SPIROMETRY
EXPERT SUPPORT IN GENERAL PRACTICE
PATRICK POELS
Spirometry expert support in general practice
The thesis has been prepared by the Department of General Practice of the Radboud University Nijmegen Medical Centre, the Netherlands, and within the programme Chronic Diseases in General Practice of the Nijmegen Centre for Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen. The Department of General Practice participates in the Netherlands School of Primary Care Research (CaRe), which has been acknowledged by the Royal Netherlands Academy of Arts and Sciences (KNAW) in 1995.

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Spirometry expert support in general practice
Thesis, Radboud University Nijmegen, with summary in Dutch

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This thesis describes studies on utilisation of spirometry and interpretation of spirometry test results in general practice. Spirometry is an essential pulmonary function test in confirming chronic obstructive pulmonary disease (COPD), unstable asthma or (more often) excluding airway obstruction in a diagnostic procedure of patients with symptoms such as dyspnoea, chronic cough, and chronic sputum production. The aim of this thesis is to assess the impact of expert support for the interpretation of spirometry test results on the diagnostic achievements of general practitioners (GPs).

**Background**

Chronic obstructive pulmonary disease (COPD, referring to chronic bronchitis and emphysema) and asthma are prevalent chronic respiratory conditions that will continue to cause increased disability in the world's population in future years. COPD and asthma are mainly diagnosed and treated in general practice in the Netherlands.

COPD is an airway disease usually characterised by progressive airflow limitation, that is not fully reversible. Smoking is considered to be the major cause of COPD. Symptoms of COPD are dyspnoea, cough and sputum production. Intermittent acute exacerbations often occur in the winter months as a result of infections. The prevalence of COPD in the general population in the Netherlands is estimated at 2.2% in men and 1.7% in women; the prevalence increases with age and COPD is predominantly diagnosed in patients after 40 years. In a general practice with 2,500 patients, 55 patients will have a physician diagnosis of COPD, generally 80% of these patients have mild or moderate COPD. Smoking cessation is the only successful intervention that can stop further decline of lung function. Medication treatment consists of bronchodilators and inhaled steroids.

Asthma can develop at any age, but is predominantly a childhood disease. Asthma is characterised by increased bronchial hyperresponsiveness, intermittent and nonproductive cough, intermittent and variable breathlessness and/or nocturnal symptoms. Contrary to COPD, the airflow obstruction is intermittent and usually fully reversible. Airflow obstruction can occur in reaction to contact with allergenic and non-specific stimuli. Concomitant eczema, allergic rhinitis and a positive family history for these signs and symptoms are common. Spirometry, reversibility testing, and peak flow monitoring are diagnostic tools to assess a diagnosis of asthma. Asthma is characterised by a normal or slightly obstructive lung function as measured with spirometry together with mostly full reversibility after inhaling bronchodilators. Severity classification of asthma is staged on the presence of clinical symptoms and medication use: intermittent, mild persistent, moderate and severe persistent. In an
average general practice with 2,500 patients about 75 patients will have a physician diagnosis of asthma. Medication treatment consists of inhaled steroids and bronchodilators. Medication treatment consists of inhaled steroids and bronchodilators.

**Spirometry tests**

In a diagnostic procedure of patients in general practice with symptoms such as dyspnoea, chronic cough, chronic sputum production, spirometry is essential in confirming (COPD or instable asthma) or (more often) excluding airway obstruction. Spirometry measures the forced vital capacity (FVC) — the maximum volume of air forcibly exhaled after full inspiration, the forced expiratory volume in one second (FEV₁) — the volume of air exhaled during the first second of the FVC manoeuvre, and the FEV₁ /FVC ratio. In general practice, most spirometers produce the graphic results of a spirometry test; the flow volume curve (figure 1). The FEV₁ and FVC values are compared with predicted normal values for age, height, and sex and often expressed as the percentage predicted. Airflow obstruction is present if the FEV₁ /FVC ratio is <0.7 and the FEV₁ is <80% of the predicted value. Spirometry contributes to distinguish patients with COPD from patients with asthma as patients with COPD will always show irreversible airflow obstruction whereas patients with asthma may or may not show airflow obstruction. Spirometry allows patients with COPD to be staged according to severity of obstruction (mild, moderate, severe or very severe).

*Figure 1 Example of a flow-volume curve*
Spirometry is an important tool within the broad concept of management in chronic respiratory diseases (COPD and asthma) and is essential for diagnosing these conditions. The central role that has been assigned to spirometry in general practice guidelines calls for its widespread implementation in the general practice setting. However, the mere existence of the guidelines alone by no means guarantees that GPs actually embrace spirometry and apply it consistently in diagnosing and managing patients who consult with respiratory symptoms. It seems that, despite the availability of the guidelines, there still are a number of practical barriers that impede wide implementation of quality spirometry facilities in general practice.

**Availability of spirometers in general practice**

In 1998, at least a third of all general practices either owned a spirometer or had easy access to external spirometry services. Although there are no recent official estimates for the Netherlands, it's quite likely that the dissemination of electronic spirometers among GPs has further progressed during the past few years. Several general practice studies indicate that introducing spirometry leads to considerable improvement in distinguishing COPD from asthma in subjects known to their GP as suffering from 'chronic respiratory disease'. The use of spirometry also contributes to the early detection of subjects with COPD or asthma in general practice. However, GPs interpret less than one spirometry test per week in daily practice.

**Interpretation of spirometry tests**

The current thesis logically flows from a broad spirometry study on the validity of spirometry in general practice and on the diagnostic value of spirometry (HASPIR study huisarts en spirometrie). The results from the HASPIR study confirmed that the spirometric parameters relevant for general practice (FEV₁, FVC, and their ratio) are valid when measurements are performed in the general practice setting. Apparently, this crucial prerequisite for broad implementation of spirometry in general practice is met. Taking this finding into consideration, the next question emerging is if GPs are able to draw the right conclusions from their spirometry tests. Apart from these published HASPIR studies, data was collected with questionnaires among participants of the HASPIR study to describe the utilisation and barriers to implementation of spirometry in primary care. However, these data were not yet analysed.

**Single training session**

In general practice postgraduate workshops of spirometry performance are often organised as part of continuous medical education. However, the precise effect of a single training workshop on the interpretative capacity of GPs is at least doubtful. A randomised study performed in New Zealand investigated the ability of GPs towards...
The investigators took random samples from the spirometry records of 15 GPs who had participated in a basic spirometry training. Subsequently, the GPs had to label the spirometric tests of their own subjects using seven pre-defined diagnoses (e.g. 'normal', 'obstructive disorder', 'inadequate test performance'). Two chest physicians judged the interpretations of the GPs as correct in 53% of the cases, an almost similar percentage as in a reference group consisting of GPs who had not received spirometry training. Results from a Dutch study show that GPs who have a special interest in respiratory disease are capable of differentiating between normal and obstructive disease patterns, whereas rare pathology (small airways disease, restrictive patterns and upper airway limitations) and mixed pathology patterns are likely to be missed. It is important to realise that, like electrocardiography (ECG), spirometry is a highly complex diagnostic tool in the perception of many GPs. A systematic approach for judging the quality of tests and the subsequent assessment of the relevant lung function indices (FEV$_1$, FEV$_1$/FVC), the accompanying predicted values, and the graphical output that most electronic spirometers provide (flow-volume and time-volume curves) seems difficult. Apparently, a basic training program alone is not sufficient to acquire the specific knowledge, skills and expertise necessary to interpret spirometry tests adequately.

**Spirometry expert support**

Ideally, the interpretative skills and confidence levels of GPs are supported after appropriate initial spirometry training. Understanding of the process of spirometry interpretation could be enhanced by organising ongoing expert support. One can think of three realistic modes to organise this 'expert support' in Dutch primary healthcare: (1) periodic repetition of postgraduate spirometry training for GPs, (2) 'case-specific' expert consultation or feedback from a secondary care respiratory consultant, or (3) 'real-time' support by a computised spirometry expert system.

The first option is rather time-consuming and non-specific: the information offered during training sessions does not pertain to a particular subject a GP would like to have an expert opinion on in the daily practice setting. The second option is supported by the published 'national primary-secondary care working agreements' ('Landelijke Transmurale Afspraken') between GPs and chest physicians with regard to the diagnosing and management of COPD and asthma. These working agreements – or parts of them - have already been implemented in some regions in the Netherlands (e.g., Nijmegen, Eindhoven), without any prior evaluation of the consequences. A disadvantage of implementing the working agreements is the amount of time demanded from respiratory consultants, a clear advantage is that the consultant may include additional (non-spirometric) diagnostic information in his/her judgement.

The third option, a computised spirometry expert system, may be an efficient alternative option: no time investment of respiratory consultants is required.
interpretation of spirometry tests can be requested by the GP at any time, and archiving of the expert information occurs automatically.

In 2000, a consensus group of experts (www.spirxpert.com/spirxpertgroup.htm) developed a computerised expert system to support GPs in their interpretation of spirometry test results with funding of the Dutch Asthma Foundation. The expert system interprets pre-and post-bronchodilator FEV₁, FVC and FEV₁/FVC values (graphical interpretation in Figure 2) and provides the GP with suggestions for further diagnostic testing when applicable (textual interpretation in Figure 2). The spirometry software expert system (SpirXP®, currently marketed as SpidaXpert® by Micro Medical Ltd, Kent, UK) is now commercially available. Empirical studies on the effect of this kind of ongoing expert support on the interpretative capacity of GPs are not available at this time.

**Figure 2 Example of a computerised spirometry expert system**

This thesis: objective and research questions

The main objective of this thesis is to assess the impact of expert support for the interpretation of spirometry test results on the diagnostic achievements of general practitioners.
Research questions:

1. For which indications do GPs use spirometry, and which GP- and practice-related factors are associated with its use?
2. Is there a need for ongoing support for spirometry test results among GPs, and which characteristics of GPs and their practice settings are associated with GPs’ need for ongoing support?
3. What is the effect of spirometry software expert support on the diagnostic achievements of GPs, and on GPs’ decision-making in diagnosing chronic respiratory disease?
4. What is the effect of spirometry software expert support or chest physician support on GPs’ diagnosis and subsequent management of chronic respiratory disease?

Outline of the thesis

Chapter 2 describes the results of a questionnaire survey of 61 GPs involved in a spirometry evaluation program. We explored the extent of spirometry utilisation for five indications from national COPD & asthma guidelines and we identified GP- and practice-related factors associated with spirometry utilisation. In chapter 3 we present the results of a questionnaire survey among 137 GPs who participated in the before mentioned spirometry evaluation program. We identified characteristics of GPs and their practice settings associated with GP’s need for ongoing support for spirometry interpretation. In chapter 4 we summarise in an editorial the need for ongoing expert support for the interpretation of spirometry tests by GPs. We highlight the importance of close collaboration between primary and secondary care with respect to spirometry test interpretation. Chapter 5 describes the results of a cluster-randomised controlled trial to assess in a simulated setting the impact of computerised spirometry interpretation expert support on the diagnostic achievements of GPs, and on GPs’ decision-making in diagnosing chronic respiratory disease. Chapter 6 describes the results of another cluster-randomised controlled trial to assess the impact of two modes of expert support (computerised expert support and consultation by a chest physician) for the interpretation of spirometry tests on GPs’ diagnosis and subsequent management of chronic respiratory disease in real patients. Finally, chapter 7 contains the general discussion of the main results and conclusions of this thesis.
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ORIGINAL ARTICLE

Variation in spirometry utilization between trained general practitioners in practices equipped with a spirometer

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Abstract

Objectives To explore spirometry utilization among general practitioners and identify practitioner and practice-related factors associated with spirometry utilization. Design Multivariate multilevel cross-sectional analysis of a questionnaire survey. Setting Some 61 general practices involved in a spirometry evaluation programme in the Netherlands. All practices owned a spirometer and were trained to perform spirometry. Subjects A total of 144 general practitioners and 179 practice assistants. Main outcome measures Extent of spirometry utilization for five indications from national COPD/asthma guidelines, practitioner and practice-related factors associated with spirometry utilization. Results The response rate was 97%. General practitioners used spirometry mostly to evaluate treatment with inhaled steroids (58%). Significant practitioner-related factors associated with spirometry utilization were general practitioners' job satisfaction, general practitioners' general interest in research, and prior participation in spirometry training. Practice-related factors associated with spirometry utilization were presence of a practice nurse, delegation of medical tasks to practice assistants, use of spirometry in different rooms, and use of protocols in practice. Conclusion Practitioner- as well as practice-related factors were associated with the extent of spirometry utilization. In particular, it is essential to improve practice-related factors (e.g. presence of a practice nurse, more delegation of medical tasks to the practice assistant).

Key Words: Asthma, COPD, family practice, primary care, spirometry

In recent years the number of spirometers in primary care has increased. Currently general practitioners' (GPs) ownership of a spirometer varies between 60% and 80% in the UK [1,2]. In general practice, equipment is no longer a limiting factor for spirometry utilization as rather inexpensive and reliable electronic spirometers have become widely available. According to guidelines for general practice [3] and respiratory care [4], spirometry constitutes an essential tool to determine the presence and severity of airflow obstruction, and to distinguish between reversible and irreversible obstruction. The Dutch College of General Practitioners' guideline on COPD [5] states that availability of spirometry is an essential precondition for GPs to test and treat most patients with mild or moderately severe COPD.

Although spirometry is feasible in primary care, general practitioners (GPs) experience barriers that impede its utilization.

- Dutch GPs used spirometry mostly to evaluate a recently initiated treatment with inhaled steroids.
- Trained GPs with a special interest in research, with adequate resources and in a practice providing structured care, are more likely to use spirometry.
- In particular, practice-related factors (e.g. presence of a practice nurse, delegation of medical tasks) are primordial to improve spirometry.
Carrying out spirometry in general practice seems justified in terms of test validity, provided that practice staff have been trained sufficiently [6]. This creates an essential precondition for implementation of spirometry in the general practice setting, but by no means guarantees actual integration of spirometry in the GP's management of respiratory diseases [7, 9]. It seems that there are still barriers with regard to successful implementation of spirometry in primary care. Local factors like inadequate reimbursement of spirometry in own practice [10], and its general complexity to fit it into daily practice are well-documented common barriers that could explain a variation in spirometry utilization between GPs [1, 11]. The variation in spirometry utilization seems also to be linked to practitioner-related factors (e.g. GPs' spirometry training level) and practice-related factors (e.g. being in a group practice) [12]. Little is known about which of these factors are easily modifiable and essential to improve. The objective of the present study was to explore spirometry utilization among trained and well-equipped GPs. In order to give concrete direction to future research on this topic, we also identified practitioner- and practice-related factors that were associated with the extent of spirometry utilization by GPs.

Approval was provided by the medical ethics review board of Radboud University Nijmegen Medical Centre.

Material and methods

Design and data collection

A questionnaire survey was mailed to 61 practices involved in a spirometry evaluation programme [6]. In that study a pair of spirometric tests (laboratory and general practice) was performed twice in about seven study subjects per practice. The current questionnaire survey took place 14 months after GPs and practice assistants had been offered an initial spirometry training programme, to ensure that practices had enough time to implement spirometry for all patients in daily practice (not only for study purposes). All of these practices owned a spirometer (MicroLoop®, Micro Medical Ltd, Rochester, Kent, UK), spirometry software (Spirare®, Diagnostica Ltd, Oslo, Norway) and had at least one practice assistant employed who was trained to perform spirometry. (In Dutch primary care, practice assistants are professionally trained for administrative and clinical patient-directed support tasks).

Questionnaires

Discussion groups and interviews with experts in the fields were used to develop questionnaires to measure potential practitioner- and practice-related factors that may explain the extent of spirometry utilization by GPs. We developed separate questionnaires for GPs and practice assistants. First, we sent a questionnaire to a contact person (GP) in each practice to collect general information on the characteristics of the practice setting, practice organization and equipment, and information regarding the composition of the practice staff. Second, we sent to all GPs and practice assistants involved in these practices a questionnaire regarding the professional experience, general training level and continuous medical education, spirometry quality assurance, value of spirometry, and utilization of spirometry in daily practice (only for GPs). We used items in this questionnaire from a validated instrument [13]. Considerable effort was expended to achieve an optimal response. A €22 incentive was offered to practice staff for returning the questionnaires. We sent reminders to non-responders at approximately four-week intervals, for a total of two mailings. Practices that did not respond to the reminders were telephoned by the researchers.

Outcomes and analyses

Spirometry utilization was assessed on the basis of GPs' self-reported utilization of spirometry for five indications for spirometry that are included in national GP guidelines for diagnosing and managing COPD and asthma (see Figure 1) [3, 5, 14]. For each indication GPs rated the extent to which they applied spirometry in their daily practice: 0 = seldom or never; 1 = sometimes; 2 = often or always use of spirometry. A total sum score (range 0–10) for these five indications was calculated.

The sum score was considered to reflect "GPs' spirometry utilization" and was used as the dependent variable in subsequent analyses. Because of the hierarchical structure of the study (GPs clustered within practices) we performed a multilevel analysis. In this analysis we accounted for the variability associated with each level of clustering. Analyses were performed in SAS V8.2 for Windows (SAS Institute Inc, Cary USA 1999-2001) and were based on a mixed-effects model (PROC MIXED). In this model both fixed and random effects can be analysed. We used a random intercept model with practice as random variable and all other variables fixed. This means that we expected that the intercept varied randomly between practices and the other regression parameters in the model.
had the same (fixed) value for each practice. The interpretation of the intercept and regression parameters is the same as in ordinary regression analyses, i.e. the value of each regression parameter (Beta) is corrected for the other variables in the model.

Univariate multilevel analyses were applied to assess the dependency of GPs' spirometry utilization on the explanatory variables. Multivariate multilevel analyses were applied with 23 explanatory variables. A backward elimination procedure was performed. Variables with a p-value of <0.05 remained in the final model (see Table II). The interclass correlation coefficient (ICC) was assessed to give insight into the proportion of variance that was accounted for by practice level. Also, the fraction of explained variance at practice level and practitioner level was calculated.

Results

Characteristics of general practices

The response rate was 97% (59/61). Reasons for non-response of the practices remained unknown in one practice and one practice had merged recently with another practice that was not involved in the spirometry evaluation programme. In Table I we compare some characteristics of the general practices, GPs, and practice assistants involved in our study with national data from the Netherlands. Compared with the national figures, single-handed practices were relatively underrepresented and group practices overrepresented among the practices in our study.

Spirometry utilization

GPs' spirometry utilization was normally distributed: mean 5.65 points (SD 2.47). Clustering of GPs within practices accounted for 16.8% of the total variation in GPs' spirometry utilization (ICC = 0.168). Figure 1 shows GPs' spirometry utilization for the five indications included in the Dutch national GP guidelines.

The indication for which the GPs reported the highest rate of spirometry utilization was “Evaluation of recently initiated treatment with inhaled steroids in COPD or asthma patients” (58%). The indication with the lowest spirometry utilization rate was “Screening of smokers on chronic respiratory disease” (22%).

Practitioner- and practice-related factors and their association with spirometry utilization

Table II shows the results of the stepwise multivariate multilevel analyses. The practitioner-related factors that were associated with GPs' spirometry utilization were GPs' job satisfaction (p = 0.003), GPs' general interest in research (p = 0.01), and GPs' participation in the spirometry training during the study (p = 0.02).

Practice-related factors associated with GPs' spirometry utilization were the presence of practice nurse support (p < 0.001), the extent of delegation of medical tasks to practice assistants (p = 0.003), use
Table I Characteristics of the general practices, general practitioners, and practice assistants involved in the study (left) and from national data in the Netherlands (right). Values are means (SD) unless otherwise stated.

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</tbody>
</table>

1Data (1 January 2004) from the Netherlands Institute for Health Service Research (http://www.nivel.nl) 2Data (1 January 2004) from the Dutch Association of Dokters Assistants (personal communication) NA = not available

Discussion

The results of this study indicate that GPs utilized spirometry mostly for diagnostic and monitoring purposes and seldom for screening purposes. We identified three practitioner- and five practice-related factors that were associated with the extent of spirometry utilization by GPs.

Table II Results of stepwise multivariate multilevel analyses

<table>
<thead>
<tr>
<th>Explanatory variable</th>
<th>Reference category</th>
<th>β</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practitioner-related factors</td>
<td>Point on sum score1</td>
<td>0.197</td>
<td>0.003</td>
<td>0.070–0.323</td>
</tr>
<tr>
<td></td>
<td>Job satisfaction (subjective)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>General interest in scientific research</td>
<td>0.997</td>
<td>0.01</td>
<td>0.238–1.759</td>
</tr>
<tr>
<td></td>
<td>Spirometry training during the study [6]</td>
<td>0.883</td>
<td>0.02</td>
<td>0.116–1.651</td>
</tr>
<tr>
<td>Practice-related factors</td>
<td>Non-participant</td>
<td>0.203</td>
<td>&lt;0.001</td>
<td>0.929–3.477</td>
</tr>
<tr>
<td></td>
<td>Delegation medical tasks – practice assistants</td>
<td>0.042</td>
<td>0.003</td>
<td>0.015–0.069</td>
</tr>
<tr>
<td></td>
<td>Spirometry used in different rooms</td>
<td>1.116</td>
<td>0.007</td>
<td>0.313–3.918</td>
</tr>
<tr>
<td></td>
<td>Task differentiation among GPs</td>
<td>1.104</td>
<td>0.01</td>
<td>1.956–2.525</td>
</tr>
<tr>
<td></td>
<td>Use of protocols in practice</td>
<td>0.515</td>
<td>0.01</td>
<td>0.112–0.918</td>
</tr>
</tbody>
</table>

Explanatory variables are sorted by descending p-value. Explained fraction of variance: $R^2 = 26.3\%$. 1Sum score (range 0–10) of five questions (Likert scale) concerning GP's satisfaction with available time for patients, work, continuous medical education, family, and leisure time. 2In Dutch primary care, practice nurses are professionally trained for support tasks, predominantly in chronic diseases (COPD & asthma or diabetes). They work under the supervision of a GP. They follow strict protocols for medical care and give education to patients. They do not order additional investigations. They are not allowed to refer patients. Nowadays, they are increasingly employed in multidisciplinary healthcare centres or group practices. 3Sum score (range 0–4) of five questions (yes = 1, no = 0) with regard to the presence of protocols for visiting patients admitted to hospital, separate office hours for diabetes care or cardiovascular disease, invitation system for cervical cancer screening; invitation system for annual influenza vaccination.
**Strengths and weaknesses of the study**

One of the strengths of our study was an excellent response rate of almost 100%. Furthermore, in an opportunistic setting (participants in a study on spirometry) we analysed the effect of introduction of spirometry in daily practice on GPs' self-reported actual utilization. Through correction in the analyses for the fact that GPs were clustered in the same practices and may share one or more practice assistants, we could assess separately practitioner- and practice-related factors that were associated with spirometry utilization. Practices were all equipped with a spirometer as an integral part of the evaluation. Consequently, the absence of a spirometer was not a limiting factor with regard to the implementation of spirometry. Generally, most trained GPs seem to prefer to perform spirometry in their own practice [15]. We took into consideration all these aspects in the setting of our study.

We could explain 26.3% of all variance in GPs' spirometry utilization, the dependent variable in our analysis. However, this subjective measure of goodness-of-fit also indicates that 73.7% of the variation could not be predicted with the current data. In particular, the variance at GP level could not be explained by this model. Apparently, there are other (psychological) factors that influence utilization that have not been asked about in the questionnaires.

A weakness of the study is the external validity. We could only analyse GPs' perception of their actual use of spirometry once equipment was available and staff had been trained in its use. Due to selective participation of GPs with a general interest in research and the fact that – compared with national data – we included a relatively small proportion of single-handed practices, our findings may not fully reflect the situation in Dutch general practice as a whole. Because no national data on spirometry ownership of general practices are available for the Netherlands, we do not know to what proportion of all practices our findings apply.

From a methodological point of view, we accept that objective assessment of GPs' actual use of spirometry instead of the perception of use would have been more sophisticated. As there was an almost complete lack of studies in this area, we chose to explore spirometry utilization by GPs first by questionnaire. There have been contradictory reports as to the accuracy of physicians' self-reported adherence to guidelines in the literature. On the one hand, questionnaires tend to have moderate to high concordance with other less subjective measures of adherence [16]. On the other hand, clinicians' self-reported adherence rates may also exceed objective rates, which may result in an overestimation of adherence of up to 25% [17]. In our case, there is no reason to assume that the degree of overestimation of spirometry utilization is indeed present – would be different for the five separate indications for spirometry from the national guidelines for GPs that were studied. One could also wonder whether a consistent overestimation would have given different results with regard to the observed associations between practitioner- and practice-related factors and spirometry utilization rates. Although we used five indications for spirometry from guidelines to assess a total sum score, we do realize that the role of spirometry in diagnostics and monitoring of asthma is still controversial in daily practice with regard to best practice.

**Comparison with previous studies**

Generally, from this study and other studies [1,18], spirometry seems to be underused for several indications in primary healthcare. The results of the current study indicate that GPs utilized spirometry in daily practice not only for diagnosis of respiratory diseases but also for management purposes. Specific utilization of spirometry for management purposes in primary care has been reported previously [1,18]. In line with these studies [1,18], GPs' utilization of spirometry for screening purposes in asymptomatic smokers was very low (22%), which seems legitimate considering the current view that widespread screening of smokers for the presence of airflow obstruction cannot be recommended at this time [19].

To the best of our knowledge, this is the first study that assessed by means of multivariate multilevel analyses practitioner- and practice-related factors that were associated with spirometry utilization. Presently, only one study is available to mirror our results. O'Dowd et al [12] determined physician-related and practice-related factors that were associated with owning a spirometer and use of spirometry in the evaluation of new asthma patients. Factors associated with frequent use of spirometry among GPs were ownership of a spirometer, GPs' belief that such testing provides data necessary for a diagnosis and, finally, a sufficient level of training to perform and interpret these tests. In our study, all practices owned a spirometer but we also found an association between adequate training level to interpret tests (p = 0.02) and actual utilization of spirometry by GPs.

**Possible implications for clinical practice**

The extent of spirometry utilization was associated with trained GPs with a special interest in research,
with adequate resources (e.g. support staff and room space) and practices providing structured care to patients (e.g. use of protocols). To attain such an optimal situation in one's own practice we suggest having a special practice nurse for respiratory diseases employed in a practice. Special office hours for respiratory diseases attended by this practice nurse under the supervision of a GP will improve the service for these patients [20,21]. Second, the autonomy of practice assistants will increase by delegation of routine tasks from the GP to the practice assistant. Increased delegation of medical tasks was associated with more successful spirometry utilization. Third, the use of protocols in practice stimulates systematic working. Fourth, continuous spirometry education and training should be facilitated to maintain standards for GPs, practice assistants, and practice nurses [18]. Training of practice staff is preferably organized by non-commercial organizations (e.g. GPs' professional organizations).

Conclusion and future research

We conclude that trained GPs with a special interest in research, with adequate resources (support staff and room space) and in a practice providing structured care (protocols), were more likely to use spirometry in this study. If a GP lacks these conditions, it is essential to improve practice-related factors in particular (e.g. presence of a practice nurse, delegation of medical tasks to the practice assistant, and the use of protocols). This exploratory study adds to the current state of knowledge regarding the utilization of spirometry in general practice. The next step would be to verify our findings in a larger sample of all GPs in the Netherlands as well as in other countries, and preferably to measure the actual utilization of spirometry by GPs in patients with an indication for this particular lung function test.

Acknowledgements

The authors would like to thank their colleagues and nurses in the participating general practices, and Jonathan Honigh, MD, for data management. Boehringer Ingelheim BV is kindly acknowledged for allowing use of their spirometry training programmes for GPs and practice assistants.

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General practitioners’ needs for ongoing support for the interpretation of spirometry tests

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General practitioners’ needs for ongoing support for the interpretation of spirometry tests

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Abstract

Background: Although one out of three general practitioners (GPs) carries out spirometry, the diagnostic interpretation of spirometry test results appears to be a common barrier for GPs towards its routine application. Methods: Multivariate cross-sectional analysis of a questionnaire survey among 137 GPs who participated in a spirometry evaluation programme in the Netherlands. We identified characteristics of GPs and their practice settings associated with GPs’ need for ongoing support for spirometry interpretation. Results: Response rate on the survey questionnaire was 98%. The need for ongoing support among the participating GPs was 69% GPs’ recent spirometry training showed a statistically significant association with the need for ongoing support for the interpretation of spirometry (odds ratio 0.43, 95% CI 0.20-0.92)

Conclusion: There is a need for ongoing support for spirometry interpretation among GPs. Recent spirometry training partially diminished this need

Key words: COPD, decision, feedback, general practice, spirometry, support systems

Introduction

Chronic obstructive pulmonary disease (COPD) is a highly prevalent condition that will contribute to global disability for many years to come. Timely and adequate diagnosis of the disease in new patients and accurate severity staging in patients who have previously been diagnosed requires spirometry. Regardless of which COPD guideline (1,2) one uses, spirometry plays a central role in diagnosing the disease, and this requires its widespread implementation in primary care. However, the mere existence of the guidelines does not guarantee that general practitioners (GPs) will actually embrace spirometry and apply it consistently in the diagnosis and management of their patients (3). There are still a number of practical barriers that impede implementation of good-quality spirometry in primary care. Examples are the absence of properly trained practice staff (4), the lack of time and practice support (e.g., practice nurses) to fit spirometry into the daily practice routine (5), and simply the absence of a spirometer in the practice (6,7).

In addition to the practical barriers, GPs’ lack of confidence in their ability to interpret the test results (8) is a crucial issue, often completely neglected in the guidelines but nonetheless a real impediment to effective implementation of spirometry. Low levels of self-confidence in the interpretation of spirometric tests influences GPs’ interpretative skills (8). Ideally, the interpretative skills and confidence levels of GPs are supported after appropriate initial spirometry training. However, it is largely unknown what kind of ongoing support GPs prefer or which factors are related to a GP’s wish to receive this support.

Therefore, the aim of the present study was to identify characteristics of GPs and their practice settings that were associated with GPs’ need for ongoing support for the interpretation of spirometric tests.

Methods

Design and data collection

We performed a multivariate cross-sectional analysis of questionnaire survey data from 137 GPs
who participated in a spirometry evaluation programme in the Netherlands (9). We have reported on the study design, data collection and questionnaires used elsewhere (5). In short, all GPs involved were sent a questionnaire regarding their professional experience, general training level, attended continuous medical education, practice equipment, barriers to spirometry applications, and their need for ongoing support for spirometry interpretation.

Outcomes and analyses

Potential GP-related and practice-related characteristics for GPs' need for ongoing spirometry interpretation support (dependent variable) were assessed. Because of the clustering of GPs within practices, we performed a multilevel logistic regression analysis. Multivariate multilevel analyses were applied to assess the association between GPs' need for ongoing support and 13 explanatory variables (e.g., type of practice, practice nurse support available). GPs' need for ongoing support was dichotomized (yes/no question). Backward elimination was used to remove variables with \( p > 0.05 \) (Table II). The intraclass correlation coefficient (ICC) was calculated to give insight into the proportion of variance that was accounted for by practice level. Also, the fraction of explained variance was calculated. Analyses were performed in SAS version 8.2 for Windows (SAS Institute Inc., Cary, USA, 1999–2001).

Table I: Characteristics of the GPs and general practices involved in the study and from national data in the Netherlands (right)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>This study</th>
<th>National data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General practitioners</strong></td>
<td>( n = 144 )</td>
<td>( N = 8209^* )</td>
</tr>
<tr>
<td>Age, % &lt; 40 years</td>
<td>25 7</td>
<td>21</td>
</tr>
<tr>
<td>Professional experience, years</td>
<td>14 3 (8 2)</td>
<td>N/A</td>
</tr>
<tr>
<td>Gender, % female</td>
<td>30 6</td>
<td>31 4</td>
</tr>
<tr>
<td>Patients per GP, number per practice</td>
<td>1862 (771)</td>
<td>2392</td>
</tr>
<tr>
<td><strong>General practices</strong></td>
<td>( n = 59 )</td>
<td>( N = 4564^* )</td>
</tr>
<tr>
<td>Type of practice, %</td>
<td>33 9</td>
<td>60 7</td>
</tr>
<tr>
<td>Single-handed</td>
<td>33 9</td>
<td>60 7</td>
</tr>
<tr>
<td>Duo</td>
<td>27 1</td>
<td>26 4</td>
</tr>
<tr>
<td>Group (( \geq 3 ) GPs)</td>
<td>30 5</td>
<td>12 9</td>
</tr>
<tr>
<td>Multidisciplinary healthcare centre</td>
<td>8 5</td>
<td></td>
</tr>
<tr>
<td>GP, number per practice</td>
<td>2 5 (1 4)</td>
<td>N/A</td>
</tr>
<tr>
<td>Practice assistants, number per practice</td>
<td>3 1 (1 4)</td>
<td>N/A</td>
</tr>
<tr>
<td>Time since introduction of spirometry, years</td>
<td>4 3 (2 9)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Results

Characteristics of general practices and GPs

In Table I, we compare certain characteristics of the general practices and GPs involved in our study with national data. We excluded seven GPs from this table due to incomplete data. These seven GPs were slightly younger and had less professional experience than the remaining 137 GPs.

Need for ongoing support for spirometry interpretation

Ninety-four GPs (69%) expressed a need for ongoing support for spirometry interpretation. The most preferred mode of support was either a local chest physician or pulmonary function laboratory (51%), or a computerized clinical decision support system (46%). Clustering of GPs within practices accounted for 20.9% of the total variation in GPs' need for ongoing support (ICC 0.209).

Characteristics of GPs and their practice settings associated with GPs' need for ongoing support

Table II shows the results of the multivariate analyses. The only practitioner-related factor associated with GPs' need for ongoing support was GP's recent spirometry training (odds ratio 0.43, 95% CI 0.20–0.92). The associations with three other factors, i.e., availability of different rooms to perform spirometry in the practice, some mode of spirometry expert support already being in place, and the presence of a practice nurse, showed borderline statistical significance (\( P = 0.08, P = 0.09, \) and \( P = 0.15, \) respectively). The proportion of explained variance of this model was 4.1%.

Discussion

The results of this study indicate that a majority of the GPs in our study expressed a need for ongoing support for spirometry interpretation. Characteristics of the practice setting were not associated with the need for ongoing support, and characteristics of the GP (recent spirometry training) were only marginally associated with the need for ongoing support.

Comparison with previous studies

This is the first study that has assessed factors associated with GPs' need for ongoing support for spirometry interpretation among GPs working in practices that are already equipped with a spirometer. We assume that, if these GPs already expressed a need for ongoing support, other GPs with less interest in spirometry would have at least the same need for support.
Table II  Results of the multivariate multilevel analyses

<table>
<thead>
<tr>
<th>Explanatory variable</th>
<th>Reference category</th>
<th>β</th>
<th>P</th>
<th>Odds ratio</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP-related characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GPs' professional experience</td>
<td>Years</td>
<td>0.013</td>
<td>0.58</td>
<td>1.01</td>
<td>(0.97, 1.06)</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>-0.399</td>
<td>0.33</td>
<td>0.67</td>
<td>(0.30, 1.50)</td>
</tr>
<tr>
<td>General interest in scientific research</td>
<td>Non-participant</td>
<td>0.095</td>
<td>0.81</td>
<td>1.10</td>
<td>(0.51, 2.37)</td>
</tr>
<tr>
<td>Spirometry training prior to study</td>
<td>No</td>
<td>-0.500</td>
<td>0.22</td>
<td>0.61</td>
<td>(0.27, 1.34)</td>
</tr>
<tr>
<td>Recent limited spirometry training in study</td>
<td>Non-attender</td>
<td>-0.844</td>
<td>0.03</td>
<td>0.43</td>
<td>(0.20, 0.92)</td>
</tr>
<tr>
<td>Continuous medical education</td>
<td>Point on sum score</td>
<td>0.219</td>
<td>0.57</td>
<td>1.24</td>
<td>(0.58, 2.66)</td>
</tr>
<tr>
<td>Complexity of spirometry interpretation</td>
<td>No</td>
<td>0.038</td>
<td>0.94</td>
<td>1.04</td>
<td>(0.36, 2.94)</td>
</tr>
<tr>
<td>Present support for spirometry interpretation</td>
<td>No</td>
<td>0.717</td>
<td>0.08</td>
<td>2.05</td>
<td>(0.92, 4.55)</td>
</tr>
<tr>
<td>(e.g., feedback from chest physician or computerized expert support)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Practice-related characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of practice</td>
<td>No single-handed</td>
<td>-0.649</td>
<td>0.26</td>
<td>0.52</td>
<td>(0.17, 1.60)</td>
</tr>
<tr>
<td>Use of protocols in practice</td>
<td>Point on sum score</td>
<td>-0.251</td>
<td>0.30</td>
<td>0.78</td>
<td>(0.48, 1.25)</td>
</tr>
<tr>
<td>Practice-nurse support</td>
<td>No</td>
<td>0.926</td>
<td>0.15</td>
<td>2.52</td>
<td>(0.72, 8.83)</td>
</tr>
<tr>
<td>Spirometry used in different rooms</td>
<td>No</td>
<td>0.765</td>
<td>0.09</td>
<td>2.15</td>
<td>(0.90, 5.14)</td>
</tr>
<tr>
<td>Delegation medical tasks – practice assistants</td>
<td>% point delegated tasks</td>
<td>-0.023</td>
<td>0.11</td>
<td>0.98</td>
<td>(1.01, 0.95)</td>
</tr>
</tbody>
</table>

Explained fraction of variance $R^2 = 41\%$

*Sum score (range 0–10) of five questions (Likert scale) concerning GP's satisfaction with available time for patients, work, continuous medical education, family, and leisure time

*Sum score (range 0–4) of five questions (yes = 1, no = 0) with regard to the presence of protocols for visiting patients admitted to hospital, separate office hours for diabetes care or cardiovascular disease, invitation system for cervical cancer screening, invitation system for annual influenza vaccination

*In Dutch primary care, practice nurses are professionally trained for supporting tasks, predominantly in chronic diseases (COPD and asthma or diabetes). They work under supervision of a GP. They follow strict protocols for medical care and educate patients. They do not order additional investigations. They are not allowed to refer patients. Nowadays, they are often employed in multidisciplinary healthcare centres or group practices.

*In Dutch primary care, practice assistants are professionally trained for administrative and clinical patient-directed support tasks.

It is important to realise that like electrocardiography spirometry is a complex diagnostic tool, at least in the perception of many GPs. A systematic approach for judging the quality of tests and the subsequent assessment of the relevant lung function indices (i.e., FEV₁, FEV₁/FVC), the accompanying predicted values, and the graphical output that most electronic spirometers now provide (i.e., flow-volume and volume-time curves) seems difficult. This is clearly illustrated by the results of a recent UK study in which low levels of self-confidence in the interpretation of spirometric tests were observed among 160 general practices that had been trained for half a day: only 33% of the practices trusted their own interpretative skills with regard to spirometry (8). Unfortunately, this kind of very limited training is often what GPs commence with. Low confidence in the ability to interpret spirometry test results was recently reported by Walters et al. (7), although these results came from focus-group interviews and did not provide insight into GP- and practice-related factors.

Thus far, a New Zealand study, which was reported in 1999, presents the only randomized prospective evaluation of the implementation of spirometry in primary-care practice formally assessing the positive impact of limited training on GPs' spirometry performance (10). In our study, a recent limited training session diminished the need for ongoing support. However, whether a limited training session is sufficient to increase the confidence of GPs in their ability to interpret test results seems improbable.

The problem that still remains is that lack of expertise in spirometry testing seems to be the limiting factor for its routine application in general practice (4,5,7,8). This has clinical repercussions, with misclassification occurring in one out of three patients with a clinical diagnosis of COPD in primary care as a result (8). Therefore, the interpretative skills of GPs are ideally supported after an initial spirometry training programme. However, the results of our study and the current literature (7,8) do not give enough insight into which GPs in which practice settings will benefit most from ongoing support nor do they help us in deciding which mode of organizing this support would be best. This ongoing support could be organized by a fellow GP with a special interest in respiratory diseases in their own practice or in another practice nearby (11), by a computerized clinical decision support system (12), or by consultation or feedback from a chest physician (13). Empirical studies on the effect of this kind of ongoing expert support on the interpretative capacity of primary-care doctors are not available at this time.
A weakness of our study is the external validity. Due to selective participation of GPs who wanted to participate in a spirometry research project and the fact that—compared with national data—we included a relatively small proportion of single-handed practices, our findings may not fully reflect the situation in Dutch general practice. Despite the fact that we investigated 13 plausible characteristics concerning the GP and his/her practice setting, we were not able to predict the need for ongoing spirometry interpretation support with this model adequately. Our model explained only 4.1% of all variance in the dependent variable. Apparently, there are other factors that influence GPs' need for ongoing support that have not been investigated in the questionnaires. Qualitative studies (e.g., in-depth or focus-group interviews) are required to further address this issue (14).

Possible implications for future research

If GPs do not perform spirometry in their own practice due to insufficient expertise in the interpretation of results, the number of patients referred for spirometry testing may soon exceed the capacity of secondary care. From the current study, we know that a recent spirometry training session is not enough to decrease the need for ongoing support for spirometry interpretation.

As spirometry does indeed seem to influence the decision-making process of GPs (15), the focus on COPD in primary care should be directed at increasing the confidence of GPs in their ability to interpret spirometry test results.

Conclusions

We conclude that most (~70%) GPs who were already equipped to use spirometry in terms of training and facilities expressed a need for ongoing spirometry interpretation support. Recent spirometry training partially diminished this need, but ongoing support for the interpretation of spirometry tests in primary care certainly seems welcome. GPs' need for ongoing support for spirometry interpretation could only marginally be explained by the characteristics of GPs and their practice settings.

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We thank our colleagues in the participating general practices. We thank Jonathan Honigh, MD, Joliet Hartman, MSc, and Arpik Kerojan, medical student, for data management. The medical ethics review board of the Radboud University Nijmegen Medical Centre provided approval for the study.

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Spirometry in chronic obstructive pulmonary disease

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Tjard R. Schermer
Chris van Weel
Peter M. Calverley
Spirometry in chronic obstructive pulmonary disease

Is available, yet underused in general practice

Chronic obstructive pulmonary disease affects about 1% of the total UK population and is a major cause of disability and mortality worldwide. Timely diagnosis and subsequent staging of severity of disease both require spirometry which in theory can be performed by trained general practitioners (GPs) and their practice staff. However, numerous barriers impede the implementation of spirometry in primary care.

Several guidelines exist for the management of patients with chronic obstructive pulmonary disease including those from the UK National Institute for Health and Clinical Excellence (NICE) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD www.goldcopd.com). All guidelines stress the central role of spirometry in diagnosing and managing the disease in primary care but this does not guarantee that GPs will use this technique consistently in the care of patients with respiratory symptoms.

Several models to provide spirometry test results exist, depending on local circumstances, these include regional primary care diagnostic services and hospital-based lung function laboratories with open access for primary care patients. However, the most practical and timely solution is for GPs to have their own spirometer in the practice. In the United Kingdom about 80% of general practices own a spirometer but these instruments are still scarce in large parts of the world.
even though prices have dropped considerably in the past few years. Trained practice staff who have the skills and time to fit and maintain spirometry of sufficient quality into the daily practice routine may also be in short supply.\textsuperscript{9} In addition to the practical issues, GPs’ lack of confidence in their ability to interpret the test results is a crucial barrier—often neglected in the guidelines to effective implementation of spirometry.\textsuperscript{10,11} Many GPs view spirometry as a complex diagnostic tool, like electrocardiography. This fact was clearly illustrated in a recent UK study that reported low levels of self confidence in interpreting spirometric tests in 160 general practices where GPs and nurses had been trained for half a day—only a third of these professionals trusted their own interpretative skills. Confidence about how to proceed once the test results are available is a crucial part of building GPs’ confidence in their capacity to diagnose and manage the disease.

Ideally once GPs have had initial spirometry training they should receive continuous advice and support. This could be done in various ways—by another GP with a special interest in respiratory diseases in the same practice or in another practice nearby; by means of a computerised clinical decision support system (SpidaXpert software; www.spirxpert.com); or by consultation or feedback from a chest physician. Although intuitively a promising idea, empirical studies on the effects of ongoing expert support on the interpretative capacity and self confidence of GPs are lacking.

So what needs to happen next? For guidelines on chronic obstructive pulmonary disease to be implemented, concrete working agreements between GPs and chest physicians need to be developed. Chest physicians can act as coaches for their local primary care colleagues in two ways—through patient oriented support (specific feedback for specific patients) or through practice oriented support (as teachers in postgraduate training programmes). This will be beneficial for both parties, as referrals will be more structured and based on agreed criteria. GPs who have performed spirometry will have better insight into the patient’s lung function, and chest physicians will benefit from having the results at the initial consultation.\textsuperscript{12} More broadly, coordinated efforts by health policy makers and the medical profession will be needed to provide the right equipment, training for staff who use it, and continuing quality assurance and support for test interpretation. The burden of chronic obstructive pulmonary disease is sufficiently large to warrant such an approach.

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Competing interests. None declared.

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Impact of a spirometry expert system on general practitioners’ decision making

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Impact of a spirometry expert system on general practitioners' decision making


ABSTRACT The present study assessed the impact of computerised spirometry interpretation expert support on the diagnostic achievements of general practitioners (GPs), and on GPs' decision making in diagnosing chronic respiratory disease.

A cluster-randomised controlled trial was performed in 78 GPs who each completed 10 standardised paper case descriptions. Intervention consisted of support for GPs' spirometry interpretation either by an expert system (expert support group) or by sham information (control group). Agreement of GPs' diagnoses was compared with an expert panel judgement, which served as the primary outcome. Secondary outcomes were: additional diagnostic test rates; width of differential diagnosis; certainty of diagnosis; estimated severity of disease; referral rate; and medication or nonmedication changes. Effects were expressed as odds ratios (ORs) with 95% confidence intervals (CIs).

There were no differences between the expert support and control groups in the agreement between GPs and expert panel diagnosis of chronic obstructive pulmonary disease (OR (95% CI) 1.08 (0.70-1.66)), asthma (1.13 (0.70-1.80)), and absence of respiratory disease (1.32 (0.61-2.86)). A higher rate of additional diagnostic tests was observed in the expert support group (2.5 (1.17-5.35)).

Computerised spirometry expert support had no detectable benefit on general practitioners' diagnostic achievements and the decision-making process when diagnosing chronic respiratory disease.

KEYWORDS Computer-assisted diagnosis, expert systems, family practice, spirometry

Although all major chronic obstructive pulmonary disease (COPD) guidelines stress the central role of spirometry in diagnosing and managing chronic respiratory disease [1, 2], this does not guarantee that general practitioners (GPs) will consequently use spirometry in the care of their patients with respiratory symptoms [3, 4]

Most common barriers that impede utilisation of spirometry in general practice are the absence of properly trained staff [5], the lack of time and practice support to fit spirometry into the daily practice routine [6], the absence of a spirometer in the practice [7], and GPs' lack of confidence in the ability to interpret the test results [8, 9]. A recent survey [4] showed that one third of Australian GPs interpreted less than one spirometry test per week. Due to this low prevalence of test interpretations, it seems difficult for GPs to become experts in this area.

The present authors have previously demonstrated the influence of spirometry on GPs' diagnostic achievements and management decisions in a nonrandomised simulation study [10]. Other recent nonrandomised studies [11, 12] confirm that spirometry increases diagnostic rates of chronic respiratory disease and may lead to management changes in a general practice population. However, an absolute prerequisite for the use of spirometry is the validity (or reliability) of spirometric tests. In a previous study with patients with COPD, SCHERMER et al. [13] observed that the most relevant indices, as measured by trained general practice staff, were comparable with those measured in pulmonary function laboratories.

Therefore, once GPs have had initial spirometry training and spirometry equipment and test validity are adequate, the next step to improve implementation of spirometry in general practice...
is to arrange for the possibility to receive continuous advice and support for test interpretation [14]. This could be carried out by means of a diagnostic computerised clinical decision support system [15, 16]. While there is already such an expert support system available on the market [17] and GPs welcome such type of support [18], empirical studies on the effects of ongoing expert support on the interpretative capacity and self-confidence of GPs are warranted.

The objective of the present study was to assess the impact of expert support for the interpretation of spirometry tests on GPs' diagnostic achievements and decision-making processes when diagnosing chronic respiratory disease.

METHODS

Study design

The study was a simulated cluster-randomised trial of GPs' diagnostic acuity of chronic respiratory disease in a process of diagnostic assessment of 10 standardised cases, with an expert system support. A diagnosis of the cases by the expert panel served as the gold standard. Differences in GPs' diagnostic achievements and decision-making processes were compared both between the study groups and within groups.

Ethical approval

The present study was approved by the Medical Ethics Review Board of the academic hospital Radboud University Nijmegen Medical Centre, Nijmegen, the Netherlands.

Participants

GPs from the catchment area of the Radboud University Nijmegen Medical Centre and from a specific general practice network of the present authors' department at this hospital [19] were invited to participate by postal mailing.

Intervention

GPs were randomly allocated to one of the following two groups: 1) the computerised spirometry expert interpretation support group, and 2) the control group. GPs in the expert support group received the spirometry test results, the flow-volume curve, and the graphical interpretation and textual interpretative notes. GPs in the control group received the spirometry test results, and the flow-volume and volume-time curves (fig 1).

The spirometry expert system (SpidaXpert, Micro Medical Ltd, Rochester, UK) [17] contains a diagnostic algorithm based on pre- and post-bronchodilator forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) and FEV1 values and the accompanying age, sex and ethnicity-specific predicted values. The expert interpretation module in SpidaXpert had been developed with funding of the Netherlands Asthma Foundation by a group of independent experts [17]. The spirometry interpretation is presented as coloured bars that indicate levels of FEV1/FVC and FEV1, and compares the values before and after bronchodilatation. The graphical representation is further elucidated by a textual interpretation, which provides information on and suggestions for additional diagnostic testing and treatment options.

GPs in the control group received the volume-time curve as sham information. Sham information was introduced in the control group to be able to compare GPs' reassessment of a diagnosis in the control group in the same way as in the expert support group. Sham information has, in fact, a placebo effect, as no new data was being presented to these GPs, earlier data (i.e. the flow-volume curve) was presented in each case again but in another way, i.e. the volume-time curve. Although it is clearly important to evaluate the quality of forced expiratory manoeuvres, i.e. end-of-test criteria [20], the volume-time curve does not add relevant new information from a diagnostic point of view to the information provided by the flow-volume curve and the numerical test results. Prior to the study, participants were informed that they would receive additional information on spirometry and were asked to reconsider their diagnosis. No further specification was given of the nature of or the background of that information.

Standardised case descriptions and gold standard

Based on the present authors' experiences in a previous study [10], it was known beforehand that GPs are quite able to diagnose common respiratory disease patterns, whereas rare pathologies and inadequate test results are more difficult for them to recognise. Furthermore, the challenge to differentiate COPD from other conditions that result in respiratory symptoms (e.g. heart failure, asthma) grows with the age of the patient. This was the reason for including case descriptions of adult patients only, with a special focus on the 50-60-yr-old age group. This category reflects daily practice patterns in primary care. The case descriptions, in which a GP would use spirometry as a diagnostic test, were as follows: COPD (classified as Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage I (n = 1), stage II (n = 1), stage III (n = 2)) [2], asthma (n = 2), allergic asthma (n = 1), lung fibrosis (n = 1), no respiratory disease (n = 1), incorrect test manoeuvre (n = 1), and exercise-induced asthma (n = 1; see supplementary material for example case).

At inclusion, a research assistant visited the participating GPs in their practice. During a 90-min audiotaped session, an example case and 10 standardised cases were presented on a laptop computer using PowerPoint slides. GPs worked through the cases in a random order. GPs first practised on one separate example case to become familiar with case structure. For each case, a concise medical history, the results of physical examination and the medication were presented to the GP first. Subsequently, absolute predicted pre- and post-bronchodilator spirometry test results (including FEV1, FVC, FEV1/FVC and flow-volume curves) were provided. GPs were asked to consider their diagnosis and management before the upcoming intervention. Next, GPs received additional information next to the spirometry test results (either the graphical representation of FEV1, FEV1/FVC together with interpretative notes (expert support group) or the volume-time curve (control group). Again, GPs were asked to reconsider their diagnosis and management after the intervention. An example of the case structure is depicted in figure 2. Due to time limitations, the present authors requested only for specific medication and nonmedication changes after the intervention in cases with already diagnosed respiratory disease (six out of 10 cases).

Before their use in the study, the cases were judged by an expert panel consisting of two chest physicians, a GP (P.J.P. Poels) with specific expertise in spirometry and a health
Recruitment of participants (n=112 GPs)

Random allocation of GPs (n=78)

Expert support group (n=36 GPs)
All GPs received allocated intervention

GPs working diagnosis (360 cases)
COPD 165
Asthma 107
Lung fibrosis 7
Absence of respiratory disease 19
Other diagnoses 62

Diagnostic assessment before intervention

GPs working diagnosis (420 cases)
COPD 184
Asthma 125
Lung fibrosis 1
Absence of respiratory disease 25
Other diagnoses 85

Intervention

Spirometry test results
Pre- and post-BD FEV1, FVC, FEV1/FVC%
Post-BD % predicted FEV1 and FVC
Flow-volume curve
Plus: Information from expert system, Graphical interpretation results, Textual interpretation results

Lane (n=357 cases)
Excluded from analysis (3 cases)

GPs working diagnosis (420 cases)
COPD 180
Asthma 123
Lung fibrosis 1
Absence of respiratory disease 23
Incorrect test 28
Other diagnoses 65

Diagnostic reassessment after intervention

Analysed (417 cases)
Excluded from analysis (3 cases)

FIGURE 1. Participants to the present study and intervention. GP general practitioner, COPD chronic obstructive pulmonary disease, BD bronchodilatation, FEV1 forced expiratory volume in one second, FVC forced vital capacity. The first six GPs used an example case with an expert panel’s diagnosis of absence of respiratory disease and a test case of exercise asthma. For the other 72 consecutive GPs, the case set was switched between these two cases. The case of absence of respiratory disease was included for them in the final case set. Therefore, information was not available from the first six GPs about the case of absence of respiratory disease equally divided among expert support (n=3 GPs) and control group (n=3 GPs).

Scientist (T.R.J. Schermer). The panel consensus diagnoses served as the gold standard in the subsequent evaluation of GPs’ diagnostic achievements.

The whole approach was piloted in four GPs before the start of the study. Shortly after the first six study visits, the case set was adjusted by switching the example case with a case out of the actual set. As a result, no data of the new introduced case were available for those first six GPs (equally divided over the two groups).

Primary and secondary outcome measures

The difference between the percentage agreement of the cases’ diagnoses between GPs and expert panel judgement before and after interpretation of spirometry served as the primary outcome. Diagnoses were directed to the following five outcome categories: 1) COPD, 2) asthma, 3) rare respiratory pathology (lung fibrosis), 4) absence of respiratory disease, and 5) incorrect test manoeuvre.

Six predefined secondary outcome measures were assessed using indicators that show the impact of the expert system intervention on the GPs decision-making processes, as follows: 1) probability of ordering additional diagnostic tests (yes/no), 2) width of the differential diagnoses (i.e., the working diagnosis plus the number of alternative diagnoses considered by the GP), 3) a GP’s certainty of the working diagnosis (self-scored 0–10, with 0=uncertain and 10=certain), 4) a GP’s
Medical history
Male 56 yrs old
Dyspnoea with exercise for 1.5 yrs
Former smoker

Physical examination
Normal pulmonary auscultation
No cardiac abnormalities
Blood pressure 150/90 mmHg

Medication
Metoprolol 50 mg
Pulmicort 400 mcg
Pantozol 40 mg
(all once daily)

Spirometry test results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre BD</th>
<th>Post BD</th>
<th>Predicted</th>
<th>Post BD %</th>
<th>Pred std</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1 (L)</td>
<td>2.94</td>
<td>3.10</td>
<td>3.75</td>
<td>85%</td>
<td></td>
</tr>
<tr>
<td>FVC (L)</td>
<td>4.59</td>
<td>5.1</td>
<td>4.74</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

EGK/SRS + Duaxem

Intervention
Expert support group
Control group

Before intervention, GPs asked to consider
Diagnosis and differential diagnosis?
Additional diagnostic tests and referral?
Certainty of diagnosis?
Severity of diagnosis?

After intervention, GPs asked to consider
Diagnosis and differential diagnosis?
Additional diagnostic tests and referral?
Certainty of diagnosis?
Severity of diagnosis?
Medication or nonmedication changes
(Optional question in six cases)

FIGURE 2. Schematic representation of a case structure detailing information presented to the general practitioner (GP) and points of consideration.

BD: bronchodilation; FEV1: forced expiratory volume in one second.

Using the following three stratification factors: 1) a GP's prior experience with the specific computerised spirometry interpretation support package (yes/no), 2) the average number of spirometry tests a GP reported to interpret per week, and 3) a GP's experience (in years) with spirometry. The researchers and the statistician (R.P. Akkermans) were blinded while assessing and reporting all outcomes.

Statistical analysis
Agreement between GPs' and expert panel judgement was expressed as percentages with 95% confidence intervals (CIs). Multilevel regression logistic modelling was used to account for the intra-cluster correlation induced by the fact that each GP assessed more than one case, and the fact that the same cases were applied repeatedly in different GPs. Multilevel logic analyses were performed for dichotomous variables and multilevel regression analyses for continuous variables. Odds ratios (ORs) with 95% CIs were calculated to evaluate differences in percentages of agreement before and after the intervention with the expert judgement between the study groups. Sensitivity, specificity, positive and negative predictive values (PPV and NPV, respectively), and the diagnostic OR (DOR) [21] with 95%

Sample size
Calculation of the sample size was based on an estimated relevant proportion of correctly interpreted cases after spirometry expert support of 25% compared with no expert support. Assuming a correctly interpreted proportion of cases without support of 50% [5], \( \alpha = 0.05 \), a power of 80% and an intra-cluster correlation \( r = 0.18 \), 31 GPs were required in each randomisation group. To allow for dropouts and subgroup analyses, the aim was to include \( \geq 70 \) GPs.

Randomisation
The research assistant used restricted randomisation (minimisation) with a computer program on a laptop computer using the following three stratification factors: 1) a GP's prior experience with the specific computerised spirometry interpretation support package (yes/no), 2) the average number of spirometry tests a GP reported to interpret per week, and 3) a GP's experience (in years) with spirometry. The researchers and the statistician (R.P. Akkermans) were blinded while assessing and reporting all outcomes.

Statistical analysis
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39
CIs were calculated for GP judgements of COPD, asthma, rare respiratory pathology and no respiratory disease after the intervention. ORs with 95% CIs were also used to evaluate differences in indicators GPs' decision-making process.

To detect possible effect modifications before intervention, subgroup analyses were performed for a GP's prior experience with spirometry, a GP's prior experience with expert support and a GP's number of interpreted spirometry tests per week.

**RESULTS**

**Baseline characteristics of GPs**

Between January and October 2006, 78 GPs were enrolled in the present study; 36 were allocated to the expert support group and 42 to the control group (fig. 1). All GPs completed the study. Relevant characteristics at baseline were similar between the two groups (table 1).

**Primary outcome: diagnostic achievements by GPs**

GPs assessed a total of 774 cases, 357 cases from the expert support group and 417 cases from the control group. There was no difference between the expert support and control group in agreement on judgement between GPs and the expert panel for presence of COPD, asthma, absence of respiratory disease and incorrect test manoeuvre after intervention (table 2). GPs' agreement with the expert panel for all cases, except the incorrect test manoeuvre case, was 66.0 (expert support) versus 65.97 (control) before intervention and 68.5 (expert support) versus 63.5% (control) after intervention.

Although the DORs in the expert support group were consistently higher than in the control group, no significant differences were found between the groups (table 3). GPs did not recognise an incorrect test manoeuvre in 28.6% (in both expert support and control groups) of cases. The highest NPVs were found for cases with the conditions of asthma and absence of respiratory disease.

**Secondary outcomes: indicators of GPs' decision-making process**

GPs in the expert support group ordered slightly more additional diagnostic tests compared with the control group (OR (95% CI) 2.5 (1.2–5.4); table 4). There were no significant differences between the two groups for other secondary outcome measures. There were also no specific changes (start, stop or lower) in medication (bronchodilators, inhaled steroids or nonpulmonary drugs) between the study groups.

**Subgroup analyses**

Neither a GP's experience with spirometry (OR (95% CI) 1.02 (0.97–1.06)), nor a GP's prior experience with expert support (0.97 (0.72–1.31)) or a GP's number of interpreted spirometry tests per week (1.02 (0.84–1.23)) was associated with the effectiveness of expert support, as their agreement with the expert panel was not different before intervention. If GPs interpreted more spirometry tests per week and had prior experience of expert support, the probability of agreement with the expert panel before intervention increased; however, this probability decreased if GPs had no prior experience with expert support (interaction effect p=0.02).

**DISCUSSION**

**Statement of principal findings**

Computerised spirometry expert support for the interpretation of spirometry tests by GPs had no detectable benefit over sham information on GPs' diagnostic achievements of chronic respiratory disease. Overall, expert support did not influence GPs' decision-making processes.

**Strengths of the study**

The present study is the first diagnostic study to assess the impact of a commercially available computerised expert support system for spirometry in a randomised simulation study in primary care. The study used standardised patients, which meant that all participants were faced with the same diagnostic challenges. This could only be achieved in an in vitro design, as the mix of practice patients in real life would make it difficult to capture the necessary variation in diagnostic challenges.

The standardised complex and original method that was used to assess the impact of expert support in the present study has been used before in a nonrandomised design [10]. Based on previous information [10], the present authors were able to create a balanced mixture of cases relevant for GPs. The confirmative role of spirometry was more strongly

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Baseline characteristics of all randomised general practitioners (GPs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Expert support group</td>
</tr>
<tr>
<td>GPs n</td>
<td>36</td>
</tr>
<tr>
<td>Type of practice</td>
<td></td>
</tr>
<tr>
<td>Single handed</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Duo</td>
<td>9 (25)</td>
</tr>
<tr>
<td>Group (&gt;3 GPs)</td>
<td>15 (42)</td>
</tr>
<tr>
<td>Multidisciplinary healthcare centre</td>
<td>10 (28)</td>
</tr>
<tr>
<td>Male %</td>
<td>64</td>
</tr>
<tr>
<td>GP's experience with spirometry in yrs</td>
<td>5.5±4.3</td>
</tr>
<tr>
<td>Spirometry results interpreted per week</td>
<td>1.4±0.8</td>
</tr>
<tr>
<td>Prior experience with expert support % yes</td>
<td>47</td>
</tr>
</tbody>
</table>

Data are presented as n (%) or mean±SD, unless otherwise indicated.
Agreement on case diagnoses between general practitioners (GPs) and expert panel judgement before and after intervention

<table>
<thead>
<tr>
<th>GP diagnosis</th>
<th>Expert support group</th>
<th>Control group</th>
<th>Expert panel judgement</th>
<th>OR* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>Before</td>
<td>After</td>
</tr>
<tr>
<td>Presence of COPD</td>
<td>32.5</td>
<td>32.5</td>
<td>32.4</td>
<td>30.7</td>
</tr>
<tr>
<td>Presence of Asthma</td>
<td>23.5</td>
<td>25.2</td>
<td>23.5</td>
<td>23.0</td>
</tr>
<tr>
<td>Presence of Rare respiratory pathology</td>
<td>0.6</td>
<td>0.3</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Presence of Absence of respiratory disease</td>
<td>2.8</td>
<td>3.6</td>
<td>3.4</td>
<td>4.4</td>
</tr>
<tr>
<td>Presence of Incorrect test manoeuvre</td>
<td>NA</td>
<td>5.9</td>
<td>NA</td>
<td>6.71</td>
</tr>
</tbody>
</table>

Prior to the intervention, GPs diagnosed COPD in 32.5% of cases and asthma in 23.5% of cases. The expert panel agreed with these diagnoses in 80% and 70% of cases, respectively. After the intervention, the OR for COPD increased to 1.08 (95% CI 0.70-1.66), indicating a small but statistically significant improvement in diagnostic accuracy.

TABLE 2

Data are presented as % unless otherwise indicated. OR, odds ratio; CI, confidence interval. COPD, chronic obstructive pulmonary disease; NA, not available. * n=357

Subgroup analyses showed no difference in baseline diagnostic achievements of GPs with prior experience of spirometry or of the expert support system used, and on the number of spirometry tests a GP interpreted per week. Therefore, the external validity seems quite good, given the fact that the participants were not specifically interested in spirometry.

Possible limitations

The present trial has some limitations. In a diagnostic assessment of chronic respiratory disease, a GP's consideration to perform spirometry in case of an intermediate prior probability of disease is a great diagnostic step [21]. This step was already foreseen in the present study design. The next step of diagnostic refinement does not seem to influence extensively the posterior probability. In the present study, the diagnostic achievements of GPs in both groups were high (prior probability of a correct diagnosis was ~66%). Overall, only 4% of initial diagnoses changed after intervention. As the posterior probability in both groups was nearly the same as the prior probability, the role for expert support to change diagnosis and management was very small. Furthermore, the diagnostic achievements of the GPs exceeded the present authors' assumptions in the power calculation (50% correct diagnoses without expert support). It is probable that instruction and support for these GPs had not been effective, as these

TABLE 3

Sensitivity, specificity, predictive values and diagnostic odds ratios (ORs) for general practitioners' judgement after intervention

<table>
<thead>
<tr>
<th>Expert support group</th>
<th>COPD</th>
<th>Asthma</th>
<th>Rare respiratory pathology</th>
<th>Absence of respiratory disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>80.6</td>
<td>83.3</td>
<td>2.8</td>
<td>39.4</td>
</tr>
<tr>
<td>Specificity</td>
<td>77.5</td>
<td>90.4</td>
<td>99.4</td>
<td>97.5</td>
</tr>
<tr>
<td>PPV</td>
<td>70.7</td>
<td>78.9</td>
<td>33.3</td>
<td>61.9</td>
</tr>
<tr>
<td>NPV</td>
<td>85.5</td>
<td>92.6</td>
<td>90.1</td>
<td>94.0</td>
</tr>
<tr>
<td>Diagnostic OR</td>
<td>14.2</td>
<td>46.9</td>
<td>4.6</td>
<td>25.7</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.46-2.98</td>
<td>24.35-90.23</td>
<td>0.59-35.90</td>
<td>9.74-67.71</td>
</tr>
</tbody>
</table>

Control group

| Sensitivity          | 76.2 | 76.2   | 0.0                       | 35.9                          |
| Specificity          | 79.1 | 90.7   | 99.7                      | 97.6                          |
| PPV                  | 71.1 | 78.0   | 0.0                       | 60.9                          |
| NPV                  | 83.1 | 89.8   | 89.9                      | 93.7                          |
| Diagnostic OR        | 12.1 | 31.3   | NA                       | 23.0                          |
| 95% CI               | 7.60-19.34 | 17.73-55.22 | 0.0-34.79 | 9.22-57.17 |

Data are presented as % unless otherwise indicated COPD, chronic obstructive pulmonary disease; PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval; NA, not available.
Impact of the intervention on six indicators of general practitioners' (GPs) decision-making process

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Expert support group</th>
<th>Control group</th>
<th>OR* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional diagnostic tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiographic imaging</td>
<td>70.2</td>
<td>5.2</td>
<td>2.5 (1.17–5.35)*</td>
</tr>
<tr>
<td>Blood tests</td>
<td>48.7</td>
<td>0.9</td>
<td>1.27 (0.25–6.41)</td>
</tr>
<tr>
<td>Lung function</td>
<td>29.2</td>
<td>0.9</td>
<td>1.0 (0.65–1.55)</td>
</tr>
<tr>
<td>Prednisone course</td>
<td>13.2</td>
<td>2.3</td>
<td>1.0 (0.59–1.70)</td>
</tr>
<tr>
<td>Electrocardiography</td>
<td>11.2</td>
<td>2.6</td>
<td>1.0 (0.61–1.63)</td>
</tr>
<tr>
<td>Other†</td>
<td>3.6</td>
<td>0.3</td>
<td>1.0 (0.55–1.80)</td>
</tr>
<tr>
<td>Width of differential diagnoses</td>
<td>2.2±1.0</td>
<td>1.7±0.9</td>
<td>1.0 (0.01–1.19)</td>
</tr>
<tr>
<td>Certainty of diagnosis</td>
<td>6.8±2.0</td>
<td>7.1±1.9</td>
<td>1.0 (0.57–1.43)</td>
</tr>
<tr>
<td>Perception of severity of diagnosis</td>
<td>6.0±2.2</td>
<td>5.9±2.3</td>
<td>1.0 (0.57–1.42)</td>
</tr>
<tr>
<td>Referral rate</td>
<td>18.6</td>
<td>1.7</td>
<td>1.0 (0.60–1.66)</td>
</tr>
<tr>
<td>Medication and nonmedication changes†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop or lower medication</td>
<td>10.2</td>
<td>NA</td>
<td>1.67 (0.85–3.28)</td>
</tr>
<tr>
<td>Inhaled corticosteroids</td>
<td>NA</td>
<td>0.9</td>
<td>1.17 (0.16–8.40)</td>
</tr>
<tr>
<td>Bronchodilators</td>
<td>NA</td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>Start medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-acting bronchodilators</td>
<td>26.9</td>
<td>NA</td>
<td>1.27 (0.73–2.20)</td>
</tr>
<tr>
<td>Long-acting bronchodilators</td>
<td>15.3</td>
<td>NA</td>
<td>1.01 (0.46–2.18)</td>
</tr>
<tr>
<td>Inhaled corticosteroids</td>
<td>31.0</td>
<td>NA</td>
<td>1.00 (0.68–1.49)</td>
</tr>
<tr>
<td>Oral corticosteroids</td>
<td>6.5</td>
<td>NA</td>
<td>1.34 (0.44–4.10)</td>
</tr>
<tr>
<td>Combinational drug</td>
<td>3.7</td>
<td>NA</td>
<td>1.27 (0.26–6.19)</td>
</tr>
<tr>
<td>Nonmedication changes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking cessation advice</td>
<td>30.1</td>
<td>NA</td>
<td>0.85 (0.57–1.26)</td>
</tr>
</tbody>
</table>

Data are presented as % or mean±SD, unless otherwise indicated. OR: odds ratio; CI: confidence interval; NA: not available. †: n=357. ‡: n=417. *: ORs express the difference in an indicator of the GPs’ decision-making process before and after the intervention, i.e. expert support compared with control. ††: includes urine test, gastroscopy, ergometry, blood pressure, temperature and oxygen saturation; ‡‡: this information was available for six out of 10 cases (expert support n=216, control group n=252 cases). *: p<0.05.

GPs could already be considered experts due to prior participation in other studies or postgraduate spirometry training programmes from the present authors’ department. Therefore, the expert system had hardly additional value and could be considered a "sort of luxury appendix" for these GPs.

A large within-group difference was found for ordering additional diagnostic tests, which may be an effect of the study design: GPs barely reassessed their diagnostics after intervention, because they expected the results of their diagnostics to have been already discounted before intervention. However, the objective was to reassess the opinion of GPs when new information, i.e. expert support, was available, regardless of their earlier assessment in the same case.

From a methodological point of view, the use of the volume-time curve as sham information could be questioned. Theoretically, such curves do not show new information to GPs after presentation of the flow-volume curves. Additionally, this is not really "usual care", as most GPs in the Netherlands are trained to look at flow-volume curves rather than volume-time curves. Conversely, the volume-time curve is much more intuitive and may have improved unconscious performance of spirometry interpretation in the control group. Furthermore, providing the expert panel and GPs in the present study with a fixed cut-off value of <0.7, instead of the lower limit of normal for the FEV1/FVC ratio in the standardised cases may have led to an overestimation of diagnosed airflow obstruction [22]. Further discussion about the pros and cons of using a fixed cut-off value versus the lower limit of normal for FEV1/FVC [23] is beyond the scope of the present paper.

Finally, a possible reason why no differences could be demonstrated in diagnostic achievements should be sought in the expert support system used. Although the expert support system used in the present study met the criteria of a good system [15], i.e. involvement of the present authors by development, integration through the computer, and the displaying of specific recommendations at the right place and time, it was not actually tested in the target group, i.e. GPs, before the study. Therefore, it may not optimally comply with the decision-making process of GPs. The information presented by the system to the GP possibly lacked explanation of exactly what the output means. These are known barriers to the adoption of expert support in primary care [24].
Relation to other studies
A recent systematic review [16] demonstrated the following two relevant issues with respect to expert support systems: 1) the effects of diagnostic expert support systems on GPs' performance were low, and 2) trials evaluating diagnostic systems were scarce. Currently, there are no similar expert support studies available with which to directly compare the present results. It is important to realise that, similarly to ECG, spirometry is a highly complex diagnostic tool in the perception of many GPs. Although a recent study evaluating the ECG interpretation skills of GPs and the value of automatic ECG recorded interpretations [25] seemed promising to compare the present study's results with, it lacked the correct design. In the present study, and similarly to the results of the study by Jensen et al. [25], the PPVs were lower than the NPVs. The highest NPVs were found for the cases with the conditions of asthma and absence of respiratory disease. This probably reflects the fact that it is more difficult for a GP to confirm the presence of a disease than to exclude its presence.

The acuity of GPs' interpretation of test results has been evaluated by others. In 1999, Eaton et al. [5] had already found that 53% of GPs' interpretation of spirometry test results was judged to be correct according to an expert panel. Recently, Raghunath et al. [9] found that the agreement in interpretation of spirometry and peak flow results between nurses, GPs and an expert panel was only 20%. The lower agreement in the latter study could probably be explained by the fact that GPs, as well as nurses, i.e., less-trained professionals, assessed a common diagnosis. Furthermore, contrary to GPs and nurses, the expert panel did not have detailed clinical history information to assess their final diagnosis on and, due to a design artefact, interpretation of their study results was difficult. Results of the present study concur with the results of Eaton et al. [5] and show that, generally, GPs have made progress in the interpretation of test results relevant for respiratory diseases in primary care. The current acuity of GPs' interpretation of test results should weaken earlier reported lack of confidence in the ability to interpret the test results [8, 9].

Unanswered questions and future research
Generally, two questions remain to be answered: 1) how can optimal quality spirometry results in primary care be achieved outside of research settings?, and 2) what is the most effective way to give continuous expert support for the interpretation of spirometry test results, given a situation of optimal quality results [14]? Continuous expert support could be provided by means of consultation or feedback from a chest physician or by means of an expert support system. The results of the present study add to current knowledge that computerised spirometry expert support had no detectable benefit over sham information on GPs' diagnostic achievements and decision-making processes when diagnosing chronic respiratory disease. The comparison of support from a chest physician versus computerised expert support for spirometry test results calls for further study.

ACKNOWLEDGEMENTS
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Diagnostic spirometry expert support in general practice: A cluster-randomised trial

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Submitted
Abstract

**Background** This study assessed the impact of two modes of expert support for the interpretation of spirometry tests on the diagnoses as established by general practitioners (GPs) and their subsequent management decisions in patients with, or suspect for chronic respiratory disease.

**Methods** We performed a cluster-randomised controlled trial with general practices as unit of randomisation. GPs from 44 Dutch general practices recorded their diagnosis and (planned) management before and after a spirometry test and interpretation for 868 patients with (possible) respiratory conditions in which spirometry plays a role in the diagnostic work-up. Intervention consisted of spirometry with either computerised expert support or chest physician support. Both interventions were compared with usual care (spirometry with no additional interpretation support). Change of GPs' diagnoses after spirometry testing and interpretation served as primary outcome. Secondary outcomes were additional diagnostic tests, specialist referral rate, and disease management changes. Differences in change of diagnosis and rates of decision-making indicators before and after intervention were expressed as percentages, interventions versus usual care, with 95% confidence intervals.

**Results** Diagnoses changed after intervention in all groups: 45.0% (95% CI 39.5 to 50.6) for software support, 47.8% (95% CI 41.8 to 53.9) for chest physician support, and 53.3% (95% CI 47.2 to 59.4) for usual care. Differences in proportions of changed diagnosis were not statistically significant: computerised support versus usual care (p=0.16), chest physician support versus usual care (p=0.36). There were no differences on secondary outcomes.

**Conclusion** Neither computerised nor chest physician support had a detectable impact on GPs' diagnosis of respiratory conditions or management decisions.
Introduction

Although major guidelines for chronic obstructive pulmonary disease (COPD) stress the central role of spirometry in diagnosing and managing chronic airways disease,12 spirometry is still underused in primary care, despite increased accessibility34. The most common barriers impeding utilisation of spirometry in the GP's practice are the absence of properly trained staff,5 the lack of time and practice support to fit spirometry into the daily practice routine,6 the absence of a spirometer in the practice7 and the GP's lack of confidence in the ability to interpret the test results89. The latter barrier could theoretically be overcome through expert support.

Expert support for the interpretation of tests of pulmonary function may be made available - depending on local circumstances - as a software expert support system10 or by consultation or feedback from a chest physician. In a simulation study we recently showed that software support for the interpretation of spirometric test results by GPs did not have demonstrable benefit11. However, GPs welcome support from a computer or a chest physician1213. GPs might value support from a chest physician more than from software, because chest physicians may act as coaches for their local GPs through specific feedback for specific patients, a role computer software cannot fulfil. In the Netherlands there are already local initiatives between chest physicians and GPs with respect to teleconsultation for spirometry test results by facsimile. However, empirical studies on the effect of this kind of expert support are warranted.

The objective of the present study was to assess the impact of two realistic modes of expert support (computerised expert support and consultation by a chest physician) for the interpretation of spirometric test results on establishing a diagnosis by GPs, and on the GP's decision-making in the management of chronic respiratory disease. A cluster-randomised design was used to minimise contamination and the unit of randomisation and analysis was the general practice.

Methods

Study design

We investigated the impact of two modes of spirometry expert support on GPs' diagnostic assessment of patients registered with respiratory conditions. General practices were allocated to one of three groups: (i) software support for interpreting spirometry, (ii) interpretation of spirometry through teleconsulting a chest physician, or (iii) usual care (i.e. spirometry without expert software or chest physician support). Practices were instructed to perform a spirometric test for selected patients. GPs recorded their diagnosis and management before and after spirometry and its interpretation (with or without support) using a standardised format. Comparison of the recordings before and after spirometry provides insight into the influence of the
pulmonary function tests with and without expert support on GP's diagnosis and patient management. For financial, practical and ethical reasons we could not have the patients in the study be assessed by a chest physician in order to confirm the diagnosis made by the GP's in the participating patients. Instead, we conducted a separate study parallel to the one reported in this paper that included an expert panel assessment of a limited number of well-documented respiratory patients from general practice.  

**General practices**
181 General practices with a Windows® compatible medical record system from three postal code regions in the Eastern part of the Netherlands were invited to participate in the study. A postal mail was sent via the user groups of two specific electronic patient data systems. Practices interested in participating in the study were requested to contact our department directly. 101 Practices responded (56%), 44 practices participated (Figure 1).

**Patients**
We were specifically interested in those patients in primary care with symptoms such as dyspnoea, chronic cough, chronic sputum production, where spirometry is pivotal in confirming or excluding airway obstruction. A list of all patients with (apparent) chronic respiratory conditions was extracted from the practice patient medical record system based on existing diagnostic labels and prescription records for respiratory medication. Diagnostic labels were the ICPC (International Classification of Primary Care (ICPC-1) codes R95 for COPD, R96 for asthma and (in practices not using the ICPC coding system yet) other codes that are commonly used in Dutch general practices to label patients with COPD or asthma. We identified repeated (i.e., two or more) respiratory prescriptions for each patient in the last year using ATC-codes: short-acting bronchodilators, long-acting bronchodilators, inhaled steroids, anticholinergic agents, and oral mucolytics. From each practice's selection list we took a random sample (n=40) of all patients aged >30 years. The sample was weighted to reflect the proportions of patients diagnosed with COPD or asthma, and patients who had repeatedly received prescriptions for respiratory medication without a formal diagnosis being assigned by the GP. Patients were excluded from analyses if they were primarily treated by a chest physician, had died, or had moved out of the practice. In these cases the GP included the next patient on the random selection list.
Recruitment of general practices in three regions in the Eastern part of the Netherlands (n=181)

Stratified randomisation of practices willing to participate (n=44)

- No response (n=80)
- Ineligible for participation (n=57)
  - Reasons were too busy (n=21)
  - No interest in spirometry (n=11)
  - Wrong EPS (n=6)
  - Illness of GP (n=6)
  - Other (n=13)

Software support (15 practices)

- Population aged ≥30 years (N=25,908)
  - Weighted random sample* of patients eligible for spirometry (n=766)
    - Not eligible according to GP (n=238)
      - GP's diagnosis before spirometry (n=528)
        - No spirometry performed (n=189)
          - Spirometry test (n=339)
            - No diagnosis reported by GP (n=19)
              - GP's diagnosis after spirometry (n=320)
  - Not eligible according to GP (n=156)

Usual care (15 practices)

- Population aged ≥30 years (N=31,105)
  - Weighted random sample* of patients eligible for spirometry (n=690)
    - Not eligible according to GP (n=203)
      - GP's diagnosis before spirometry (n=487)
        - No spirometry performed (n=172)
          - Spirometry test (n=315)
            - No diagnosis reported by GP (n=43)
              - GP's diagnosis after spirometry (n=272)
    - Not eligible according to GP (n=156)

Chest physician support (14 practices)

- Population aged ≥30 years (N=35,524)
  - Weighted random sample* of patients eligible for spirometry (n=642)
    - Not eligible according to GP (n=185)
      - GP's diagnosis before spirometry (n=457)
        - No spirometry performed (n=156)
          - Spirometry test (n=301)
            - No diagnosis reported by GP (n=25)
              - GP's diagnosis after spirometry (n=276)**

Abbreviations: GP - general practitioner, EPS - electronic patient system

* From each practice's selection list we took a random sample (n=40) of all patients aged ≥30 years
** No consultation used for 46 patients
Interventions

The intervention pertained to the cluster level (i.e., all the GPs in a particular practice). General practices were randomly allocated to one of the three study conditions: GPs, practice nurses, and practice assistants from all participating practices participated in a baseline spirometry workshop, which was developed and pre-tested before the study. Furthermore, all practices were equipped with an electronic spirometer (Microloop II® or Microplus®, Micro Medical Ltd, Rochester, UK). The expert software group was equipped with a software-based expert system (SpidaXpert®, Micro Medical Ltd, Rochester, UK). The chest physician supported group and the usual care group were equipped with standard spirometry software (SpidaS®, Micro Medical Ltd, Rochester, UK).

The SpidaXpert® expert software contains a diagnostic algorithm that is based on pre- and post-bronchodilator FEV1 and FEV1/FVC values and predicted values and their lower limits of normal for age, sex, and height. In the SpidaXpert® software, results are presented using coloured bars that display the pre- and post-bronchodilator values of FEV1 and FEV1/FVC relative to the 95% confidence limits, accompanied by a textual interpretation that provides information on and suggestions for additional diagnostic testing and treatment, if appropriate.

GPs in the chest physician support group used a printout of the spirometric test results (i.e., FEV1, FVC, FEV1/FVC, MEF50, flow/volume curve) generated by the standard spirometry software to communicate with a local chest-physician by facsimile. Standard forms, which had previously been piloted among 10 GPs and the involved chest physicians, were used for the mutual exchange of information between GPs and chest physicians. GPs in the usual care group did not receive any additional support for the interpretation of spirometric test results.

Pulmonary function tests

Patients from the practices’ random selection lists were offered a spirometry test (pre-bronchodilator and post-bronchodilator) either during a regular consultation or on separate office hours at the GP’s invitation. Reasons for patients not to attend the practice for the spirometry test were recorded. We instructed practices to measure forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) until three acceptable and reproducible recordings (with a difference <5%) were obtained, the highest sum of both values was used to select the best test.

Primary and secondary outcomes

Change of diagnosis (dichotomised as yes/no) in an individual patient after intervention at the GP level served as the primary study outcome. GPs’ diagnoses were inquired using a standardised format which comprised nine pre-printed diagnostic categories: asthma, asthma with persistent obstruction, COPD, restrictive...
lung disease, diffusive ventilatory defect, heart failure, other respiratory disease, and
no respiratory disease GPs could record a maximum of three diagnoses per patient
before as well as after reconsidering the patients' diagnosis after spirometry expert
intervention (if applicable) In case of one diagnosis before and one diagnosis after
intervention we defined a change of diagnosis if the content of the diagnosis before
and after spirometry was not the same In case a GP recorded two or three
diagnoses before and the same number of diagnoses after the intervention we
decided on a change of diagnosis if the recorded sets of diagnoses before and after
intervention were not exactly concordant

Four predefined secondary outcome measures were assessed to study the potential
impact of expert software and chest physician support on the GP’s decision-making
process (1) ordering additional diagnostic tests (i.e., peak expiratory flow
measurement, allergy test, diagnostic prednisolone test, chest X-ray, and other
tests], (2) referral to secondary care (i.e., to a chest physician, cardiologist, or other
specialist], (3) changes in respiratory pharmacotherapy, (4) GP’s perception of the
influence of expert support on their interpretation of spirometry test results (self-
scored on a 5 point scale [1=no influence at all, 5=very strong influence])

Sample size
Calculation of the sample size was based on an estimated relevant 15% change in
diagnosis between either one of the spirometry expert support groups and the
unsupported group (i.e., the usual care group) Assuming that 15% of diagnoses in
the usual care group would change upon reassessment of the diagnosis with the new
input of the spirometry test result, and assuming a 30% rate of changed diagnoses in
each of the supported groups, an average of 20 patients per practice from 39
practices (13 per group) needed to be included in the study (α = 0.05, 1-β = 0.80,
intra-cluster correlation r = 0.07)

Randomisation of practices
Restricted computised randomisation (minimisation) was applied (RA) using three
stratification factors region (three postal code regions), GP’s prior experience with
spirometry (<4 or ≥4 years), and the proportion of patients receiving repeated
respiratory prescriptions with a diagnostic label (COPD, asthma) of the total number
of patients receiving repeated respiratory prescriptions (<50% or ≥50%) in a
practice The researchers and the statistician (RA) were blinded during the analysis
and writing the results section of this paper Given the nature of the intervention, GPs
could not be blinded
**Statistical analysis**

For each study arm change in diagnosis was expressed as percentage with 95% confidence intervals (95% CI). We performed multilevel logistic regression analyses for dichotomous variables and multilevel regression analyses for continuous variables in SAS V8.2 for Windows (SAS Institute Inc., Cary USA 1999-2001). Both models were random intercept models, with general practice as a random factor. All analyses were performed on an intention to treat basis and included all patients with a diagnostic assessment by GPs before and after spirometry, regardless of actual use of expert support. To detect possible effect modification, subgroup analyses were performed using Chi-square testing by categorizing patients according to a prior diagnosis of asthma or COPD, and patients who had repeatedly received prescriptions for respiratory medication without a formal diagnosis.

**Results**

**Baseline characteristics**

Between February 2004 and May 2006 we enrolled 44 general practices (table 1). The software supported group contained slightly more single-handed practices. Five practices dropped out after randomisation (figure 1). The reasons were too busy (n=3), and dissociation of GPs in practices (n=2). Drop-out practices tended to have more experience with spirometry, a smaller practice population size and had less frequently a practice nurse employed (data not reported). Of the practice staff 85% attended the baseline spirometry workshop. The mean age of the sampled patients was 56.5 years (SD 14.3). There was no statistical difference between the three groups for the percentage predicted FEV1 or FEV1/FVC values.

The weighted random practice population sample comprised 2098 patients out of a total practice population of 92,537 patients (Figure 1). 626 Patients were not eligible according to their GP, the two main reasons being primarily treated by a chest physician (75%) and inaccurate reasons for selection (i.e., use of oral corticosteroids for rheumatic in stead of respiratory disease) (9%). GPs recorded their diagnosis and management before spirometry in 1472 patients. Spirometry was not performed in 517 (35%) of these patients. The reasons for not performing spirometry were if patients did not respond to the GP’s invitation to visit the practice for a spirometry test (29%), suffered from severe co morbidity (12%), had died (3%), had left the practice (9%), recently had a spirometry test performed (3%), felt they had no respiratory problems (5%), and other reasons (39%). GPs recorded their diagnoses and patient management decisions again after spirometry in 868 patients. A diagnosis was missing for 87 patients after spirometry. The GPs’ reasons for not reporting a diagnosis were the standard format was lost (30%), patients had left the practice (13%), patients had died (6%), patients were under treatment of a chest
physician (8%), GPs could not interpret the spirometry results (13%), and for other reasons (30%). There was no difference between the three groups with respect to the proportion of patients that had previously had a spirometry test (p=0.21). The analysis of all outcomes was based on 868 patients from 39 practices (figure 1).

Table 1 Baseline characteristics of all 44 randomised general practices and 868 patients

<table>
<thead>
<tr>
<th>General practices</th>
<th>Usual Care</th>
<th>Software support</th>
<th>Chest physician support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practices</td>
<td>15</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Type of practice, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- single handed</td>
<td>5 (33)</td>
<td>10 (67)</td>
<td>5 (36)</td>
</tr>
<tr>
<td>- duo</td>
<td>5 (33)</td>
<td>5 (33)</td>
<td>4 (29)</td>
</tr>
<tr>
<td>- group (≥ 3 GPs)</td>
<td>4 (27)</td>
<td>-</td>
<td>4 (29)</td>
</tr>
<tr>
<td>- multidisciplinary health care centre</td>
<td>1 (7)</td>
<td>-</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Number of patients per GP, range (median)</td>
<td>640-2800 (1750)</td>
<td>712-3400 (1600)</td>
<td>783-2880 (1545)</td>
</tr>
<tr>
<td>Practice nurse present, % yes</td>
<td>33</td>
<td>47</td>
<td>29</td>
</tr>
<tr>
<td>Average experience (years) with spirometry of all GPs in practice, range (median)</td>
<td>1-10 (4.0)</td>
<td>0-14 (3.0)</td>
<td>0-11 (4.5)</td>
</tr>
</tbody>
</table>

| Patients | | | |
| Number of patients | 272 | 320 | 276 |
| Age, mean (SD) | 55 (13.9) | 59 (14.3) | 55 (14.4) |
| Gender, % female | 62.5 | 58.1 | 54.7 |
| Patients selection from practices' lists | | | |
| - with diagnoses of COPD or asthma, n (%) | 164 (60) | 178 (56) | 189 (69) |
| - repeated respiratory | 108 (40) | 142 (44) | 87 (31) |
| Spirometry results* | | | |
| Number of patients | 170 | 239 | 174 |
| FEV₁, mean (SD) | 2.57 (0.89) | 2.34 (0.90) | 2.66 (0.84) |
| FEV₁ % predicted | 88.26 (21.09) | 83.12 (22.59) | 87.80 (18.69) |
| FEV₁/FVC %, mean (SD) | 71.71 (10.89) | 72.02 (12.18) | 75.73 (9.45) |

* Electronic data available for 33 out of 39 practices, we could not extract the database of the spirometry software in 6 general practices due to changes in hardware during the study that led to lack of compatibility of USB ports and disk drives
Primary outcome change of diagnoses in the analysed patient population

Before spirometry, GPs recorded a total of 954 diagnoses (1.10 diagnosis per patient). In 91% of the patients, GPs recorded one diagnosis, in the remaining 9% more than one diagnosis. The GPs in the software supported group less frequently reported more than one diagnosis compared to the GPs in the other groups (p=0.006). Sorted by frequency, the recorded diagnoses were asthma (n=450), COPD (n=270), no respiratory disease (n=102), asthma with persistent obstruction (n=52) and other diagnoses (n=80).

After spirometry, GPs recorded a total of 985 diagnoses (1.13 diagnoses per patient). In 87% of the patients, GPs recorded one diagnosis, in the remaining 13% two or more diagnoses. These diagnoses were asthma (n=416), COPD (n=266), no respiratory disease (n=152), asthma with persistent obstruction (n=66) and other diagnoses (n=85).

In all three groups of analysed patients, the diagnoses changed considerably after spirometry. 45.0% (95% CI 39.5 to 50.6) with software support, 47.8% (95% CI 41.8 to 53.9) with chest physician support and 53.3% (95% CI 47.2 to 59.4) with usual care. The differences were not statistically significant for software support versus usual care (p=0.16), chest physician support versus usual care (p=0.36). The intra-cluster correlation was 0.065.

Table 2 provides detailed insight into change of a COPD diagnosis after spirometry for the subgroup of patients aged ≥ 40 years. COPD diagnoses changed in patients as follows: 20.1% (95% CI 15.7 to 25.2) with software support, 23.5% (95% CI 18.2 to 29.5) with chest physician support and 27.1% (95% CI 21.4 to 33.4) with usual care. These differences were not statistically significant for software support versus usual care (p=0.09), chest physician support versus usual care (p=0.42).

Table 2 Differences in the proportion of changed COPD diagnoses after spirometry as indicated by the GP in patients aged ≥ 40 years

<table>
<thead>
<tr>
<th>Prior diagnosis</th>
<th>COPD</th>
<th>COPD</th>
<th>COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual care (n = 225)</td>
<td>Software support (n=293)</td>
<td>Chest physician support (n=230)</td>
</tr>
<tr>
<td></td>
<td>Posterior diagnosis</td>
<td>Posterior diagnosis</td>
<td>Posterior diagnosis</td>
</tr>
<tr>
<td>COPD</td>
<td>Yes, %</td>
<td>No, %</td>
<td>Yes, %</td>
</tr>
<tr>
<td>Yes, %</td>
<td>25.3</td>
<td>14.6</td>
<td>22.5</td>
</tr>
<tr>
<td>No, %</td>
<td>12.4</td>
<td>47.5</td>
<td>8.5</td>
</tr>
</tbody>
</table>

54
Figure 2 depicts the direction of change of a diagnosis from before to after spirometry. The additional value of spirometry testing appeared to be substantial in all three groups. Generally, most changes were observed among GPs who did not receive expert support. A prior diagnosis of COPD (Fig 2a) changed in ~35% into another diagnosis (mostly asthma); this shift in diagnoses was not statistically significant different between the groups: software support versus usual care (p=0.13), chest physician support versus usual care (p=0.09).

A prior diagnosis of asthma (Fig 2b) changed in ~30% of cases; this shift was significantly different between groups: software support versus usual care (p=0.01), chest physician support versus usual care (p<0.001).

Finally, the diagnosis “no respiratory disease” (Fig 2c) changed in ~50% of cases (mostly into asthma or COPD); this shift in diagnoses was not significantly different between the groups; software support versus usual care (p=0.77), chest physician support versus usual care (p=0.24).

Table 3 Secondary outcomes: Impact of the spirometry interventions on three indicators of GPs’ decision-making process.*

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Usual care (N=272)</th>
<th>Software support (N=320)</th>
<th>p</th>
<th>Chest physician support (N=276)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Additional diagnostic tests#, %</td>
<td>12.5</td>
<td>18.1</td>
<td>0.21</td>
<td>8.7</td>
<td>0.32</td>
</tr>
<tr>
<td>(2) Specialist referral rate**, %</td>
<td>5.2</td>
<td>5.7</td>
<td>0.82</td>
<td>7.6</td>
<td>0.23</td>
</tr>
<tr>
<td>(3) Changes in respiratory pharmacotherapy$, % yes</td>
<td>39.0</td>
<td>38.9</td>
<td>0.97</td>
<td>32.7</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Stop medication,
- short acting bronchodilators | 47.4 | 53.2 | 0.68 | 42.9 | 0.58 |
- long acting bronchodilators | 46.2 | 43.5 | 0.88 | 57.1 | 0.57 |
- inhaled corticosteroids | 53.5 | 36.7 | 0.11 | 38.8 | 0.26 |

Start medication,
- short acting bronchodilators | 10.2 | 13.5 | 0.40 | 7.9 | 0.55 |
- long acting bronchodilators | 4.5 | 7.1 | 0.37 | 1.9 | 0.34 |
- inhaled corticosteroids | 11.7 | 8.3 | 0.37 | 15.9 | 0.42 |

* P values apply to testing software support versus usual care and chest physician support versus usual care
# Additional diagnostic tests included peak flow measurement, allergy test, diagnostic prednisolone test, chest X-ray, histamine provocation test and electrocardiography.
** Referrals included: chest physician, cardiologist, internist and ENT-surgeon
$ We report about 146 patients (usual care), 247 patients (software support), and 168 patients (chest physician support) Due to technical problems with software data for medication prescriptions were missing for 46.3% of the patients in usual care group, for 22.8% in software support group, and 39% in chest physician support group
Figure 2 Diagnosis after spirometry in patients with a diagnosis before spirometry of COPD (a), asthma (b) and no respiratory disease (c).
Secondary outcomes indicators of GP’s decision-making

There were no differences between software support or physician support compared with usual care for the additional diagnostic tests rate, the referral rate, or for changes in respiratory pharmacology (table 3). Data on prescriptions were only available for 65% of the practices, the missing patients were more frequently female and slightly younger (data not reported).

GP’s self-scored perception of the influence of expert support for the interpretation of the spirometry test on assigning a diagnosis was (mean (SD)) 2.4 (1.2) with software support and 2.2 (1.7) with chest physician support, the latter low figure may have been affected by the fact that a chest physician was never consulted in 16% of cases.

Subgroup analyses

Based on the initial selection lists from the practices that we used to identify patients for this study, we distinguished two categories of participants: patients who already had a prior diagnosis of asthma or COPD, and patients selected because they had received repeated respiratory prescriptions without a formal diagnosis being assigned by their GP (see Table 1). We found a difference in change of diagnosis after intervention: changes were more frequent in patients without a formal prior diagnosis (56.4%) than in patients with a prior diagnosis of COPD or asthma (43.6%) (p<0.001). In the patients without a formal diagnosis this change differed statistically significant between the software support and the usual care group (p=0.05), but not between the chest physician support and the usual care group (p=0.46).

Discussion

Main findings

Spirometry was important for GPs’ diagnosis but no added value on their decision-making could be found for software expert support or chest physician support in establishing a final diagnosis in patients with chronic respiratory symptoms. In over 40% of cases spirometry led to modifying the diagnosis. Not surprisingly, diagnoses changed more often in patients in whom a formal diagnosis had not been made prior to spirometry but this was the case in all three study groups. Overall, support for the interpretation of spirometry tests did not seem to influence GP’s decision-making process.
**Strengths of the study**

This is the first study that assesses the impact of two current modes of expert support for interpreting spirometry in a randomised design in primary care. We offered standardised training and supplied practices with the same equipment, thus creating a uniform point of departure in the three study groups. To avoid bias analyses were performed blinded by both the investigators and the statistician (RA). As the participating general practices were not specifically selected the external validity of the results is good despite the fact that the study was organised in the Eastern part of the country, we have no reasons to assume that the results are not applicable to other parts of the country where GPs perform spirometry in their own practice. We selected patients with a prior diagnosis of asthma or COPD for revision of the current diagnosis, and patients who had repeatedly received prescriptions for respiratory medication without a formal diagnosis for assessing a new diagnosis. For both categories of patients spirometry seems to have additional value.

**Possible limitations**

Our study has some limitations. We could only look at changes in GP's diagnoses, rather than changes in the correctness of their diagnoses. Although the latter option would have been more informative, financial, practical and ethical barriers were perceived in sending a patient to an expert (i.e., a chest physician) to confirm and re-diagnose the patient in a short time.

Despite randomisation, we found some between-group differences in patient characteristics that might have influenced the results of this study. In the software support group the absolute and relative number of patients that had been evaluated was larger than in the other groups. Moreover, the mean FEV₁ and FEV₁% predicted were lower. Contrary, in the chest physician supported group the mean FEV₁/FVC ratio was higher and the standard deviation smaller, thus this patient population was more homogeneous with less severe pulmonary obstruction.

Finally, we did not ask GPs if our method of the patient selection matched their opinion of clinical relevancy. Therefore we cannot explain why many patients without a formal diagnosis were being assigned with a new diagnosis. Possibly, a GP has no detailed insight into the prescriptions in daily practice. Alternatively, a GP might regard patients with recurrent cough as having (seasonal) intermittent infections, without feeling a need for additional diagnostic investigations.

**Relation with other studies**

The observed change of diagnosis after spirometry and the effects on pharmacological management are in line with the results from other studies.¹⁸ ¹⁹
However, these studies reported on a change of diagnosis (20-70%) after adding information (spirometry) required to demonstrate obstruction which was, for whatever reason, not available before. It is quite surprising that in our setting both kinds of expert support did not seem to influence the GPs' diagnostic approach and decision-making. Difficulties in differentiating between COPD and asthma appears to be common in primary care. Changing a diagnosis does have consequences for clinical practice; a new diagnosis of asthma was commonly made in patients with a former diagnosis of COPD or subjects judged to have no respiratory disease. In these cases prescriptions for respiratory medication (i.e., starting inhaled corticosteroid treatment) will need to be initiated.

From a recent in-depth evaluation of the same spirometry expert system that was used in this study we know that expert support does not seem influence GP's decision-making in a simulated setting. From that study we also know that GP's diagnostic correctness was about 67%. Another descriptive study found that a GP is able to predict a diagnosis of COPD or asthma correctly in up to 75% of cases based on simple criteria. Both studies suggest that the added value of expert support on the correctness of a diagnosis is low. Although we anticipated that support from a chest physician would have influenced GPs more often than the software support, GP's perception of this kind of support on their diagnostic choices or decision-making was similar.

Software support has been a hot topic in the literature on medical informatics in the past decade. Recently, an updated systematic review showed that effects of computerised decision support on doctor's performance in diagnostic evaluations were low. For respiratory conditions, only the study of Kuilboer et al. reported a positive effect of a guideline-based critiquing system on GP's monitoring (not diagnosing) of asthma and COPD. Contrary to a critiquing system that provides explanations based on a GP's formulated decision, the spirometry expert system we used in our study does not provide feedback to a GP's own formulated decision, it automatically generates comments based exclusively on spirometric data. Theoretically, the correspondence model with the chest physician that we used resembles a critiquing system. GPs had to formulate their working diagnosis and treatment in order to get feedback on their facsimile. However, we did not find statistically relevant influence on GP's decision-making. Neither the current study in clinical practice, nor the simulation study performed earlier can be added to this short list of effective diagnostic support systems.
Unanswered questions and future research

Despite the availability of guidelines, diagnostic confusion between asthma and COPD is common. In about 40% of cases, spirometry led to modifying the diagnosis and management, regardless of the use of expert support. However, we do not know if the changes in our study have direct implications on patient outcome.

There is another dilemma. On the one hand, GPs express a need for expert support as interpreting spirometry seems difficult, on the other hand, trained GPs have shown to diagnose respiratory conditions accurately. From the current study, we know that GP’s perception of this expert support had no influence on their diagnostic choices and decision-making. Therefore, we should look for other GP-related factors that make them uncertain to interpret the tests. Qualitative studies are necessary to address this point.

Finally, the need for high quality test results in primary care remains because only tests of sufficient quality are useful for clinical use. Although in research settings, trained practice staff have demonstrated that they can perform spirometry of sufficient quality, the optimal model for performing spirometry among untrained practice staff is unclear. The current models with software or chest physician support do not seem to be adequate. However, several COPD support services, in which chest physicians work together with specialized lung nurses and a regional primary care laboratory, may be more appropriate in primary care. Whether these services are superior in terms of correctness of a diagnosis to within-practice testing would require further research.

In conclusion, spirometry was important for GPs’ diagnosis but their decision-making was neither affected by software support nor by chest physician support, compared to usual care for chronic respiratory disease.

Acknowledgements

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General discussion and conclusions
This thesis has given new insight into the effect of spirometry expert support in general practice. At the start of this thesis (2002), logistic problems of organisation of spirometry in general practice and infrequent utilisation were relevant barriers to daily application. We introduced and evaluated two modes of spirometry expert support to facilitate GPs' diagnostic achievements in this challenge. The main findings from this thesis are.

- GPs used spirometry mostly to evaluate treatment with inhaled steroids (~60%). GP-related factors associated with spirometry utilisation were: GPs' job satisfaction, GPs' general interest in research, and prior participation in spirometry training. Practice-related factors associated with spirometry utilisation were: presence of a practice nurse, delegation of medical tasks to practice assistants, use of spirometry in different rooms, and use of protocols in practice. Especially practice-related factors are concrete to improve spirometry utilisation (e.g. presence of a practice nurse, more delegation of medical tasks to the practice assistant).

- About 70% of the GPs expressed the need for ongoing support for the spirometry test interpretation. The preferred mode of support was either by a chest physician (51%) or by a computerised expert support system (46%). Recent spirometry training seemed to partially diminish this need for expert support.

- Guidelines stress the central role of spirometry in diagnosing and managing COPD in primary care, but this does not guarantee that GPs will use spirometry consistently due to several barriers: absence of an own spirometer, lack of trained staff, and lack of GP's confidence to interpret test results. Coordinated efforts by health policy makers and the medical profession will be needed to provide the right equipment, training for staff who use it, and continuing quality assurance and support for test interpretation.

- In a simulated setting computerised spirometry expert support for the interpretation of spirometry tests by GPs had no detectable benefit over sham information on GPs' diagnostic achievements of chronic respiratory disease. GPs were able to diagnose 65% of the cases correctly. Overall, input of expert support did not seem to influence GPs' decision-making process.

- In a clinical setting neither software expert support nor chest physician support represented detectable added value over no support in establishing a final diagnosis in patients with chronic respiratory symptoms. In over 40% of cases spirometry led to modification of the pre-existing diagnosis. Diagnoses changed more often in patients in whom a formal diagnosis had not been made prior to spirometry. Finally, expert support did not influence the GPs' decision-making process.
The results of this thesis showed that GPs were quite able to interpret spirometry tests correctly and expert support had no apparent additional value. In the mean time (2002-2007), several external factors have influenced the increase of the volume of spirometry tests in general practice in our country, the introduction of the practice nurse on nationwide scale, the introduction of a financial incentive for GPs for spirometry tests, increased availability of spirometers, and a new guideline for COPD that gives spirometry a central role in diagnosing and staging this disease. The increasing volume of spirometry tests performed stresses the importance of spirometry quality assurance in general practice. Furthermore, which training methods or feedback are suitable to optimise and monitor spirometry test performance and interpretation in the near future? In the subsequent paragraphs the main findings from the studies reported in this thesis are discussed, and put in perspective of practical implications and recommendations for future research.

**Influence of spirometry on diagnosis and management**

Recent studies showed the important influence of spirometry on GPs’ diagnosis and management. Results from the HASPIR study from our own research department show that in a simulation setting spirometry reduces GPs’ diagnostic uncertainty, but increases the use of additional diagnostics and referrals. In a practice setting spirometry showed impact on pharmacological and nonpharmacological management. The most striking finding in chapter 6 was how much the results of spirometry affected a final diagnosis. In about 40% of cases the results led to modification of a pre-existing diagnosis. This is not surprising for a respiratory condition where the diagnosis often hinges on the presence or absence of airway obstruction (such as in COPD), and on the reversibility of airway obstruction. After all, no GP would ever think of treating hypertension without having established high blood pressure, and similarly treating patients with chronic respiratory symptoms without assessing their pulmonary function should become a thing of the past. The results of this study (chapter 6) underscore again the importance of office spirometry for the treatment of patients with chronic respiratory symptoms. However, the study in chapter 6 was not designed to specially investigate the additional value of spirometry. Upcoming studies should focus on this additional value of spirometry on top of history-taking and clinical examination in subjects who consult their GP with signs and symptoms that may point to an underlying obstructive airway disease.

**Computerised expert support and chest physician support**

The results of the explorative study in chapter 3 demonstrate that 70% of the GPs welcomed continuous support for the interpretation of their test results. GPs preferred a local chest physician or pulmonary function laboratories or a computerised expert support system. Another option would be support from a GP with a special interest in
respiratory disease in the same practice or in another practice nearby. If such a GP is not available or this kind of task differentiation between GPs in a general practice group is not possible a chest physician can act as coach for local GPs in two ways: through patient oriented support (specific feedback for specific patients) or through practice oriented support (as teachers in postgraduate training programmes) (chapter 4). Results of the studies presented in chapter 5 add to knowledge that computerised spirometry expert support had no detectable benefit over sham information on GPs' diagnostic achievements and decision-making process when diagnosing chronic respiratory disease. Contrary to our prior expectations, the results of the study presented in chapter 6 showed that neither chest physician support, nor computerised expert support had detectable impact on GPs' diagnosis and subsequent management of respiratory diseases. Although we expected that support from a chest physician would have influenced GPs more than the software support, GPs' perception of this kind of support on their diagnostic arsenal was similar.

Expert support has been a hot topic in the literature on medical informatics the past decade. Recently, a third update of a systematic review shows that effects of computerised decision support on the doctor's performance in diagnostic evaluations is low. Most studies in this review focussed on effective strategies of computerised support systems related to disease management systems, drug-dosing or prescribing systems or reminder systems. The minority focussed on diagnostic systems. For respiratory conditions, only the study of Kuilboer et al. reported a positive effect of a guideline-based critiquing system on GP's monitoring of asthma and COPD. Contrary to a critiquing system that provides explanations based on a GP's formulated decision, the expert system used in our study (Spirxpert or SpidaXpert®) does not provide feedback to a GP's own formulated decision, it automatically generates preformatted comments based exclusively on spirometric data. Theoretically, the correspondence model with the chest physician that we used resembles a critiquing system. GPs had to formulate their working diagnosis and treatment in order to get critique on their facsimile. However, we did not find statistically relevant influence on GP's decision-making.

Successful examples of other diagnostic expert systems used in collaboration between primary and secondary care are scarce. For dermatologic conditions, teledermatology consultations (i.e. similar with the teleconsultation of the chest physician in our study) have shown to be effective to reduce the number of referrals by 25-50%. This is probably due to the fact that dermatologic conditions ask for a visual inspection rather than a complex physiologic evaluation and interpretation in pulmonary conditions.
General role of expert support in general practice

There is a dilemma. On the one hand decision support systems are promoted as tools to improve primary care for patients with chronic illness. On the other hand, there is a lack of effective diagnostic expert support systems that have been tested with success in general practice populations. This could be due to some features of the expert systems, or due to some features of the users of these systems, or both. A recent rigorous review of trials to identify features critical to success identified four predictors of effective decision support: (1) systems that enhance practice generate decision support automatically as part of the normal clinical workflow and at (2) the time and place of decision making, (3) they use computers to deliver support, (4) and they offer specific recommendations rather than mere assessments.

Although the expert support system we used meets the criteria of a good system—involved in development, integrated in computer, displaying specific recommendations at the right place and time—it was not actually tested in the target group (i.e., GPs) before the study. Therefore, it may not optimally fit into the decision-making process of GPs. The information presented by the spirometry expert system to the GP possibly lacked explanation of what the output exactly means. These are known barriers to the adoption of expert support in primary care. Other barriers that influence the adoption of clinical decision systems in general practice are time pressure in primary care, barriers arising from infrequent use, GP concerns about patient reaction if they use a support system, limited skills and confidence in information technology, difficulties in data entry, and problems related to the given advice. These factors may possibly have influenced the results of our studies reported in chapter 5 and 6.

Introduction of a practice nurse

The new discipline of practice nursing has been introduced on a nationwide scale in Dutch general practices in the last five years. These nurses are trained to do supporting tasks in chronic diseases, especially diabetes and chronic respiratory conditions (COPD and asthma). They work under direct supervision of a GP and generally follow protocols to provide non-acute medical care (for instance, assisting smoking cessation) and patient education. It is estimated that approximately 65% of all general practices in our country have a practice nurse employed to support the care for their patients with COPD and asthma (Schellekens, August 2007, personal communication). In chapter 2 we observed a positive relation between spirometry utilisation in a practice and the presence of a practice nurse. Although a practice nurse can probably take over specific tasks (i.e., spirometry test performance) from a GP without reducing the quality of care, the exact effects of the involvement of a practice nurse is not known. From a Dutch study on the effects of a practice nurse on care given to patients with asthma or COPD we learned that patient satisfaction...
improved with the care provided by these nurses, but we also learned that this does not reduce the GP's workload. The results of a systematic review on this topic showed that there is overall little robust evidence to support nurse management of chronic disease services for COPD. However, further research is necessary to determine the exact value of the practice nurse on specific elements of the care given to patients with COPD or asthma (e.g., spirometry performance, and test interpretation).

**Spirometry: availability, utilisation, and incentives**

There are global differences between developed countries with respect to the availability of office spirometers. In Italy, the use of office spirometers is low and GPs do not have serious alternatives of open-access to spirometry facilities or pulmonary function laboratory. Contrary, in other countries spirometers are available in the majority of the general practices (65% in Australia, 66% in the United States, and 91% in Spain). In the Netherlands, up to 65% of the general practices has an own office spirometer (Schellekens, August 2007, personal communication). GPs in our country buy spirometers themselves or pharmaceutical industries offer or let GPs handheld spirometers, for screening purposes.

Since 2003, literature has risen about the (under) utilisation of spirometry in general practice. Despite increased accessibility and despite the fact that national guidelines in most countries give hand-out to GPs when to use spirometry, there is apparently still underuse of spirometry in most countries. This underuse has something to do with GPs' believe that spirometry is not necessary to diagnose COPD. A clear consequence of this is given by a Belgium survey that demonstrated that more than half of the GPs assessed a diagnosis of COPD without performing spirometry. Other factors that explain underuse of spirometry in the GP's practice are the absence of properly trained staff, the lack of time and practice support to fit spirometry into the daily practice routine (chapter 3), the absence of a spirometer in the practice, inadequate reimbursement of spirometry tests, and GP's lack of confidence in the ability to interpret the test results.

The actual use of spirometry in our country has increased the last years. Based on information from an insurance company in the South-West part of our country, we know that in 2006 200,000 spirometry tests were performed in general practices (Schellekens, August 2007, personal communication). A further 25,000 tests were performed in regional primary care diagnostic services and 10,000 tests were performed in hospital based pulmonary function laboratories with open access for general practice patients. The number of tests performed in general practice has almost doubled the last three years. The higher financial incentives for GPs to perform spirometry (since 2006) could partly explain this increase. In conclusion, in
our country the availability of spirometers and the actual use of spirometry tests have risen the last years.

**New national COPD guideline**
The recent guideline for diagnosing and managing of COPD\(^{32}\) stressed the important role of spirometry in diagnosing COPD in Dutch general practice. Although symptoms and clinical signs enable GPs to predict a diagnosis of COPD or asthma correctly in up to 75% of cases,\(^ {33}\) spirometry can play an additional role in diagnosing and management of respiratory diseases in several ways,\(^ {34}\)\(^ {35}\) by assessing a new diagnosis of COPD, by accurate severity staging in patients who have previously been diagnosed, by differentiating between COPD and asthma, by monitoring a treatment of inhaled steroids, or by screening smoking adults for airflow obstruction. The results in chapter 2 show that GPs in the Netherlands did not use spirometry for all indications from national guidelines consistently; GPs used spirometry mostly for diagnostic and monitoring purposes and rarely for screening purposes. However, there is a tendency today to promote screening among smoking patients for the presence of COPD, despite the fact that the value of screening for COPD is unknown.\(^ {36}\) A recent European study demonstrated that 8.0% of patients between 20-44 years of age are at risk for COPD (Gold stage 0) in the Netherlands.\(^ {37}\) However, smoking cessation is the only effective treatment for patients with COPD\(^ {38}\) and the results of smoking cessation programs are disappointing. Therefore GPs should not focus on these asymptomatic patients. GPs should focus on symptomatic current or former smoking patients in their practice.\(^ {39}\) These patients deserve a systematic pulmonary evaluation, including full spirometry testing. Starting such a diagnostic evaluation in stead of just prescribing antibiotics is enough challenge for GPs.

**Spirometry quality assurance**
Given the increased volume of spirometry tests in general practice, there is a need for high quality test results in primary care because only tests of sufficient quality are useful for clinical use. The exact model how to organise spirometry performance and interpretation in general practice is unknown and depends on local circumstances.\(^ {40}\) Although in research settings trained practice staff have demonstrated that they can perform this spirometry of sufficient quality\(^ {41}\) little is known about the quality of spirometry tests outside a research setting.
We recently found that the quality of spirometric tests performed in the general practices that were not involved in spirometry research activities was adequate; the reproducibility of FEV\(_1\) and FVC was < 5% and < 200 ml for 85% and 82% of the 1282 spirometry tests that were available for review.\(^ {42}\) The duration of the forced expiration was concrete to improve. One option to increase test performance is
simply by an intervention like a periodic outreach visit by lung function technicians in primary care.\textsuperscript{43} Another option is the use of continuous training of test performance by means of a new CD (Spirometry Fundamentals\textsuperscript{©}).\textsuperscript{44}

If GPs perform spirometry in the own practice, they should own a diagnostic spirometer that provides the flow-volume as well as the volume-time curve to be able to assess acceptable test results adequately.\textsuperscript{45} GPs should regard implementation of quality checks for their equipment as well as for the test procedure itself as an inevitable part of their work if they want to take the use of spirometry in the management of their patients seriously.\textsuperscript{46} The new guidelines from the ATS/ERS\textsuperscript{45} provide clear instructions for the performance and interpretation of spirometry. A simplified instruction for the performance and a structured interpretation of spirometry tests is now already available for practice nurses, practice assistants\textsuperscript{47} and GPs.\textsuperscript{48} However, this ATS/ERS guideline\textsuperscript{45} needs to be translated to general practice to be implemented successfully. In the Netherlands the primary care group for COPD and asthma (www.cahaq.nl) will soon start with this challenge. In conclusion, spirometry outside a research setting seems possible with adequate equipment and maintenance of the training level of professionals.\textsuperscript{49}

**Spirometry training methods**

It is clear that GPs experience barriers to the consistent use of spirometry.\textsuperscript{50} Good studies why GPs sustain or refrain from spirometry even if they have an own spirometer available are scarce. Qualitative research methods, such as in-depth interviews and focus-group studies are indicated to explore barriers to spirometry utilisation.\textsuperscript{51} Although two studies have been performed on this topic\textsuperscript{52,53} the results of one intervention study has not been published\textsuperscript{52} and the results of the other small study should be interpreted with caution because of the poor study design.\textsuperscript{53} The main reasons in this latter study why GPs perceive barriers to spirometry were GPs' reluctance to make a formal diagnosis with use of spirometry, and GPs' low confidence in ability to interpret the test results. Two recent studies showed again that GPs have difficulties with interpretation of spirometry tests in daily practice.\textsuperscript{31,54} Therefore, several efforts to increase GP's knowledge about or experience with spirometry interpretation have been investigated. Examples of generic methods to achieve this goal are by teaching spirometry through the internet,\textsuperscript{55} by educational articles,\textsuperscript{56} guidelines\textsuperscript{45} or fact sheets,\textsuperscript{57} by teaching spirometry earlier in medical schools\textsuperscript{58}, by teaching spirometry in the vocational training for GPs, or by initiatives to standardise spirometry postgraduate training\textsuperscript{59} None of these before mentioned generic methods to increase GPs' knowledge about spirometry interpretation have been studied thoroughly on its effect in daily practice.
Some methodological considerations

From a methodological point of view there are some remarks with respect to the presented studies in this thesis.

Firstly, the information about the variation in utilisation (chapter 2) and the need for expert support (chapter 3) was based on a rather selected group of 144 GPs who participated in a spirometry training program. Although not presented elsewhere, the information on the need of expert support among GPs was derived from only 144 out of approximately 8200 GPs in our country. We do not know if their opinions fully reflect the situation in Dutch general practice.

In addition, the case evaluation study (chapter 5) was artificial in that sense that the prevalence of disease did not reflect the true population prevalence. For instance, restriction is a rather rare disease. It is difficult to know exactly how many different cases (e.g., obstruction, restriction, and insufficient test performance) could be used to reflect actual prevalence’s of the disease patterns within the constitution of the case. In reflection, we could have used in the mix of the case descriptions of the simulation study in chapter 5, more COPD cases (GOLD stage 1 or 2) in stead of GOLD stage 3. In daily general practice, GPs are most confronted with COPD patients classified as GOLD stage 1 (27%) and 2 (55%).

Another methodological problem has been unanswered with respect to the case study. Presently, we randomised the GP as unit of analysis. Another option would have been to randomise each case per GP. Which one preferred is unknown. Furthermore, the actual use of the expert system (chapter 6) should have been monitored preferably by means of a log system that could have given us insight into the use of the database. In the present design, we are not completely sure that GPs have seen the interpretative results themselves. Practice nurses, who perform often spirometry, could have interpreted the results for the GPs when we asked them to return the standardised formats after spirometry test had been performed. We have tried to arrange for a “user log” in the expert system, but for technical reasons this was infeasible.

Subsequently, we did not ask GPs if our method of the used patient selection matched their opinion of clinical relevancy (chapter 6). Therefore we cannot explain why many patients without a formal diagnosis were assigned with a new diagnosis. Possibly, a GP has no detailed insight into the prescriptions in daily practice. Alternatively, a GP might regard patients with recurrent cough as having (seasonal) intermittent infections, without feeling a need for additional diagnostic investigations.

Furthermore, we did not analyse specifically the databases of the spirometry results from all the practices. We asked on a standard form GPs’ interpretation of the test results, without checking the raw spirometric data for each patient. This would have been given more information about the interpretation of the GPs given the raw data. It would also give insight into the number of tests performed before and after
bronchodilators and GPs' selection of the best tests. This is definitely worth further study.
Finally, due to changes in hardware that led to lack of USB ports and disk drives we could not copy the database of the spirometry software in 25% of the practices and we could not use data about prescription in 35% of the practices.

Conclusions and recommendations for daily practice and future research
In conclusion, in general practice diagnostic spirometry is an essential tool in patients with recurrent symptoms such as dyspnoea, chronic cough, and chronic sputum production. Due to spirometry a pre-existing diagnosis will change in 40% of the patients. GPs are quite able to diagnose common respiratory disease patterns. Given this high prior probability of correct interpretations of spirometry test results (up to 70%), the role for expert support to change diagnosis and management is small. Neither support by expert software nor by a chest physician had influence on the diagnostic achievements of GPs in patients with respiratory conditions. Expert support did not influence GP's referrals or additional diagnostic tests. There is a discrepancy between the objective diagnostic achievements of GPs and their own perception of the capability to interpret the spirometry results, probably due to infrequent test interpretations. Further qualitative studies are necessary to address this point. Given the low frequency of spirometry use in daily practice, centring of interpretation expertise seems necessary. The optimal model to realise this in general practice is a main challenge for further research.

Based on this thesis the following recommendations can be given:

• We should look further for other GP-related factors that make them uncertain to interpret the tests. On the one hand GPs experience barriers to spirometry test results interpretation (chapter 3). On the other hand GPs are quite capable to assess a respiratory diagnosis adequately (chapter 5). From the results of chapter 6 we know that GP's perception of expert support had no influence on their diagnostic choices and decision-making. A qualitative study is necessary and suitable to address this point by organising a focus group study with users of an expert system. This focus group study should also identify GP's preferences with respect to the specific features of expert support.

• The current models with expert software or chest physician support are not adequate enough. Several new COPD support services, in which chest physicians work together with specialised (lung) nurses and a regional primary care laboratory, may be more appropriate in primary care. The question arises where should spirometry testing being performed in terms of correctness of a
diagnosis, adequacy of test results, or patient friendliness. General practice, the regional primary care laboratory or in the hospital? Given the numbers of spirometry tests being performed in 2006 the preferred logistic way is certainly somewhere in a primary care setting. Chest physicians can give valid interpretations of the lung function of patients in general practice by means of written information where GPs can trust on. From another part of medicine (dermatology) we know also that patients prefer services from GPs with a special interest in dermatology above hospital outpatient care. For spirometry testing presently four models are realistic in the Netherlands: (1) spirometry performed by a practice nurse and interpreted by a GP, (2) spirometry performed by a practice nurse and interpreted in general practice by a GP with special interest in respiratory disease in the same practice or nearby, (3) spirometry performed by a nurse in a regional primary care laboratory and interpreted by either a chest physician or a GP with a special interest in respiratory disease, (4) spirometry performed at the hospital pulmonary function laboratory by lung function assistants and interpreted by a chest physician. Further randomised studies are necessary to assess the optimal spirometry setting.

- Although not mentioned in other studies the absence of a well-integrated spirometry software system in the electronic medical record system is probably a relevant barrier in Dutch general practice. Presently, there are more than seven different electronic medical record systems and more than 25 different spirometers on the market. Only a few brands of spirometers have software that can be integrated with only three electronic medical record systems. Integration of the results of spirometry tests in the electronic medical record system (including excellent documentation of the test results) in stead of a stand-alone use of the spirometry software on a separate computer will definitely facilitate GPs to apply spirometry in daily practice routine more often. We encourage manufactures of spirometers and software to develop adequate new interfaces with Dutch electronic medical record systems. Meanwhile, GPs can visit (soon) the website of the Dutch College of General Practitioners (www.nhg.org) to get insight into the features and restrictions of the available diagnostic spirometers and accompanied software that are currently available in the Netherlands.

- It is necessary to adjust the computerised spirometry expert support system in order to take GPs by the hand and lead them to the diagnostic assessment, an expert system should use a stepwise approach and quickly offer concise textual and visual summaries of most important test results. In this stepwise approach a GP should work through a couple of sentences in one screenshot that contains the individual items of the interpretation of spirometry tests results acceptability of
test results, reproducibility of the test results, flow-volume and volume-time curve, presence of obstruction, severity of obstruction, reversibility of obstruction followed by the graphical and textual interpretation by the expert software. A new study would be necessary to assess the feasibility of this new expert system among potential users.

As the effect of the current spirometry expert system was neither associated with GPs' professional experience nor with GPs' weekly number of spirometry tests interpretations, we can not specially recommend the current expert system to GPs in daily practice.

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Chapter 1
In this chapter the rationale for this thesis is explained. Chronic obstructive pulmonary disease (COPD) and asthma are prevalent chronic respiratory conditions that will continue to cause increased disability in the world's population in future years. COPD and asthma are mainly diagnosed and treated in general practice in the Netherlands. Spirometry is an important tool within the broad concept of management in chronic respiratory diseases (COPD and asthma) and is necessary for diagnosing these conditions. However, there are still a number of practical barriers that impede wide implementation of quality spirometry facilities in general practice: the absence of properly trained staff, the lack of time and practice support to fit spirometry into the daily practice routine, the absence of a spirometer in the own practice, and GP's lack of confidence in the ability to interpret the test. The latter barrier could theoretically be overcome through expert support. Expert support for the interpretation of tests of pulmonary function may be made available - depending on local circumstances - as a software expert support system or by consultation or feedback from a chest physician. However, the value of expert support for GPs with respect to the interpretations of spirometry tests and their subsequent management of patients with (suspected) chronic respiratory disease was not known.
To provide further evidence on this issue, we performed two cross-sectional studies to get insight into the variation in spirometry utilisation between practices and GPs' needs for expert support in daily practice. We designed two cluster-randomised trials on the impact of expert support for the interpretation of spirometry test results on the diagnostic achievements of GPs.

Chapter 2
In this chapter, we explored the spirometry utilisation for five indications from national COPD/asthma guidelines among GPs and identified GP-related and practice-related factors associated with spirometry utilisation. For this purpose, we used data from a questionnaire survey among 144 GPs from 61 general practices involved in a spirometry evaluation program. GPs used spirometry mostly to evaluate treatment with inhaled steroids (~60%). Significant GP-related factors associated with spirometry utilisation were general practitioners' job satisfaction, general practitioners' general interest in research, and prior participation in spirometry training. Practice-related factors associated with spirometry utilisation were presence of a practice nurse, delegation of medical tasks to practice assistants, use of spirometry in different rooms, and use of protocols in practice. In conclusion, GP- as well as practice-related factors were associated with the extent of spirometry utilisation. Especially practice-related factors (e.g., presence of a practice nurse, more delegation of medical tasks to the practice assistant) are concrete to improve.
Chapter 3
In this chapter we determined GPs' needs for ongoing support for the interpretation of spirometry tests. We used data from a questionnaire survey among 137 GPs involved in the in chapter 2 mentioned spirometry evaluation program. Seven out of ten GPs expressed a need for ongoing support for the spirometry interpretation, preferably organised by a local chest physician or pulmonary function laboratory, or a computerised clinical decision support system. Recent spirometry training partially diminished this need.

Chapter 4
In this editorial the need for continuous advice and expert support for the interpretation of spirometry test results is depicted. Although spirometry is more and more available in general practice, it is still underused due to practical issues and GPs' lack of confidence in their ability to interpret the test results. Ideally once GPs have had initial spirometry training they should receive continuous support by another GP with a special interest in respiratory disease in the same group practice, by means of a computerised decision support system, or by consultation or feedback from a chest physician. Coordinated efforts by health policy makers and the medical profession will be needed to provide the right equipment, training for staff who use it, and continuing quality assurance and support for test interpretation. The burden of COPD is sufficiently large to warrant such an approach.

Chapter 5
In this chapter we report on the results of a simulated cluster-randomised trial of GPs' diagnostic acuity of chronic respiratory disease in a process of diagnostic assessment of standardised cases. Using a stepwise approach, 78 GPs completed 10 standardised paper case descriptions each. Intervention consisted of support for GPs' spirometry interpretation either by an expert system (expert support group) or by sham information (control group). Differences in GPs' diagnostic achievements and in GPs' decision-making before and after intervention were compared between the study groups. Agreement of GPs' diagnoses was compared with an expert panel judgement, which served as the primary outcome. Other decision-making related outcomes were additional diagnostic test rates, width of differential diagnosis, certainty of diagnosis, estimated severity of disease, referral rate, and medication or non-medication changes. We found no differences between the expert support and the control group in the agreement between the diagnosis of the GP and expert panel. We observed only a slightly higher rate of additional diagnostic tests in the expert support group. In conclusion, computerised spirometry expert support had no detectable benefit on GPs' diagnostic achievements and decision-making process when diagnosing chronic respiratory disease.
Chapter 6
In this chapter a study was presented to assess the impact of two modes of expert support for the interpretation of spirometry tests on general practitioners’ (GPs) diagnosis and subsequent management of chronic respiratory disease. In a cluster-randomised controlled trial, with general practices as unit of randomisation, GPs from 44 practices recorded their diagnosis and management before and after interpreting spirometric test results in 868 patients. Intervention consisted of software support or chest physician support versus no support (usual care) for the interpretation of the tests. The primary outcome was change of GPs’ prior diagnoses after spirometry. Other decision-making related outcomes were additional diagnostic tests rate, referral rate, and changes in pharmacotherapy. Spirometry was important for GPs’ diagnosis but no added value on their decision-making could be found for software expert support or chest physician support in establishing a final diagnosis in patients with chronic respiratory symptoms. In over 40% of cases spirometry led to modifying the diagnosis. Not surprisingly, diagnoses changed more often in patients in whom a formal diagnosis had not been made prior to spirometry but this was the case in all three study groups. Overall, support for the interpretation of spirometry tests did not seem to influence GP’s decision-making process.

Chapter 7
In this chapter the results of the different studies are discussed using current literature. Its implications are discussed, as well as some recommendations are given. This thesis showed that there is variation in spirometry utilisation among practices and showed that GPs have a need for continuous support for the spirometry test results. However, neither support by expert software nor by a chest physician had influence on the diagnostic achievements of GPs and subsequent management in patients with respiratory conditions. We therefore should continue to focus on both factors that make GPs uncertain to interpret the tests and on new COPD support services to enhance spirometry utilisation and interpretation in general practice.
Samenvatting
Hoofdstuk 1
In dit hoofdstuk wordt de achtergrond van dit proefschrift beschreven. COPD (chronic obstructive pulmonary disease) en astma zijn beiden veel voorkomende chronische luchtwegaandoeningen, die grotendeels in de huisartsenpraktijk worden gediagnosticeerd en behandeld. COPD en astma behoren wereldwijd tot de hoofdoorzaken van ziekte en sterfte (vooral COPD). Om deze aandoeningen te diagnosticeren is toepassing van spirometrie noodzakelijk. Toch gebruiken lang niet alle huisartsen daadwerkelijk de spirometer. Naast een aantal praktische redenen als te weinig tijd, scholing en ruimte in de praktijk, blijkt vooral de interpretatie van de spirometrie uitslagen voor de huisarts een knelpunt voor uitgebreide toepassing.

Een mogelijke oplossing hiervoor is een meer routinematige ondersteuning voor de huisarts bij de beoordeling van de spirometrie uitslagen. Dit zou bijvoorbeeld kunnen met behulp van een geautomatiseerd expertsysteem, geïnstalleerd in de spreekkamer. Dit programma geeft de huisarts patienten-specifieke informatie over de spirometrie test. Een andere optie is patienten-specifieke teleconsultatie of feedback van een longarts door de uitlatten van een spirometrie test uit de huisartsenpraktijk naar de longarts te faxen voor beoordeling. Hoewel deze vormen van "expert support" in Nederland in de praktijk daadwerkelijk gebruikt worden, is het niet bekend of deze vormen van ondersteuning wel effectief zijn.

Om meer inzicht te krijgen in de hierboven beschreven onderwerpen, hebben we een aantal studies opgezet. Naast twee clustergerandomiseerde trials om de invloed van routinematige ondersteuning vast te stellen op de diagnostiek en het beleid bij patiënten bij wie de huisarts een chronische luchtwegaandoening vermoedt, zijn een tweetal cross-sectionele onderzoeken uitgevoerd.

Hoofdstuk 2
In dit hoofdstuk wordt onderzocht hoe Nederlandse huisartsen gebruik maken van spirometrie in hun praktijk. Er werd gekeken of er een relatie bestond tussen een aantal huisarts- en praktijkkenmerken en de mate van daadwerkelijke spirometrie inzet voor vijf indicaties voor spirometrie afkomstig uit de NHG-standaarden. In totaal namen 61 praktijken met 144 huisartsen deel aan het onderzoek. Naast twee clustergerandomiseerde trials om de invloed van routinematige ondersteuning vast te stellen op de diagnostiek en het beleid bij patiënten bij wie de huisarts een chronische luchtwegaandoening vermoedt, zijn een tweetal cross-sectionele onderzoeken uitgevoerd.
Hoofdstuk 3
In dit hoofdstuk wordt onderzocht of huisartsen behoefte hebben aan routinematige ondersteuning bij de spirometrie uitslagen. Er werd gekeken of er een relatie bestond tussen een aantal huisarts- en praktijkkenmerken en de behoefte aan ondersteuning. We gebruikten hiervoor informatie van een vragenlijst onderzoek onder 137 huisartsen die deelnamen aan een spirometrie evaluatie studie (hoofdstuk 2). Uit het onderzoek blijkt dat 69% van de huisartsen behoefte heeft aan routinematige ondersteuning bij de interpretatie van spirometrie uitslagen. De voorkeur van de huisartsen gaat uit naar ondersteuning door een regionale longarts, een regionaal huisartsenlaboratorium, of een geautomatiseerd expertsysteem. De behoefte aan routinematige ondersteuning was lager indien de huisarts recent een spirometrie nascholing had bijgewoond.

Hoofdstuk 4
Dit hoofdstuk betreft een redactioneel artikel over de beschikbaarheid van spirometrie en de toepassing ervan in de eerste lijn. Hoewel steeds meer huisartsen in westere landen de beschikking hebben over een eigen spirometer, is het gebruik in de dagelijkse praktijk hiervan laag. Naast een aantal praktische redenen als te weinig tijd, scholing en ruimte in de praktijk, blijkt vooral de interpretatie van de spirometrie uitslagen voor de huisarts een knelpunt voor uitgebreide toepassing. Idealiter zou een huisarts na initiële spirometrie nascholing over routinematige ondersteuning bij de spirometrie uitslagen beschikken. Dit zou bijvoorbeeld op drie manieren kunnen met behulp van een collega huisarts in dezelfde praktijk of huisartsengroep, met behulp van een geautomatiseerd expertsysteem geïnstalleerd in de spreekkamer, of met behulp patiënten specifieke consultatie of feedback van een regionale longarts door de uitslagen van een spirometrie te faxen voor beoordeling. Gezien de huidige prevalentie COPD is het noodzakelijk dat beleidsmakers en de beroepsgroepen van huisartsen en longartsen samen nadenken over de allocatie van spirometers en ondersteuning om het diagnostische proces van COPD in de eerste en tweede lijn optimaal te organiseren.

Hoofdstuk 5
Het doel van de in hoofdstuk 5 beschreven studie was te bepalen wat de invloed is van een spirometrie-expertsysteem op de diagnostiek en het beleid bij patiënten bij wie de huisarts een chronische luchtwegaandoening vermoedt. We organiseerden een clustergerandomiseerde trial onder 78 huisartsen die elk 10 gestandaardiseerde casusbeschrijvingen beoordeelden. De interventie bestond uit input van een expertsysteem (SpidaXpert®) bij de casusevaluatie, de huisartsen in de controlegroep ontvingen alleen de volume-tijd curve als aanvullende informatie. We vergeleken verschillen in de diagnostiek en het beleid van de huisarts bij de 10 casus.
voor en na interventie tussen de twee groepen. De primaire uitkomst was de mate van overeenstemming van de diagnose van de huisarts met die van een expertpanel. Secundaire uitkomstmaten waren aanvragen voor aanvullend onderzoek, verwijzingen naar een specialist, 'breedte' van de differentiaaldiagnose, mate van zekerheid over de diagnose, ingeschatte ernst van de aandoening en wijzigingen in medicatie. Er was geen verschil tussen de huisartsen in de expertsysteem- en controlegroep wat betreft het correct vaststellen van de diagnoses. Wel vroegen de huisartsen in de expertsysteemgroep iets meer aanvullend onderzoek aan.

**Hoofdstuk 6**

Dit hoofdstuk betreft een studie naar de invloed van routinematige ondersteuning bij de interpretatie van spirometrieuitslagen met behulp van een spirometrie-expertsysteem of een longarts op de diagnostiek en het beleid bij patiënten bij wie de huisarts een chronische luchtwegaandoening vermoedt. In een clustergerandomiseerde triaal, met huisartspraktijken als eenheid van randomisatie, legden huisartsen uit 44 praktijken voor en na spirometrie hun diagnose en beleid vast bij 868 patiënten. De interventie bestond uit of input van een expertsysteem (SpidaXpert®) of hulp van een regionale longarts versus geen hulp bij de beoordeling van spirometrie uitslagen. De primaire uitkomst was de mate van verandering van de huisartsdiagnose. De secundaire uitkomsten waren aanvragen voor aanvullend onderzoek, verwijzingen naar een specialist en wijzigingen in medicatie. Hoewel spirometrie belangrijk was voor de diagnostiek van de huisarts, was er geen verschil tussen de huisartsen in de expertsysteemondersteunde of longartsondersteunde groep en de controlegroep wat betreft verandering van de diagnoses of verandering in beleid. In 40% van de patiënten veranderde de diagnose na interventie. De verandering vond voornamelijk plaats bij patiënten die nog geen luchtwegaandoening hadden.

**Hoofdstuk 7**

In de algemene discussie in hoofdstuk 7 worden de belangrijkste bevindingen van dit proefschrift geplaatst in een breder kader van huidige wetenschappelijke kennis. Daarnaast worden relevante methodologische aspecten van de studies besproken en aanbevelingen voor toekomstig onderzoek gegeven. Dit proefschrift laat zien dat er variatie is in het gebruik van spirometrie in huisartspraktijken. Bovendien hebben huisartsen behoefte aan ondersteuning bij de interpretatie van de spirometrie-uitslagen. Echter, noch ondersteuning door een spirometrie-expertsysteem noch door een longarts bleek effect te hebben op de diagnostiek en het beleid bij patiënten bij wie de huisarts een chronische luchtwegaandoening vermoedt. Daarom zal toekomstig onderzoek zich moeten richten op enerzijds het achterhalen van redenen waarom huisartsen onzeker zijn over hun interpretatie van spirometrie uitslagen.
Anderzijds zal het zich moeten richten op de optimale organisatie van de spirometrie uitvoering en interpretatie in de eerste of tweede lijn
Dankwoord
Mijn proefschrift is af. Een kort overzicht van de bewandelde weg. Na toelating tot de huisartsopleiding in Nijmegen (2002) kreeg ik de gelegenheid om me te orienteren welk onderzoek ik wilde verrichten. Na een aantal verkennende gesprekken koos ik voor het huidige SPRINT onderzoek (Spirometrie in de huisartspraktijk interpretatie en integratie). Vanaf 2003 heb ik de huisartsopleiding gecombineerd met dit onderzoek. Deze combinatie was niet altijd even gemakkelijk. Ik verkeerde immers in twee werkkirings met regelmatig tegengestelde agenda’s. Met dank aan mijn beide huisartsopleiders - Wim van Jaarsveld (Ede) en Christine Schellevis (Terborg) - rondde ik in 2005 het huisartsendeel van mijn opleiding af. Nu, een aantal jaar later, is ook het onderzoek klaar. Dit proefschrift was natuurlijk nooit tot stand gekomen zonder de hulp en inzet van een heleboel andere mensen. Ik wil een aantal mensen in willekeurige volgorde hiervoor bedanken.

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Patrick Poels was born on 29 January 1972 in Nijmegen, The Netherlands. He grew up in Molenhoek. In 1990 he passed secondary school at the 'Nijmeegse Scholengemeenschap Groenewoud' in Nijmegen (atheneum). He started Agricultural Economics at the Wageningen University. After passing his propaedeutical exam in 1991, he started Medical School at the Radboud University Nijmegen (previously 'Katholieke Universiteit Nijmegen'). He graduated from Medical School in 1998. Subsequently, he worked as a resident at the Emergency Department in Hospital Bernhoven in Veghel (1998-1999), and at the Department of Surgery in VieCuri Medical Centre in Venlo (1999-2000). Meanwhile he started research on vocal fold lesions at the Department of Otorhinolaryngology in Hospital Bernhoven (Prof. dr. F.I.C.R.S de Jong) in 1998. In 2000 he participated in research on the efficacy of adenotonsillectomy in children at the Julius Center for Health Sciences and Primary Care (Prof. dr. A.W. Hoes and dr. A.G.M. Schilder, University Medical Centre Utrecht). In 2002 he started with the 3-year General Practitioner's training at the Radboud University Nijmegen Medical Centre.

In 2003 he started with the so-called 'combined residency and research-training program (AIOTHO)' at the Department of General Practice (Prof. dr. C. van Weel) of the Radboud University Nijmegen Medical Centre, resulting in the work described in this thesis.

In 2005 he started working as a general practitioner in general practice.

He is married to Marion Poels-de Bruijn. They live in the city of Arnhem. They have two children, Charlotte (2003) and Pieter (2005).
Stellingen

Behorend bij het proefschrift

Spirometry expert support in general practice

1. Spirometrie expert support heeft geen meetbare invloed op het diagnostisch handelen van de huisarts (dit proefschrift)

2. De huisarts is bekwaam in het diagnosticeren van veel voorkomende chronische luchtwegaandoeningen (dit proefschrift)

3. Er is een lange adem nodig om de spirometrie uitvoering en interpretatie in de eerste lijn te optimaliseren (dit proefschrift)

4. Exploratie van de onzekerheid bij spirometrie interpretatie onder huisartsen is mogelijk met kwalitatief onderzoek (dit proefschrift)


6. Als je kind gezond is heb je wel duizend wensen, als je kind ziek is heb je er maar één

7. “Een muesli sandaal” is een sociometrisch voorbeeld om snel mee uit de voeten te kunnen

8. “Made in Holland” wordt niet meer gemaakt

9. De incidentie van zeldzame ziekten lijkt in bepaalde families hoger

10. “Keuzemoeheid” is een nieuwe aandoening die veroorzaakt wordt door overmatige marktwerking in de zorg en samenleving

Patrick Poels

Nijmegen, 11 maart 2008