

PROTOCOL SUMMARY

Case finding for COPD in primary care: a systematic review

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Keywords COPD, case finding, primary care

The full version of this paper, with online appendices, is available online at www.thepcrj.org

Introduction

Chronic obstructive pulmonary disease (COPD) is an important and rising cause of morbidity and mortality worldwide, and early detection of undiagnosed disease forms part of the national clinical outcomes strategy for COPD in the UK. It is currently the fourth leading cause of death¹ and is projected to become the third leading cause by 2020.² It is responsible for a large level of healthcare use, costing the UK National Health Service over £800 million per year.³ Much of the burden of COPD remains undetected,^{4,5} with estimates from prevalence studies suggesting that over 10% of the UK population aged above 35 years may have undiagnosed airflow obstruction⁶ compared with the diagnosed prevalence of 1.6%.⁷ There is a national drive in the UK to identify people with undiagnosed COPD so that they receive treatments that may benefit their symptoms and quality of life, and this forms part of the Outcomes Strategy for COPD and Asthma.⁸

There are a number of published studies of case finding for COPD in primary care from a variety of settings worldwide.⁹⁻¹¹ However, they are of variable quality and mostly lack a comparator. Two systematic reviews^{12,13} conducted for the US Preventive Service Task Force looked at the use of spirometry for population screening for COPD, but these did not fully address the scope of the proposed review, were limited in their search strategy, and need updating. Furthermore, no systematic review protocols on case finding for COPD were identified in the PROSPERO database.¹⁴ There is therefore a need to review systematically the various approaches to case finding that have been studied in primary care, including their cost-effectiveness. Many of these approaches use screening questionnaires to identify which patients should undergo spirometry, each reporting different levels of test accuracy.^{9,15-18} One narrative review by van Schayck *et al.*¹⁹ compared existing symptom-based questionnaires but requires updating.

Objectives

The primary objective of this review is to summarise the different approaches to case finding for COPD studied in primary care, and their case finding yield. The review will also consider the cost-effectiveness of case finding and the test accuracy of screening questionnaires for COPD.

The review specifically aims to address the following questions about case finding for COPD in primary care:

1. What approaches to case finding have been studied?
2. What is the yield from case finding for each approach?
3. What is the most effective method of case finding?
4. What is the cost per case of COPD detected through case finding?
5. What is the test accuracy of screening questionnaires for COPD?

The review will be conducted and reported in accordance with the PRISMA statement.²⁰ (see Appendix 1, available online at www.thepcrj.org)

Study criteria

Studies will be included in the review if they fulfil the following criteria:

Population

Individuals aged ≥ 35 years with no prior diagnosis of COPD, with or without a smoking history, in primary care. This includes individuals with other respiratory conditions such as asthma. Where possible, the populations will be subgrouped by age, smoking status (e.g. active smokers, ever smokers), and presence of symptoms.

Interventions

Questionnaires, clinical examination, spirometry, peak flow, decision aids/risk algorithms, and lung imaging (including chest x-ray and computed tomography), either alone or in combination.

Outcomes

The primary outcomes of interest are derived from the number of new cases of spirometry-defined COPD identified and include:

- Proportion of targeted patients identified with COPD

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Table 1. Diagnostic criteria for COPD

Standard	Diagnostic criteria for COPD
GOLD	Chronic symptoms + normal spirometry (GOLD stage 0) or post-bronchodilator FEV ₁ /FVC <0.7 with or without symptoms (GOLD stages 1-3)
ERS/ATS	Presence of chronic symptoms or exposure to cigarettes or environmental or occupational pollutants + post-bronchodilator FEV ₁ /FVC <0.7
NICE	Chronic symptoms + post-bronchodilator FEV ₁ /FVC <0.7 (2010 updated) Chronic symptoms + pre-bronchodilator FEV ₁ /FVC <0.7 + FEV ₁ % predicted <80% (2004)

GOLD=Global Initiative for Obstructive Lung Disease;²⁷ ERS=European Respiratory Society;²⁸ ATS=American Thoracic Society;²⁸ NICE=National Institute for Health and Clinical Excellence;^{29,30} FEV₁= forced expiratory volume in 1 second; FVC= forced vital capacity.

- Cost per case of COPD detected
- Sensitivity and negative predictive value of COPD screening questionnaires (these two measures of screening test accuracy have been prioritised as they reflect the ability of the questionnaire to exclude COPD)
The secondary outcomes are:
 - Positive predictive value of case finding interventions for COPD
 - Number-needed-to-screen to identify one individual with COPD
 - Specificity, positive predictive value, positive and negative likelihood ratios, and area under the curve of COPD screening questionnaires

Study designs

Randomised controlled trials, single arm trials, quasi-experimental and screening test accuracy studies will be considered eligible for inclusion if the studies confirm the diagnosis of COPD by spirometry according to either the Global Initiative for Obstructive Lung Disease (GOLD), European Respiratory Society (ERS), American Thoracic Society (ATS), National Institute for Health and Clinical Excellence (NICE) or other nationally accepted criteria (Table 1). Economic evaluations will also be included.

Methods

Search strategy

Bibliographic databases will be searched including Medline, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), HTA Database and NHS Economic Evaluations Database (NHS EED). Studies in progress will be sought from trial registers including the UK Clinical Research Network, MetaRegister of Current Controlled Trials, UK International Clinical Research Network Portfolio (NIHR CRN), and WHO International Clinical Trials Registry Platform (ICTRP). Ongoing studies and other grey literature will also be sought from conference abstracts from the ERS, ATS, British Thoracic Society, Index of Scientific and Technical Proceedings, and the Conference Papers Index. Systematic reviews in progress will be sought from the International Prospective Register of

Systematic Reviews (PROSPERO). A comprehensive search of relevant articles on the internet will be searched using Google Scholar, Turning Research Into Practice (TRIP), HTAi VORTAL and DogPile, limited to the first one hundred articles per search. Reference lists from relevant papers will be hand searched. Experts will be contacted to identify additional studies. Studies already known to the authors will also be included. There will be no language restrictions. The search will include studies published up to 15 years before the date of the search.

Search terms

Search terms will be used to broadly identify articles that examine case finding for COPD. This will include two main search term headings:

- COPD: chronic obstructive pulmonary disease, chronic obstructive airways disease, chronic obstructive lung disease, COPD, COAD, emphysema, chronic bronchitis, airflow obstruction, airflow limitation (terms combined with OR)
- Case finding: case finding, screening, early detection, secondary prevention, risk, spirometry, questionnaire, peak flow, chest X-ray, computed tomography, CT, decision aid, algorithm, sensitivity, specificity (terms combined with OR)

These search terms will be inputted as MESH or MESH-like terms and as free text.

Search terms will be combined as: COPD AND case finding.

The search strategy will be piloted on Medline and amended according to the number of articles produced and their relevance to the research questions.

Selection of relevant studies

A list of all citations and their abstracts will be produced. Articles will then be selected in two phases:

1. The first 10% of citations will be screened independently by two reviewers and included if they broadly fit with the inclusion criteria in order to maximise the sensitivity of the search. Disagreements will be resolved through discussion and through a third reviewer where agreement cannot be reached. The remaining 90% of citations will be screened by one reviewer. Articles will be included if their title or abstract suggests relevance to at least one of the five research questions.
2. Full text versions of all included articles will then be screened for relevance independently by two reviewers using an explicit set of inclusion and exclusion criteria (Table 2). Disagreements will be resolved through discussion and by a third reviewer where agreement cannot be reached.

A log of included and excluded studies will be constructed at each stage of the study selection process.

Data extraction

Data will be extracted from each included study by one reviewer using a predetermined data extraction form (see Appendix 2, available online at www.thepcrj.org) and checked for accuracy by a second reviewer. This will include information on the population, intervention, comparator, study design, and specific outcome measures. Population characteristics of particular interest will include mean age, sex ratio, smoking history, and occupational exposures. The data extraction form will be piloted on at least two studies identified in the scoping search.

Table 2. Inclusion and exclusion criteria for study selection

	Inclusion criteria	Exclusion criteria
Population	<ul style="list-style-type: none"> Age ≥ 35 years 	<ul style="list-style-type: none"> Age < 35 years
Setting	<ul style="list-style-type: none"> Primary care 	<ul style="list-style-type: none"> Secondary/tertiary care Occupational settings
Intervention	<ul style="list-style-type: none"> Screening questionnaire Clinical examination Spirometry Peak flow meter Chest x-ray Computed tomography Case finding algorithm 	<ul style="list-style-type: none"> None
Reference standard	<ul style="list-style-type: none"> Spirometry with airway obstruction defined according to NICE, ERS/ATS, GOLD or any nationally recognised standard 	<ul style="list-style-type: none"> Any other reference standard
Outcomes	<ul style="list-style-type: none"> Case finding yield Positive predictive value of case finding interventions Number-needed-to-screen to identify an individual with COPD Cost per case of COPD detected Sensitivity, specificity, positive and negative predictive value, positive and negative likelihood ratio and area under the curve of case finding questionnaires 	<ul style="list-style-type: none"> None
Study design	<ul style="list-style-type: none"> Randomised controlled trials Single arm studies Quasi-experimental studies Screening test accuracy studies Health economic evaluations 	<ul style="list-style-type: none"> Any other study design

GOLD=Global Initiative for Obstructive Lung Disease;²⁷ ERS=European Respiratory Society;²⁸ ATS=American Thoracic Society;²⁸ NICE=National Institute for Health and Clinical Excellence.^{29,30}

Quality assessment

The quality of studies assessing the yield from case finding interventions for COPD and the screening test accuracy of COPD case finding questionnaires will be assessed according to criteria adapted from the QUADAS and QUADAS-2 checklists.²¹ The quality of randomised controlled trials comparing the effectiveness of case finding interventions will be assessed according to criteria outlined in the Cochrane handbook²² as well as the QUADAS checklists.²¹ The quality of economic evaluations will be assessed according to items derived from the CHEC-List²³ and Drummond.²⁴ These items are listed in the Quality assessment form (see Appendix 3, available online at www.thepcrj.org).

The quality assessment will be conducted independently by two reviewers and disagreements resolved through discussion. Where consensus is not achieved, this will be resolved by a third reviewer. The quality assessment of each included study will be tabulated and a summary presented in a bar chart.

Risk of bias across studies

The case finding yield will be presented on separate funnel plots to assess the risk of bias across studies. The x-axis will include the proportion of individuals identified with COPD (p) and $\ln(p/[1-p])$. These different scales have been chosen to account for the skew that will be induced by virtue of the case finding yield being a proportion, which cannot be less than one. The y-axis will include

the number of individuals targeted and the inverse variance of p to reflect the size of the studies. An approximately symmetrical plot will be taken to indicate a reduced risk of bias across studies.

Methods of analysis/synthesis

The included studies will initially be described and analysed through a narrative systematic review. The case finding yield will be presented as the proportion of patients targeted through case finding who are identified with COPD. The number-needed-to-screen will be calculated as the reciprocal of the case finding yield. These will be sub-grouped by intervention, population, and definition of COPD. The case finding yields will be mathematically pooled where there is sufficient clinical and methodological homogeneity. A decision will then be made on whether to use a fixed or random effects model based on the level of heterogeneity identified amongst the included studies. However, a random effects model is more likely given the level of heterogeneity identified in the scoping review. This will be performed using REVMAN-Review Manager version 5.1. No attempt will be made to pool estimates of the positive predictive value and cost-effectiveness of case finding interventions, or the test accuracy of screening questionnaires.

Grading the overall quality of evidence and strength of recommendations

The overall quality of evidence and strength of recommendations

will be graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.^{25,26} These will be summarised for each outcome using GRADEPro.

Handling editor Alan Crockett

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Conflicts of interest SMMH and REJ are funded by the National Institute for Health Research (NIHR) which is currently funding a large randomised controlled trial of case finding for COPD in the West Midlands, UK as part of the Birmingham Lung Improvement Studies (BLISS) for which REJ and PAA are principal investigators.

Contributorship SMMH performed the literature search, designed the methodology and wrote the manuscript. PAA advised on the research questions and methodology. REJ advised on the research questions and methodology and helped edit the manuscript.

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PROSPERO registration number: CRD42012002074

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Available online at <http://www.thepcrj.org>

Appendix 1. PRISMA 2009 Checklist

PRISMA 2009 Checklist



Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria; participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	N/A
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	1, 2 & 3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2 & appendix
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	2,3
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	3

Appendix 1. PRISMA 2009 Checklist

PRISMA 2009 Checklist



Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	3
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	3
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	N/A
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	N/A
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	N/A
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	N/A
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	N/A
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	4

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Appendix 2.

Data extraction form	
Study reference	
Author(s)	
Title	
Year of publication	
What review objectives does the study address?	
1. What approaches to case finding have been studied?	Yes/No/Unclear
2. What is the yield for case finding for each approach?	Yes/No/Unclear
3. What is the most effective method of case finding?	Yes/No/Unclear
4. What is the cost per case of COPD detected through case finding?	Yes/No/Unclear
5. What is the test accuracy of screening questionnaires for COPD?	Yes/No/Unclear
Study characteristics	
Study design	
Country	
Setting	
Objective	
Population	
Intervention/index test	
Test threshold	
Reference test	
Definition of COPD	
Comparator	

Appendix 2.

Outcome				
Results				
Population characteristics				
Mean age (range)				
Male %				
Smoking history				
Occupational exposures				
No. of patients initially targeted				
No. of patients who received case finding intervention				
No. of patients identified at-risk by case finding intervention				
No. of patients who received spirometry				
No. of patients who received spirometry of an acceptable standard				
No. of patients identified with COPD/airway obstruction				
Case finding yield (no. of patients identified with COPD/no. of patients initially targeted) *100				
Positive predictive value (no. of patients identified with COPD/no. of patients identified at-risk by case finding intervention)				
Number-needed-to-screen to identify one individual with COPD (1/case finding yield)				
Cost data		Yes/No		
Cost per person identified with COPD				
Screening test accuracy		Yes/No		
		COPD	Normal	Total
Screening/case finding test	Positive			
	Negative			
	Total			
Sensitivity				
Specificity				
Positive predictive value				
Negative predictive value				

Appendix 2.

Positive likelihood ratio	
Negative likelihood ratio	
Area under the ROC curve	
Comments	

Appendix 3.

Quality assessment form	
Study reference	
Author(s)	
Title	
Year of publication	
Quality items	
Generic	
Was there a clear description of recruitment?	Yes/No/Unclear
Was there a clear description of participants?	Yes/No/Unclear
Was there a clear description of withdrawals?	Yes/No/Unclear
Was a participant flow diagram included?	Yes/No/Unclear
Was the study industry sponsored?	Yes/No/Unclear
Specific	
Diagnosis of COPD	
Was there adequate quality control of spirometry?	Yes/No/Unclear
Was the diagnostic criteria for COPD in accordance with ERS/ATS, GOLD, NICE or other national standard?	Yes/No/Unclear
Single arm and quasi-experimental studies and RCTs assessing the yield from case finding interventions and screening test accuracy studies for case finding questionnaires	
Was the spectrum of participants representative of patients who will receive the test in practice?	Yes/No/Unclear
Was the selection criteria clearly described?	Yes/No/Unclear
Was quality controlled spirometry used as the reference standard?	Yes/No/Unclear
Was spirometry performed within six months of the case finding intervention?	Yes/No/Unclear
For single arm studies and RCTs assessing the yield from case finding did all participants with a positive case finding	Yes/No/Unclear

Appendix 3.

intervention result or a random selection of such participants receive verification of COPD using spirometry? For screening test accuracy studies did the whole sample or a random selection of the sample receive verification of COPD using spirometry?	
Was the reference spirometry independent of the result of the case finding intervention?	Yes/No/Unclear
Was the case finding intervention described in sufficient detail to permit its replication?	Yes/No/Unclear
Was the execution of the confirmatory/reference spirometry described in sufficient detail to permit its replication?	Yes/No/Unclear
For screening test accuracy studies were the results of the case finding questionnaire interpreted without knowledge of the results of spirometry?	Yes/No/Unclear/NA
Were the spirometry results interpreted without knowledge of the results of the case finding intervention?	Yes/No/Unclear
Were the same clinical data available when the results of the case finding intervention were interpreted as would be available when the test is used in practice?	Yes/No/Unclear
Were uninterpretable, indeterminate or intermediate test results reported?	Yes/No/Unclear
Were withdrawals from the study explained?	Yes/No/Unclear
RCTs comparing case finding interventions	
Was the method of random sequence generation adequately described?	Yes/No/Unclear
Was the method of allocation concealment adequately described?	Yes/No/Unclear
Were comparison groups similar except for the intervention they received?	Yes/No/Unclear
Were study personnel blinded to intervention arm?	Yes/No/Unclear
Were outcome assessors blinded to intervention arm?	Yes/No/Unclear
Was the completeness of outcome data described for each outcome, including attrition and exclusions from the analysis?	Yes/No/Unclear

Appendix 3.

Was there any evidence of selective outcome reporting?	Yes/No/Unclear
Were there any other sources of bias?	Yes/No/Unclear
If yes, please specify	
Health economic evaluations	
Was the perspective of the evaluation clearly stated?	Yes/No/Unclear
Were the competing alternatives adequately described?	Yes/No/Unclear
Was there evidence that the effectiveness of the intervention had been established?	Yes/No/Unclear
Were the effects of the intervention identified, measured and valued appropriately?	Yes/No/Unclear
Were important costs and consequences adequately described?	Yes/No/Unclear
Were costs and consequences valued credibly?	Yes/No/Unclear
Was an incremental analysis of costs and consequences of alternatives performed?	Yes/No/Unclear
Were all future costs and outcomes discounted appropriately?	Yes/No/Unclear/NA
Was an adequate sensitivity analysis performed?	Yes/No/Unclear
Were all important outcomes and issues of concern addressed?	Yes/No/Unclear
Comments	