

## ORIGINAL RESEARCH

## The quality of COPD care in general practice in Denmark: the KVASIMODO Study

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**Abstract**

**Aim:** We studied the quality of care for COPD patients in a large sample of general practices in Denmark. We focussed on whether participation by general practitioners (GPs) in an educational programme could enhance the use of spirometry in the diagnosis and staging of the disease and improve adherence to COPD guidelines.

**Methods:** We performed two audit surveys of GPs' patients' notes, one year apart, before and after an educational programme for participating GPs and their staff. A total of 154 GPs participated in the study. 2549 patient records were included in the first survey and 2394 in the second.

**Results:** Based on analysis of all patient records, we observed a substantial improvement in the quality of care: recording of FEV<sub>1</sub> improved from 52.7% of cases in the first survey to 71.4% in the second ( $p < 0.001$ ). There was a significant improvement in the recording of body mass index and provision of smoking cessation advice, recommendation of physical activity, checking of inhalation technique, dietary instruction, and referral to pulmonary rehabilitation. We also found a decline in the use of inhaled corticosteroids in patients with mild COPD, from 60.2% in the first survey to 48.8% in the second. When analysing the results focussing on the performance of single GPs there was an improvement in quality, but this was less than the improvement for patients overall – suggesting that improvement in quality of care was not equally distributed throughout the GPs' practices.

**Conclusion:** We conclude that it is possible to improve the quality of COPD care by educating GPs and their staff.

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**Introduction**

Chronic obstructive pulmonary disease (COPD) represents a major health problem in Denmark. The number of deaths caused by COPD has risen by 50% since 1985, and COPD is now the fourth most frequent cause of death with almost 4000 deaths each year.<sup>1</sup> It is estimated that Denmark, with its

(approximately) 5 million inhabitants, has between 150,000 and 200,000 patients suffering from COPD, and that the economical burden of COPD for Danish society amounts to at least DKK 3 billion (0.5 billion euro) a year.<sup>2</sup>

Given that COPD is now perceived as both a preventable and a treatable disease, it is widely accepted that it deserves

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more attention, especially in general practice. The general practitioner (GP) often represents the first point of contact for a COPD patient within the healthcare system, thus providing the possibility of early diagnosis and intervention in general practice. The first Danish guidelines on the diagnosis and treatment of COPD, aimed at general practice, were published in 1998.<sup>3</sup> In recent years several other guidelines, including the international GOLD guidelines,<sup>4</sup> have been used and discussed at various educational meetings and on the internet.

The level of implementation of COPD guidelines in Denmark is unknown, and it is a widespread impression that many GPs still find it difficult to diagnose and treat this common condition. This paper describes the results of a COPD quality assurance project, KVASIMODO, which aimed to improve the implementation of COPD guidelines by providing an educational programme to participating GPs and their staff. The main focus of KVASIMODO was on the use of spirometry, which is a mandatory investigation in the diagnosis and staging of COPD.

### Methods and materials

The KVASIMODO project consists of a descriptive cross sectional investigation focussing on the quality of care for COPD patients in general practice. An initial first audit survey of the participating GPs' patients' files (Survey 1) was followed by an educational programme for the GPs and their staff; a second audit survey (Survey 2) was then conducted exactly one year after the first survey. The primary efficacy

parameter was the proportion of patients having spirometry testing, and the secondary parameters were compliance with treatment principles according to the GOLD guidelines.<sup>4</sup> The time-line of the KVASIMODO project is shown in Figure 1.

Denmark has a population of approximately 5 million, and a total of 3600 GPs. We aimed to include 200 GPs from all parts of Denmark, except from Northern Jutland where an epidemiology project on COPD was already in progress. For the GPs, inclusion was on a voluntary basis. Written information about the project and the invitation to participate was distributed by the sponsoring companies' representatives. Each GP had to identify 20 COPD patients who consecutively attended his or her practice from September 1 to December 31 2003 (Survey 1) and 20 consecutive patients during a similar period in 2004 (Survey 2). The case definition for COPD was as follows: age more than 55 years; and at least two prescriptions for an inhaled bronchodilator (short- or long-acting beta-2-agonist, short- or long-acting anticholinergic drug, or a combination of the two) within the previous year. Patients who were considered to have asthma without concomitant COPD were not included. We chose this practical definition, instead of a spirometry-based definition, since we suspected that the implementation of spirometry testing was quite low. Also, this approach gave us the possibility to investigate how often treatment with bronchodilators (for COPD) is initiated without measuring lung function. In addition, it made it easier for the GPs to identify possible cases, since prescribing data is always recorded.

Figure 1. The time-line of the KVASIMODO project.

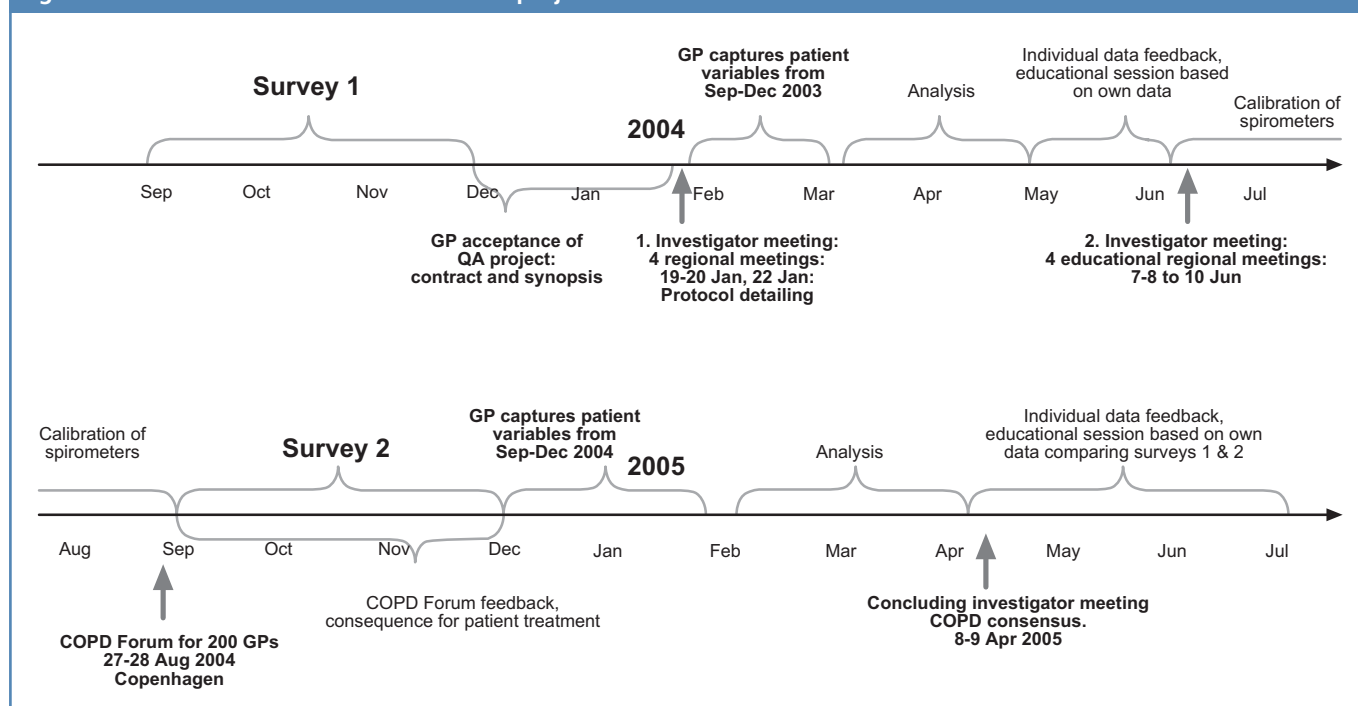
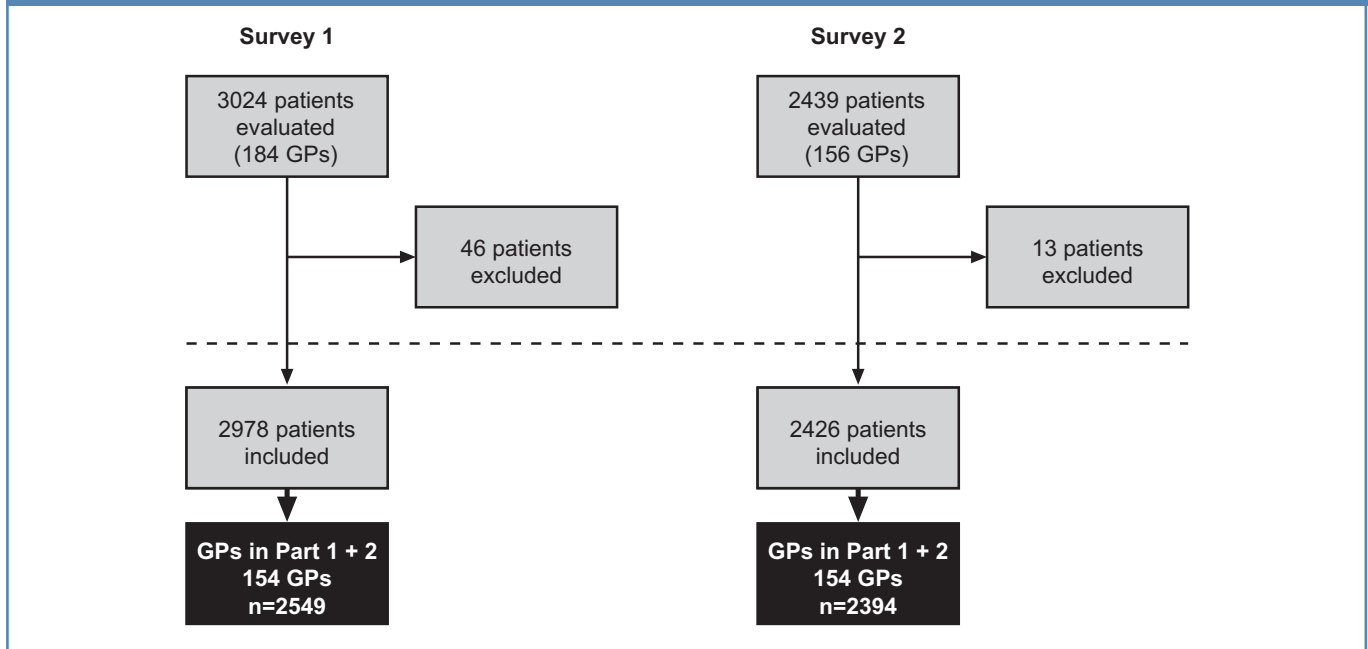


Figure 2. Flow chart depicting the participating GPs and the number of patients included in both surveys.



After identifying 20 cases, the GP was asked to perform an internal audit of the information *already* available in his/her clinical notes in order to fill in the clinical record form (CRF) for each included patient. If the information requested in the CRF was not available a missing value was recorded, since no additional patient investigation was allowed in order to complete the CRF. The CRF consisted of 5 parts: 1) inclusion criteria; 2) exclusion criteria; 3) diagnostic procedures; 4) non-pharmacological treatment; and 5) pharmacological treatment. All data from the individual CRF was entered into a consolidated web-based database. Quality control of the CRFs was performed by consultants from the sponsoring companies. The education programme on COPD which took place between the two surveys was based on the GOLD guidelines and was designed by a group of Danish pulmonologists and GPs with a special interest in COPD (the Steering Committee of the KVASIMODO Project). It was directed towards the participating GPs and their staff (nurses, laboratory technicians and secretaries) and consisted of the following components:

- An individual meeting with a consultant from one of the two sponsoring companies, focussing on the GOLD guidelines
- A regional meeting with approximately 30 GPs and their staff, where a pulmonary specialist together with one of the GPs from the Steering committee discussed different aspects of the guidelines
- A symposium for all the participating GPs and their staff. The symposium consisted of plenary sessions and workshops, and included practical issues like performing and interpreting spirometry and the teaching of inhaler technique.

The aim was that participation in the KVASIMODO project would lead to an increase in the number of spirometric investigations by at least an average of 2.5 measurements per physician in the one-year period between the two surveys. Based on this number, and with a significance level of 5% (two-dimensional, paired t-test) and a weight of 80%, the number of GPs to be included in the KVASIMODO project was calculated to be 196. This calculation takes into account the fact that the group of physicians recurs in both of the two-dimensional investigations. Based on a correlation coefficient of 0.20 between the first and the second investigation, approximately 20 patients per physician seemed to be an adequate number of study subjects.

We analysed the data from individual patient records, focussing on the overall quality of care. In a secondary analysis we focussed on the performance of the participating GPs, and here the key question was: Did the doctor improve his or her performance? We showed changes in quality of care by comparing the numbers of satisfactory quality cases in both the first and second surveys (Tables 2 and 3) and the improvement amongst the participating doctors (Table 4).

We used chi-square test, Cochran-Armitage Trend Test, and Mann-Whitney Two-Sample Test and Binomial test, when appropriate.

The KVASIMODO project was approved by The Danish Data Protection Agency and was both recommended and approved by the Danish College of General Practitioners.

## Results

A total of 205 GPs were interested in participating in the

**Table 1. General characteristics of the COPD patients included in the 1st (n = 2549) and 2nd survey (n=2394). In each cell 'n' indicates the number of cases with sufficient information for the analysis.**

| Characteristic  | Survey 1    |        | Survey 2    |        | Significance (P) |
|---|-------------|--------|-------------|--------|------------------|
| Women %   | 55.8%       | n=2528 | 54.4%       | n=2359 | NS               |
| Age, years (Mean with SD in parenthesis)                      | 70.7 (8.7)  | n=2536 | 70.1 (8.4)  | n=2386 | P=0.02           |
| BMI, kg/m <sup>2</sup> (Mean with SD in parentheses)          | 25.9 (5.7)  | n=1078 | 25.7 (5.3)  | n=1661 | NS               |
| History of asthma, %  | 18.9%       | n=2491 | 16.5%       | n=2354 | P=0.02           |
| History of cardiovascular diseases, %                         | 45.5%       | n=2406 | 44.8%       | n=2289 | NS               |
| No of tobacco pack years (Mean with SD in parentheses)        | 33.5 (22.4) | n=1266 | 43.3 (21.3) | n=1690 | NS               |
| Current smokers, %  | 42.3%       | n=2348 | 41.2%       | n=2325 | P=0.02           |
| FEV <sub>1</sub> in % predicted (Mean with SD in parentheses) | 56.4 (23.3) | n=761  | 58.1 (21.9) | n=1302 | P=0.04           |
| Severity assessed by spirometry                               |             |        |             |        |                  |
| Mild, %   | (16.7%)     |        | (16.4%)     |        |                  |
| Moderate, %   | (38.8%)     |        | (46.0%)     |        |                  |
| Severe, %   | (44.5%)     | n=761  | (37.6%)     | n=1302 | P=0.04           |
| Severity assessed subjectively by the GP                      |             |        |             |        |                  |
| Mild, %   | 25.9%       |        | 24.1%       |        |                  |
| Moderate, %   | 39.2%       |        | 40.1%       |        |                  |
| Severe, %   | 34.9%       | n=2353 | 35.8%       | n=2296 | NS               |
| No. of exacerbations last year                                | 1.48        | n=2472 | 1.17        | n=2331 | P<0.01           |

KVASIMODO project. During the first survey 21 GPs dropped out mainly because of difficulties in retrieving patient data from their notes and files; during the second survey a further 28 GPs dropped out, mainly due to excessive daily workload.

Figure 2 shows the flow chart depicting the number of the GPs and the number of cases included in the study. A total of 184 GPs completed Survey 1 and 156 completed Survey 2. In order to show the effects of participating in the project we only present results using the CRFs from the 154 GPs who participated in *both* surveys. This resulted in 2549 CRFs from Survey 1 and 2394 from Survey 2 (Figure 2). At the start of Survey 1, 86% of the GPs had a spirometer.

Table 1 shows the general characteristics of the COPD patients included in the first and second surveys. The majority of patients were women and approximately 40% were still smoking. The mean age was 70 years. The mean forced expiratory volume in one second (FEV<sub>1</sub>) – in patients with available information on age, height and spirometry – was 57% of the predicted value.

Tables 2 and 3 show the results of both audit surveys – the presence of relevant information in the GPs' files on the a

*priori* selected relevant indices of optimal care for their COPD patients. The data from both surveys are presented. In general, we observed a significant improvement between Survey 1 and Survey 2 (Tables 2 and 3). With regard to the quality of diagnosis, only about 50% of the CRFs in the first survey included relevant spirometric data (FEV<sub>1</sub> and FEV<sub>1</sub>/forced vital capacity (FVC) ratio), whereas the corresponding figures approached 70% in the second survey (p<0.01) – see Table 2. The recording of FEV<sub>1</sub> as a percentage of its predicted value (which requires information on FEV<sub>1</sub>, gender, age and height) was only available in about 30% of cases in Survey 1 but in over 54% of cases in Survey 2. Information on body weight improved significantly from about 40% of the cases in Survey 1 to 60% in Survey 2 (Table 2).

In terms of treatment options, we observed significant improvement with regard to antismoking advice, information on physical activity, inhalation technique and referral to pulmonary rehabilitation, between the two surveys (Table 3). We also observed a significant decline in the inappropriate use of inhaled corticosteroids in patients with mild COPD – from 60% in the first survey to 50% in the second. Treatment

**Table 2. Presence of information in the patient files for the patients included in the study by the 154 GPs who participated in both surveys.**

| Variable   | Survey 1 Information | Survey 2 Information | Significance (P) |
|--|----------------------|----------------------|------------------|
| Information on exposure to pulmonary harmful substances? | 98.8%                | 99.9%                | P<0.01           |
| Height   | 42.3%                | 69.4%                | P<0.01           |
| Weight   | 40.1%                | 64.0%                | P<0.01           |
| History of asthma  | 97.7%                | 98.3%                | NS               |
| History of cardiovascular diseases                       | 96.5%                | 95.6%                | NS               |
| No. of tobacco pack years                                | 49.7%                | 70.6%                | P<0.01           |
| Information on present smoking status                    | 92.1%                | 97.1%                | P<0.01           |
| FEV <sub>1</sub> (information on)                        | 52.7%                | 71.4%                | P<0.01           |
| FEV <sub>1</sub> / FVC (information on)                  | 48.6%                | 67.1%                | P<0.01           |
| FEV <sub>1</sub> as % predicted (information on)         | 29.8%                | 54.3%                | P<0.01           |
| Reversibility testing for bronchodilator                 | 46.5%                | 62.5%                | P<0.01           |
| Reversibility testing for corticosteroids                | 44.2%                | 59.4%                | P<0.01           |
| Date of latest X-ray                                     | 81.6%                | 81.5%                | NS               |
| No. of exacerbations last year                           | 97.0%                | 97.4%                | NS               |

**Table 3. Selected indices of compliance with guidelines regarding the treatment of the patients.**

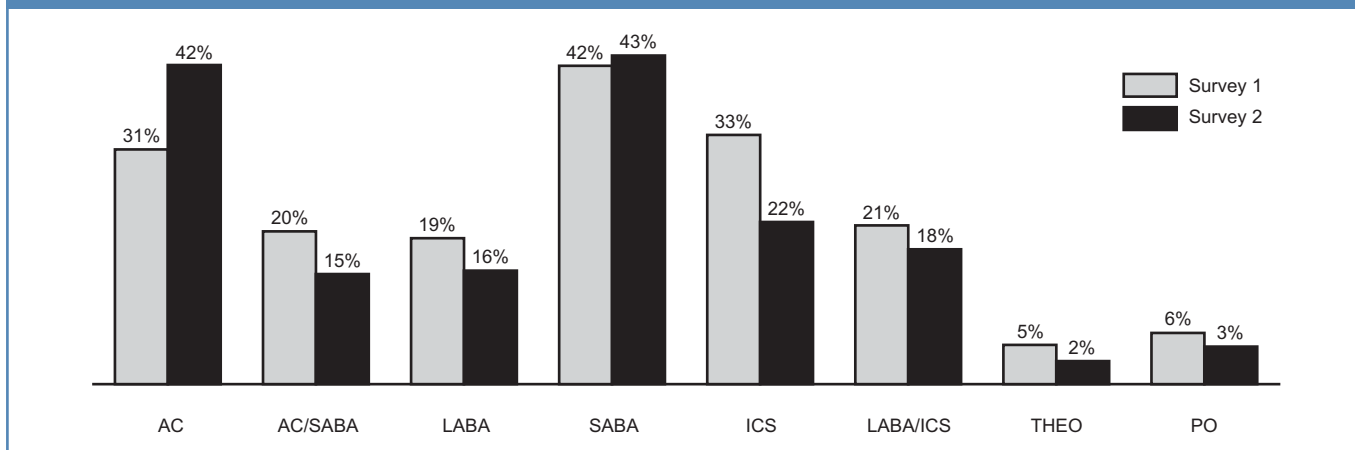
| Non-pharmacological & Pharmacological treatment                      | Survey 1 | Survey 2 | Significance |
|--|----------|----------|--------------|
| Information in inhalation technique documented, All                  | 68.5%    | 72.0%    | P<0.01       |
| Smoking cessation advice given Smokers only                          | 46.0%    | 57.4%    | P<0.01       |
| Referred for COPD rehabilitation (Moderate and severe disease)       | 16.7%    | 20.2%    | P<0.01       |
| Advice on physical exercise given, All                               | 64.8%    | 78.8%    | P<0.01       |
| Dietary instruction given (BMI <20)                                  | 48.6%    | 59.6%    | P=0.07       |
| Influenza vaccination, All   | 71.2%    | 75.1%    | P<0.01       |
| Inhaled corticosteroids in mild COPD (incl. ICS/LABA combinations)   | 60.2%    | 48.8%    | P<0.01       |
| Inhaled corticosteroids in severe COPD (incl. ICS/LABA combinations) | 85.9%    | 85.1%    | NS           |

with inhaled corticosteroids in the most severe patients remained unchanged at around 85% (Table 3).

In particular, we focussed on pharmacological treatment in the subgroup of patients who had mild COPD without asthma. Figure 3 shows the distribution of the use of different

pharmacological agents among these patients. Overall, we observed a significant decline in the use of inhaled corticosteroids – either alone or in combination with long acting beta-2-agonists – from 56% in the first survey to 41% in the second (p<0.01).

**Figure 3. Distribution of pharmacological treatment in patients with mild COPD without asthma at the first (n=499) and at the second survey (n=449). AC = anticholinergic drugs, SABA= short acting inhaled beta-2-agonist, LABA= long term inhaled beta-2-agonists, ICS=inhaled corticosteroids, Theo=theophylline, PO= prednisolone.**



**Table 4. Changes in the quality of COPD care provided by the participating GPs, from the 1st to the 2nd survey, for selected variables. The columns show the number (and percentage) of GPs according to the observed change.**

| Variable   | Baseline mean percentage** | Quality improved | Quality unchanged | Quality declined | Significance*** |
|--|----------------------------|------------------|-------------------|------------------|-----------------|
| Spirometry performed<br>n=154                        | 60%                        | 117 (76%)        | 11 (7%)           | 26 (17%)         | P<0.001         |
| Smoking status registered<br>n=154                   | 92%                        | 56 (36%)         | 77 (50%)          | 21 (14%)         | P<0.001         |
| Pack years calculated<br>n=154                       | 49%                        | 101 (65%)        | 24 (16%)          | 29 (19%)         | P<0.001         |
| BMI measured<br>n=154                                | 32%                        | 119 (77%)        | 14 (9%)           | 21 (14%)         | P<0.001         |
| Antismoking advice given<br>(smokers only)<br>n=148* | 67%                        | 70 (45%)         | 23 (16%)          | 48 (32%)         | NS              |
| Inhalation technique checked<br>n=154                | 67%                        | 70 (45%)         | 24 (16%)          | 60 (39%)         | NS              |

“Quality Improved”: % of patients with correct registration at 2nd Survey > than at 1st survey

“Quality unchanged”: % of patients with correct registration at 2nd Survey = % at the the 1st survey

“Quality declined”: % of patients with correct registration at 2nd Survey < than at 1st survey

\* Only 148 GPs included smoking patients

\*\* This value is the mean percentage of patients for the selected variable calculated among all GPs

\*\*\* The p-values are calculated from a binomial test testing the hypothesis that no change in quality has occurred, comparing improved quality with either unchanged or declined quality (combined).

Table 4 shows the analysis of results on the performance of the individual participating GPs. The doctors could improve their quality, not change it, or worsen the quality. The first column in the table shows the mean value at baseline for each variable for the participating GPs; for example, ‘60%’

for spirometry means that, on average, the GP had documented spirometry in 60% of their cases. The p-values are calculated from a binomial test testing the hypothesis that no change in quality has occurred (Table 4). The test compares the numbers that have improved their quality with those who

have either not changed or declined (combined). The table shows a significant improvement for most of the study indicators including spirometry, recording of smoking status, calculation of smoking pack years, and measurement of body mass index (BMI), whereas there was no significant change in quality with regard to smoking cessation advice and instruction on inhalation technique.

Finally, we also performed a sensitivity analysis on the 28 GPs who dropped out of the project at the second survey stage. In this analysis, their results were included as “no change” or “quality declined”. With regard to our main variable – performing spirometry testing – we still observed a significant improvement ( $p < 0.001$ ) with 95% confidence limits (0.57-0.71), which should be compared with the null hypothesis of unchanged quality (0.50).

## Discussion

Our study shows that, although the quality of care for COPD patients in general practice in Denmark is not optimal, a substantial improvement was achieved during the KVASIMODO project.

In terms of the study design and the potential for bias, in addition to describing the quality of COPD care we wanted to ascertain whether or not participation in an educational program can improve compliance with established guidelines and thus improve quality of care. The method used was an internal audit. Although some cross-checking was done on a random sample of the cases, we cannot exclude “observer bias”, particularly during Survey 2, since the GPs themselves completed the CRFs. On the other hand, it is unlikely that secular trends would have affected compliance with the guidelines since the period between Surveys 1 and 2 was only one year.

Although our study covers most of Denmark, the GPs included in the present study are not likely to be representative of all Danish GPs because participation in the project was voluntary. We therefore assume that most of the participating GPs are more interested in COPD than the average Danish GP. In keeping with this, we observed that the percentage of GPs in this study who owned spirometers was 86 %, somewhat higher than the 75% estimated for the whole of Denmark. These observations suggest that the quality of COPD care in general practice throughout Denmark may be even lower than we observed in our first survey. This is in line with studies from other European countries showing poor adherence to COPD guidelines.<sup>5</sup>

The cases were included on the basis of prescription of inhaled bronchodilators, age, and absence of asthma. In both surveys the GPs were asked to include the patients consecutively from their files starting from a certain date; this means that the patients included in the two surveys are not

the same. More female than male patients were recruited and this reflects the fact that there are now more deaths and hospital admissions due to COPD in women than in men.<sup>1</sup> In general, our study comprises patients who are very similar to those included in previous studies of COPD in general practice.<sup>6</sup>

Approximately 40% of the patients had severe COPD according to spirometric criteria, but this estimate is uncertain since severity assessment depends on a calculation of FEV<sub>1</sub> in terms of ‘% predicted’ – which was only possible in about 30% of cases in the first survey and 50% in the second.

Our main goal was to promote spirometry, which is a mandatory tool for diagnosing and treating COPD.<sup>4</sup> Previous studies have shown that implementation of spirometry in general practice is feasible and has significant positive consequences with regard to correct diagnosis and treatment of both asthma and COPD.<sup>7-12</sup> Although all patients included in the present study were thought to have COPD and were treated with inhaled bronchodilators, spirometry data documenting presence of airway obstruction in the initial survey was available in GP’s files in only 50% of cases and a severity assessment (based on FEV<sub>1</sub> % predicted values) was only available in 30%. This low figure was observed in spite of the fact that more than 80% of the 154 GPs actually had a spirometer in their practice. Similar studies from other countries have shown that spirometry is often underused.<sup>11, 13, 14</sup> Some investigators declared that the barriers responsible for spirometry underuse included both organisational and technical reasons.<sup>15</sup> In our study, GPs and their staff completed the education program which, in addition to theoretical background, also included the practical use of spirometry; this could be an explanation for the increased implementation of spirometry between the two surveys (Table 2).

In addition to training in spirometry, the education program included information on the correct non-pharmacological and pharmacological treatment of COPD. In accordance with this, we observed a substantial improvement in most of the relevant indices including the provision of antismoking advice, advice on physical activity, influenza vaccination, instruction in inhalation technique, and choice of inhaled medication.

With regard to medical treatment, we decided to focus on the use of inhaled corticosteroids, which, in contrary to bronchodilators, are recommended for use only in a subgroup of COPD patients who have moderate to severe COPD – i.e. an FEV<sub>1</sub> less than 50% predicted, together with a history of multiple exacerbations. We observed that a substantial proportion of patients with mild COPD were receiving inhaled corticosteroids. This is most likely to be explained both by an erroneous assessment of the disease severity and lack of knowledge that these medications are not indicated in mild COPD.

Our data were analysed in two ways: firstly, focussing on the overall quality of care provided for patients (all GPs combined) – as shown in Tables 2 and 3; and secondly, focussing on individual GPs (Table 4). In general, both analyses showed an improvement, but it was most pronounced at the patient level. This could be caused by a skewed distribution of the quality between different GPs, with relatively little room for improvement in many of the GP practices and also a risk of a decline in quality caused by both true decline and a regression towards the mean phenomenon. Table 4 shows that, in some of the GP practices, the quality actually declined in spite of their participation in the project. This reminds us that it may be difficult to maintain high quality and raises the question as to whether or not the overall improvement that we observed in the KVASIMODO project is long-lasting. Undoubtedly, recurrent audit is necessary to keep quality high in the long term.

We think that our results can be extrapolated to other countries suggesting that similar programs directed at GPs are worthwhile pursuing. In addition to education, it has also been suggested that an alternative way of reimbursing GPs should be introduced. At present, most of the contacts between the GP and the COPD patient are in connection with an acute exacerbation. In this situation there is no focus on long-term treatment including smoking cessation, rehabilitation and dietary advice. It would be beneficial if GPs were encouraged to see COPD patients when their disease is stable, as has been suggested by the new NICE guidelines – where a consultation at least once a year for stable COPD patients (twice-yearly for severe COPD) is recommended.<sup>16</sup> An establishment of a chronic disease management program has even been shown to reduce the number of days in hospital for patients with COPD.<sup>17</sup>

We conclude that the quality of care for COPD patients in general practice can be improved by implementing an educational program which focusses on spirometry and COPD guidelines.

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### Conflict of interest statement

Peter Lange, Finn Vejlo Rasmussen, Michael Skov Jensen, Klaus Roslind and Lill Moll Nielsen have served on an advisory board as consultants for Boehringer Ingelheim Denmark and Pfizer Denmark during the KVASIMODO project.

Hanne Borgeskov is employed by Boehringer Ingelheim Denmark.

Jens Dollerup is employed by Pfizer Denmark.

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