KREP
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KARNATAKA RADIOLOGY EDUCATION PROGRAM

CLINICAL RESEARCH – BRIDGING IMAGING & INNOVATION

SESSION – 4 – AVOIDABLE MISTAKES IN RESEARCH (II)

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8. UNCLEAR STATISTICAL ASSUMPTIONS

PROBLEM STATEMENT

NOT CLEARLY STATING THE STATISTICAL ASSUMPTIONS USED IN YOUR ANALYSIS CAN LEAD TO INCORRECT CONCLUSIONS AND DIFFICULTIES IN REPLICATING THE STUDY. AMBIGUITY IN STATISTICAL METHODS CAN UNDERMINE THE CREDIBILITY OF THE RESEARCH FINDINGS.

HOW TO AVOID?

CLEARLY OUTLINE THE STATISTICAL METHODS AND ASSUMPTIONS USED IN YOUR STUDY. PROVIDE A DETAILED EXPLANATION OF WHY SPECIFIC STATISTICAL TESTS WERE CHOSEN AND HOW THEY WERE APPLIED. THIS TRANSPARENCY ALLOWS OTHER RESEARCHERS TO UNDERSTAND AND REPLICATE YOUR STUDY, ENHANCING ITS CREDIBILITY AND RELIABILITY.
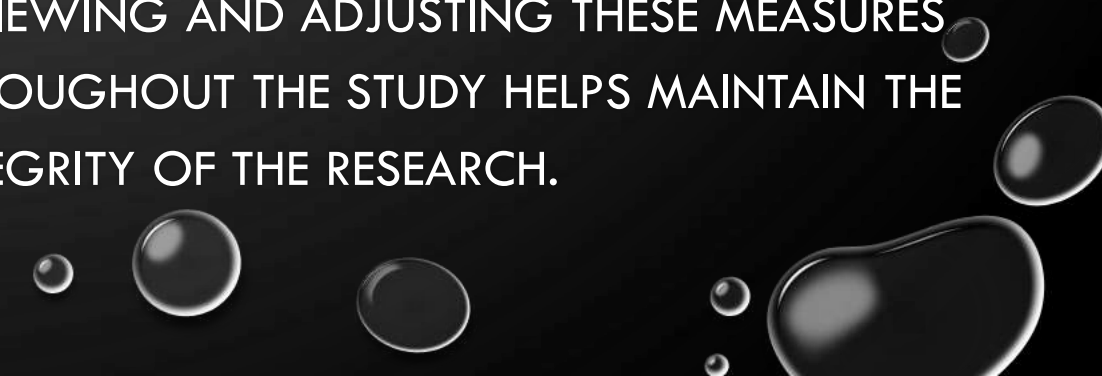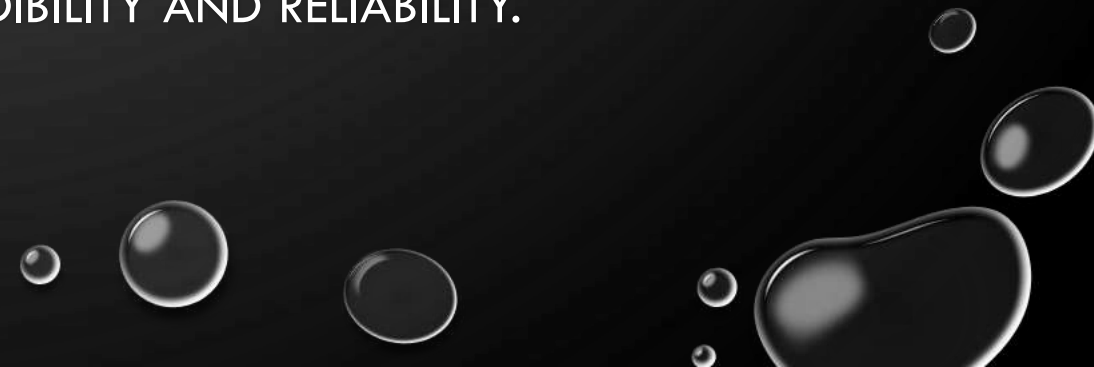
9. INADEQUATE BIAS CONTROL

PROBLEM STATEMENT

NOT IMPLEMENTING MEASURES TO CONTROL FOR BIASES CAN LEAD TO SKEWED RESULTS, WHICH MAY NOT ACCURATELY REFLECT THE TRUE EFFECTS BEING STUDIED. BIAS CAN ENTER THE STUDY THROUGH VARIOUS SOURCES, SUCH AS SELECTION BIAS, MEASUREMENT BIAS, AND OBSERVER BIAS.

HOW TO AVOID?

IDENTIFY POTENTIAL SOURCES OF BIAS AND IMPLEMENT STRATEGIES TO MINIMIZE THEIR IMPACT. THIS CAN INCLUDE RANDOMIZATION TO ENSURE EQUAL DISTRIBUTION OF PARTICIPANTS, BLINDING TO PREVENT OBSERVERS FROM BEING INFLUENCED BY KNOWLEDGE OF THE TREATMENT, AND USING STANDARDIZED MEASUREMENT TOOLS. REGULARLY REVIEWING AND ADJUSTING THESE MEASURES THROUGHOUT THE STUDY HELPS MAINTAIN THE INTEGRITY OF THE RESEARCH.

PROBLEM STATEMENT

POOR DATA MANAGEMENT PRACTICES, SUCH AS INADEQUATE DATA STORAGE, DOCUMENTATION, OR BACKUP, CAN LEAD TO DATA LOSS, CORRUPTION, OR MISINTERPRETATION. THIS CAN COMPROMISE THE INTEGRITY AND RELIABILITY OF THE RESEARCH FINDINGS.

HOW TO AVOID?

ESTABLISH CLEAR PROTOCOLS FOR DATA COLLECTION, STORAGE, AND DOCUMENTATION. USE SECURE AND RELIABLE SYSTEMS FOR DATA STORAGE, REGULARLY BACK UP DATA, AND MAINTAIN DETAILED RECORDS OF DATA HANDLING PROCEDURES. ENSURING PROPER TRAINING FOR ALL TEAM MEMBERS INVOLVED IN DATA MANAGEMENT CAN ALSO HELP PREVENT ERRORS AND ENSURE CONSISTENCY.

11. INSUFFICIENT DOCUMENTATION

PROBLEM STATEMENT

FAILING TO MAINTAIN THOROUGH AND ACCURATE DOCUMENTATION OF THE RESEARCH PROCESS, INCLUDING PROTOCOLS, METHODOLOGIES, AND RESULTS, CAN LEAD TO DIFFICULTIES IN REPLICATING THE STUDY AND VERIFYING THE FINDINGS. INCOMPLETE DOCUMENTATION CAN ALSO HINDER THE ABILITY TO TRACK AND ADDRESS ISSUES THAT ARISE DURING THE RESEARCH.

HOW TO AVOID?

ESTABLISH A SYSTEMATIC APPROACH TO DOCUMENTATION FROM THE BEGINNING OF THE STUDY. RECORD ALL PROCEDURES, METHODOLOGIES, AND OBSERVATIONS IN DETAIL. USE STANDARDIZED FORMATS FOR DATA ENTRY AND REPORTING TO ENSURE CONSISTENCY. REGULARLY UPDATE AND REVIEW DOCUMENTATION TO CAPTURE ANY CHANGES OR ADJUSTMENTS MADE DURING THE STUDY. PROPER TRAINING FOR RESEARCH TEAM MEMBERS ON DOCUMENTATION PRACTICES CAN FURTHER ENHANCE ACCURACY AND RELIABILITY.

12. MISINTERPRETATION OF STATISTICAL RESULTS

PROBLEM STATEMENT

MISINTERPRETING STATISTICAL RESULTS CAN LEAD TO INCORRECT CONCLUSIONS ABOUT THE DATA. THIS CAN OCCUR DUE TO A LACK OF UNDERSTANDING OF STATISTICAL CONCEPTS, IMPROPER APPLICATION OF STATISTICAL TESTS, OR OVERLOOKING THE LIMITATIONS OF THE STATISTICAL METHODS USED.

HOW TO AVOID?

ENSURE THAT RESEARCHERS AND TEAM MEMBERS HAVE A STRONG UNDERSTANDING OF STATISTICAL CONCEPTS AND METHODS. SEEK TRAINING OR CONSULT WITH A STATISTICIAN TO PROPERLY INTERPRET AND APPLY STATISTICAL TESTS. CLEARLY COMMUNICATE THE LIMITATIONS AND ASSUMPTIONS OF THE STATISTICAL METHODS USED IN THE STUDY TO AVOID OVERGENERALIZATION OR MISINTERPRETATION OF THE RESULTS.

PROBLEM STATEMENT

FAILING TO ADEQUATELY FOLLOW UP WITH STUDY PARTICIPANTS CAN RESULT IN INCOMPLETE DATA, LEADING TO POTENTIAL BIASES AND GAPS IN THE RESEARCH FINDINGS. THIS CAN AFFECT THE STUDY'S OVERALL VALIDITY AND RELIABILITY.

HOW TO AVOID?

- DEVELOP CLEAR AND CONSISTENT FOLLOW-UP PROTOCOLS TO ENSURE THAT ALL PARTICIPANTS ARE CONTACTED AND MONITORED THROUGHOUT THE STUDY. SCHEDULE REGULAR FOLLOW-UP APPOINTMENTS AND MAINTAIN OPEN COMMUNICATION WITH PARTICIPANTS. USE REMINDERS AND TRACKING SYSTEMS TO ENSURE COMPLIANCE AND ADDRESS ANY ISSUES THAT ARISE PROMPTLY. PROPER FOLLOW-UP ENSURES COMPREHENSIVE DATA COLLECTION AND ENHANCES THE CREDIBILITY OF THE RESEARCH.

14. OVERLOOKING ETHICAL CONSIDERATIONS

PROBLEM STATEMENT

FAILING TO PRIORITIZE ETHICAL CONSIDERATIONS CAN LEAD TO VIOLATIONS OF PARTICIPANT RIGHTS, LOSS OF TRUST, AND POTENTIALLY HARMFUL CONSEQUENCES. THIS INCLUDES INADEQUATE INFORMED CONSENT, LACK OF PARTICIPANT CONFIDENTIALITY, AND NOT ADHERING TO ETHICAL GUIDELINES.

HOW TO AVOID?

ENSURE THAT YOUR STUDY COMPLIES WITH ESTABLISHED ETHICAL GUIDELINES, SUCH AS OBTAINING INFORMED CONSENT FROM ALL PARTICIPANTS, MAINTAINING CONFIDENTIALITY, AND PROVIDING PARTICIPANTS WITH THE RIGHT TO WITHDRAW FROM THE STUDY AT ANY TIME. SEEK APPROVAL FROM AN INSTITUTIONAL REVIEW BOARD (IRB) OR ETHICS COMMITTEE BEFORE BEGINNING THE STUDY. REGULARLY REVIEW AND UPDATE ETHICAL PROTOCOLS TO ALIGN WITH BEST PRACTICES AND REGULATIONS.

15. INADEQUATE TRAINING FOR RESEARCH TEAM

PROBLEM STATEMENT

FAILING TO PROVIDE SUFFICIENT TRAINING FOR RESEARCH TEAM MEMBERS CAN LEAD TO ERRORS IN DATA COLLECTION, HANDLING, AND ANALYSIS. THIS CAN COMPROMISE THE OVERALL QUALITY AND RELIABILITY OF THE STUDY.

HOW TO AVOID?

ENSURE THAT ALL TEAM MEMBERS RECEIVE THOROUGH TRAINING ON THE STUDY PROTOCOLS, DATA COLLECTION METHODS, AND ETHICAL GUIDELINES. REGULARLY UPDATE TRAINING TO REFLECT ANY CHANGES IN PROTOCOLS OR BEST PRACTICES. ENCOURAGE CONTINUOUS EDUCATION AND SKILL DEVELOPMENT TO MAINTAIN HIGH STANDARDS OF RESEARCH QUALITY.

QUIZ

- WHAT IS THE RISK OF BIAS ASSESSMENT/ METHODOLOGICAL QUALITY TOOL APPLIED TO COMPARE CT ABDOMEN VERSUS MRI ABDOMEN DIAGNOSTIC PERFORMANCE STUDIES?
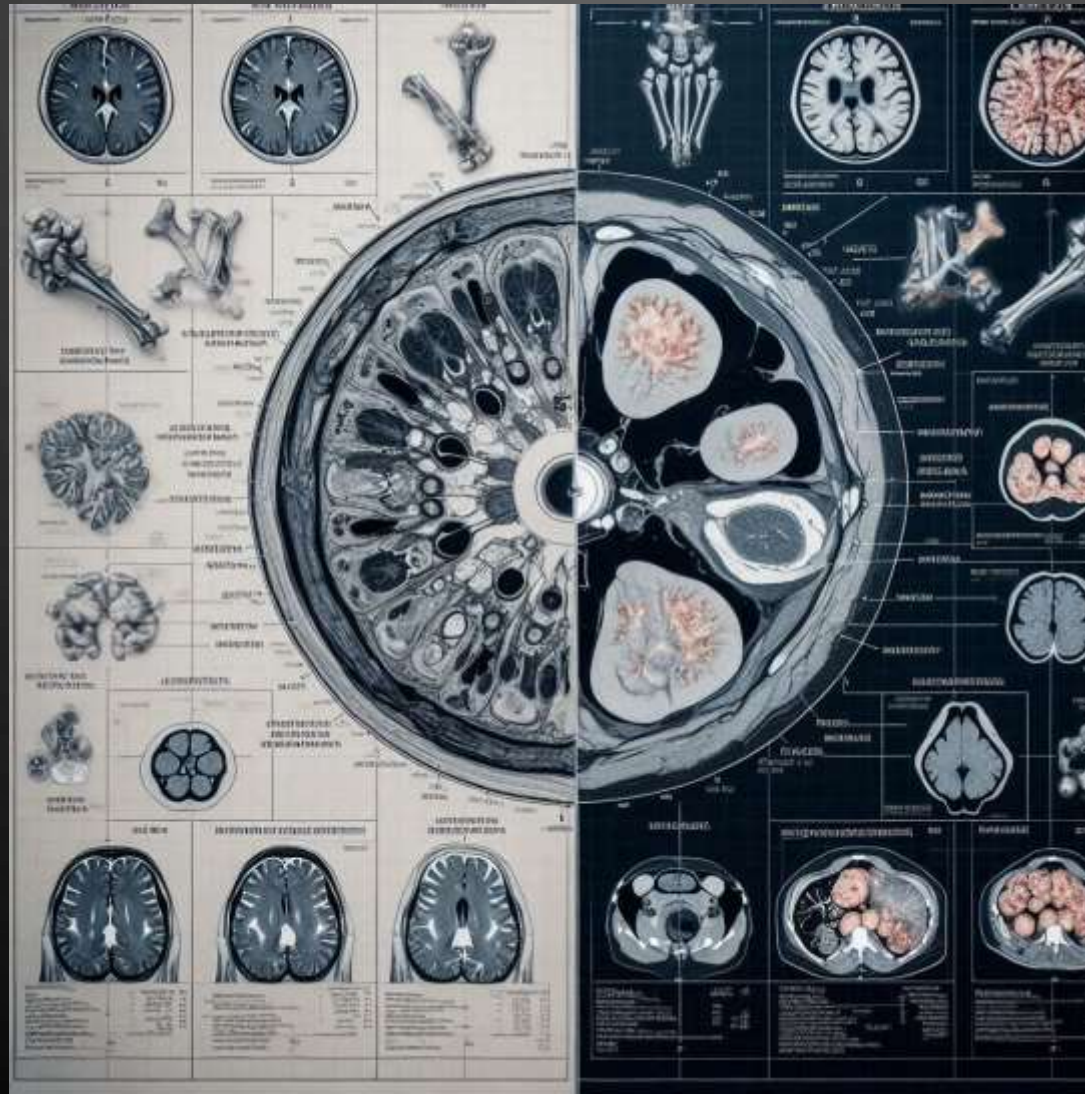
ANSWER – QUADAS-C TOOL

✓ **PURPOSE:** TO EVALUATE THE RISK OF BIAS IN STUDIES THAT COMPARE THE ACCURACY OF TWO OR MORE DIAGNOSTIC TESTS.

✓ **EXTENSION OF QUADAS-2:** QUADAS-C INCLUDES ADDITIONAL QUESTIONS TO EACH QUADAS-2 DOMAIN, FOCUSING ON COMPARATIVE ACCURACY STUDIES.

✓ **USAGE:** IT SHOULD BE USED ALONGSIDE QUADAS-2 TO PROVIDE SEPARATE RISK OF BIAS JUDGMENTS FOR SINGLE TEST ACCURACY AND COMPARATIVE ACCURACY

Domain	Description	Signaling Questions (Comparative)
Patient Selection	Assessment of whether the included patients are representative of the target population.	Were the same inclusion and exclusion criteria applied to both tests?
Index Test	Evaluation of the index test(s) under review.	Were the index tests conducted in the same way for all patients?
Reference Standard	Evaluation of the reference standard used to verify the index test results.	Was the reference standard applied equally to both tests?
Flow and Timing	Assessment of the flow of patients through the study and the timing of the index tests and reference standard.	Were there any differences in the flow and timing between the tests?