METHODOLOGICAL EVALUATION CRITERIA FOR RISK OF BIAS ASSESSMENT IN ADULT ADHD DIAGNOSTIC STUDIES

SYSTEMATIC FRAMEWORK FOR BIAS EVALUATION

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

II. INTER-RATER RELIABILITY ASSESSMENT

Structured Evaluation Protocol:

1. Initial Documentation Review:

- Abstract screening
- Methods section analysis
- Results interpretation
- Limitations acknowledgment

2. Systematic Data Extraction:

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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
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3. Quality Metrics Assessment:

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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: _________
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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

IV. QUALITY CONTROL MEASURES

Implementation Protocol:

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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
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V. RECOMMENDED DOCUMENTATION FORMAT

Study Quality Assessment Template:

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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: _____________
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Resolution Process: _____________
Final Classification: ___________
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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.