3-6-2023

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JAMA Network Open

Original Investigation | Health Informatics

Evaluation of Risk of Bias in Neuroimaging-Based Artificial Intelligence Models for Psychiatric Diagnosis
A Systematic Review

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Abstract

IMPORTANCE Neuroimaging-based artificial intelligence (AI) diagnostic models have proliferated in psychiatry. However, their clinical applicability and reporting quality (ie, feasibility) for clinical practice have not been systematically evaluated.

OBJECTIVE To systematically assess the risk of bias (ROB) and reporting quality of neuroimaging-based AI models for psychiatric diagnosis.

EVIDENCE REVIEW PubMed was searched for peer-reviewed, full-length articles published between January 1, 1990, and March 16, 2022. Studies aimed at developing or validating neuroimaging-based AI models for clinical diagnosis of psychiatric disorders were included. Reference lists were further searched for suitable original studies. Data extraction followed the CHARMS (Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modeling Studies) and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines. A closed-loop cross-sequential design was used for quality control. The PROBAST (Prediction Model Risk of Bias Assessment Tool) and modified CLEAR (Checklist for Evaluation of Image-Based Artificial Intelligence Reports) benchmarks were used to systematically evaluate ROB and reporting quality.

FINDINGS A total of 517 studies presenting 555 AI models were included and evaluated. Of these models, 461 (83.1%; 95% CI, 80.0%-86.2%) were rated as having a high overall ROB based on the PROBAST. The ROB was particular high in the analysis domain, including inadequate sample size (398 of 555 models [71.7%; 95% CI, 68.0%-75.6%]), poor model performance examination (with 100% of models lacking calibration examination), and lack of handling data complexity (550 of 555 models [99.1%; 95% CI, 98.3%-99.9%]). None of the AI models was perceived to be applicable to clinical practices. Overall reporting completeness (ie, number of reported items/number of total items) for the AI models was 61.2% (95% CI, 60.6%-61.8%), and the completeness was poorest for the technical assessment domain with 39.9% (95% CI, 38.8%-41.1%).

CONCLUSIONS AND RELEVANCE This systematic review found that the clinical applicability and feasibility of neuroimaging-based AI models for psychiatric diagnosis were challenged by a high ROB and poor reporting quality. Particularly in the analysis domain, ROB in AI diagnostic models should be addressed before clinical application.

JAMA Network Open. 2023;6(3):e231671. doi:10.1001/jamanetworkopen.2023.1671

Key Points

Question Are there potential risks to translating neuroimaging-based artificial intelligence (AI) models into direct clinical applications, such as psychiatric diagnosis?

Findings In this systematic review of 517 studies presenting 555 neuroimaging-based AI models for psychiatric diagnostics, most models had a high overall risk of bias and had poor clinical applicability. All articles provided incomplete reports for validation.

Meaning Findings of this study suggest that, in their current form, neuroimaging-based AI models for psychiatric diagnosis need to address risk of bias before use in clinical practice.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Introduction

Given the lack of biomarkers to guide psychiatric diagnoses, machine learning has been increasingly applied to develop brain-based hallmarks. Thus, neuroimaging-based artificial intelligence (AI) models have proliferated rapidly during the past 3 decades. Rather than enabling a clinician-based diagnosis of discrete symptoms, neuroimaging-based AI models enable an objective, symptom-centered, individualized and neurobiologically explicable estimate of psychiatric conditions.[1,2] In this vein, these models show considerable potential to be translated for use in early diagnosis, treatment development, and clinical decision-making.[3-7] However, lack of an evidence-based systematic appraisal of AI models impedes stakeholder enthusiasm for applying them in clinical practice.[8,9]

Systematic appraisals of clinical AI models may provide solid evidence to validate their reliability in medical practice. For instance, despite global efforts to develop AI diagnostic models for COVID-19, these models built either through traditional multivariable analysis or imaging-based AI technique were found to have poor clinical implications due to a high risk of bias (ROB).[10,11] Furthermore, systematic appraisals revealed the high ROB in clinical models across all medical specialties, especially in psychiatric diagnoses.[12,13] During the past 3 decades, advances in neuroimaging-based techniques opened radically new venues for psychiatric diagnosis by providing potentially more reliable and sensitive brain biomarkers in AI prediction models.[14,15] Despite their strengths, the absence of systematic appraisals for biomarker-based AI models leaves a gap between the experimental proof-of-concept models and clinical applicability.

In addition, poor reporting quality impedes the establishment of better practices in AI-based psychiatric diagnosis. Despite the developments of multifarious benchmarks for reporting clinical prediction models (eg, STARD [Standards for Reporting of Diagnostic Accuracy], DECIDE-AI [Early-Stage Clinical Evaluation of Decision Support Systems Driven by Artificial Intelligence], and TRIPOD [Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis]),[16-19] the reporting quality in current publications still needs to be improved, with approximately 80% of articles providing incomplete information and less than 50% of contents following the TRIPOD guideline, limiting clinical potential and contributing to research waste.[20-22] Even after 3 decades of neuroimaging-based AI model developments, it remains unclear whether the reports of such developments are unbiased and complete enough to warrant translation into clinical practice for psychiatric diagnosis.

In this study, we sought to systematically assess the ROB and reporting quality of neuroimaging-based AI models for psychiatric diagnosis that were developed in the past 3 decades. To this end, we used the Prediction Model Risk of Bias Assessment Tool (PROBAST) and modified Checklist for Evaluation of Image-Based Artificial Intelligence Reports (CLEAR) benchmarks.[23,24]

Methods

The study protocol was registered at PROSPERO (CRD42022340624) and followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline (**Figure 1**[25-541]).[542,543] The Chinese Army Medical University Institutional Review Board officially censored the study and deemed it exempt from approval and the requirement for informed consent given that no original human or animal participants were involved.

Retrieval Strategy

Following retrieval benchmarks,[543,544] we conducted a literature search in PubMed in June 2022 using Boolean codes and RSS (Really Simple Syndication) feeds (eMethods 1 in Supplement 1). We initially included studies that (1) were published between January 1, 1990, and March 16, 2022; (2) were peer-reviewed, full-length original articles published in journals or conference proceedings; and (3) developed or validated neuroimaging-based AI models for diagnosing psychiatric diseases that were defined in the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition).

We screened studies from the initial literature pool by following these inclusion criteria: (1) at least 1 algorithm was used to build the AI model for psychiatric diagnosis; (2) training features were limited to neuroimaging-based biomarkers (eg, [functional] magnetic resonance imaging, electroencephalogram, and functional near-infrared spectroscopy); and (3) minimum fundamental information for the AI model was reported. Reference lists were further searched for suitable original studies. Exclusion criteria were articles that (1) were not peer-reviewed original research (eg, preprint, review, meta-analysis, or comments), (2) involved non–neuroimaging-based features (eg, behavioral factors or blood and genes) or nonhuman participants, (3) used nondiagnostic AI models (eg, prognostic model) for unclassified psychiatric disorders, and (4) used discriminatory AI algorithm that differentiated cohorts rather than diagnosed psychiatric conditions.

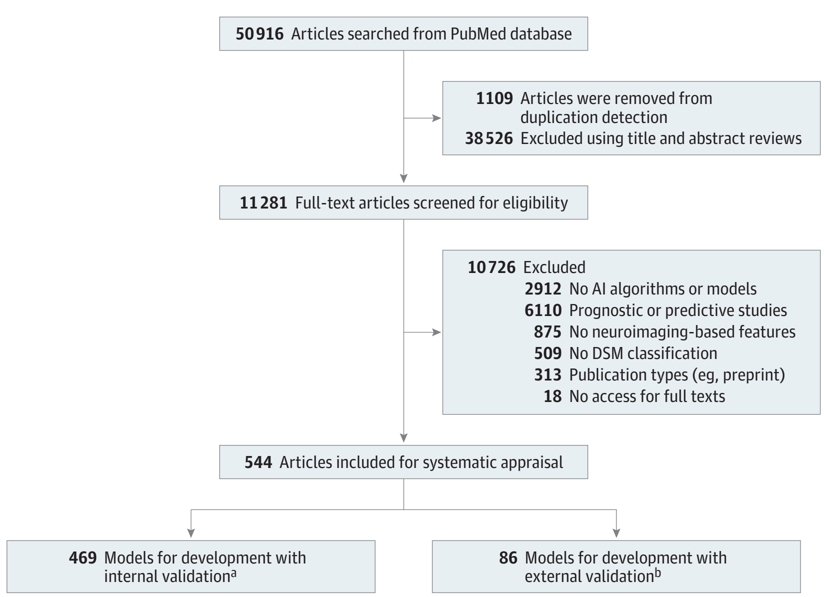
Data Extraction and Analysis

Data extraction adhered to the CHARMS (Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modeling Studies) and PRISMA guidelines.[19,544] We used a closed-loop cross-sequential design for quality control on data extraction and screening (5 assessors). Details on data extraction are provided in eMethods 2 and 3 in Supplement 1.

We built on a global geospatial model to illustrate the distribution of the sample population for these AI models. Sample population was defined according to information in the original article if applicable (eMethods 3 in Supplement 1). Global geospatial map was constructed by first fine-grained classification, which included 251 countries or regions. Geospatial source data were adjusted by the United Nations Statistics Division M49 codes and EasyShu team.

The PROBAST[24] was used to assess the ROB of the neuroimaging-based AI models for psychiatric diagnosis. The PROBAST encompassed 20 signaling questions covering 4 ROB domains: participants, predictors, outcome, and analysis. Each question may be answered by yes, probably yes, no, probably no, or no information. Answering *no* or *probably no* to a signaling question indicated a potential high ROB. Overall ROB was rated high if a *no* or *probably no* answer was given for any signaling question. Overall low ROB was defined as answering all of the signaling questions with a *yes* or *probably yes*. The PROBAST criterion was modified to assess its applicability to each included

Figure 1. Evidence Review Pipeline Based on PRISMA 2020 Guideline



DSM indicates *Diagnostic and Statistical Manual of Mental Disorders*.

[a] Of the 555 artificial intelligence (AI) models, 469 were tested at the internal sample and 86 at the independent external sample, including intellectual disability,[25-28] autism spectrum disorder,[29-147] attention-deficit/hyperactivity disorder,[44,51,72,148-381] bipolar disorder,[290,314,321,327,328,339,343,346,382-406] major depressive disorder,[309,346,359,363,381,405,407-473] social anxiety disorder,[474-477] unspecified anxiety disorder,[346,478,479] general anxiety disorder,[480] obsessive-compulsive disorders,[346,481-496] posttraumatic stress disorder,[346,409,497-503] somatic symptom disorder,[504] anorexia nervosa,[505-507] binge-eating disorder,[508] insomnia disorder,[509,510] conduct disorder,[511-513] antisocial personality disorder,[514-516] other or unknown substance use disorder,[517-520] alcohol use disorder,[346,521-536] opioid use disorder,[537] borderline personality disorder,[538-540] disruptive behavior disorders,[541] and social anxiety disorder.[346]

[b] Eighty-six AI models[30,32,34,36,42,44,46,53,59-61,63,69,70,72,81,82,88,91,117,149,151,156,162-164,169,170,172,180,182,187,191,197,212,213,220,221,247,254,258,260,261,263,269,272,278,280,283-285,287,290,301,305,307,319,335,352,353,355,356,359,385,407,417,422,443,452,454,483,484,510,519,526,532,534] were tested at the independently external sample.

study by adding 1 signaling question for the first 3 ROB domains (participants, predictors, and outcome) (eMethods 4 in Supplement 1)

We adopted the modified 25-item CLEAR statement[23] to evaluate the reporting quality (ie, feasibility) of the included studies, which included 4 domains (data, technique, technical assessment, and applications). To ensure applicability to neuroimage-based AI models, we removed 3 items (eMethods 5 in Supplement 1). The eligible 22 items were transformed for signaling questions to form the modified CLEAR statement (eTable 1 in Supplement 1). The CLEAR criteria for assessing the overall reporting quality of these studies were fully in line with the PROBAST.

To ensure adequate assessment validity, 5 independent assessors with multidisciplinary expertise were involved, including a clinical psychiatrist (Y.Y.), research fellows for psychiatry (X.L.) and AI (K.M.), a neuroscientist (Z.G.), and a psychologist (Z.C.). We built a closed-loop cross-sequential framework for validating assessment quality. Furthermore, another independent assessor (C.L.) was invited to validate assessment quality (eMethods 6 in Supplement 1).

Statistical Analysis

Geospatial models were built using R packages, version 4.0.5 (R Core Team). Interactive interfaces for sample population map were generated from EasyShu, version 2.4 (EasyShu) and coded with C++. Bootstrapping simulation (n = 2000) was performed to estimate 95% CIs for proportions using MATLAB (MathWorks Inc). Cohen κ test was also conducted to quantify the reliability of assessment quality across these 5 subsets. A prior 2-sided significance level for these statistics was set as $P = .05$.

Results

A total of 517 studies presenting 555 development-purpose AI models were eligible for inclusion in the analysis[25-541] from the 50 916 records that were retrieved from the PubMed search in June 2022. Of the 555 models, 469 (84.5%) were for internal-sample validation[25-29, 31, 33, 35, 37-41, 43, 45, 47-52, 54-58, 62, 64-68, 71, 73-80, 83-87, 89, 90, 92-116, 118-127, 129-134, 136, 139-145, 147, 148, 150, 152-155, 157-161, 165-168, 171, 173-179, 181, 183-186, 188-196, 198-211, 214-219, 222-246, 248-253, 255-257, 259, 262, 264-268, 270, 271, 273-277, 279, 281, 282, 286, 288, 289, 291-300, 302-304, 306, 308-318, 320-334, 336-351, 354, 357, 358, 360-384, 386-406, 408-416, 418-442, 444-451, 453, 455-469, 471-482, 485-502, 504-509, 511-518, 520-525, 527-531, 533, 535-541] and 86 (15.5%) were for external-sample validation[30, 32, 34, 36, 42, 44, 46, 53, 59-61, 63, 69, 70, 72, 81, 82, 88, 91, 117, 128, 135, 137, 138, 146, 149, 151, 156, 162-164, 169, 170, 172, 180, 182, 187, 197, 212, 213, 220, 221, 247, 254, 258, 260, 261, 263, 269, 272, 278, 280, 283-285, 287, 290, 301, 305, 307, 319, 335, 352, 353, 355, 356, 359, 385, 407, 417, 422, 443, 452, 454, 470, 483, 484, 503, 510, 519, 526, 532, 534] (Figure 1). Based on the United Nations Statistics Division classification, the samples for training or testing these models covered 15.5% (39 of 251) of countries or areas globally (**Figure 2**), with 97.5% (38 of 39) of samples located in high-income or upper-middle-income areas.

Nearly half of the models (48.3% [268 of 555]) were found in studies authored by those with academic training in computers and data science[27, 32-37, 39-42, 44-48, 50, 52, 58, 70-73, 75, 76, 79, 82, 85, 87, 89, 90, 92, 93, 95, 96, 99-118, 121, 123, 128-130, 132-136, 139, 141, 142, 144, 146, 151, 152, 156, 161-164, 166-168, 170, 173, 175-177, 179, 180, 182, 184, 185, 187, 190, 193, 195, 200, 202, 204-206, 208-210, 212, 214, 220, 224-228, 230, 232-235, 239, 240, 245, 247, 250, 251, 256, 257, 259, 260, 263, 266, 271, 272, 275-277, 283, 288, 289, 293, 297, 301-303, 306, 308, 311, 313, 314, 316, 318-320, 323-326, 328-336, 339-341, 344, 345, 348, 350, 353, 354, 357-359, 362, 365-380, 392, 394, 399, 401-403, 410, 411, 413-416, 425, 430-433, 436, 440, 445-449, 451, 452, 455-457, 462, 463, 465, 466, 469, 470, 472, 476, 478-480, 484, 488-491, 496, 510-513, 516, 519, 520, 523, 525, 526, 530, 531, 533-535, 537, 539, 541] (eTable 2 in Supplement 1). Schizophrenia (25.4% [141 of 555 models])[247-381] and autism spectrum disorder (21.4% [119 of 555 models])[29-147] were the most common psychiatric diseases to be diagnosed with these models (eTable 3 in Supplement 1). Full technical details are provided in eTables 3 to 9 in Supplement 1. Assessor reliability quality was found to be satisfied, with an acceptable Cohen κ coefficient mean of 0.68 (median [range], 0.96 [0.02-1.00]) across 5 subset pools (eMethods 6 in Supplement 1).

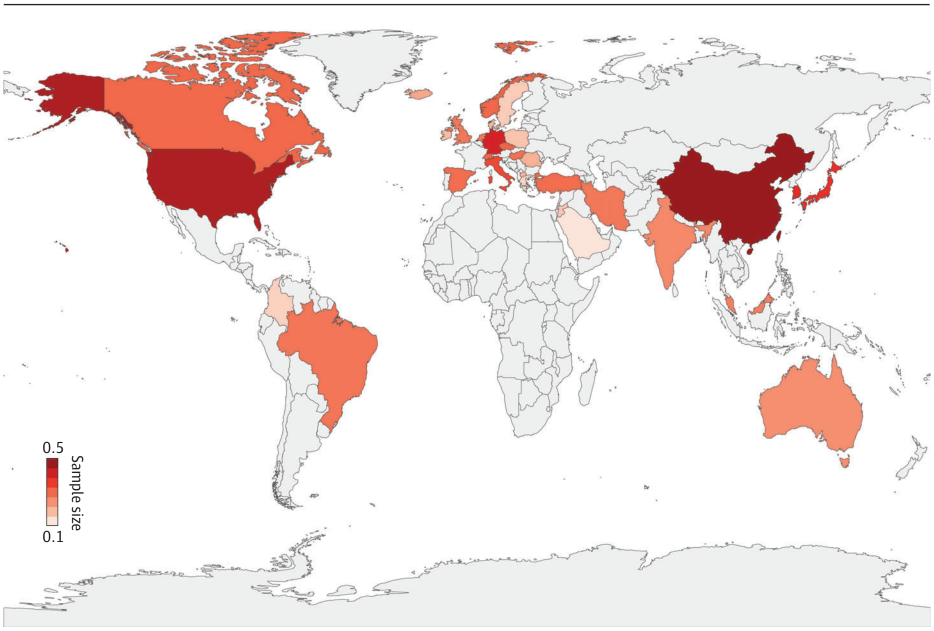
Overall ROB for AI Models

In total, 461 of 555 AI models (83.1%; 95% CI, 80.0%-86.2%) were rated as having high overall ROB.[25,32-41,43-50,52-60,62-69,71-81,83,85,87-92,94-111,113-124,126-130,133,135,136,141,142,145,146,148,149,151,153,155,156,158,161,163,166-170,172-177,179-183,186,187,189-193,195,197-212,214-227,229,230,232-242,245-247,249,251-253,256-260,262,264,265,268,270,273-281,283-322,324-336,338-345,347-370,372-426,428-435,439-462,464-473,475,477-480,482-485,487,491,493,495,498,500,502-505,507-513,515-517,519-533,536-541] Two of 555 models (0.4%; 95% CI, 0.00%-0.01%) were rated with high overall ROB in the participants domain.[26,31] Overall, the ROB in the participants domain remained low for existing neuroimaging-based AI diagnostic models.

In the predictors domain, 187 of 555 models (33.7%; 95% CI, 29.9%- 37.6%) were rated with high ROB[37,38,47,55-57,59,60,62,68,69,78,79,81,85,89,92,99,100,104,107,113,115,117,121,129,130,133,135,136,148,150,154,158,160,161,167,169,170,173,175,178,183,190,191,193,195,197,201,204,206,207,210,212,215,216,224,225,229,232-235,238,240,242,247,251,253,257,260,274,277,279,283,285,286,290,295,299,303-307,317-320,322,326,332-336,339,340,345,347,349-353,357,358,360,363-365,376,385,388-393,398,400,402-406,409-411,413,415-418,421,423-426,428-430,433,434,441,442,444,449,451,452,459,461,464,466,468,472,475,478,484,488,491,493,502,504,505,516,529,532,533,537,538,540,541] (**Table 1**). Defining predictors by knowing the outcome of these models was the unique source of the high ROB in this domain (ie, signaling question 2.2: were predictor assessments made without knowledge of outcome data?). In the outcome domain, high ROB was scored for 198 of 469 models (35.7%; 95% CI, 31.8%-39.7%)[26,32,33,35-37,39,41,44,45,48,53-57,59,60,62,68,69,78,79,81,85,89,92,99,100,104,107,113,115,117,121,129,130,133,135,136,148,150,154,158,160,161,167,169,170,173,175,178,183,190,191,193,195,197,201,204,206,207,210,212,215,216,224,225,229,232-235,238,240,242,247,251,253,257,260,274,277,279,283,285,286,290,295,299,303-307,317-320,322,326,332-336,339,340,345,347,349-353,357-360,363-365,376,385,388-393,398,400,402-406,409-411,413,415-418,421,423-426,428-430,433,434,441,442,444,449,451,452,459,461,464,466,468,472,475,478,484,488,491,493,502,504,505,516,529,532,533,537,538,540,541] (Table 1). These models had a high ROB because the outcome knowledge of testing data sets was leaked into the predictors of the training set (ie, signaling question 3.3: were predictors excluded from the outcome definition?).

In the analysis domain, most models were rated as having high overall ROB (461 of 555 [83.1%; 95% CI, 80.0%-86.2%]).[25,32-41,43-50,52-60,62-69,71-81,83,85,87-92,94-111,113-124,126-130,133,135,136,141,142,145,146,148,149,151,153,155,156,158,161,163,166-170,172-177,179-183,186,187,189-193,195,197-212,214-227,229,230,232-242,245-247,249,251-253,256-260,262,264,265,268,270,273-281,283-322,324-336,338-345,347-370,372-421,423-426,428-435,439-462,464-473,475,477-480,482-485,487,491,493,495,498,500,502-505,507-513,515-517,519-533,536-541] Inadequate

Figure 2. Geospatial Model for Sample Population



Total sample sizes for countries were geologically mapped into corresponding location in the global map. To improve readability, original total sample size underwent log-transformation.

sample size (398 of 555 [71.7%; 95% CI, 68.0%-75.6%]),[25-31, 33, 35, 37-41, 43, 45, 46, 48, 49, 54-61, 64-67, 70, 71, 73, 77, 79, 80, 82-85, 87-92, 94-101, 106, 108, 110, 111, 113, 114, 119, 120, 122, 124, 126, 128, 129, 133-135, 137, 138, 141-144, 146-149, 151-153, 155, 156, 161, 163, 164, 166, 169, 171, 172, 174, 175, 177-180, 182, 183, 185-191, 194, 195, 197, 199, 203-205, 207, 209-212, 214-220, 222-227, 229, 230, 232, 233, 236, 237, 239-243, 246, 247, 249, 250, 252, 256-267, 269, 270, 274, 277-279, 281-283, 285-297, 300-304, 307, 309-311, 313-316, 320-325, 328-336, 338, 340-345, 347-356, 358, 359, 361, 364, 366, 369-390, 392, 393, 396-401, 403-417, 419-421, 423-445, 447-452, 454, 456, 459-462, 464-469, 472, 473, 477, 480, 482-484, 487-490, 492-496, 498, 501-504, 507, 508, 512, 513, 515-517, 519-532, 536-540] poor model performance examination (with 100% of models lacking calibration examination), and lack of handling data complexities (550 of 555 [99.1%; 95% CI, 98.3%-99.9%],[27,28,31-541] with the majority of models undergoing no adjustment on data complexities [eg, signal question 4.6: were complexities in the data, such as censoring, competing risks, and sampling of control participants, accounted for appropriately?]) all contributed to the potential high ROB of these AI models in the analysis domain (Table 1). Although almost all of the models were rated with high ROB on calibration and data complexities issues, 52 models[27, 28, 31, 42, 51, 61, 70, 82, 84, 86, 93, 112, 132, 139, 171, 184, 213, 228, 231, 243, 244, 248, 250, 254, 255, 261, 263, 266, 269, 271, 272, 282, 323, 337, 346, 371, 422, 436-438, 463, 474, 476, 481, 486, 506, 514, 518, 534, 535] were still rated with low overall ROB in the analysis domain because these issues were judged as having limited implications for the models.

Table 1. ROB Assessment for All Included AI Models Using the PROBAST (N = 555)

Signaling question[a]	Answers, No. (%) Yes or probably yes	No information	No or probably no
Domain 1: participants			
Were appropriate data sources used (eg, cohort, RCT, or nested case-control study data)?	555 (100.0)	0	0
Were all inclusions and exclusions of participants appropriate?	553 (99.6)	0	2 (0.4)
Domain 2: predictors			
Were predictors defined and assessed in a similar way for all participants?	555 (100.0)	0	0
Were predictor assessments made without knowledge of outcome data?	368 (66.3)	0	187 (33.7)
Were all predictors available at the time the model was intended to be used?	555 (100.0)	0	0
Domain 3: outcome			
Was the outcome determined appropriately?	555 (100.0)	0	0
Was a prespecified or standard outcome definition used?	555 (100.0)	0	0
Were predictors excluded from the outcome definition?	357 (64.3)	0	198 (35.7)
Was the outcome defined and determined in a similar way for all participants?	555 (100.0)	0	0
Was the outcome determined without knowledge of predictor information?	358 (64.5)	0	197 (35.5)
Was the time interval between predictor assessment and outcome determination appropriate?	555 (100.0)	0	0
Domain 4: analysis			
Was there a reasonable number of participants with the outcome?	157 (28.2)	0	398 (71.7)
Were continuous and categorical predictors handled appropriately?	555 (100.0)	0	0
Were all enrolled participants included in the analysis?	393 (70.9)	0	162 (29.1)
Were participants with missing data handled appropriately?	44 (7.9)	37 (6.6)	474 (85.5)
Was selection of predictors based on univariable analysis avoided?	355 (63.9)	0	200 (36.1)
Were complexities in the data (eg, censoring, competing risks, and sampling of control participants) accounted for appropriately?	0	5 (0.9)	550 (99.1)
Were relevant model performance measures evaluated appropriately?	0	0	555 (100.0)
Were model overfitting and optimism in model performance accounted for?	497 (89.5)	16 (2.8)	42 (7.7)
Did predictors and their assigned weights in the final model correspond to the results from the reported multivariable analysis?	53 (9.6)	0	502 (90.4)

Abbreviations: AI, artificial intelligence; PROBAST, Prediction Model Risk of Bias Assessment Tool; RCT, randomized clinical trial; ROB, risk of bias.

[a] The criteria for answering the signaling questions largely adhered to the PROBAST but were slightly modified to fit the current study (eMethods 4 in Supplement 1).

Clinical Applicability Concerns in AI Models

In total, by using the PROBAST, a third of the models were assessed for high concerns about their clinical applicability in the predictors and outcome domains. High concern for clinical applicability in the participants domain was found for 2 of 555 models (0.4%; 95% CI, 0.00%-0.01%).[26,31] Furthermore, high concerns regarding clinical applicability were found for 199 of 555 models (35.9%; 95% CI, 31.9%-39.9%) in the predictors domain[25,33,35,37,39,41,44,45,48,53-57,59,60,62,78-81,85,89,92,99,100,104,107,113,115,117,121,122,129,130,133,135,136,148,150,154,158,160,161,167,169,170,172,173,175,178,183,190,191,193,195,197,201,204,206,207,210,212,215,216,224,225,229,232,233,235,238,240,242,247,251,253,257,260,274,277,279,283,285,286,290,295,299,303,305-307,312,317-320,322,326,332-336,339,340,345,347,349-353,357-360,363-365,376,385,388-393,398,400,402-406,409-411,413,415-418,421,423-426,428-430,433,434,441,442,444,449-452,458,459,461,464,466,468,472,475,478,484,488,491,493,502,504,505,516,529,532,533,537,538,540,541] and for 217 of 555 models (39.1%; 95% CI, 35.0%-43.2%) in the outcome domain.[26,32,34-37,39,41,44,45,48,53-57,59,60,62,68,69,75,78,79,81,85,89,92,99,100,104,107,113,115-117,121,129,130,133,135,136,148,150,154,158,160,161,167,169,170,173,175,178,183,190,191,193,195,197,201,204,206,207,210,212,215,216,224,225,229,232-235,238,240,242,247,251,253,257,260,274,277,279,283,285,286,288,290,295,297-300,303-308,311,315-320,322,326,332-336,339,340,343,345,347,349-353,357,358,360,363-365,367,373,376,382,385,388-393,398,400,402-406,409-411,413,415-418,420-426,428-430,433,434,436,441,442,444,446,449,451,452,459,461,464,466,468,472,475,478,484,488,491,493,502,504,505,516,520,529,532,533,537,538,540,541] In addition, none of these AI models were perceived to be applicable to clinical practice to date.

Reporting Quality of AI Models

Overall, all models were assessed for poor reporting quality based on the modified CLEAR statement. Reporting completeness (ie, number of reported items/number of total items) for these AI models was found to be insufficient at 61.2% (95% CI, 60.6%-61.8%). Full results for reporting quality are presented in **Table 2**.

All of the models showed overall poor reporting quality in the data domain across 13 signaling questions. Lack of reporting for how to handle out-of-distribution images was the main source of the poor reporting quality rating in the data domain. In addition, 378 of 555 models (68.1%; 95% CI, 64.2%-72.0%) lacked reports for quality control (eg, signaling question: was how to handle neuroimaging artifacts reported?), incurring a low reporting quality rating.[27,28,31-33,35-42,46,49-51,53,54,56-58,61,63,64,68-78,80,87-91,94,96-98,100,101,103,105,112-115,121,122,125,127,129,134,137,138,141-144,147,149,154-158,160-162,164,165,170-177,179-182,185-191,193-196,199,203,207,209,210,214,215,217,219,222,223,226-239,242-246,248-261,263-265,268,269,271-284,286-291,293-295,297-303,305,306,308-315,321,323-327,332-342,344-347,349,351,353,355-358,360-366,368-370,372-375,377-380,382-385,387-392,394-402,404-407,409-421,425-430,433-438,440-447,449-454,457-467,469,471,472,475-477,479-483,485,487,489-494,496-498,501,504,508,509,511,513-516,518-520,526,528,530-537,539,540] Overall, a mean 58.9% (95% CI, 58.0%-59.7%) of models required contents in the data domain.

Approximately half of the models (258 of 555 [46.48%; 95% CI, 42.3%- 50.6%]) were assessed for poor reporting quality in the technique domain across 3 signaling questions.[25,28,29,33-35,44,45,47-49,51,53,54,56,59,60,62,66,73,75,78,79,81,83,84,95,99,100,107,114,117,122,124,126,128-131,133,135,137,142,144-148,151,153,155,159,161,163,165-167,169,171,173,174,177,179,183,184,197,199,201-204,206-208,210-213,216,217,221,224,225,229,231,233-237,243,245-248,253,255,257-259,274,275,278,279,283-285,288,291,294,297,299,302,304-307,311,314,317-326,328-331,333-336,339,343-347,350,351,353,355,357,360-362,364,365,372,375,376,379,382,384,385,389,390,396,399,402-406,413,415-418,420-425,429-434,436,439-442,445,446,448-453,456,464,466,470-476,478,480,481,486,487,492,493,495,498,500,502-507,509,511,513,515,516,518,521,528-532,535,536,539,541] The unique source for the degraded reporting quality in this domain was the absence of algorithmic details, which limited reproducibility (eg, signaling question: were details for algorithm development reported?). The mean reporting completeness for these models in the technique domain was satisfied (84.5%; 95% CI, 83.1%-85.8%).

All models were rated for poor reporting quality in the technical assessment domain across 4 signaling questions. Of the 555 models, 544 (98.0%; 95% CI, 96.9%-99.2%) lacked reports for how to evaluate AI performance publicly.[25-68,70-127,129-144,146-178,180-470,472-479,481,483-501,503-506,508-536,538-541] Additionally, the absence-of-bias assessment was associated with degraded reporting quality in this domain (eg, signaling question: were bias assessments discussed?). Thus, the overall reporting completeness for these AI models was the poorest in the technical assessment domain (39.9%; 95% CI, 38.8%-41.1%).

One-hundred fifty of 555 models (27.0%; 95% CI, 23.3%-30.7%) were rated with poor reporting quality in the applications domain across 2 signaling questions.[26,28,29,32,36,38,41,45,50,51,60,65,69,74,78,82,84,94,97,99,105,107,108,112,117,119,120,125,132-134,138,139,141,143,146,150,159,172,183,186,190,193,194,200,203,204,214,219,220,222,223,228-230,232,233,241,243,244,251,257,259-261,263,267,269,274,280,281,284-286,291,293,297,298,300,301,311-313,315,316,321,329,337,340,343,354,361,363,369-371,379,392,395,397,399,405,408,411,413,418,419,422,423,432,440,445,446,448,449,456,457,461,471,473,474,476,481,484,485,490,496,506,513,514,520,527,538-540] Lacking intrinsic reports or discussions of the clinical implications of these models was the main source of the poor rating in this domain (eg, signaling question: were use cases and target conditions discussed?). The mean overall reporting completeness in the applications domain was found to be favorable (84.6%; 95% CI, 81.8%-86.5%).

Table 2. Reporting Quality for All Included AI Models Using the Modified CLEAR (N = 555)

Signaling question[a]	Answers, No. (%)		
	Yes or probably yes	No information	No or probably no
Domain 1: data			
Were neuroimaging types reported?	555 (100.0)	0	0
Was how to handle neuroimaging artifacts reported?	177 (31.9)	0	378 (68.1)
Were technical acquisition details reported?	532 (95.9)	0	23 (4.1)
Were preprocessing procedures reported?	501 (90.0)	0	54 (10.0)
Was synthetic neuroimaging made public if used?	17 (3.1)	0	538 (96.9)
Were public neuroimages referenced adequately?	188 (33.9)	0	367 (66.1)
Were patient-level metadata reported enough (eg, geographic location, sex and gender distribution, and race and ethnicity), and how it was extracted?	362 (65.2)	0	193 (34.8)
Were potential biases from using patient information and metadata reported?	356 (64.2)	0	199 (35.8)
Were data set partition methods reported?	555 (100.0)	0	0
Were sample sizes for subsets (ie, training, validation, and test) reported?	555 (100.0)	0	0
Were external test sets reported?	87 (15.7)	0	468 (84.3)
Were class distributions and balance processes reported?	364 (65.6)	0	191 (34.4)
Were out-of-distribution neuroimages reported?	0	0	555 (100.0)
Domain 2: technique			
Were labeling methods reported appropriately?	555 (100.0)	0	0
Were references to common/accepted diagnostic labels reported?	555 (100.0)	0	0
Were details for algorithm development reported?	297 (53.5)	0	258 (46.5)
Domain 3: technical assessment			
Was how to publicly evaluate algorithm reported?	11 (2.0)	0	544 (98.0)
Were model performance measures reported?	555 (100.0)	0	0
Were benchmarking, technical comparison, and novelty discussed?	322 (58.0)	0	233 (42.0)
Were bias assessments discussed?	0	0	555 (100.0)
Domain 4: applications			
Were use cases and target conditions discussed?	529 (95.3)	0	26 (4.7)
Were potential impacts on the health care team and patients introduced?	405 (73.0)	0	150 (27.0)

Abbreviations: AI, artificial intelligence; CLEAR, Checklist for Evaluation of Image-Based Artificial Intelligence Reports; PROBAST, Prediction Model Risk of Bias Assessment Tool.

[a] All items were translated from modified CLEAR statements into signaling questions that adhered to the PROBAST. Based on the PROBAST rating criteria, each domain was rated as poor reporting quality if 1 or more items were answered with *no* or *probably no*. Overall reporting quality was determined by rating for each item, with 1 or more items answered by *no* or *probably no* being poor reporting quality.

Discussion

Despite the tremendous potential for neuroimaging-based AI models in psychiatric research and clinical translation, the present study showed a high ROB that was associated with barriers to translation of the models into clinical application. To our surprise, the majority of models exhibited a high ROB. These models further exhibited low potential for both clinical and health care applicability based on the PROBAST. Thus, optimistic claims with respect to reliable AI-based psychiatric diagnosis should be considered with caution. Furthermore, poor reporting quality (with a mean reporting completeness of 61.2%) was found to be associated with additional barriers to clinical and practical translation of these models. Despite their high potential, the AI models presented to date do not fulfill the criteria for being recommended for use in psychiatric diagnostics, and several challenges remain on the way to translation.

In this study, we found that 83.1% of existing AI models exhibited a high ROB for psychiatric diagnosis. These findings align with results of a multivariable statistical model (eg, clinical prediction model [CPM]) for diagnosing both somatic and psychiatric disorders that showed 98% and 94% of the models, respectively, had a high ROB in diagnosis.[12,545] In addition, high ROB was observed for prognostication of oral health (75% of models) and cardiovascular health (81% of models).[546,547] Thus, compared with traditional statistical models, the current AI models did not fulfill the promise of superior technical (statistical) model merits (ie, unbiased prediction) in clinical practice. In addition, unlike neurological or physiological diseases with clear nosological landmarks, neuroimaging-based AI models may outperform traditional clinical models for psychiatric diagnosis only if these neuromarkers were associated with apparently differentiable actionability. This situation may be an additional source of high ROB in these models.

The main reason for incurring high ROB in these AI models was found in the analysis domain, especially the sample size and model configurations. Inadequate sample size represented a long-debated concern leading to inflated model performance in neuroimaging-based AI.[8,9,548] Despite the ongoing debate, a sample of more than 200 participants for building AI models is increasingly becoming commonly acceptable.[549-552] However, about 80% of AI models for psychiatric diagnosis were trained on far smaller samples, leading to a high ROB and resulting in poor generalizability. On the other hand, model configurations, including data leakage, performance optimization, and absence of handling data complexities, represented key challenges to increasing model ROB. Data leakage, for instance, referred to the role that knowledge of outcome played in feature selection in the training set.[553] Compared with traditional statistical models, the number of neuroimaging-based features (eg, voxel and functional connectivity) was large. For dimension reduction, univariate analysis was consistently used for feature selection in the whole data set, which made testing the data set no longer independent.[9,551] In addition, unlike CPM, the data structure for AI models allows for a substantial variation in optimizing and turning parameters to manipulate performance.[554,555] Fine-tuning the models may thus improve diagnostic performance, but such tailor-built configurations sacrifice generalizability for unseen patients.[556] On balance, a high ROB in the analysis domain should be addressed to prompt clinical applications in future AI models.

Standardized and transparent reports for a clinical diagnostic model are increasingly advocated to improve clinical applicability and unbiased practice.[557,558] However, we found that the reporting completeness following a benchmark assessment was only 61.2%, critically limiting replicability and applicability. The finding of insufficient reporting resonated with the study by Heus et al[559] that found low overall reporting completeness (ie, 44%) for CPM across clinical domains. With regard to AI models for other clinical diseases, the reporting completeness was still approximately 50%.[560,561] Going forward, complete and transparent reporting quality is imperative for applicable and feasible AI diagnostic models in clinical practice.

Taken together, a concise guideline that consists of 3 aspects is proposed in this study: (1) adopt appropriate reporting guidelines (eg, CLEAR) and benchmarks (eg, PROBAST-AI) before building models; (2) increase attention on the quality of models (eg, adequate sample size, rigorous calibration examination, and controls for data complexities); and (3) propel translational or accessible diagnostic models (eg, report more details for technical assessments and access enough model materials for clinical validations or applications).

Limitations

This study has limitations. One limitation is the potential overestimation of ROB due to the lack of a suitable benchmark. Despite the extension of the PROBAST to AI models, the applicable version is pending.[562] Results of the current study could be validated by the PROBAST-AI when it becomes available. Similarly, the findings regarding the reporting quality of these models could be enriched by the development of a psychiatry-specific image-based AI model reporting checklist. A second limitation is the rating heterogeneity of the benchmarks we used. Although it had acceptable reliability, a certain assessment was found to have heterogeneity by assessors with specific expertise, especially in different assessment domains (eMethods 6 in Supplement 1). Thus, it would be highly beneficial if experts with interdisciplinary scientific training validated the findings by rating the AI models. A third limitation is that we did not test the models' clinical performance; thus, it is prudent for future studies to examine these models in clinical practice to determine their applicability.

Conclusions

In this systematic review of risks for available neuroimaging-based AI models for psychiatric diagnosis, most AI models had an overall high ROB, especially in the analysis domain. Furthermore, the overall reporting quality was poor, and the mean reporting completeness for these models was 61.2%. Existing AI models may not be as mature for direct clinical applications as is claimed given their high ROB and poor reporting quality. In the analysis domain, ROB in of AI diagnostic models should be addressed before clinical application.

ARTICLE INFORMATION

Accepted for Publication: January 15, 2023.

Published: March 6, 2023. doi:10.1001/jamanetworkopen.2023.1671

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Author Contributions: Dr Chen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Dr Chen and Ms X. Liu contributed equally to this work.

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Obtained funding: Zhengzhi.

Administrative, technical, or material support: Chen, X. Liu, Yang, Yu, C. Liu, Zhengzhi.

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Conflict of Interest Disclosures: None reported.

Funding/Support: This work was funded by grant CWS20J007 from the Chinese People's Liberation Army (PLA) Key Research Foundation, grant 20220102 from the Army Medical University Academic Rising Star Foundation, and grant 2022160258 from PLA Talent Program Foundation.

Role of the Funder/Sponsor: The funders had a role in reviewing and approving this manuscript for publication. The funders had no role in the design and conduct of the study or the collection, management, analysis, and interpretation of the data.

Data Sharing Statement: See Supplement 2.

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SUPPLEMENT 1.
eMethods 1. Searching Strategy and RSS Feed
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SUPPLEMENT 2.
Data Sharing Statement