Methodological Evaluation Criteria for Risk of Bias Assessment in Adult ADHD Diagnostic Studies

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1 Systematic Framework for Bias Evaluation

1.1 I. Established Criteria - QUADAS-2 Framework

The Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool provides the foundational framework for evaluating risk of bias, specifically adapted for adult ADHD diagnostic studies.

Domain 1: Patient Selection

Low Risk Criteria

- Consecutive or random sampling explicitly documented
- Case-control design avoided or appropriately justified
- Inappropriate exclusions avoided
- Clear documentation of recruitment strategy

Unclear Risk Indicators

- Insufficient description of sampling methodology
- Ambiguous selection criteria
- Limited documentation of recruitment process
- Unclear timeline of participant enrollment

High Risk Markers

- Non-consecutive or non-random sampling
- Inappropriate case-control design
- Inappropriate exclusions affecting representativeness
- Substantial selection bias evident

Domain 2: Index Test

Low Risk Criteria

- Test conducted according to standardized protocol
- Threshold pre-specified
- Test interpreters blinded to reference standard
- Clear documentation of test administration

Domain 3: Reference Standard

Low Risk Criteria

- DSM-5/ICD-10 criteria properly implemented
- Reference standard results interpreted blind to index test
- Standardized diagnostic protocol followed
- Multi-informant data collection

Domain 4: Flow and Timing

> **Low Risk Criteria**
>
> - Appropriate interval between index test and reference standard
> - All participants receive same reference standard
> - All participants included in analysis
> - Clear documentation of assessment timeline

1.2 II. Inter-rater Reliability Assessment

1.2.1 Structured Evaluation Protocol

1. Initial Documentation Review:
    - Abstract screening
    - Methods section analysis
    - Results interpretation
    - Limitations acknowledgment
2. Systematic Data Extraction:

Study Characteristics Form:

☐ Sample size calculation documented
☐ Inclusion/exclusion criteria specified
☐ Recruitment strategy detailed
☐ Timeline of assessments provided
☐ Diagnostic protocol described
☐ Blinding procedures documented
☐ Statistical analyses appropriate

3. Quality Metrics Assessment:

Risk Assessment Checklist:

PATIENT SELECTION

☐ Sampling method: _____
☐ Selection criteria: _____
☐ Exclusions justified: _____
☐ Documentation complete: _____

INDEX TEST

☐ Protocol standardized: _____
☐ Thresholds pre-specified: _____
☐ Blinding maintained: _____

REFERENCE STANDARD

☐ Diagnostic criteria: _____
☐ Blinding procedures: _____
☐ Protocol adherence: _____

FLOW AND TIMING

☐ Assessment intervals: _____
☐ Complete follow-up: _____
☐ Missing data handled: _____

1.3 III. Inter-rater Agreement Procedures

1. Independent Assessment Phase:
    - Minimum two qualified raters
    - Standardized extraction forms
    - Blinded to other rater's decisions
    - Documentation of rationale
2. Consensus Building Process:
    - Initial agreement calculation
    - Discrepancy identification
    - Structured resolution discussion
    - Final consensus determination
3. Statistical Analysis:
    - Kappa coefficient calculation
    - Percent agreement analysis
    - Systematic bias evaluation
    - Reliability metrics documentation

1.4 IV. Quality Control Measures

Quality Assurance Checklist:

☐ Rater qualification verified
☐ Training protocol completed
☐ Extraction forms standardized
☐ Regular calibration meetings
☐ Documentation requirements met
☐ Resolution process followed
☐ Statistical analysis completed
☐ Results interpretation agreed

1.5 V. Recommended Documentation Format

Study Quality Assessment Template:

Study ID: _____
Primary Rater: _____
Secondary Rater: _____
Date of Assessment: _____

RISK OF BIAS DETERMINATION:

Patient Selection: Low Unclear High
Evidence: _____
Rationale: _____

Index Test: Low Unclear High
Evidence: _____
Rationale: _____

Reference Standard: Low Unclear High
Evidence: _____
Rationale: _____

Flow and Timing: Low Unclear High
Evidence: _____
Rationale: _____

CONSENSUS DETERMINATION:
Initial Agreement: _____
Resolution Process: _____
Final Classification: _____

1.6 VI. Clinical Implications

The systematic implementation of these criteria ensures:

1. Standardized evaluation across studies
2. Reliable risk assessment
3. Transparent decision-making
4. Reproducible methodology
5. Clinical validity enhancement

This framework provides a structured approach to evaluating methodological rigor in adult ADHD diagnostic studies, facilitating reliable inter-rater assessment and maintaining consistency in bias evaluation.