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The LEADING Guideline

Reporting Standards for Expert Panel, Best-Estimate Diagnosis, and Longitudinal Expert All Data (LEAD) Studies

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The LEADING Guideline Reporting Standards

Abstract

Accurate assessments of symptoms and diagnoses are essential for health research and clinical practice but face many challenges. The absence of a single error-free measure is currently addressed by assessment methods involving experts reviewing several sources of information to achieve a more accurate or best-estimate assessment. Three bodies of work spanning medicine, psychiatry, and psychology propose similar assessment methods: The Expert Panel, the Best-Estimate Diagnosis, and the Longitudinal Expert All Data (LEAD). However, the quality of such best-estimate assessments is typically very difficult to evaluate due to poor reporting of the assessment methods and when it is reported, the reporting quality varies substantially. Here we tackle this gap by developing reporting guidelines for such studies, using a four-stage approach: 1) drafting reporting standards accompanied by rationales and empirical evidence, which were further developed with a patient organization for depression, 2) incorporating expert feedback through a two-round Delphi procedure, 3) refining the guideline based on an expert consensus meeting, and 4) testing the guideline by i) having two researchers test it and ii) using it to examine the extent previously published articles report the standards. The last step also demonstrates the need for the guideline: 18 to 58% (Mean = 33%) of the standards were not reported across fifteen randomly selected studies. The LEADING guideline comprises 20 reporting standards related to four groups: The *Longitudinal design*; the *Appropriate data*; the *Evaluation – experts, materials, and procedures*; and the *Validity* group. We hope that the LEADING guideline will be useful in assisting researchers in planning, reporting, and evaluating research aiming to achieve best-estimate assessments.

Keywords: Expert Panel; LEAD; Best-Estimate Diagnosis; Reference standard; Criterion standard; Gold standard; Medical assessments; Psychiatric assessments; Psychological assessments.

Open data (Delphi surveys 1 and 2), code (analyses), and material (surveys): <https://osf.io/fkv4b/>

Introduction

Establishing valid and reliable assessments of symptoms and diagnoses is the foundation of health and clinical sciences. Given that reliable biological markers or specific objective signs for most mental health problems are lacking and many medical conditions only show objective markers in late stages, accurate diagnostic assessments are difficult^{1,2}. Essentially every single measure of a psychological construct has some potential source of bias (e.g., self-report and recall bias) or can be seen as fallible in some respect^{3,4} – which can result in inaccurate assessments and delayed treatments.

The absence of a single error-free measure can be addressed by involving multiple experts reviewing several sources of information to form a *best-estimate assessment* or a reference standard⁵⁻⁷. To understand the quality of such an assessment, it is crucial to understand how it was reached (i.e., the quality of the specific assessment method used). However, the quality of best-estimate assessments is typically very difficult to evaluate due to poor reporting of the assessment method, and when the method is reported, the reporting quality varies substantially⁷. Here we tackle this problem by developing a guideline for how to report assessment methods that aim to achieve such a best-estimate assessment standard, i.e., where experts review several sources of (longitudinal) information to achieve a more accurate assessment than a single, error-prone measure.

Assessment

Assessment includes the evaluation, integration, and interpretation of several sources of information (e.g., outcomes of different measures, tests, or scans) to derive a valid and reliable decision (e.g., a best-estimate diagnosis)⁸. Accurate assessments are crucial for understanding the prevalence of clinical problems^{9,10}, detecting and starting early treatment^{11,12}, validating measurement tools^{13,14}, and evaluating interventions/therapies^{15,16}. In clinical practice, under- or over-estimation of disorders can have severe negative impacts on people's lives. In research, they threaten the validity of scientific results. For policy and implementation development, assessments are the basis for guideline development and methods for economic and societal evaluations of interventions. Furthermore, obtaining more accurate assessments has become increasingly important considering that high-accuracy assessments are needed in diverse fields such as Biological Psychiatry (e.g., to find reliable biomarkers linked to reference standard assessments¹⁷⁻¹⁹) and Artificial Intelligence (e.g., to train models on reference standard assessments²⁰⁻²²). In addition, technologies such as smartphone sensor data and video calls have made it easier to collect highly relevant, rich, and longitudinal data.

A methodological solution

Through our literature search and based on the expertise of the author team, we identified three bodies of literature that have proposed similar assessment methods: The Expert Panel method in medicine^{7,23,24} – as well as the Best-Estimate Diagnosis^{6,25} and the Longitudinal Expert All Data (LEAD)⁵ methods in psychiatry and clinical psychology. All three use expert panels or consensus teams to establish a more accurate assessment. They share the same goal of attaining best-estimate assessments through similar methodological approaches while accentuating different parts of it. The Best-Estimate Diagnosis method accentuates the use of informants and objective tests next to self-reported data^{6,25}; and the Expert Panel method focuses on the characteristics, constitution, and procedure of the panel^{7,23}. Only the LEAD method requires a longitudinal design⁵, although longitudinal data are also used in some Expert Panel designs (≈27% of studies⁷). Herein we collectively refer to these three approaches as the *assessment methods*.

The result of the *assessment methods* is a consensually derived criterion (e.g., a best-estimate assessment) that has been used for many different applications where there is no single error-free measure. It has, for

The LEADING Guideline Reporting Standards

example, been used to i) understand the accuracy of a measurement tool or marker through comparison to a best-estimate assessment²⁶⁻³¹; ii) establish the prevalence of symptoms and disorders^{9,10,32}; iii) establish the temporal stability or development of symptoms and disorders³³⁻³⁵; iv) improve (earlier) detection or screening of symptoms or disorders^{11,12,36}; v) study genetics and family history³⁷⁻³⁹; and vi) examine classification systems or diagnostic criteria⁴⁰⁻⁴². The applications span diverse fields, including medicine, psychiatry, clinical psychology, public health/epidemiology, and artificial intelligence. Box 1 provides more examples of how the assessment methods have been applied in different types of studies across fields.

Box 1 | Overview of applications of the assessment methods across different study designs and fields

The absence of a single error-free measure can be mitigated by involving multiple experts reviewing several sources of information to form a best-estimate assessment. The developed guideline aims to assist users in planning, evaluating, and reporting assessment method procedures to derive such best-estimate assessments. The guideline has been developed with stakeholders from a broad range of fields and backgrounds and is relevant to areas in which the assessment methods are used, such as medicine, psychiatry, clinical psychology, and epidemiology. Below we show use cases and areas where the assessment methods have been applied.

1. To evaluate a measure's accuracy against a reference standard. To understand the accuracy of a measurement tool, there is a need to compare it to a more accurate or best-estimate assessment. For example, it has been used:

- *in psychiatry*, for evaluating MINI-KID diagnoses for children and adolescents²⁶
and evaluating DSM diagnoses in patients with psychosis.²⁷
- *in clinical psychology*, for evaluating MDI depression severity scores.²⁸
- *in medicine*, for evaluating deep learning models assessing liver cancer²⁹
and evaluating prediction rules for coronary artery disease.³⁰
- *in public health/epidemiology*, for evaluating electronic health record algorithms for assessing asthma.³¹

2. To establish the prevalence of symptoms or disorders. For example, it has been used:

- *in public health/epidemiology*, for assessing the prevalence and familiarity of pathological gambling.⁹
- *in psychiatry*, for assessing the prevalence of eating disorders in patients with personality disorders.¹⁰
- *in medicine*, for assessing the prevalence of clinically relevant incidental findings when diagnosing pulmonary embolism.³²

3. To establish the temporal stability or development of symptoms or disorders. For example, it has been used:

- *in clinical psychology*, for learning about autism spectrum disorder diagnoses during childhood³³
and for learning about the course of bipolar disorder.³⁴
- *in psychiatry*, for assessing diagnostic stability in individuals with autism spectrum disorder.³⁵

4. To improve (earlier) detection or screening of symptoms or disorders. For example, it has been used:

- *in psychiatry*, for the assessment of personality disorders.¹¹
- *in medicine*, for the early detection of heart failure.³⁶
and for early detection of injuries in physically abused older adults.¹²

5. To study genetic history and family heritability. For example, it has been used:

- *in psychiatry*, for learning about genetic risks for ADHD.³⁷
- *in clinical psychology*, for studying familial aggregation and heritability of subtypes of depression³⁸
and for studying the familial transmission of mania and depression.³⁹

6. To examine classification systems or diagnostic criteria. For example, it has been used:

- *in clinical psychology*, for evaluating the DSM criteria for hoarding disorder.⁴⁰
- *in psychiatry*, for examining a DSM alternative model for personality disorders⁴¹
and for comparing DSM-IV and -5 criteria of autism spectrum disorders.⁴²

Reporting issues

The assessment methods possess high potential for achieving best-estimate reference standards in many situations. However, the quality of such proclaimed best-estimate assessments varies substantially and is typically very difficult to evaluate due to poor reporting of the method *how* they were achieved (e.g., see reviews of expert panels^{7,23}). A systematic review of assessment methods and reporting of expert panels⁷ has demonstrated that the methods used for panel or consensus diagnoses vary substantially across studies and that many aspects of the procedure are often unclear or not reported at all. Many recent studies fail to report central aspects of the three assessment methods, including the quality, structure, or presentation of the data⁴³, the training and qualifications of the experts⁴⁴, the method for avoiding biases and achieving consensus¹³, and the time span of the longitudinal design-component⁴⁵. The poor operationalization of the assessment methods jeopardizes the goal of achieving best-estimate assessments – where a vaguely described method makes it difficult to evaluate the research. Referring to an assessment as a best-estimate (and sometimes even as a gold standard) while vaguely describing or poorly operationalizing the method for achieving the assessment is alarming^{46,47}.

The degree of validity

These assessment methods aim to achieve high validity (i.e., the degree to which the assessment captures what it aims to measure). Typically, the assessment methods aim to achieve as high validity as possible (i.e., a “leading” assessment), or, depending on resources, at least more accurate than a single error-prone measure. Despite this central aim, research often fails to clearly describe the degree of validity of the attained assessment. Using these assessment methods does not automatically guarantee high validity – it depends on how well the method is executed.

In addition, the assessments are often described with different terms: *reference standard* is often used in medicine, and *criterion standard* or *best-estimate diagnosis* is often used in psychology. We propose that the reporting of these assessment methods benefit from more explicitly describing *what* was measured and *how well* it measures up to different standards – whether and how they relate to a state-of-the-art assessment. Whereas *reference* and *criterion standards* fail to convey an intention of “nearing” a state-of-the-art assessment, the *best-estimate diagnosis* narrowly focuses on the classification of a diagnosis and not on symptom severity. Therefore, we here use the term *best-estimate assessment* in the context of describing a “leading”, state-of-the-art assessment.

Reporting standards

Previous well-established guidelines have focused on the complete reporting of specific study designs, such as the *STrengthening the Reporting of OBservational studies in Epidemiology* (STROBE)⁴⁸ for observational studies; the *Statement for Reporting for Diagnostic Accuracy* (STARD)⁴⁹ for diagnostic accuracy studies; the *Consolidated Standards of Reporting Trials* (CONSORT)⁵⁰ for randomised trials, and the *Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis* (TRIPOD)⁵¹ for prediction model studies (see the supplementary material [SM] for other relevant

The LEADING Guideline Reporting Standards

guidelines). The STARD guidance is most closely related to the reporting of the assessment methods since best-estimate assessments are often used to evaluate a measure's (diagnostic) accuracy. However, none of the guidelines are sufficient for complete reporting of the assessment methods, where (multiple) experts review several sources of (longitudinal) information to form a best-estimate assessment. Although an earlier systematic review identified and structured the various choices involved in Expert Panel procedures⁷, no attempt was made to develop a formal guideline for the reporting of Expert Panel assessments.

Aim

Our aim is to develop reporting standards for comprehensive reporting of these assessment methods – which can help researchers plan, carry out, and report studies employing these assessment methods, as well as help readers evaluate them. We call the reporting guideline the LEADING guideline, emphasizing the methodological components and the importance of describing *what* was assessed and *how well* (i.e., how it relates to a “leading” assessment). We further revise the original meanings of LEAD (*Longitudinal, Expert, All Data*⁵) to *Longitudinal, Evaluation – experts, materials and procedures*, and *Appropriate Data*). In short, the LEADING guideline aims to guide the reporting of assessment methods to improve evaluations of the assessment standard.

Methods

Development stages

We developed the reporting guideline over four stages: 1) drafting reporting standards; 2) incorporating expert feedback; 3) refining the final guideline, and 4) testing the guideline. The development method largely followed Moher and colleagues' guidance for developing reporting guidelines⁵² (See Table S1 for elaborations on each recommended step). For organizational purposes, a working group (V.E., K.K., & O.K.) was set up, and a steering group (H.A.S., J.B., E.F., D.K., P.G., I.A., & P.B.) was formed to provide a wide range of expertise. The steering group included seven experts and was selected to cover a diverse range of expertise and fields related to the assessment methods (e.g., psychiatry/clinical psychology, medicine, epidemiology/public health, and Artificial Intelligence). See the SM for information regarding ethics.

Drafting reporting standards

The working group drafted the original reporting standards. First, the working group, with the support of the steering group, identified relevant research using or describing the assessment methods, including the three bodies of literature: Expert Panel⁷, Best-Estimate Diagnosis⁶, and LEAD⁵. Second, relevant reporting guidelines and systematic reviews were identified, including a review of expert panels applications⁷; the STROBE statement⁴⁸; and the STARD guidance⁴⁹ (other complementary reporting guidelines and systematic reviews are presented in the SM). The aim was for the reporting standards in the LEADING guideline to complement rather than repeat these guidelines (i.e., new standards should extend or complement existing standards rather than repeat them⁵²). The use of multiple reporting guidelines may often be appropriate; for example, when reporting a randomised trial that includes best-estimate assessments, one may use CONSORT⁵⁰ to report the trial design and main results, and the LEADING guideline for describing the specifics for reaching the best-estimate assessment.

Potential standards were drafted by the working group with the objective of encompassing a comprehensive reporting of the assessment methods. The reporting standards were grouped into four groups: *Longitudinal*

The LEADING Guideline Reporting Standards

design, Appropriate data, Evaluation – experts, materials and procedures, and Validity. Empirical and theoretical inclusion rationales were stated for the groups and the individual standards. Lastly, the standards with inclusion rationales were further developed through a workshop with a patient organization for depression, followed by receiving feedback from the steering group members to receive a wide range of perspectives early in the process.

Incorporating expert feedback

To systematically collect expert feedback from different perspectives, we used a consensus-building procedure called the *Delphi technique*⁵³. We used an iterative process based on two rounds of questionnaires (i.e., Delphi surveys), enabling feedback from round 1 to feed into round 2. Delphi participants received relevant background research, the reporting guideline aims, as well as the groups and the individual standards with their inclusion rationales. They provided feedback through open- and closed-ended response formats. Through open-ended responses, experts could propose new standards and provide feedback on clarifications and reformulations of existing standards, their inclusion rationales, and evidential support. In addition, two closed-ended questions⁵⁴ about standard inclusion (*This item should be included in the reporting checklist*) and perception of study quality (*Whether this information is present or not would influence my perceptions of the quality of a study*) were answered with rating scales ranging from 1 = *Strongly disagree* to 7 = *Strongly agree*.

The first and/or last authors of articles since 2013 ($n = 87$ articles, $n = 124$ authors; the search strategy is detailed in the SM) using any of the three assessment methods as well as the seven steering group members, were invited via email to participate in the Delphi Round 1 ($n = 131$ participants emailed). In total, 27 participants completed the survey (response rate 21%). Only participants from Round 1 who provided their contact details were invited to Round 2 ($n = 25$). In total, 20 participants completed the survey (response rate 80%). All participants provided their informed consent. Figure 1 presents the research experiences and demographics of the Delphi participants. Participants reported a wide range of academic backgrounds (e.g., Medicine, Psychiatry or Clinical Psychology, Artificial Intelligence, Journal Editors), and an extensive variety of relevant methodological experiences (e.g., Biological Markers, Ecological Momentary Assessments, and Expert Panels; Figure 1), with an age range of 30 – 70 years ($M = 51.54$, $SD = 12.40$).

The LEADING Guideline Reporting Standards

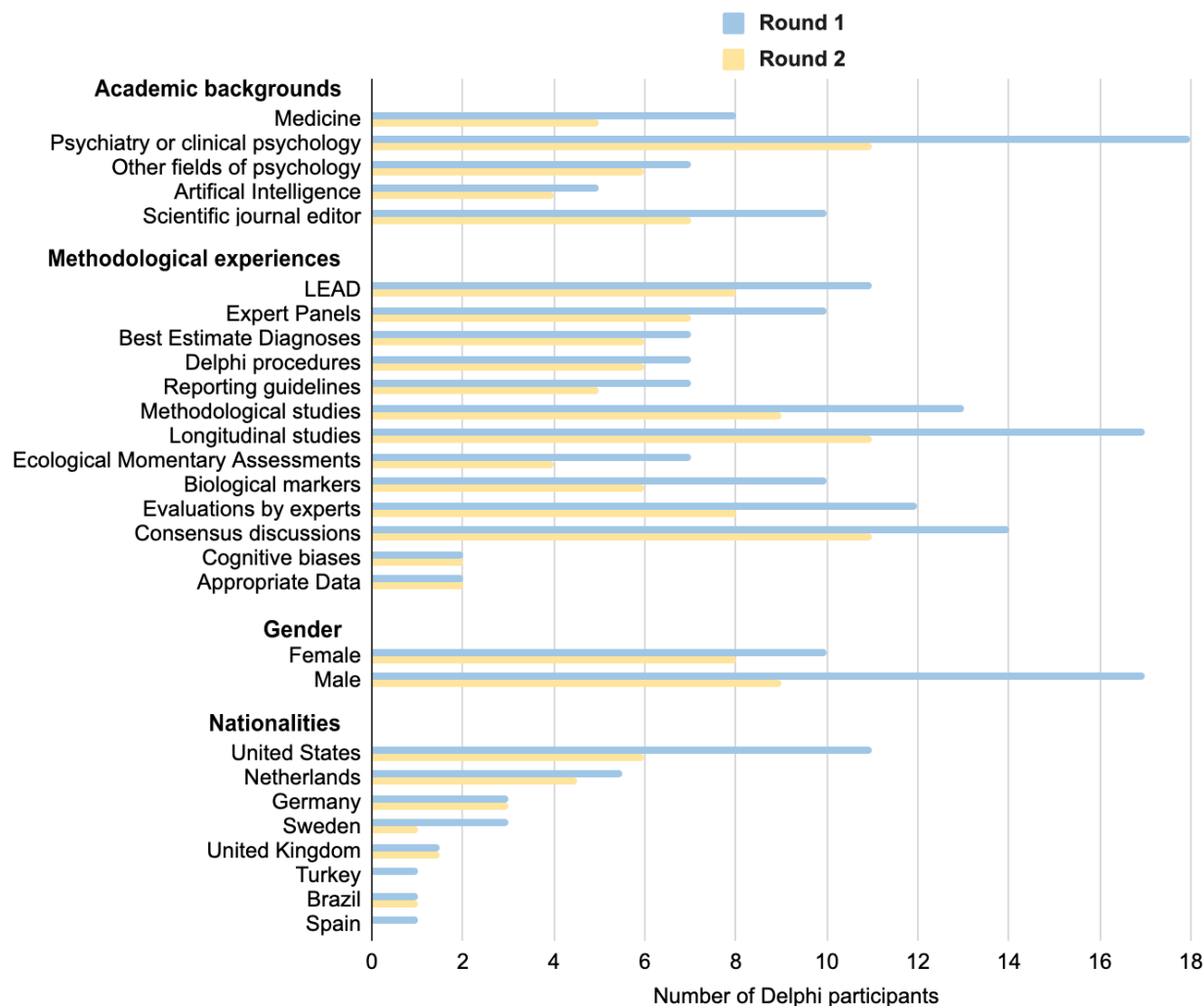


Figure 1 | Research experiences and demographics of the Delphi participants. In Round 2, the demographics and reported experiences are known for 17 of the 20 participants.

Delphi survey results. In Round 1, the mean ratings for the *item inclusion* scale ranged from 5.37 - 6.67 ($M = 6.06$; $SD = 0.31$; Table S2). The feedback resulted in the removal of one reporting standard and the clarification and reformulation of 20 standards. The standard *on Transparency and replicability* was rated as relevant but removed because it is achieved by reporting the other reporting standards. Standard 4.2 *Validity and Standard* needed a major clarification about the meaning of validity as well as standard. Minor clarifications and reformations, such as grammar, or word changes, were made for 19 standards. (see open material). The mean ratings in Round 2 ranged from 5.47 – 6.70 ($M = 6.20$; $SD = 0.37$; Table S3), with open feedback resulting in minor clarifications and reformulations of nine standards.

Refining the final guideline

The guideline was finalized by the authors in an expert consensus meeting. The meeting was held online with nine members of the working group and steering group. The content and structure of the consensus meeting were prepared by the working group, and the meeting was led by the last author (O.K.). Participants had access to the guidelines, elaboration and explanation (inclusion) rationales, and the drafted paper before the meeting, where they also had the option to provide comments and feedback in writing. The meeting

The LEADING Guideline Reporting Standards

included going through the findings of Delphi Rounds 1 and 2 and discussing the draft of the paper, including the individual reporting standards and groups. The criteria for including a reporting standard was that the median of Delphi expert responses was at least *Agree* on the question about its inclusion. We decided to not carry out another Delphi round since i) the median agreement for each reporting standard in both Delphi Rounds 1 and 2 ranged from *Agree* to *Strongly Agree*, ii) no new standards were suggested, and iii) only minor changes were needed after Round 2, which taken together suggest consensus.

Testing the guideline

After the Delphi rounds, the guideline was tested i) by researchers with experience of each method piloting the reporting of each standard and ii) by the authors (V.E., K.K.) using it to evaluate published articles. The two test procedures resulted in minor clarifications being added to three standards (2.4 *The access to the index measure*, 3.3 *Blindness and conflict of interest*, and 3.4 *Instructions and training*). Also, a concrete example of how to report the items was added to the general guideline instructions.

Incorporating test-user feedback. Two test users (Ph.D., with experience using the LEAD and Expert Panel method) who had not been involved in the development of the guideline (e.g., in the Delphi procedure) were recruited to test the guideline (see the SM for more details). They were asked to report each standard and/or provide feedback about the formulation of the standards.

Reports of the standards in 2022. Three separate targeted searches (LEAD, Expert-panel, Best-estimate) were conducted, and the first author examined which standards were reported in fifteen randomly selected articles applying the assessment methods in 2022. Out of the fifteen articles, three were randomly selected and examined by the second author. This procedure also provided information about the strengths and shortcomings of contemporary reporting of published articles using these methods (see Results section).

Results

The reporting guideline is presented in Table 1 (see Figure 2 for an overview). It comprises 20 standards for comprehensive reporting of the assessment methods divided into four groups: 1. *The Longitudinal design* group (4 standards), 2. *The Appropriate data* group (4 standards), 3. *The Evaluation – experts, materials, and procedures* group (10 standards), and 4. *The Validity* group (2 standards). The reporting standards encourage researchers to elaborate on what was done and why – whilst avoiding normative standards, such as a minimum number of experts. Each standard description in Table 1 is accompanied by an example. Further *Explanations and Elaborations* regarding the individual reporting standards and the four groups are presented in the SM including Table S4 and S5.

Table 1 | The LEADING guideline reporting standards

Group	#	Reporting standards
Longitudinal Design <i>Report the longitudinal design, by describing:</i>	1.1	The time period. The data collection period covered for each participant (i.e., start and end of the data collection) and to what extent the length is sufficient for capturing the targeted symptoms. <i>For example, the weeks/months a participant is followed and how this matches the criteria for the targeted disease/disorder.</i>
	1.2	The number of time points. Whether and how data were collected on multiple occasions between the start and the end of the time period, the sufficiency of the data collection, and of its frequency and intensity for capturing the target.

The LEADING Guideline Reporting Standards

		<p><i>For example, report the number of check-ins with the participants and the included measures for each assessment.</i></p>
	1.3	<p>History or lifetime information. Whether and which data from before the start of the data collection were taken into account and how these data are relevant for the assessment of the target.</p> <p><i>History or lifetime data may include self-report of medical history, childhood memory accounts, or other-than-self information such as from relatives or from medical records.</i></p>
	1.4	<p>The targeted time point(s) of the experts' assessment. The time point(s) for which the experts provide their assessment, on which time period the data of the assessments are based (i.e., past data, future data, or both), and justifications for the targeted time point(s).</p> <p><i>For example, the experts can assess the presence of a diagnosis at the start of the study and thus base their assessment on future data from that reference point; or in the middle of the study time period and thus have access to both past and future data from that reference point.</i></p>
	2.1	<p>The type and quality of the data. The type, quality, and relevance of the data and why these data sources are sufficient and suitable for capturing the target.</p> <p><i>For example, describe the validity and reliability of the data – and how it relates to capturing the targeted construct.</i></p>
Appropriate data	2.2	<p>The data triangulation. Whether and why the data come from different methodological approaches and the degree to which these approaches complement each other.</p> <p><i>For example, how self-reported data is complemented by objective/physical tests and/or other informant data.</i></p>
Report the appropriateness of the data, by describing:	2.3	<p>The data presentation. How the data were structured and presented to the experts for their assessments and why.</p> <p><i>For example, were the data presented in a case report; and was the information presented with or without any interpretation?</i></p>
	2.4	<p>The access to the index measure. For an assessment accuracy study, the extent the experts had access to the index measure and why (i.e., an assessment that is being compared to the best-estimate assessment), and how its information was weighted in their assessment.</p> <p><i>For example, were experts blind to the measure (its outcome and/or its raw data) that is being validated?</i></p>
	3.1	<p>The expert and panel characteristics. The characteristics of the experts and the panel, as well as how these characteristics are relevant for assessing the target.</p> <p><i>Relevant characteristics may include clinical and research experiences, professions, education, and demographics.</i></p>
Evaluation – experts, materials and procedures	3.2	<p>The number of experts and panels. The total number of experts and panels, and how many experts/panels were assessing each case and why.</p> <p><i>For example, how many and are the same expert(s)/expertise(s) present in every assessment?</i></p>
Report the evaluation experts, materials and procedures, by describing:	3.3	<p>Blindness and conflicts of interest. Whether and to what extent the experts are blind to the research aims and/or have any conflicts of interest.</p> <p><i>This may include experts' study authorship or the experts' relationship to the index measure or any other assessment method. If the study examines an index measure (i.e., an assessment that is being compared with the best-estimate assessment), declare the authors' as well as the experts' relationship to it.</i></p>
	3.4	<p>Instructions and training. The instructions, training, and/or preparation that the experts specifically received for this assessment task and why they did or did not receive this.</p> <p><i>For example, provide information regarding 1) whether the assessment method and procedure are kept standardized across the individual assessments, 2) the methods to ensure experts' preparedness for the assessment, or 3) any specific measures to limit biases.</i></p>
	3.5	<p>The assessment procedure. The procedure that the experts followed for their assessment.</p> <p><i>For example, describe whether there was a standardized procedure and what this procedure included (such as following clear diagnostic criteria).</i></p>

The LEADING Guideline Reporting Standards

	3.6	The assessment response format. The response format used by the experts for their individual assessments, what it included, and how it was structured. <i>For example, describe any assessment sheet, including assessment questions and answer options.</i>
	3.7	The data combination method. The method or guidelines for how the data should be weighted, judged, and combined by the individual experts to reach a conclusion in their individual assessment. <i>For example, should any data sources be evaluated first or weighted more strongly; or are the experts asked to assess certain diagnostic criteria/symptoms first, before forming a final diagnosis?</i>
	3.8	Independent expert assessments. Whether and how the experts first evaluated the data individually and made their first individual assessments independently. <i>For example, how it was ensured the experts first reviewed the data individually/independently before discussing their assessment outcome with the other panel members.</i>
	3.9	The inter-rater and inter-panel reliability. The inter-rater/inter-panel reliability, how it was calculated and evaluated, or why it was not possible to calculate it. <i>For example, which reliability metric was used and over how many experts/panels and cases the reliability was calculated.</i>
	3.10	The solution to disagreements. The approach for solving (any) disagreements between the individual expert assessments, the rationale for the chosen approach, and potential problems that may have occurred and how these were assessed. <i>Methods may include reaching a consensus, taking the average, or majority vote. Potential problems may, for example, include power imbalances in the expert panel.</i>
Validity	4.1	The assessment description. Description of <i>what</i> the assessment actually is. <i>For example, is the assessment a diagnosis, symptom severity assessment, course of illness assessment, or treatment response assessment?</i>
<i>Report what was assessed and how well, by describing:</i>	4.2	The validity and standard. Reflect on the degree of validity and describe the standard that the method aims to achieve, <i>how</i> well the assessment method measures up to that degree, and how it compares with current standards. <i>For example, reflect on evidence supporting or against validity aspects such as construct, face, and criterion validity; and state whether the assessment should be seen as a best-estimate assessment standard or an accepted reference standard (see Table S2 for more examples).</i>

Instructions. The LEADING guideline comprises these 20 reporting standards for comprehensive reporting of assessment methods involving expert(s) reviewing several sources of information (over time) to achieve a more accurate assessment (e.g., see Expert Panel, Best-Estimate diagnosis, and Longitudinal Expert All Data methods). The standards aim to help researchers plan, carry out, and report studies employing these assessment methods, as well as help readers evaluate them. As such, avoid simply answering yes or no to the standards when you instead can (succinctly) *describe* justifications and courses of action. Make sure the reports of the standards are clear, specific, and justified. To exemplify, standard 1.1 *The time period* could be reported as ‘*The time span was 6 weeks, which covers more than the 2 weeks a person should have the symptoms for meeting the criteria for Major Depressive Disorder according to the DSM-5.*’

Not all of the reporting standards will be applicable to all types of studies – however, it is typically better to describe how a standard is not applicable than to leave the information out. Since the guideline covers the reporting of the assessment method, the method section would suit the reporting of most standards in most cases. However, the reporting guideline does *not* standardize where standards should be reported (e.g., in the *Introduction, Methods, Results, or Discussion*), so when standards are considered less relevant or not applicable to a specific study, they can, for example, be described in an Appendix. Since the guideline focuses specifically on the reporting of the assessment method, it is recommended to use a complementary guideline for the reporting of the other study components: Which complementary guideline is dependent on the study type in which the assessment method is employed (e.g., see STARD for diagnostic accuracy studies; STROBE for observational studies; and CONSORT for randomised trials).

The LEADING Guideline Reporting Standards



Fig 2 | Overview of the LEADING guideline reporting standards. For more details about each standard, see Table 1.

Using the LEADING guideline to evaluate published studies

Evaluating a random selection of 15 articles indicates severe heterogeneity in *what* of the methods is reported and *how*, suggesting the need for a guideline that enables comprehensive reporting of these assessment methods (Table 3; see the SM for the search strategy). Across the fifteen studies, 18 to 58% of the standards were *not* reported. Regarding the reporting standards, the access to the index measure (2.4), the expert and panel characteristics (3.1), the number of experts and panels (3.2), and the assessment description (4.1) were mostly reported (green in 73-100% of the studies). However, the data presentation (2.3), the instructions and training (3.4), the data combination method (3.7), the inter-rater and inter-panel reliability (3.9), and the validity and standard (4.2) were *not* reported at all in the majority of the studies (red in 60-87% of the studies).

The LEADING Guideline Reporting Standards

Table 3 | Reports across the LEADING guideline standards in 15 randomly selected articles published in 2022

LEADING reporting standards	LEAD*					Expert Panel*					Best-Estimate Diagnosis*					green %	red %
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
1.1 The time period	green	orange	red	red	orange	green	green	orange	orange	green	green	green	orange	red	orange	47	20
1.2 The number of time points	orange	red	red	red	red	red	green	green	red	green	green	green	green	orange	orange	47	40
1.3 History or lifetime information	green	green	orange	green	green	orange	red	orange	green	orange	orange	green	orange	orange	orange	47	7
1.4 The targeted time point(s)	green	red	orange	orange	orange	green	green	green	green	orange	green	orange	orange	orange	orange	47	7
2.1 The type and quality of data	green	red	orange	orange	green	orange	green	green	red	green	green	green	green	orange	orange	60	13
2.2 The data triangulation	green	red	green	orange	orange	orange	orange	orange	red	green	orange	green	orange	orange	orange	27	13
2.3 The data presentation	red	red	red	red	orange	orange	green	red	red	green	red	red	red	red	red	13	73
2.4 The access to index measure	green	gray	gray	gray	green	green	green	green	orange	green	gray	gray	gray	green	gray	88	0
3.1 The expert and panel characteristics	green	green	orange	orange	red	green	green	green	green	green	orange	green	green	green	green	73	7
3.2 The number of experts and panels	green	green	red	red	red	green	green	green	green	green	green	green	green	orange	orange	73	20
3.3 Blindness and conflicts of interest	red	orange	orange	orange	red	green	red	orange	orange	red	orange	green	orange	orange	orange	20	33
3.4 Instructions and training	red	red	red	orange	red	red	green	orange	red	red	red	red	red	orange	orange	7	73
3.5 The assessment procedure	orange	orange	green	green	green	orange	green	green	green	orange	orange	green	green	green	green	60	0
3.6 The assessment response format	green	green	red	red	red	green	orange	red	orange	green	red	green	red	orange	red	33	47
3.7 The data combination method	red	red	red	red	red	orange	orange	red	red	red	red	red	red	red	red	0	87
3.8 Independent expert assessments	green	red	red	red	red	green	green	red	red	green	green	orange	red	red	red	40	53
3.9 The inter-rater and inter-panel reliability	red	red	red	red	orange	red	green	green	green	green	green	gray	red	red	red	29	64
3.10 The solution to disagreements	green	orange	red	red	red	green	orange	orange	green	green	red	gray	orange	orange	orange	36	29
4.1 The assessment description	green	green	green	green	green	green	green	green	green	green	green	green	green	green	green	100	0
4.2 The validity and standard	red	orange	red	red	orange	red	red	red	orange	green	red	orange	red	orange	red	7	60
green %	60	26	16	16	25	50	70	45	40	70	42	65	42	40	16		32 ¹
red %	30	47	58	53	45	20	15	30	35	15	32	18	32	30	37		33 ²

Notes. **red** = not reported; **orange** = insufficiently reported; **green** = (minimally) sufficiently reported; **gray** = not applicable to report. ¹ Mean of reporting standards; ² Mean of studies.

* Five articles for each assessment method were randomly selected (see SM for search strategy): 1 = Morrisson et al. (2022)¹⁴; 2 = Mackenhauer et al. (2022)⁵⁵; 3 = Hendriks et al. (2022)⁵⁶; 4 = Paap et al. (2022)⁵⁷; 5 = Aydin et al. (2022)⁵⁸; 6 = Sadleir et al. (2022)⁵⁹; 7 = Khan et al. (2022)⁶⁰; 8 = Blackmore et al. (2022)¹³; 9 = Loots et al. (2022)⁶¹; 10 = Leroux et al. (2022)⁶²; 11 = Peterson et al. (2022)⁶³; 12 = Reiersen et al. (2022)⁶⁴; 13 = Bradshaw et al. (2022)⁶⁵; 14 = Hesam-Shariati et al. (2022)⁶⁶; 15 = Shima et al. (2022)⁶⁷.

The first author (V.E.) reviewed reports of the standards across the fifteen randomly selected articles published in 2022 (i.e., five from each method). Each reporting standard was rated using four categories: standard not reported (red); standard reported vaguely or insufficiently (orange); standard (minimally) sufficiently reported (green); or standard not applicable to the study (gray). The second author (K.K.) reviewed one randomly selected article from each method; there were no disagreements between red versus green (only between orange and red/green/gray). Discussing their disagreements to reach consensus resulted in changing six ratings (10%) of the first author: one change from orange to red; one change from red to orange; one change from orange to green; and three changes from green to orange. Considering that most changes were from green to orange, and that green refers to a *minimal* description, this suggests that the table is conservative in regards to the severity of the current state of poor reporting (i.e., potentially showing a more positive picture; for more information see the SM).

Discussion

Our objective was to develop a guideline that supports comprehensive reporting of studies collecting longitudinal, appropriate data that experts evaluate to achieve an assessment that is more accurate than using a single error-prone measure. The aim is to help researchers plan, report, and evaluate the assessment method-related elements of their study design.

The LEADING reporting standards were established through an open process, incorporating relevant empirical evidence and methodological work, complementary reporting guidelines, and comprehensive iterations of expert feedback and patients' perspectives. As this guideline focuses on the assessment methods, we recommend that researchers also rely on established guidelines for other parts of their research, such as sampling and other epidemiological aspects (e.g., STROBE⁴⁸, CONSORT⁵⁰, and STARD⁴⁹). We encourage knowledge about and adherence to the LEADING guideline via scientific journals, editorials, and the EQUATOR network, as well as inclusion in research method courses in clinical studies.

Limitations

Based on the expertise of the author group and our literature search, we identified three assessment methods with similar approaches from related fields and drafted applicable reporting standards. We presented the rationale for selecting these three methods and each reporting standard with supporting evidence in the Delphi survey for review, which did not bring up additional methods or reporting standards. However, as we did not carry out a systematic literature review of the three identified literature bodies or for each of the reporting standards, we cannot exclude the existence of other assessment methods with similar approaches. We welcome any suggestion about similar methods to which the guideline is applicable.

Although the Delphi survey participants and the author group had a wide range of experiences and backgrounds, psychiatry and clinical psychology ($n = 18$) were overrepresented as compared to, for example, other areas of medicine ($n = 8$) in the Delphi and author group. Geographically, Europe and North America were the most common in the Delphi and author group, whereas several areas were not represented. The Delphi participants were the first or last authors of studies employing the assessment methods. However, the quality of the articles, and the education or experience of the authors, were not taken into account as selection criteria (although it was self-reported as presented in Figure 1). Finally, the number of Delphi participants (27 in Round 1, 20 in Round 2) is relatively small compared to some other standard developments (e.g., 73 in the development of STARD⁶⁸), but it is comparable to others (e.g., 24 for development of the TRIPOD statement⁵¹). Even though the response rate in Round 1 (21%) can be considered low, the number of participants was sufficient to cover a broad range of academic backgrounds, methodological experiences, and demographics (Figure 1). The same limitation is applicable to the size of the steering group ($n = 7$) as well as the test-user group ($n = 2$). The LEADING guideline should be regarded as an evolving reporting guideline requiring ongoing evaluation, refinement, and revision. Suggestions and recommendations for improvements are welcomed by emailing the corresponding authors.

Conclusions

The LEADING guideline emphasizes the transparent reporting of the methodological components of the assessment method, and the importance of reporting *what* was assessed and *how* well. Considering the increasing need for high-accuracy assessments in diverse fields, we hope that the LEADING guideline will

be useful in assisting researchers in planning, carrying out, reporting, and evaluating research that aims to achieve accurate assessments.

Data sharing statement

Open data (Delphi surveys 1 and 2), code (analyses), and material (surveys) can be found on the Open Science Framework: <https://osf.io/fkv4b/>

Patient and Public Involvement statement

Prior to the Delphi procedure, the reporting standards with inclusion rationales were discussed in an online workshop with a patient organization for depression (the chairman and vice chairman from Libra Balans Skåne), followed by receiving feedback from the steering group members to receive a wide range of perspectives early in the process.

Acknowledgment

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The LEADING Guideline Reporting Standards

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Competing Interests

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Contributorship statement

The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Contributor Roles

E = Equal; S = Supporting; L = Lead

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The LEADING Guideline Reporting Standards

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Transparency declaration

The lead author (the manuscript’s guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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