

Accuracy of self-diagnosis in conditions commonly managed in primary care: diagnostic accuracy review

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### Citation

Annette Pluddemann, Hayley Jones, Carl Heneghan. Accuracy of self-diagnosis in conditions commonly managed in primary care: diagnostic accuracy review. PROSPERO 2018 CRD42018110288 Available from:  
[http://www.crd.york.ac.uk/PROSPERO/display\\_record.php?ID=CRD42018110288](http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018110288)

### Review question

#### Primary objective

Our primary objective is to summarize the accuracy of self-diagnosis of common conditions in primary care, compared with diagnosis by a healthcare provider.

#### Secondary objective

To summarise any associated relevant information relating to self-diagnosis of common conditions in primary care, such as information on patient preference, timing, or cost (only using information from studies we include for accuracy data). Where there is substantial qualitative information reported, this will only be summarised briefly; detailed qualitative approaches will not be used.

### Searches

The search strategy will be developed in consultation with a healthcare librarian experienced with supporting systematic reviews. No language restrictions will be applied. The search strategy will use multiple electronic databases, from inception onwards including:

MEDLINE

EMBASE

Cochrane Central Register of Controlled Trials (CENTRAL)

Trip database

Web of Science for conference proceedings, dissertations, and theses

World Health Organization International Clinical Trials Registry Platform (ICTRP),

ClinicalTrials.gov

Database of Abstracts of Reviews of Effects (DARE)

We will also search Science Citation Index Expanded for study reports that cite the included studies.

The search may use relevant filters, but in order to maximise sensitivity, will not be limited to these. The reference lists of relevant studies will be examined and additional tools such as the “related articles” feature in PubMed will also be used to identify relevant publications.

### Types of study to be included

Prospective or retrospective studies comparing the results of self-diagnosis of common self-limiting conditions in primary care by free-living individuals, to the results of a reference standard test performed by a healthcare service provider, will be included. Studies with a case-control design will be excluded. In case of

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duplicate publications we will include the study report with the highest methodological quality. There will be no language restrictions.

We will exclude studies comparing self-diagnosis with diagnosis by allied health professionals such as a pharmacists.

#### Condition or domain being studied

Self-diagnosis of conditions commonly managed in primary care.

#### Participants/population

Adults ( $\geq 18$  years of age) self-diagnosing conditions common in primary care.

#### Intervention(s), exposure(s)

Index tests will be the self-testing or self-diagnosis of relevant conditions, compared with diagnosis by a healthcare practitioner.

#### Comparator(s)/control

Comparator tests will comprise diagnosis by a healthcare practitioner.

#### Context

#### Main outcome(s)

Diagnostic accuracy measures (e.g. sensitivity, specificity, likelihood ratios, predictive values, etc.) and primary data for 2x2 tables.

#### Additional outcome(s)

Qualitative information regarding patient preference, timing or cost will be summarised briefly as available. No detailed qualitative approaches will be used.

#### Data extraction (selection and coding)

Selection of studies:

Two reviewers will independently apply the selection criteria to the titles and abstracts of the study reports identified by the searches. If the decision to exclude a study cannot be made on the basis of the title and the abstract, the full study report will be retrieved for inclusion assessment. The final decision on inclusion will be based on the full study report. Disagreements between reviewers will be resolved by discussion, or if necessary by a third reviewer. Study identification will be summarised in a PRISMA flow diagram.

Data extraction and management:

Two reviewers will independently extract information from selected studies into a data extraction sheet. Disagreements will be resolved by discussion, or if necessary with the help of a third reviewer.

Where this is insufficient (or unclear) information, where there is an email address provided, the authors will be contacted via email for clarification. Where data is not available for completion of 2x2 tables, the studies will be excluded from the analysis.

Data to be extracted:

The following information will be extracted from the included studies, where available:

Study identification - author, year, location

Study research question

Study design and setting

Target condition definition/diagnostic criteria

Participant characteristics and numbers, including exclusions

Index test

Reference standard

Flow of participants through study including losses to follow-up

Patient presentation and prior testing

Conduct of the study including timing of the tests, and information on masking

Absolute counts of true positive (TP), false positive (FP), false negative (FN) and true negative (TN) diagnoses.

Statistical analyses that were performed, including whether all participants were included in analyses

Additional summary information on participant preference, timing, or cost, as available.

### Risk of bias (quality) assessment

To assess methodological quality, we will use the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool (Whiting et al 2011). Two reviewers will independently assess studies' methodological quality; disagreements will be resolved by discussion, or if necessary, by a third reviewer. The QUADAS-2 tool facilitates assessment of bias in four areas: patient selection; index test; reference standard; flow and timing; and also facilitates assessment of applicability of the studies to the review research question.

The data will be presented in a tables showing risk of bias and applicability within each domain assessed for each study. These data will be considered in relation to interpreting the results of the studies.

### Strategy for data synthesis

Statistical analysis and data synthesis:

Analyses will be conducted for each category of condition specified. Summary tables will detail study information including the patient sample, condition, study design, the test under evaluation, and the comparator.

Meta-analysis:

For each test, where the data is available, RevMan will be used to produce paired forest plots to explore the between-study variability of sensitivity and specificity across the included studies. For each study estimate of sensitivity and specificity, corresponding 95% confidence intervals will be shown to illustrate the uncertainty related to each study estimate. If accuracy has been reported at multiple common thresholds, forest plots will be sub-grouped on threshold.

Bivariate meta-analysis methods (Reitsma et al 2005) will be used to generate pooled estimates of sensitivity and specificity where sufficient data is available for each test or condition. These will be plotted with 95% confidence and prediction ellipses in Receiver Operating Characteristic (ROC) space. Where appropriate, summary ROC curves will also be plotted, drawing on the equivalence of the bivariate method and the hierarchical summary ROC meta-analysis model (Rutter and Gatsonis 2001; Harbord et al 2007). For these analyses, we will use WinBUGS or the metandi command in Stata, as appropriate, and feed parameters directly into Revman to produce Cochrane-standardised output.

Where appropriate, meta-analysis models that include multiple thresholds will be employed (e.g. Steinhauser et al 2016 or similar).

### Analysis of subgroups or subsets

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Investigating heterogeneity:

For medical conditions for which data from more than one study are available, it may be possible to investigate heterogeneity in the results. Two approaches will be used to explore the sources of between-study heterogeneity: 1) inclusion of study level characteristics as covariates in the bivariate model (meta-regression) 2) carrying out sub-group analyses. These approaches will only be carried out if there is sufficient data available and sub-group specific pooled estimates are thought to be of clinical relevance. Any meta-regressions will be carried out using WinBUGS or the xtmelogit command in Stata.

Sensitivity analyses:

If there appear to be any outliers in the data, these studies will be removed from the analysis to evaluate the impact on the overall pooled estimates.

### Contact details for further information

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### Organisational affiliation of the review

University of Oxford

### Review team members and their organisational affiliations

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Dr Hayley Jones. University of Bristol  
Professor Carl Heneghan. University of Oxford

### Anticipated or actual start date

01 October 2018

### Anticipated completion date

20 December 2019

### Funding sources/sponsors

This project is funded by National Institute for Health Research School for Primary Care Research (NIHR SPCR) [ProjectNumber 390]

### Conflicts of interest

Dr. Plüddemann reports grants from NIHR, grants from NIHR School of Primary Care Research, during the conduct of the study; and occasionally receives expenses for teaching Evidence-Based Medicine. Dr. Heneghan reports receiving expenses and fees for his media work. He has received expenses from the WHO and holds grant funding from the NIHR, the NIHR School of Primary Care Research, The Wellcome Trust and the WHO. He has received financial remuneration from an asbestos case. He has also received income from the publication of a series of toolkit books published by Blackwells. On occasion, he receives expenses for teaching EBM and is also paid for his GP work in NHS out of hours. CEBM jointly runs the EvidenceLive Conference with the BMJ and the Overdiagnosis Conference with some international partners which are based on a non-profit making model.

### Language

English

### Country

England

### Stage of review

Review\_Ongoing

### Subject index terms status

Subject indexing assigned by CRD

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Subject index terms

Humans; Primary Health Care; Self-Examination

Date of registration in PROSPERO

19 September 2018

Date of publication of this version

19 September 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions

19 September 2018

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