia.<sup>33</sup> Considering the centrality of assessing the course and predictors of cognitive decline in OABD research, the assessment of subjective cognition is a key domain that should be included. In addition, subjective cognition is associated with other clinical variables that are also very relevant to BD such as depression, metacognition, stress, quality of life, etc.<sup>34</sup> The incorporation of subjective cognition

can also be achieved in a resource, time, and cost-friendly manner, as there are tools available for rapidly assessing subjective cognition (e.g., PROMIS cognitive function scales), and specifically one validated for use in BD, translated into multiple languages, and recommended by the ISBD: The Cognitive Complaints in Bipolar Disorder Rating Assessment (COBRA). The COBRA had one-factor structure with very high internal consistency (Cronbach's  $\alpha = 0.913$ ). A high convergent validity was indicated by a strong correlation with the Frankfurt Complaint Questionnaire ( $r = 0.888$ ,  $p < 0.001$ ). Patients with BD experienced greater cognitive complaints compared to control group, suggesting a discriminative validity of the instrument. Significant correlations were found between the COBRA and some objective cognitive measures (e.g., memory and executive function).

**Psychotic Symptoms - Brief Psychiatric Rating Scale-18 (BPRS)**<sup>35</sup>

Strengths include inter- and intra-rater reliability of the Brief Psychiatric Rating Scale reported as high as could be expected.<sup>35</sup>

The updated GAGE-BD dataset includes ( $n = 4$ ) studies that used BPRS, while none used PANSS (from initial datasets). *Characteristics:* time to administer: 20 minutes; availability: free access and validation in 13 languages, including English, Spanish, French, Chinese, German, and Portuguese. Alternatives considered: PANSS. Some authors agree that ideally, both scales should be considered,<sup>36</sup> however, making a reasonable balance between exhaustive assessment and time resources, and considering that BPRS has a wider availability of translations. Thus, since a single scale should be used in the essential elements for prospective data collection in OABD, the consensus favored the BPRS. This instrument will be considered as optional as certain sites may have limited resources.

**Comorbidities—Cumulative Illness Rating Scale-Geriatric (CIRS-G)**<sup>37</sup>

Strengths include that CIRS illness severity and comorbidity indices, as well as individual items, are significantly associated with mortality, acute hospitalization, medication usage, laboratory test results, and functional disability.<sup>37</sup> The CIRS-G shows good divergent validity vis-a-vis functional disability in predicting mortality and hospitalization. The updated GAGE-BD dataset includes  $n = 8$  studies using this scale. *Characteristics:* time to administer: 15 minutes; availability: free access and translation available in at least seven languages, including English, Spanish, French, and Portuguese. Alternatives considered: Given that this scale has been validated in the geriatric population and has good acceptability within the research community in BD, the working group has agreed by consensus to select the CIRS-G as part of the essential elements.

**Function - Functional Assessment Short Test for Older Adults (FAST-O)**<sup>38</sup>

In 2020, a valid adapted version of the Functional Assessment Short Test (FAST for use in older adults with bipolar disorder (OABD) was developed (FAST-O). The authors found that the FAST-O has strong psychometric qualities and conclude that this scale is a short, efficient solution to replace global rating scales or extensive test batteries to assess daily



functioning of older psychiatric patients in a valid and reliable manner. *Characteristics*: time to administer: 15 min. Alternatives considered: GAF and SOFAS.

Given that this scale has been specifically validated in the OABD population, the working group has agreed by consensus to select the FAST-O as part of the essential elements for prospective data collection in OABD. Alternative considered: The 12- and 36-item self-administered WHODAS 2.0 is deemed internally consistent and a reliable scale demonstrating overall good correlation with other measures of disability. However, it appears that it is a multidimensional scale, and its total score may represent different combinations of several contributing factors. Thus, the FAST-O can be more reliable as a total score when creating a functional profile.

- a. Quality of Life in Bipolar Disorders (QoL-BD):<sup>39</sup> There is wide recognition that symptom ratings alone are inadequate to measure outcomes in BD, and quality of life (QoL) has been proposed as an important separable construct. The Quality of Life in Bipolar Disorder (QoL-BD) scale supports the use of the instrument as a feasible, reliable, and valid disorder-specific QoL measure for BD. Internal reliability of the QoL-BD is impressive, test-retest reliability is appropriate, and the direction and magnitude of correlations with external measures are as expected. Significantly, data suggest that the greater specificity of the QoL-BD relative to the Quality-of-Life Enjoyment and Satisfaction Questionnaire renders the new instrument more sensitive to clinical change in BD.<sup>39</sup>

#### 4.1 | Strengths and limitations

Our essential data dimension recommendations have several important strengths. They capture perspectives and a rich insight of a large group of OABD international experts ( $n = 34$ ) across multiple continents. Our process involved a systematic review, an in-depth consensus consultation, and hands-on experience harmonizing large-scale international data ( $n \geq 4500$ ). Priority was given to scales that are accessible, with no/low cost, and available in multiple languages. Attempts were made to be somewhat comprehensive while minimizing site burden during data collection. The recommended data elements also have certain limitations, including that most of the scales proposed have not been specifically developed for the older population and that could make us fail to adequately assess factors particularly relevant to OABD. Additionally, there is a potential compromise between data detail and the time required for its collection, e.g., the MoCA cognitive screening measure, which is less extensive than a complete neuropsychological assessment, however, relatively easy and quick to perform. Although we initially aimed to include many more scales, we determined that the essential dimensions would be a requirement for participation in a future global consortium for prospective OABD data collection. Large cohort studies are essential for a better understanding of conditions

such as BD,<sup>40,41</sup> and this is particularly true for OABD patients. As a compromise, additional data (e.g., neuroimaging, in-depth neurocognitive testing, biobank data) would still be welcome as complementary data for additional sophisticated analyses.

#### 4.2 | Concluding remarks

These recommendations for essential data dimensions in OABD will improve on previous efforts to collect standardized data. Even the GAGE-BD initiative, which has successfully integrated data across many different international sites, has been somewhat limited by the challenging process of harmonizing data when different measurement tools were used to evaluate similar construct dimensions. The potential short-term impact is to establish a standardized operational procedure for international researchers and clinicians to collect and analyze OABD data.

The possibilities for use of these recommended essential data dimensions are exciting. We are in the process of proposing prospective global consortia of research in OABD. Similarly, the recommendations can facilitate large-scale clinical trials to assess novel pharmacological, technological, and behavioral treatments and prevention strategies for OABD. We hope that these efforts will lead to a better understanding of OABD and BD across the lifespan. In the future as we perform prospective data collection, we plan to have 1-2 people from the Depression and Bipolar Support Alliance (DBSA) with lived experience join our steering committee.

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#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon request.

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## SUPPORTING INFORMATION

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