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RESEARCH PAPER

Early detection of COPD in general practice: patient or practice managed? A randomised controlled trial of two strategies in different socioeconomic environments

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Abstract

Background: The burden of chronic obstructive pulmonary disease (COPD) is high. Health benefits can be gained in primary care by early detection and preventive measures.

Aims: To compare the effectiveness of two strategies for population-based early detection of COPD, taking into account different socioeconomic status (SES) settings.

Methods: Practices were randomised on strategy and stratified on SES setting. The Respiratory Health Screening Questionnaire (RHSQ) was distributed to all participants. In the practice-managed condition, the practice was responsible for the whole procedure, while in the patient-managed condition, patients were responsible for calculating their RHSQ risk score and applying for a spirometry test. The main outcome measure was the rate of COPD diagnoses after screening.

Results: More new COPD patients were detected in the practice-managed condition (36%) than in the patient-managed condition (18%). In low SES practices, more high-risk patients were found (16%) than in moderate-to-high SES practices (9%). Recalculated for a standard Dutch practice (2,350 patients), the yield would be 8.9 new COPD diagnoses, which is a 20% increase of known cases.

Conclusions: The practice-managed variant of this screening procedure shows a substantial yield of new COPD diagnoses for both low and moderate-to-high SES practices.

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Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most prevalent causes of morbidity and mortality worldwide. It represents the largest fraction of mortality for respiratory diseases, which form the third most common cause of death in the European Union (8%).[1-5] The worldwide prevalence of COPD in the general population is rising steeply to 10% among those aged 40 years or more.[6-8] The prevalence of detected COPD in Dutch general practices is 2%.[9] In many western countries, another 2% of COPD remains undiagnosed.[10]

Miravitlles *et al*. found that only 60% of people with chronic respiratory symptoms consulted a physician and only 45% of them underwent spirometry.[11] Our research showed that high-risk patients detected by screening reported having had respiratory symptoms previously without seeking help.[12] Smokers are particularly unaware of having symptoms and neglecting to see a doctor. They feel shame and guilt because of a self-inflicted disease associated with persistent smoking habits[13] and they adapt to slowly developing respiratory problems.[14]

Cigarette smoking is the main causal factor of COPD in the

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western world and is also the most important risk factor that can be influenced.[15,16] Starting age, total pack-years, and current smoking status are all predictors of COPD mortality.[17] Definitive smoking cessation makes sense at any stage of the disease and slows the decline of forced expiratory volume in one second (FEV_1) from 60mL/year to 30mL/year.[18] Even temporary cessation helps to slow the decline.[19] The success of smoking cessation is greater when people participate in a prevention programme that includes spirometry.[20]

Low socioeconomic status (SES) is also an important risk factor for COPD. It correlates significantly with lower lung function, even after adjustment for smoking status, occupational exposures, and race or ethnic origin.[21] The impact of low SES on lung function is variable, but FEV_1 reductions of >300mL in men and >200mL in women have been reported.[22] Non-smokers with low SES can be seen as independent groups at risk of COPD.[23]

A third risk factor for COPD – independent of SES and smoking – is poor health literacy. It is associated with more severe COPD stages, greater COPD helplessness, worse respiratory-related quality of life, and more use of COPD-related emergency healthcare.[24]

Early detection programmes combined with smoking cessation interventions may delay the progression of COPD.[25] The literature reveals several COPD case-finding initiatives among patients in waiting rooms, patients with co-morbidities,[26-31] and among smokers,[32-34] but only a few population-based screening studies of COPD.[12,35-37] All these studies report 13–41% additional COPD diagnoses.

The Respiratory Health Screening Questionnaire (RHSQ) is a population-based questionnaire for early COPD detection in a random population, and it includes a validated set of questions and a score card system (Table 1).[38,39] The RHSQ was piloted in a Dutch general practice population in 2008 and found 11% of the respondents to be at high risk. After post-bronchodilator spirometry, 39.6% of these high-risk respondents were diagnosed with COPD.[12] These results prompted us to evaluate this combination of questionnaire and spirometry on a larger scale. Anticipating a possible nationwide rollout of the RHSQ, we had to take into account the consequences of extra workload for family practices. A standard Dutch practice has 2,350 patients, including 700 in the target group for the RHSQ (age 40–70 years). It was estimated that conducting the RHSQ would take about 10 hours per standard practice (half for preparation, half for settlement). We therefore tested two strategies: one in which the practice is responsible for the whole procedure and another in which the practice is responsible for only the recruitment and the respondent is responsible for handling the RHSQ and requesting a spirometric test when indicated.

The aim of this study was to determine the yield of a population-based early detection procedure including (a) risk screening by the RHSQ and (b) spirometric testing of high-risk patients in primary care. Our research questions were:

- How many new COPD diagnoses are found by this procedure?
- Is there a difference between a practice-managed and a patient-managed strategy?
- How does the SES profile of the practice influence the effectiveness of these strategies?

Methods

Setting and design

We conducted a cluster randomised controlled trial among 16 family practices of different sizes from May to September 2012. The practices were located in four cities in the middle and south of the Netherlands. The RHSQ was sent to all eligible patients registered with these practices. In the patient-managed condition, patients were responsible for calculating their RHSQ scores and for demanding a spirometry test in case of a high-risk score. In the practice-managed condition the family practice was responsible for the whole process.

Practices were stratified based on socioeconomic status (SES). There is no universally accepted definition of SES, and stratification criteria vary from occupation, educational level, income, and residential area.[40] We took the criterion of residential area based on the Dutch Health Authority public register. In this register practices are classified as low SES or moderate to high SES depending on the socioeconomic profile of their adhering area (based on postal codes).

Population

People aged 40–70 years, excluding those already diagnosed with asthma or COPD or with other serious lung diseases such as lung cancer, pneumoconiosis, tuberculosis, bronchiectasis, and pneumonectomy, were eligible to take part in the study. People using oxygen supplementation and those with impaired mobility were also excluded. Ethical approval was obtained from Medical Ethics Review Board (MERB), Atrium Hospital, Heerlen (MERB number 12N33).

Intervention

The RHSQ is a validated questionnaire for screening patients at risk of COPD (Table 1).[38,39] It was posted to patients and responders had the opportunity of mailing or emailing by log-in code. It contains 10 simple questions about age, smoking history, body weight, body length, and respiratory complaints (Table 1). The standard version includes a scoring card to calculate the risk of COPD: low risk (<16.5 points), medium risk (16.5–19.5 points), or high risk (>19.5 points). People in the patient-managed condition used this scoring card to calculate their risk themselves; the scoring card advised them to consult the family practitioner in case of a high-risk score. In the practice-managed condition the scoring card was removed and risks were calculated by the family practice; people with a high-risk score were explicitly invited for a spirometry test.

The spirometry test was conducted according to the prevailing guidelines of the Dutch College of General Practitioners.[41] A COPD diagnosis was based on the combination of a post-bronchodilator FEV_1/FVC ratio <0.7 and the physician's clinical evaluation.[42] All participants gave informed consent.

Outcome measures

The main outcome measure was the number of new COPD diagnoses after spirometry per practice. Secondary outcome measures were the rate of RHSQ high-risk scores and the yield of new COPD diagnoses in a standard Dutch practice (2,350 patients). Determinants were the intervention strategy, the SES profile of the practice, the smoking status of the patient, and the practice

Table 1. Respiratory Health Screening Questionnaire (RHSQ) score card

Question		Answer	Score
1.	What is your age?	40–49	0
	Age group, years	50–59	4
		60–69	8
2(a)	How many cigarettes have you smoked per day?	……. cigarettes	
2(b)	Are you smoking now?	Yes O	
		No O	
3(a)	How many years have you smoked?	……. years	
	Pack years I have smoked	0–14	0
		15–24	2
		25–49	3
		50+	7
4.	What is your weight?	…… kg	
5.	What is your height?	…… m	
	Body mass index, kg/m^2	>29.7	0
		25.4–29.7	1
		<25.4	5
6.	Does the weather affect your cough?	Yes	3
		No	0
		Do not cough	0
7.	Do you have phlegm without a cold?	Yes	3
		No	0
8.	Do you have phlegm in the morning?	Yes	0
		No	3
9.	Do you wheeze (frequency)?	Never	0
		Sometimes or often	4
10.	Have or had any allergies?	Yes	0
		No	3

prevalence of COPD prior to the screening.

Data sampling and analysis

Data from questionnaires and spirometry tests were collected in a central database and completed with interview data about smoking status. To get insight into the reasons for non-response, a sample of 10 non-responders per practice were approached by telephone with one open question – their reason for non-participation.

Descriptive and testing statistics were calculated by SPSS-19. Differences between groups were assessed by $\chi 2$ tests after correction for cluster randomisation and stratification by logistic regression. Correlation between prior prevalence and percentage of newly detected COPD was evaluated by Pearson's correlation test.

Results

Response and demographics

The enrolled practices included 11,498 patients aged 40–70 years. A total of 1,390 patients (597 with a known COPD diagnosis) met one or more of the exclusion criteria. The RHSQ was distributed in the enrolled practices to 10,108 people and a total of 3,573 responded. The response to the questionnaire was 50% in the practice-managed condition (52% low SES, 47% moderate to high SES) and 27% in the patient-managed condition (24% low SES, 29% moderate to high SES). Table 2 shows that both conditions were similar with respect to age and gender, but not for smoking behaviour. The patient-managed condition yielded fewer smokers, which suggests a response bias on smoking behaviour in favour of non-smokers. Table 3 shows that respondents in low SES practices were on average older, more often current smokers, and had more pack-years than respondents in moderate to high SES practices.

The attendance for spirometry among high-risk respondents was 54% in the practice-managed condition (49% low SES, 64% moderate to high SES) and 75% in the patient-managed condition (78% low SES, 73% moderate to high SES). Reasons for non-participation in low SES practices were lack of time, other health problems, no understanding, and no risk awareness while, in moderate to high SES practices, reasons for non-participation were no complaints, forgotten, lack of time, and no interest.

Test outcomes

Table 4 shows that there was no significant difference in the rate of high-risk scores between respondents in the two conditions, which does not reveal evidence for a response bias based on the risk test score. In the practice-managed condition, however, high-risk respondents had more COPD than in the patient-managed condition (36% vs. 18%, $p<0.05$). This difference was even larger among active smokers (54% vs. 25%).

Low SES practices had significantly more high-risk respondents than moderate to high SES practices (16% vs. 9%, $p<0.05$). However, there was no significant difference between the two

Table 2. Characteristics of respondents by trial condition

	Total (n=3,573)	Patient-managed (n=1,717)	Practice-managed (n=1,856)	p Value
Mean (SD) age*	53.6 (8.5)	53.5 (8.4)	53.7 (8.5)	0.319
Male**	1,797 (50.3%)	875 (51.0%)	922 (49.7%)	0.466
Smoking status**				
Never	1,608 (45%)	827 (48%)	777 (42%)	
Former	458 (13%)	197 (12%)	261 (14%)	
Current	1,505 (42%)	688 (40%)	817 (44%)	0.000
Pack years*** (median, min–max)	18 (0.5–129)	15 (0.5–100)	20 (0.5–129)	0.000

* Chi-square test. ** Student t test. *** Mann–Whitney U test (pack years=0 excluded).

Table 3. Characteristics of respondents by socioeconomic status (SES)

	Total (n=3,573)	Low SES (n=1,613)	Average SES (n=1,960)	p Value
Mean (SD) age*	53.6 (8.5)	54.4 (8.8)	52.9 (8.2)	0.000
Male**	1,797 (50.3%)	821 (51.0%)	976 (49.8%)	0.488
Smoking status**				
Never	1,608 (45%)	699 (43%)	905 (46%)	
Former	458 (13%)	185 (12%)	273 (14%)	
Current	1,505 (42%)	725 (45%)	780 (40%)	0.003
Pack years*** (median, min–max)	18 (0.5–129)	15 (0.5–100)	20 (0.5–129)	0.000

* Chi-square test. ** Student t test. *** Mann–Whitney U test (pack years=0 excluded).

groups with respect to the chance of having COPD.

On the practice level, there was no correlation between the prior prevalence of COPD and the percentage of newly detected COPD diagnoses (Pearson's coefficient –0.167).

The yield of our screening procedure for early detection was 73 new COPD diagnoses out of 10,108 participants for both strategies, giving an average of 8.9 new COPD diagnoses per standard Dutch practice in the practice-managed condition and 3.0 in the patient-managed condition. Thus, the practice-managed approach was approximately three times as effective as the patient-managed approach.

Cost per detected case

Table 5 shows that, for a standard Dutch practice, 77 RHSQs had to be distributed (61 low SES, 111 moderate to high SES), three

Table 4. Results of the RHSQ and spirometry test by strategy and socioeconomic status (SES)

Results (by SES setting)	All strategies	Patient-managed strategy	Practice-managed strategy
All practices			
RHSQs distributed	10,108	6,393	3,715
Responders (% of distributed)	3,570 (35%)	1,715 (27%)	1,855 (50%)
High risk on RHSQ (% of responders)	437 (12%)	186 (11%)	251 (14%)
Show up for spirometry (% of high risk)	275 (63%)	140 (75%)	135 (54%)
COPD diagnosis (% of show up)	73 (27%)	**25 (18%)†**	**48 (36%)†**
Smokers among show up (% of show up)	129 (47%)	53 (38%)	76 (56%)
COPD diagnosis among smokers (% of show up)	54 (42%)	13 (25%)	41 (54%)
COPD diagnoses in a standard practice*	**5.3**	**3.0**	**8.9**
Low SES practice			
RHSQs distributed	4,422	2,476	1,946
Responders (% of distributed)	1,613 (36%)	598 (24%)	1,015 (52%)
High risk on RHSQ (% of responders)	**252 (16%)‡**	86 (14%)	166 (16%)
Show up for spirometry (% of high risk)	148 (59%)	67 (78%)	81 (49%)
COPD diagnosis (% of show up)	46 (31%)	14 (21%)	32 (40%)
Smokers among show up (% of show up)	78 (53%)	29 (43%)	49 (60%)
COPD diagnosis among smokers (% of show up)	35 (45%)	8 (28%)	27 (55%)
Moderate to high SES practice			
RHSQs distributed	5,686	3,917	1,769
Responders (% of distributed)	1,957 (34%)	1,117 (29%)	840 (47%)
High risk on RHSQ (% of responders)	**185 (9%)‡**	100 (9%)	85 (10%)
Show up for spirometry (% of high risk)	127 (69%)	73 (73%)	54 (64%)
COPD diagnosis (% of show up)	27 (21%)	11 (15%)	16 (30%)
Smokers among show up (% of show up)	51 (40%)	24 (33%)	27 (50%)
COPD diagnosis among smokers (% of show up)	19 (37%)	5 (21%)	14 (52%)

*Extrapolation for a standard Dutch practice including 2,350 patients.

†A pro-active approach results in more positive spirometry than a re-active approach ($p<0.01$).

‡Low SES practices have more high-risk scores on the RHSQ than moderate to high SES practices ($p<0.001$).

RHSQ=Respiratory Health Screening Questionnaire.

Table 5. Number of start conditions needed to detect one COPD diagnosis in a standard Dutch practice (2350 patients)

Start condition (by SES setting)	Patient-managed	Practice-managed
All practices		
RHSQs distributed	256	77
Responders for spirometry (all high-risk)	6	3
Cost per detected case (all high-risk)	€698	€256
Cost per detected case (high-risk smokers)	€642	€228
Low SES practices		
RHSQs distributed	177	61
Responders for spirometry (all high-risk)	5	3
Cost per detected case (all high-risk)	€512	€224
Cost per detected case (high-risk smokers)	€484	€196
Moderate to high SES practices		
RHSQs distributed	356	111
Responders for spirometry (all high-risk)	7	3
Cost per detected case (all high-risk)	€926	€324
Cost per detected case (high-risk smokers)	€870	€296

Cost per unit: €2 for a RHSQ, €28 for a spirometry test (in case of high risk) and €18 for a COPD consultation (in case of a positive diagnosis).

RHSQ=Respiratory Health Screening Questionnaire, SES=socioeconomic status

spirometry tests had to be performed (in both SES settings) and, additionally, one COPD consultation had to be undertaken to detect one new COPD diagnosis in the practice-managed condition. The total cost of the detection programme was €256 per detected case (€224 low SES, €324 moderate to high SES). In the patient-managed condition, 256 RHSQs had to be distributed and six spirometry tests had to be performed, with a cost of €698 per detected case.

Discussion

Main findings

Our study has shown that the use of the RHSQ among all those aged 40–70 years followed by spirometry testing of high-risk scoring respondents is effective and can best be provided following a practice-managed strategy. A greater responsibility for the patient in this procedure appeared less effective, especially for smokers. We found a return of 8.9 newly detected COPD cases per standard primary care practice, which is an increase of 20% over the known prevalence. An investment of €224–324 per detected case seems reasonable for a disease where health benefits can be gained with early detection, since the earlier COPD is detected and behaviour changes are induced, the slower the decline in FEV_1 and the better the quality of life prognosis will be,[22] especially among smokers[18] and low SES groups.[43]

Interpretation of findings in relation to previously published work

Most newly detected COPD patients in our study were active smokers. This indicates room for improvement, because smoking cessation is still the most effective way to reduce the progression of COPD and to improve survival in COPD patients. Some studies have shown that smokers who know that they have COPD are more successful quitters,[20,44] although this observation is not consistent in the literature.

The RHSQ has previously been used only for targeted screening studies among active smokers: Kotz *et al*.[33] found 41% COPD after screening, Price *et al*.[34] found 19%, and Freeman *et al*.[32] reported 17%. To our knowledge, this is the first study where the RHSQ has been used for population-based screening. In its most effective condition (practice-managed), the yield of COPD after screening was 36% among high-risk respondents. This is more than population-based screening studies using different questionnaires: Van Schayck *et al*.[37] reported 18% COPD after screening and Calverley *et al*.[35] reported 13%. Only Martinez *et al*.[36] reported a higher yield of COPD after screening (38%), but their study recruited also from specialist sources.

The possibility that the RHSQ would be less effective in low SES practices because of an expected lower response is not supported by our results. There was no response bias; the RHSQ returned more high-risk persons and more COPD patients after screening in low SES practices than in moderate to high SES practices. The latter finding is in line with the literature, which reports more COPD among low SES groups.[21]

The assumption that a higher prior prevalence of COPD in a specific practice would leave less room for the detection of new COPD patients is not supported by our study. Furthermore, the apparent underdiagnosis of COPD is illustrated by the relatively low proportion of mild COPD in the Netherlands; of all known COPD cases, 28% have mild disease, 54% have moderate disease, 15% have severe disease, and 3% have very severe COPD.[45] This raises the question of how the potential of undetected COPD can be estimated. The Dutch College of General Practitioners (NHG) estimates the prevalence of known COPD cases at 20/1,000, which means that a standard family practice (2,350) has 47 cases of COPD.[41] Soriano *et al*. estimate that there is another 2% of undetected COPD patients, which makes the potential prevalence of known and unknown COPD cases 4%.[10] In our most effective strategy (practice-managed) we detected an average of 8.9 new COPD patients per standard Dutch practice. Together with the 47 cases already known, this amounts to 56 COPD cases per family practice, which is 2.4% of the total population, far less than the 4% estimated by Soriano *et al*. This makes it worthwhile to improve further the response of our early detection procedure.

Strengths and limitations of this study

Although the 50% response to the questionnaire is acceptable, the 54% response to the invitation for spirometry is rather low and needs improvement. One way to improve the response is to conduct the intervention in another season. Our study period included the summer holidays, a time when many people are on vacation, especially in low SES practices when many ethnic Mediterranean people leave for a long visit to their native country. Many candidates for the RHQS may have missed the invitation.

A practical limitation of our study is the fact that the whole intervention was performed under time pressure with the help of external practice nurses and supplementary administrative support. For the personnel of a primary care practice it is impossible to screen and test all patients aged 40–70 years within a period of three months. Without external practice nurse support, it would be more feasible to spread out the effort over a longer time – for example, 15 or 30 months with every month one- or two-year cohorts. We performed a feasibility study for this implementation strategy in 10 other practices and report the results of this study in this same issue of the *PCRJ*.[46]

Implications for future research, policy and practice

Future research should focus on the implementation of early diagnosis and treatment of COPD in general practice. Especially important is a full cost-effectiveness study investigating early detection of COPD in combination with smoking cessation.

Conclusions

A population-based COPD screening procedure among those aged ≥40 years with the RHSQ and spirometry is an effective method for the early detection of COPD in primary care. The yield is higher in low SES practices than in moderate to high SES practices. Regardless of SES, this procedure should preferably be managed by the family practice and not by the patients themselves.

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