# QUADAS-3: Updated Tool to Evaluate Risk of Bias and Applicability Concerns in Diagnostic Test Accuracy Studies

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KEYWORDS: Risk of bias assessment, applicability, diagnostic test accuracy, systematic review

## INTRODUCTION

The QUADAS-2 tool, published in 2011, was designed to evaluate the risk of bias and applicability of diagnostic test accuracy (DTA) studies. The publication reporting QUADAS-2 has been cited over 12, 000 times and it is the recommended tool to assess risk of bias and applicability of studies for major HTA organizations. Although feedback on QUADAS-2 has generally been positive, some signaling questions have been identified as problematic and the tool could be improved based on features included in more recently developed tools.

## OBJECTIVES

To update QUADAS-2 to develop the new QUADAS-3 tool.

## METHODS

We established a core-group of methodological experts to lead the development of the QUADAS-3 tool supported by a wider steering group.

We followed the following steps:

- Summarised modifications made to QUADAS-2 for the Cochrane Handbook
- Web-based survey of reviewers that have used QUADAS-2
- Considered developments from more recent tools in terms of tool structure and implementation
- Undertook a review of methodological studies that had evaluated QUADAS-2
- Undertook a review of 50 Cochrane DTA reviews to highlight challenges with the assessment of applicability

We have produced a draft tool which has undergone piloting. The results of the piloting, which also included a comparison of the use of signalling questions with signalling statements, was used to inform the final version of the tool.

## RESULTS

The new tool follows a similar structure to the QUADAS-2 tool but with some major updates. Key changes include:

- An option to define separate synthesis questions rather than just a single review question
- A new section on defining the ideal test accuracy trial for each synthesis question
- Assessment of risk of bias and applicability at the accuracy estimate level rather than the study level
- A change in answers to signaling questions to include options of "probably yes" and "probably no" and to replace "unclear" with "no information"
- Replacement of "Flow and Timing domain" with new "Analysis" domain
- Changes to some signaling questions
- Inclusion of a section for judging overall risk of bias and applicability (across domains)

DOI: 10.54103/2282-0930/29260

## CONCLUSIONS

The QUADAS-3 tool incorporates several changes compared to the previous version (QUADAS-2) which we hope will improve its validity, usability, and usefulness. QUADAS-3 will be introduced at the conference and the results of piloting discussed.

DOI: 10.54103/2282-0930/29260