Background

• In diagnostic accuracy research, test results are typically presented as a dichotomy
• However, in many cases, results do not exclusively fall into “positive” and “negative” categories
  • There is often a subset of results that are relatively uninformative and lead to an “inconclusive” diagnostic outcome
• Inconclusive test results are often overlooked in diagnostic accuracy research
  • Require extra attention from clinicians e.g. repeating the test or using more costly (in terms of invasiveness, time, and expense) diagnostic tools
Inconsistent Reporting

• STARD statement recommends: “report how indeterminate results, missing responses and outliers of the index tests are handled”
  • Advocates the reporting of “uninterpretable, indeterminate, and intermediate results”

• Explored whether inconclusive results are consistently reported in diagnostic accuracy research

• Searched the literature using the term “STARD” to identify systematic reviews assessing adherence to the STARD statement
Inconsistent Reporting

- Identified 22 systematic reviews comprising 1156 primary diagnostic accuracy studies

- 35% (400/1156) of diagnostic accuracy studies explicitly reported uninterpretable, indeterminate, intermediate, and missing results

- Wide variation in adherence across systematic reviews (range 0-66%), indicating that there was inconsistency in the quality of reporting in different clinical areas and/or the reviewers’ interpretation of the STARD statement
Types of Inconclusive Result

- Missing Results
- Uninterpretable Results
- Negative Results
- Valid Inconclusive Results
- Positive Results
Valid Inconclusive Results

- Depends on the measurement scale of the test
- Report all valid inconclusive results on their original scale (before any grouping of results), broken down by the reference standard

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Disease Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Disease Present</td>
</tr>
<tr>
<td>Positive</td>
<td>True Positive</td>
</tr>
<tr>
<td>Valid Inconclusive</td>
<td>Disease Present but Valid Inconclusive Result</td>
</tr>
<tr>
<td>Negative</td>
<td>False Negative</td>
</tr>
</tbody>
</table>
Invalid Inconclusive Results

Recruitment

- Missing Results
- Uninterpretable Results
- Valid Inconclusive Results
- Negative Results
- Positive Results
Invalid Inconclusive Results

- Often not directly related to test accuracy
  - Still an essential consideration in the evaluation of the overall clinical utility of the test
  - Report separately from the cross-tabulation of valid results by disease status

- Consideration of any known underlying causes need to be reported
  - Their presence may be informative
Analysing Inconclusive results

• No single ‘optimal’ approach
  • Diagnostic accuracy should always be analysed in line with how the test will be used in clinical practice

• Reviewed options:
  • Exclude
  • Exclude but report any additional summary statistic that accounts for them
  • Group with the positive or negative categories

• If valid inconclusive results are excluded from analyses (rarely justifiable), accuracy statistics should be reported when the inconclusive results are included as a secondary (sensitivity) analysis
Conclusion

• Reporting and analysis of inconclusive test results neglected in diagnostic accuracy studies

• Clearly report all inconclusive results, broken down by the reference standard when possible

• Complete transparency regarding the handling of inconclusive results in the analysis phase

• Readers should be able to recalculate key statistics if they disagree with the approach adopted by the author
Thanks to co-authors

- Rafael Perera
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- Sue Mallett