

# Evaluation of a regional disease management programme for patients with asthma or chronic obstructive pulmonary disease

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## Abstract

**Objectives.** To assess the impact of a population-based disease management programme for adult patients with asthma or chronic obstructive pulmonary disease (COPD) on process measures, intermediate outcomes, and endpoints of care.

**Design.** Quasi-experimental design with 12-month follow-up.

**Setting.** Region of Maastricht (the Netherlands) including university hospital and 16 general practices.

**Participants.** Nine hundred and seventy-five patients of whom 658 have asthma and 317 COPD.

**Intervention.** Disease management programme.

**Main outcome measure(s).** Endpoints of care are respiratory health, health utility, patient satisfaction, and total health care costs related to asthma or COPD.

**Results.** Quality aspects of care, disease control, self-care behaviour, smoking status, disease-specific knowledge, and patients' satisfaction improved after implementation of the programme. Lung function was not affected by implementation of the programme. For COPD patients, a significant improvement in health utility was found. For patients with asthma, significant cost savings were measured.

**Conclusions.** Organizing health care according to principles of disease management for adults with asthma or COPD is associated with significant improvements in several processes and outcomes of care, while costs of care do not exceed the existing budget.

**Keywords:** asthma, COPD, disease management, outcome and process assessment, programme evaluation, quality of health care

Disease management programmes aim to improve quality of care and reduce health care costs [1,2] by identifying chronic conditions more quickly, treating them more effectively, and thereby slowing the progression of the disease. This is pursued through a combination of enhanced screening, monitoring and education, coordination of care among providers and settings (e.g. outpatient and in-patient care), and standardization of care using evidence-based guidelines [3,4]. The assumption is that for the growing group of chronically ill patients better care today will result in better health and less-expensive care in the future [4].

In the region of Maastricht (the Netherlands), a disease management programme for patients with asthma or chronic obstructive pulmonary disease (COPD) has been implemented. The programme focuses on all patients with asthma

or COPD on the list of a general practitioner, who are treated either by a general practitioner or by a pulmonologist at the outpatient department of the regional (university) hospital. Main features of the programme include central coordination, assignment of patients to a general practitioner, respiratory nurse specialist or pulmonologist, and central data collection with annual feedback. The nurse specialists function as a liaison between central organization, pulmonologists, and general practitioners. Apart from the diagnostic and therapeutic tasks listed in the (inter)national guidelines for pulmonologists and general practitioners, the nurse specialists focus on patient education and promotion of self-management.

This article describes the changes in process measures, intermediate outcomes, and endpoints of care after the introduction of a disease management programme.

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## Methods

### Patients and setting

The region of Maastricht encompasses approximately 120 000 inhabitants, 90 general practitioners, and one (university) hospital. Between May 2002 and March 2003, patients were recruited from 16 general practices (20 general practitioners) and the hospital's outpatient department. General practitioners interested in participating in the programme were selected on the condition that they offered a part-time working place to a nurse specialist within their practice. Patients with a diagnosis of asthma or COPD were invited to participate in the study. Patients with serious comorbidity—such as lung cancer or congestive heart failure—were not eligible for inclusion in the disease management programme. They received care as usual from their general practitioner, the medical specialists involved, and, in some cases, from a case manager.

### The disease management programme

The disease management programme targets everyone who is currently diagnosed or will be diagnosed with asthma or COPD. It is comprised of the six components of disease management distinguished by the Disease Management Association of America [3]. The population of patients diagnosed with asthma or COPD was identified using databases of general practitioners and the database of the hospital. Also, patients 'suspected' of suffering from any of these conditions, based on medication use or medical history, were selected from the databases. A collaborative team for this programme consisted of a medical specialist, general practitioner, and respiratory nurse specialist. The tasks and responsibilities of each type of care provider were described in a multidisciplinary protocol. Evidence-based guidelines were at the basis of the protocol, outlining the programme in detail. Medical specialists and general practitioners were encouraged to adhere to the (inter)national treatment guidelines [5–9], while the protocol for care provision by the nurse specialist was based on the Dutch guidelines for general practitioners [7–9]. Where appropriate, care was transferred to the lowest possible level. For the nurse specialists, this means that they independently performed diagnostic and therapeutic activities, while using their nursing skills to enhance patient education and promotion of self-management. As they were based in the hospital but met patients in the office of the general practitioner, they were functioning as a liaison between primary and secondary care. Processes and outcomes of care were monitored by the integrated care department of the hospital coordinating the programme. Data from the electronic patient record systems were used as steering information to manage the programme and to provide structural feedback to care providers. The main difference between usual care and the care delivered within the disease management programme is concerned with the central coordination, the re-assignment of patients, and the introduction of the respiratory nurse specialist in this role.

### Study design and procedures

A one-group pre-post test design was applied [10]. This design was chosen as the disease management programme and was implemented on a regional basis and it was impossible to find a fully comparable region. All potential regions were in the process of implementing innovations that would bias the measure of usual care, such as self-management programmes or electronic patient record devices (e-health).

Patients identified from all databases were invited to participate in the programme. After obtaining written informed consent, patients were sent the first questionnaire and were invited for the initial consultation. This consultation was carried out by the nurse specialist at the general practitioner's office. During this consultation, the respiratory nurse specialist performed spirometry, assessed perceived breathlessness, wheezing, night-time awakening, as well as exacerbations. On the basis of this information, the collaborative practice team (general practitioner, nurse specialist, and pulmonologist) confirmed or reconsidered the diagnosis. They classified the severity of the disease and required intensity of care in accordance with either COPD [5] or asthma guidelines [6]. On the basis of this classification, patients were assigned to the general practitioner, nurse specialist, or pulmonologist. Subject to approval of the patient, patients with intermittent or mild asthma or mild COPD were assigned to the general practitioner. Patients with moderate persistent asthma or moderate COPD were given quarterly outpatient appointments from the respiratory nurse specialist at the practice of the general practitioner. Patients with severe persistent asthma or (very) severe COPD requiring high intensity of care received health care from the pulmonologist. The consultations with the respiratory nurse lasted 30 minutes, while the scheduled consultation time with general practitioners and pulmonologists did not change by protocol in comparison to the usual care situation. Nurses and general practitioners regularly discussed patients who were seen by the nurse in the general practitioner's office. The nurse reported to the medical specialist once a week.

### Data collection

Data collection covered a period of 3 months before a patient entered the programme and 12 months afterwards. Clinical data (e.g. lung function, frequency and severity of symptoms, level of dyspnoea, number of exacerbations, body weight, and fat-free mass index) were obtained from care provider registries. Costs were measured retrospectively every 3 months starting at entry into the programme, whereas all other data were collected at entry, after 6 months and after 12 months by postal questionnaires.

### Lung function

Evaluation of lung function was based on spirometry. Spirometry is the most common lung function test, measuring the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled. It is an important tool used for assessing

conditions such as asthma and COPD. Changes in lung function are expressed as: (i) changes in post-bronchodilator forced expiratory flow in 1 second as a percentage of the predicted value; (ii) reversibility of the forced expiratory flow in 1 second as a percentage of the predicted value; (iii) the ratio of the forced expiratory flow in 1 second to the forced vital capacity (i.e. the maximum air volume a person can breathe out after deep inhalation, or breathe in after deep exhalation), also referred to as the Tiffeneau index.

### Quality of care

Quality of care was measured via the Dutch Quality of Care Through Patients Eyes (QUOTE) Questionnaire for patients with asthma or COPD [11]. For the purpose of this study, only indicators reflecting aspects of quality of care that are specifically targeted by the programme were included in the statistical analysis, i.e. coordination and accessibility of care, regular control of medication use, and understandable education in the area of non-medical self-care. The questionnaire was self-administrative. Patients reported how they perceived the coordination and accessibility of care, whether their care provider regularly checked the appropriateness of their inhalation technique, and if they were given education concerning non-medical self-care. Cronbach's alphas for internal consistency of these indicators were 0.79, 0.74, 0.74, and 0.81 respectively [12]. These indicators were chosen because they reflect aspects of care quality that are directly targeted by the disease management programme.

### Self-care behaviour and disease-specific knowledge

Measurement of self-care behaviour and disease-specific knowledge was performed using a validated Dutch instrument [13]. Two dimensions of self-care were measured with a 5-point scale: compliance and condition maintenance [13]. Self-reported smoking status was measured on a dichotomous scale. Disease-specific knowledge was measured by means of 22 questions on asthma and COPD (Cronbach's  $\alpha = 0.70$ ) and expressed as the proportion of correct answers, transformed into a 0–10 scale [13].

### Endpoints of care

Respiratory health was measured using the Dutch version of the St. George's Respiratory Questionnaire (SGRQ) [14]. Total scores on the SGRQ range from 0 to 100, with a score of 0 indicating no impairment. Patient satisfaction was assessed using an instrument derived from industrial marketing management, which has previously been applied in the same area of research [15–18], providing a mark ranging from 1 to 10 (1 = extremely dissatisfied and 10 = extremely satisfied). Health utility was measured using the Dutch EuroQol-5D (EQ-5D). The single index value of the EQ-5D ranges from 0 to 100; zero indicates 'worst imaginable health state' and 100 indicates 'best imaginable health state' [19].

Cost calculations were based on actual resource use, which was measured using a 15-item questionnaire and verified with care providers' administrative data. Direct health care costs

were calculated using current prices, when available, or tariffs [20]. Productivity losses were measured in terms of sick leave days and calculated using the age-dependent friction cost method. Implementation and overhead costs were calculated using a bottom-up approach. Data collected on resource use included: (i) the number of planned consultations with the general practitioner, respiratory nurse specialist or pulmonologist; (ii) the number of consultations with other care providers; (iii) the amount and type of medication used; (iv) the number of sick leave days due to asthma or COPD; (v) the number of non-routine consultations due to an exacerbation; and (vi) the number and duration of hospital admissions.

### Statistical analyses

Missing responses were handled by using the last observed response (carry-forward procedure) [21]. Differences in process and intermediate indicators between the three measurement points were assessed using repeated measurement analysis. Continuous outcome variables were analysed using MANOVA; dichotomous variables were analysed using Cochran's  $Q$  test [22]. All repeated measurement analyses were carried out for the study population as a whole as well as for separate subgroups as defined by the primary responsible care provider (e.g. medical specialist, respiratory nurse specialist, and general practitioner) with  $\alpha = 0.05$ .

Before–after comparisons of the end results of care were analysed using paired-samples  $t$ -tests (two-sided;  $\alpha = 0.05$ ) for normally distributed data. Cost data were log-transformed for this purpose. Data processing and analysis were performed using SPSS 12 for Windows.

## Results

### Patient inclusion, assignment, and follow-up

A total of 1062 patients were found eligible of whom 975 were included in the study (92%). Of the patients included, 10% were assigned to the pulmonologist, 65% to the respiratory nurse specialist, and 25% to the general practitioner. Response rates on both quality of care questionnaires and cost questionnaires ranged from 67 to 96%. Seventy percent of the patients ( $n = 685$ ) completed the 12-month follow-up. The most common reason for dropping out of the study was unwillingness to complete questionnaires. Patient characteristics at baseline are presented in Table 1.

### Missing data analysis

Patients assigned to the general practitioner were less likely to complete data collection than patients assigned to the respiratory nurse specialist or pulmonologist. As a result, forced expiratory flow in 1 second as a percentage of the predicted value for patients who did not complete follow-up was on average 19.2 [standard deviation (SD) = 2.0] higher than for patients with complete data ( $P = 0.000$ ). Furthermore, patients lost to follow-up were on average 4.6 (SD = 1.3)

Table 1 Patient characteristics at baseline

Variable <sup>1</sup>	Asthma				Chronic obstructive pulmonary disease			
	All patients (n = 658)	Intermittent/Mild (n = 141)	Moderate (n = 451)	Severe (n = 66)	All patients (n = 317)	Mild (n = 93)	Moderate (n = 153)	(Very) Severe (n = 71)
Age (years)	54 (±17)	50 (±16)	54 (±17)	58 (±15)	61 (±14)	57 (±14)	62 (±14)	66 (±12)
Sex (% male)	41%	42%	41%	39%	56%	48%	55%	69%
Current smoker (%)	43%	43%	45%	31%	40%	44%	48%	30%
Pack years	19 (±17)	16 (±14)	20 (±17)	22 (±18)	38 (±22)	23 (±16)	32 (18)	37 (±23)
FEV <sub>1</sub> (% predicted)	89.9 (±18.9)	98.6 (±18.8)	90.1 (±20.5)	69.9 (±16.3)	56.2 (±17.2)	91.8 (±10.0)	64.7 (±8.3)	38.2 (±4.9)
FVC (% predicted)	105.4 (±19.2)	110.2 (±20.0)	106.0 (±19.1)	90.9 (±18.7)	83.7 (±18.8)	97.3 (±17.1)	84.5 (±18.6)	64.5 (±20.1)
Tiffeneau ratio	0.72 (±0.14)	0.74 (±0.15)	0.72 (±0.14)	0.65 (±0.16)	0.51 (±0.14)	0.63 (±0.1)	0.56 (±0.1)	0.44 (±0.1)
FEV <sub>1</sub> reversibility	11.5 (±4.8)	12.0 (±4.9)	11.5 (±4.8)	10.2 (±4.3)	4.5 (±5.9)	5.1 (±5.8)	4.5 (±6.0)	3.6 (±5.7)
PEF (% predicted)	92.3 (±24.0)	99.6 (±23.6)	92.4 (±24.1)	75.8 (±25.0)	49.1 (±14.3)	68.4 (±14.1)	45.2 (±14.5)	32.0 (±13.8)
Dyspnoea (MRC score)	1.8 (±1.0)	1.4 (±0.8)	1.9 (±1.1)	2.2 (±1.2)	2.8 (±1.2)	1.6 (±0.9)	2.2 (±1.0)	3.0 (±1.1)
Body mass index (kg/m <sup>2</sup> )	26.4 (±4.8)	25.5 (±5.3)	26.6 (±4.8)	27.3 (±4.5)	25.1 (±4.9)	26.5 (±4.1)	26.7 (±5.5)	24.8 (±4.7)
Fat free mass index (kg/m <sup>2</sup> )	17.7 (±2.2)	17.3 (±2.6)	17.6 (±2.1)	19.7 (±2.7)	17.1 (±3.5)	17.8 (±2.4)	17.8 (±2.5)	17.2 (±2.4)

<sup>1</sup>All variables are presented as means (±SD) unless stated otherwise.FEV<sub>1</sub>, Forced expiratory flow in 1 second; FVC, Forced vital capacity; PEF, Peak expiratory flow; MRC, Medical Research Council.

years younger than patients with complete data ( $P = 0.000$ ). The proportion of male/female patients did not differ.

### Lung function

No significant changes were found for patients with asthma or COPD (Table 2) with regard to forced expiratory flow in 1 second as a percentage of the predicted value, reversibility of the forced expiratory flow in 1 second or Tiffeneau index.

### Quality of care

The proportion of patients that received self-management education more than doubled within 6 months after inclusion (35–77%;  $P = 0.001$ ), reaching 81% after 12 months ( $P = 0.001$ ) (Table 3). Also, the proportion of patients whose effective use of medication was checked regularly increased, as did the proportion of patients reporting good accessibility and coordination of care (Table 3).

### Self-care behaviour and disease-specific knowledge

Self-care behaviour of patients improved in terms of (i) compliance with the medication regimen, (ii) physical activity, and (iii) smoking. Furthermore, disease-specific knowledge increased by 10% (Table 4).

### Resource utilization

The average number of routine follow-up consultations doubled within 6 months after implementation of the disease

management programme (from 0.53 to 0.99;  $P = 0.02$ ). This indicates that the guidelines—advising one routine consultation every 3 months—were met more closely than before. This effect was found to be fairly stable in the remaining follow-up (Table 5).

The number of non-routine consultations decreased on average by 28%, and hospitalization was reduced by 50%. Costs for medication increased by an average of €5 per 3 months. Furthermore, the number of sick leave days due to asthma or COPD decreased by an average of 55%.

### Endpoints of care

Patient satisfaction improved from 7 points at baseline to 8 points after 1 year ( $P < 0.001$ ). Respiratory health, as expressed by SGRQ scores, did not change significantly in both patient groups. Health utility improvement was statistically significant for patients with COPD but not for patients suffering from asthma. In both patient groups, total health care costs related to asthma or COPD decreased, although this decrease was statistically significant only for patients with asthma (Table 6).

### Discussion

The introduction of the disease management programme is associated with significant improvements in several processes and outcomes of care delivery within existing budgets. The findings in this study are to some extent consistent with results from other studies. Improved patient satisfaction and

**Table 2** Lung function

Variable <sup>1</sup>	Asthma			Chronic obstructive pulmonary disease		
	Baseline	12 months	<i>P</i> value	Baseline	12 months	<i>P</i> -value
FEV <sub>1</sub> % predicted <sup>2</sup>	89.9 (±21.0)	90.5 (±17.2)	0.43	56.2 (±17.2)	55.2 (±16.2)	0.08
FEV <sub>1</sub> % reversibility <sup>3</sup>	11.5 (±4.8)	12.1 (±4.3)	0.13	4.5 (±5.9)	3.3 (±3.5)	0.11
Tiffeneau index	0.72 (±0.14)	0.72 (±0.11)	0.71	0.51 (±0.14)	0.52 (±0.12)	0.59

<sup>1</sup>All variables are presented as means (±SD) unless stated otherwise.

<sup>2</sup>Forced expiratory flow in 1 second in percentage of predicted value.

<sup>3</sup>Percentage reversibility of forced expiratory flow in 1 second.

**Table 3** Quality of care

Variable	Baseline	12 months	<i>P</i> -value
Percentage of patients receiving understandable self-management education	35	81	<0.001
Percentage of patients receiving control of effective medication use	29	74	<0.001
Percentage of patients reporting good accessibility of primary responsible care provider	57	73	0.02
Percentage of patients reporting good coordination of care	63	77	0.01

**Table 4** Self-care behaviour and disease-specific knowledge

Variable <sup>1</sup>	Baseline	12 months	<i>P</i> -value
Compliance with medication scheme (scale 1–5)	3.2 (±0.7)	4.3 (±0.7)	<0.001
Physical activity (scale 1–5)	1.9 (±1.2)	2.4 (±1.2)	0.02
Smoking status (% smoking)	40	36	0.02
Disease specific knowledge (scale 0–10)	4.6 (±2.2)	5.6 (±2.0)	<0.001

<sup>1</sup>All variables are presented as means (±SD) unless stated otherwise

improvements in process measures have often been reported as a result of disease management programmes [2,4]. The improvements we found for indicators related to self-management (e.g. patient education, self-care behaviour, and compliance) are of particular importance, as self-management is considered one of the key elements of care for the chronically ill. The clinical relevance of these improvements is obvious.

However, the clinical relevance of the improvement in health utility among COPD patients, as shown on the aggregated level, is debatable. The timeframe of our study may have been too short to detect clinically relevant changes for

this parameter. The advantage of including such a generic parameter lies in its potential to compare the impact of a disease management programme for patients suffering from asthma or COPD with interventions that are aimed at other populations. This can support decision-making on a macro level [23]. The finding that the costs for patients with asthma decreased significantly is not common. The varying perspectives adopted regarding cost measurement may play a role here, making comparison with other studies difficult [4]. Furthermore, power calculations are usually based on one specific clinical parameter as primary outcome, not on health care costs. Because costs are typically characterized by relatively high levels of uncertainty [24], the number of patients included is often too small to detect any significant changes for this parameter.

Although the number of patients included was sufficiently high to be able to detect small changes in patient satisfaction, respiratory health, health utility, and health care costs, the effects cannot simply be attributed to the disease management programme, as no parallel control group was available. Theoretically, the effects that were found could also be caused by other changes in health care [10]. In this respect, it is important to note that the improvements observed in almost all process and outcome measures occurred directly after implementation of the programme (especially in the respiratory nurse specialist subgroup). To our knowledge, no other changes in health care or specific co-interventions occurred during this time period that could have caused

**Table 5** Resource utilization (per 3 months)

Variable <sup>1</sup>	Baseline	12 months	<i>P</i> -value
Number of routine follow-up consultations	0.53 (±0.74)	0.88 (±0.62)	0.02
Number of non-routine consultations	1.00 (±0.62)	0.72 (±0.56)	0.004
Hospitalization (days)	0.10 (±0.30)	0.05 (±0.2)	0.03
Medication costs	48 (±21)	53 (±31)	0.02
Sick leave due to asthma or chronic obstructive pulmonary disease (days)	0.22 (0.77)	0.12 (±0.18)	<0.001

<sup>1</sup>All variables are presented as means (±SD).

**Table 6** Changes in endpoints of care between baseline and 12-month follow-up

Variable <sup>1</sup>	Asthma			Chronic obstructive pulmonary disease		
	Baseline	12 months	<i>P</i> -value	Baseline	12 months	<i>P</i> -value
Patient satisfaction	6.99 (±0.55)	7.90 (±0.88)	<0.001	7.01 (±0.57)	7.94 (±0.91)	<0.001
Health status	34.21 (±18.6)	34.03 (±19.4)	0.64	38.82 (±18.3)	37.64 (±18.5)	0.12
Health-related quality of life (EuroQol-5D)	72 (±16)	73 (±16)	0.43	67 (±15)	69 (±14)	0.02
Annual total health care costs per patient (in euros)	766 (±648)	698 (±633)	0.002	1423(±1248)	1381 (±1213)	0.09

<sup>1</sup>Variables are presented as means (±SD).

improvements of comparable magnitude. For example, the decrease in hospitalization of 50% would not be expected, given the natural course of either asthma or COPD. More importantly, discharge policy for patients with asthma or COPD did not change during follow-up either. Furthermore, we observed a decrease of 54% in the number of sick leave days within 6 months after implementation of the programme, whereas an overall decrease in sick leave of 15–18% was registered in the Netherlands between 2002 and 2003 [25].

We are aware that generalizability of study results is difficult when interventions are designed to fit into local health care structures. Providing a careful description of the programme and paying explicit attention to the differences with usual care should alleviate this. Taking into consideration all strengths and weaknesses of the study, the recommendation is to implement disease management programmes for patients with asthma or COPD, designed around a collaborative practice team in which the nurse specialist plays a key role on a larger scale. Attention needs to be paid to adequate integration of the programme into (local) health care structures, as well as a careful description of the processes and function of its components. Further research is needed to investigate the relationship between structure, processes, and outcomes of health care, guiding the choice for indicators to be measured when evaluating disease management programmes. This should lead to objective information becoming available in a timely fashion, which can be useful for decision-making at different levels [23].

## Conclusion

In the region studied, redesigning care for adults suffering from asthma or COPD according to principles of disease management was associated with significant improvements in several processes and outcomes of care. Quality aspects of care, self-care behaviour, smoking status, disease-specific knowledge, and patient satisfaction improved after implementation of the programme. Although disease control improved, as shown by the decrease in the number of exacerbation-related hospitalizations, average lung function values and SGRQ scores did not change significantly during the 1-year follow-up. For patients with COPD, a small but statistically significant improvement in health utility was found. However, the clinical relevance of the improvement, as shown on the aggregated level, is questionable. Among patients with asthma, significant cost savings were measured.

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**Accepted for publication 8 September 2006**