



**HARMONY**

Novel tools for test evaluation and  
disease prevalence estimation



ΤΜΗΜΑ ΔΗΜΟΣΙΑΣ  
ΚΑΙ ΕΝΙΑΙΑΣ ΥΓΕΙΑΣ  
DEPARTMENT OF PUBLIC  
AND ONE HEALTH

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# STARD - BLCM

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# The STARD family

- 
- **STARD**
    - STARD 2015
    - STARDdem
    - STRADAS-paraTB
    - STARD-BLCM
    - STARD for Abstracts



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## Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



## Reporting guidelines for main study types

[Randomised trials](#)

[CONSORT](#) [Extensions](#)

[Observational studies](#)

[STROBE](#) [Extensions](#)

[Systematic reviews](#)

[PRISMA](#) [Extensions](#)

[Study protocols](#)

[CIPIT](#) [PRISMA-P](#)

# STARD-BLCM Checklist

TITLE OR ABSTRACT

ABSTRACT

INTRODUCTION

METHODS

Study design

Participants

Test methods

Analysis

RESULTS

Participants

Test results

DISCUSSION

OTHER INFORMATION

Section & Topic	No	Item
<b>TITLE OR ABSTRACT</b>		
	<b>1</b>	Identification as a study of diagnostic accuracy, using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC) <b>and Bayesian latent class models</b>
<b>ABSTRACT</b>		
	<b>2</b>	Structured summary of study design, methods, results, and conclusions (for specific guidance, see <a href="#">STARD for Abstracts</a> )
<b>INTRODUCTION</b>		
	<b>3</b>	Scientific and clinical background, including the intended use and clinical role of the <b>tests under evaluation</b>
	<b>4</b>	Study objectives and hypotheses, <b>such as estimation of diagnostic accuracy of the tests for a defined purpose through BLCM</b>

METHODS		
<i>Study design</i>	<b>5</b>	Whether data collection was planned before the <b>tests</b> were performed (prospective study) or after (retrospective study)
<i>Participants</i>	<b>6</b>	<b>Eligibility criteria and description of the source population</b>
	<b>7</b>	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)
	<b>8</b>	Where and when potentially eligible participants were identified (setting, location and dates)
	<b>9</b>	Whether participants formed a consecutive, random or convenience series

<i>Test methods</i>	<b>10</b>	<b>Description of the tests under evaluation, in sufficient detail to allow replication, and/or cite references</b>
	<b>11</b>	Rationale for choosing the <b>tests under evaluation in relation to their purpose</b>
	<b>12</b>	Definition of and rationale for test positivity cut-offs or result categories of <b>the tests under evaluation</b> , distinguishing pre-specified from exploratory
	<b>13</b>	Whether clinical information was available to the performers or readers of <b>the tests under evaluation</b>
<i>Analysis</i>	<b>14a</b>	<b>BLCM model</b> for estimating measures of diagnostic accuracy
	<b>14b</b>	<b>Definition and rationale of prior information and sensitivity analysis</b>
	<b>15</b>	How indeterminate results of <b>the tests under evaluation</b> were handled
	<b>16</b>	How missing data of <b>the tests under evaluation</b> were handled
	<b>17</b>	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory
	<b>18</b>	Intended sample size and how it was determined

RESULTS		
<i>Participants</i>	19	Flow of participants, using a diagram
	20	Baseline demographic and clinical characteristics of participants
	21	<b>Not applicable: the distribution of the targeted conditions is unknown, hence the use of BLCM</b>
	22	Time interval and any clinical interventions between <b>the tests under evaluation</b>
<i>Test results</i>	23	Cross tabulation of the <b>tests' results (or for continuous tests results their distribution by infection stage)</b>
	24	Estimates of diagnostic accuracy <b>under alternative prior specification</b> and their precision (such as 95% <b>credible/probability intervals</b> )
<i>Discussion</i>	25	Any adverse events from performing <b>the tests under evaluation</b>

DISCUSSION	
	<b>26</b> Study limitations, including sources of potential bias, statistical uncertainty, and generalisability
	<b>27</b> Implications for practice, including the intended use and clinical role of <b>the tests under evaluation in relevant settings (clinical, research, surveillance etc.)</b>
OTHER INFORMATION	
	<b>28</b> Registration number and name of registry
	<b>29</b> Where the full study protocol can be accessed
	<b>30</b> Sources of funding and other support; role of funders

# Considerations

Biological considerations

Methodological considerations

Convergence diagnostics

Goodness of fit tests

Prior selection – The ParaTB paradigm

# Biological considerations

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- Support your work from a biological perspective
  - e.g. definition of infection in latent analysis

# Definition of infection

- Define which status you are estimating Se & Sp for.
- Different test combinations give different Se's and Sp's
- You are based on the cross-classified test results
  - e.g. ELISA and FC culture for paratuberculosis
  - see (Nilesen et al., 2002; Kostoulas et al., 2006a; 2006b)

# No Gold Standard

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Definition of the targeted infection status gets  
complicated but..."better"

Detectable immune response (ELISA)

Detectable isolation of the pathogen (Culture)



# Target Variable Bias

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Statistically sound  
modeling & description



The interested reader must be able to reproduce your methods (and results) with the information you provide

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# Explicit description of the BLCM model

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Model Assumptions

# Biologically justify model building

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Conditional dependencies

Identifiability



# Conditional dependencies

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# Identifiability

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# Definition and rationale of prior information and sensitivity analysis

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