Asthma and COPD
Diagnoses and prescriptions in Swedish primary care

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Ale tryckteam AB
ABSTRACT

**Aims:** The overall aim of this thesis was to evaluate the quality of the diagnoses and the prescribing of medication to patients with asthma and COPD (Chronic Obstructive Pulmonary Disease) in Swedish primary care. The specific aims were to study the adherence to recommended guidelines and quality indicators in diagnosis and treatment of patients with asthma and COPD and to survey the relationship between the diagnosis of asthma/COPD and the prescribing of asthma/COPD medication.

**Methods:** All visits to health care centres in Skaraborg, Sweden, are documented in computerized medical records constituting the Skaraborg Primary Care Database (SPCD). In a register-based retrospective observational study, all patients were identified; patients diagnosed with asthma or COPD during 2000–2005 (n = 12,328) and all individuals with at least one prescription of asthma/COPD medication issued during 2004–2005 (n = 14,101) regardless of diagnoses. In a detailed analysis for a 5 % random sample (n = 945) data from patients’ medical records were manually extracted. Information on performed investigations at initial visits and at follow-up was collected and compliance with procedures as recommended by national guidelines was used for quality assessment. For prescriptions information about indication, number and type of prescriptions was retrieved.

**Results:** Among 499 patients with asthma 167 (33 %) were investigated with spirometry or Peak Expiratory Flow (PEF) during initial visits in agreement with guidelines. Correspondingly, 40 out of 124 patients with COPD (32 %) were investigated with spirometry. During follow-up evaluation in agreement with guidelines was performed on 130 (60 %) of patients with asthma and on
35 patients out of 77 (45 %) with COPD. The prescribing of inhaled corticosteroids (ICS) reached quality target, still every second patient with asthma made an acute visit during follow-up.

Asthma/COPD medication was prescribed in primary care to approximately 6 % of the total population in Skaraborg. In total 54 % of the medication users had recorded diagnoses of asthma, COPD or both. Consequently 46 % had no recorded asthma/COPD diagnosis. The incongruence between diagnosis and medication was present in all age-groups. Among patients with recorded asthma 37 % had no medication prescribed.

Conclusions:

- There is incongruence between diagnoses of asthma or COPD and prescription of medication, consistent in all age-groups, which indicates that the levels of asthma/COPD medication cannot be used as proxy for asthma/COPD disease prevalence.
- Asthma/COPD medication is often prescribed outside recommendations and used both as a diagnostic tool and in an off-label manner.
- Patients with asthma seem to be inadequately treated, since approximately one third of all patients with recorded diagnoses of asthma are non-medicated, one third use medication sparsely and only one third use medication continuously.
- Adherence to recommended guidelines is low since only one third of the patients with diagnoses of asthma or COPD during initial visits, and about half of the patients during follow-up, had a clinical evaluation, including spirometry or PEF, in agreement with recommendations.
- The prescribing of ICS-treatment reaches the quality indicator target, still patients with asthma seem to be uncontrolled in their disease, since acute visits were common, indicating that treatment targets are not reached and that adherence to medication is low.
- There is substantial room for quality improvement in the clinical evaluation of patients with asthma and COPD and there is a need to observe the extent of off-label prescribing in asthma/COPD medication.

**Keywords** asthma, COPD, diagnostic guidelines, quality indicators, prescribing, off-label

PUBLICATIONS

This thesis is based on the following publications.


II. Weidinger P, Nilsson JLG, Lindblad U. Diagnosis of asthma/COPD related to drug prescribing in Swedish primary health care (pending revision).
### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>GINA</td>
<td>Global Initiative for Asthma</td>
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<tr>
<td>GOLD</td>
<td>Global Initiative for Chronic Obstructive Pulmonary Disease</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>ICD-10</td>
<td>International Classification of Disease, tenth revision</td>
</tr>
<tr>
<td>ICS</td>
<td>Inhaled Glucocorticosteroids</td>
</tr>
<tr>
<td>LABA</td>
<td>Long Acting Beta-2 Agonists</td>
</tr>
<tr>
<td>PEF</td>
<td>Peak Expiratory Flow</td>
</tr>
<tr>
<td>SABA</td>
<td>Short Acting Beta-2 Agonists</td>
</tr>
<tr>
<td>SCB</td>
<td>Statistics Sweden</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>PHCC</td>
<td>Primary Health Care Centre</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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1 INTRODUCTION

Many people have symptoms, some of which may indicate a disease. Some of the persons may decide to visit the doctor. The doctor asks about the medical history and complaints, does the relevant tests, and after that labels the symptoms, i.e. sets the diagnosis. Hopefully, there is accessible treatment for the disease and the doctor chooses the appropriate medication, which often includes one or several medicines. Hopefully the patient takes the prescription to the local pharmacy and they dispense the medicines. In ideal cases the patient then takes the medicines in the dose and for the time period prescribed by the doctor. During this period the patient is either cured or the symptoms are alleviated …. But…. is it really that easy? The answer to that question is in many cases unfortunately no…The pathway from an emerging disease to a satisfying treatment is often not that simple, which will be discussed below, with the chronic respiratory diseases of asthma and COPD (Chronic Obstructive Pulmonary Disease) as examples.

1.1 Respiratory diseases: Asthma and COPD

Asthma and COPD are common chronic diseases and also two of the leading causes of morbidity and mortality worldwide [1]. Asthma and COPD are two distinct disorders that share one common functional feature, the airflow limitation [2-3]. In asthma the airflow limitation is reversible, either spontaneously or after treatment, whereas in COPD the airflow limitation is in most cases progressive and not reversible. Among the middle-aged and elderly, the diseases may co-exist.

Asthma is defined as a chronic inflammatory disorder of the airways, associated with variable airway hyper responsiveness that leads to periods of wheezing, breathlessness, chest tightness and coughing, particularly at night time or early mornings [2]. The prevalence of asthma varies between countries, and there are estimates that about 5 percent of the population in the world and approximately 8 percent in Sweden have asthma [4]. During the second half of the 20th century, there was a large increase in the prevalence of asthma [5]. Recent data suggest that the prevalence is levelling off [6-7]. Asthma exists in all age groups, and is most common in children and adolescents. However, other wheezing disorders are common among children and it might not always be easy to differentiate them from asthma, which is why many diagnosis of asthma in the young might be misclassifications [8].
The cause of asthma is not well known, and there seems to be both genetic and environmental factors that play a part in the aetiology [9].

COPD has also been increasing during recent decades and is expected to increase further. In Sweden, as well as in other western societies, approximately 4–6 percent of the adult population has COPD, but as with the case of asthma, the estimate varies between countries [10]. COPD effects mostly elderly and the disease is characterised by a chronic airway inflammation with a non-reversible airflow obstruction. The major risk factor of developing COPD is smoking even though genetics also seems to be of importance [11].

1.2 Primary care

The role of primary care as specialists and the first in line health care provider, and also as a gatekeeper to other specialist care, makes it an important instance for first contact with health care. Patients confront the primary health care centre (PHCC) with a wide range of problems. One role is to monitor patients with already diagnosed and treated chronic diseases. Most patients, however, appear with poorly defined early symptoms, which may or may not be their first presentation of a chronic disease such as asthma or COPD. When a patient experiences new symptoms the challenge for the general practitioner (GP) is to determine if the symptoms may indicate a serious event, a short-term problem likely to resolve without treatment, or an evolving chronic disease. The majority of the patients with asthma and COPD are diagnosed and treated by the GPs in Sweden [12], and there is a well established organization for management of these patients. Many PHCC have special nurse-led asthma clinics with medically responsible GPs and nurses specially trained in asthma and COPD management [13-14].
1.3 The diagnostic process

Diagnosis is central to the work of all medical profession. In most medical conditions a correct diagnosis is the prerequisite for all further actions leading to either a cure or relief of symptoms. As Balint [15] discusses, physicians are often confronted with an “unorganized illness”, an agglomeration of symptoms and complaints, which may be unclear, unconnected and mysterious. Their job is to understand and to organize these symptoms and complaints into an “organized illness”. In other cases the presentations are more clear cut and require less organizational work. According to Schiff et al [16], the diagnostic process can be divided into seven stages; (1) access/presentation, (2) history taking, (3) physical examination, (4) testing, (5) assessment, (6) referral, and (7) follow-up. These stages may be concurrent, recurrent and complex, and the result is that the “unorganized illness” becomes “organized”. This process of making a diagnosis is primarily cognitive and is difficult to quantify and to describe. Even the decision maker may not always be aware of how or why a given diagnosis was reached [17]. Although most of the diagnoses made by the doctor arrive with ease and accuracy, diagnostic errors do occur. Diagnostic errors should be distinguished from medical errors, which are an increasingly explored area, including topics such as medication errors or surgical mistakes [18]. However diagnostic errors have received little attention [19]. Diagnostic errors are diagnoses that are missed, delayed or incorrect and make up a large fraction of all medical errors and cause suffering and injury among those affected. Diagnostic errors are due to several factors, where cognitive factors are the most prevalent [20].

1.3.1 The diagnostic process of asthma and COPD

Since the diagnostic process requires more or less organizing work, i.e. can be more or less complex, each diagnosis should preferably be considered separately. Early diagnosis of chronic respiratory disease in primary care depends on early recognition of suggestive symptoms. The diagnostic process includes the stages described above. At the first presentation of symptoms there are commonly symptoms such as coughing, wheezing, and breathlessness, shortness of breath and chest tightness. The GP has to characterize the problem and exclude infectious diseases and other non-respiratory causes. Through history-taking the chronicity of the symptoms is clarified and the patients’ age is an important consideration. In the young, it may not be easy to differentiate asthma from other wheezing disorders, since
for children under the age of 6 years, objective lung function testing is difficult and asthma is therefore primarily a diagnosis of exclusion. Moreover, different wheezing disorders are common among children, since one third of all preschool children experience such periods [8]. From the age of 6 years asthma and the differential diagnosis allergic rhinitis are the predominant airway diseases. In adults over the age of 40 years COPD becomes more common.

1.3.2 Guidelines as a support in the diagnostic process of asthma and COPD

For many diseases there is international consensus about how the diagnostic procedure and the follow-up should proceed. As a guide and as a support in the diagnostic process there are evidence-based recommendations in the form of official guidelines, which in many countries are transformed into national guidelines. In asthma and COPD the diagnostic process is supported by international guidelines [2-3], transformed into Swedish guidelines [20]. Doctors are recommended to adhere to these guidelines to achieve optimal treatment results. When diagnosing asthma the recommended testing is done by objective measurement of lung function with Peak Expiratory Flow (PEF) or with spirometry [2,20]. When diagnosing COPD only spirometry can be used for detecting the irreversibility of the airways [3,20]. In both asthma and COPD spirometry is also recommended with at least 1–2 years’ intervals for monitoring of airway function.

1.3.3 Limitations in the diagnostic process

Both the diagnostic procedure and the delivery of care vary. A comprehensive review of medical practice in the United States concluded that only half of the recommended health care is delivered to patients as often as it could be [21]. Similar results were found in the United Kingdom, Australia and New Zealand [22]. In the diagnostic process of both asthma and COPD the recommended testing with objective measurements of airway function are largely underused [23-26].

Both in asthma and in COPD under-diagnosis has been shown to be common [27]. There are reports that show that 50 percent of the individuals with asthma are undiagnosed and/or untreated in the general population [28]. Underpresentations to the GPs of respiratory symptoms by asthmatic patients
contribute significantly to the under-diagnosis [29]. In patients with COPD the disease is usually not diagnosed until the disease has progressed to the moderate to severe stages, and under-diagnosis is common [10-11]. Since the disease is progressive early detection is a prerequisite in order to minimize further disease progress. In asthma over-diagnosis is also a matter of concern. Previous studies show that in 30 percent of the patients reporting a physician-diagnosed asthma, the diagnosis could be excluded when using objective measurements [30].

1.4 The medication process
The treatment of an illness can be non-pharmacological and/or pharmacological. Non-pharmacological treatments such as life-style changes, cognitive treatments or stress reduction are common for some diagnoses, as the only treatment or as a complement to medicines. Research and development in the pharmaceutical area during recent decades has made great progress, and the availability of medications has improved. For most conditions there are available treatments either as a cure (as with antibiotics), as chronic preventive treatment (as with anti-asthma or anti-diabetic medication) or as symptom alleviation (as with painkillers). With this abundant availability of drugs, prescribing medicines has become a cornerstone of medical practice. Medication errors have received much attention in the literature in contrast to errors in the diagnostic process. The documented prevalence of medication errors varies from 2–75 percent [31]. However, compared with other epidemiological fields in health care there is no single definition of a medication error, and much of this variation is due to inconsistency in the definitions [31]. Standardization attempts have been made by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [32]. A short and clear definition was formulated by Ferner and Aronsson as “A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm of the patient” [33].

1.4.1 Treatment of asthma and COPD
In asthma the first-in-line recommendation is pharmacological treatment. Treatment of asthma also includes avoidance of “triggers” such as allergens, viral infections, pollutions and drugs. Patients need to be aware of these factors and to know how to treat their asthma if they get exposed to trigger
factors. The pharmacological treatment is preventive and the goal is that the patient should be free from symptoms and have no limitations in daily activities, have normal lung function, no emergency visits and a satisfactory quality of life. There should be no serious side-effects of the treatment [20]. The treatment is adjusted in a stepwise manner based on experienced symptoms and objective measurements [2,20]. International and Swedish national guidelines recommend the use of short-acting beta-2 agonists (SABA) for bronchodilation as the first step in treatment, and in addition, inhaled corticosteroids (ICS) for treatment of the underlying inflammation in the airways. For more severe asthma, the addition of long-acting beta-2 agonists (LABA) might be required. In asthma the goal is to reach optimum control. After reaching asthma control continuous monitoring is essential in order to reach the lowest effective step of treatment. Since both asthma and COPD are chronic diseases the treatment is likely to continue over many years. In patients with asthma, severity can be estimated from the minimum level of treatment required to achieve good control, while on controller therapy. Patients with severe asthma can have good control of the disease, while patients with mild asthma can have poor control of the disease, depending on how the treatment is managed.

In COPD the main treatment is cessation of smoking, while treatment with medication is secondary according to current guidelines. The pharmacological treatment goal for patients with COPD is to reduce symptoms and improve quality of life. The treatment often consists of combinations of ICS and LABA and of anti-cholinergics [3,20].

### 1.4.2 Patient adherence to medication

Compliance or adherence are both descriptions of medicine-taking behaviour. Adherence is a more modern term and concerns any type of health behaviour and implies that the patient takes a more active role in the decision process. The definition of adherence according to the World Health Organization [34] is "the extent to which a person’s behaviour – taking medicine, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a health-care provider". Adherence and non-adherence are complex phenomena. Non-adherence to long-term therapies is estimated to be about 50 percent [34]. Many of the reasons for non-adherence are behavioural and non-adherence can therefore be both intentional and non-intentional [35]. Non-adherence to medication leads to increased use of health care services [36-37], can lead to therapy failure and have negative effects on patients’ health [36]. Adherence to asthma/COPD treatment is
particularly low and international studies show that only 40–80 percent of the asthma medications and 45–60 percent of the COPD medications are used as prescribed [38-40]. A Swedish thesis reported the adherence to long-term treatment with asthma/COPD medication to be 57 percent, with both oversupply (22 %) and undersupply (21 %). Patients who were undersupplied had medication available half of the prescribed treatment time [41].

1.4.3 Prescribing of medication to non-recommended diagnoses

Off-label prescribing, i.e. the prescribing of medications to non-recommended diagnoses, is common. In such prescribing a registered medicine is used in a manner not included in the licence, such as the use of drugs in non-approved age groups, unrecommended doses, formulations or indications [42]. In the United States, 40 percent of the medications for asthma were prescribed off-label [43]. Even though not recommended, it may sometimes be clinically appropriate. However, in the United States, 73 percent of the off-label prescriptions had no or little scientific support [42], and was associated with a number of safety, clinical and ethical issues.
2 AIM

2.1 General aim
The overall aim of this thesis was to evaluate the quality of diagnoses and medication in patients with asthma and COPD in Swedish primary care.

2.2 Specific aims
- To study the adherence to recommended guidelines and quality indicators in diagnosis and treatment of patients with asthma and COPD.
- To survey the relationship between the diagnosis of asthma/COPD and the prescribing of asthma/COPD medication.
3 POPULATION AND METHODS

3.1 Setting

3.1.1 Skaraborg Primary Care Database (SPCD)

The Skaraborg area in the Swedish region Västra Götaland, is located in the southwest of Sweden, and had approximately 255,000 inhabitants in 2005, corresponding to 2.8 percent of the Swedish population [44]. It is a rural area with small municipalities and a few medium-sized towns. Income levels and educational levels are somewhat below the national average. The area has a well established health care system with, during the period of the studies, 24 primary care PHCCs, one private clinic and a few private general practitioners. The PHCCs of the area have developed management programmes for patients with asthma and COPD including spirometry and care promoted by specially trained nurses. Both studies in this thesis were performed using data from Skaraborg Primary Care. All PHCCs share the same computerized medical record system operated locally at each PHCC. The Skaraborg Primary Care Database (SPCD) was initiated in 2000, as a database for research and auditing, automatically extracting data from each local PHCC database. Patients and staff identities are blinded and assigned specific identification numbers. In the database diagnoses are coded according to the 10th version of the International Classification of Diseases (ICD) adapted for primary care [45]. The ICD-codes are recorded in the computerized medical record either by the physician during the patient’s visit or by the secretary from the physician’s dictation. Prescription information is automatically recorded in the computerized medical record at the time of the prescription and includes the name of the drug, potency, ATC-code (Anathomical Therapheutic Chemical Classification) [46] and amount of drug prescribed.

3.2 Population and data collection

3.2.1 Population data (study 1 and study 2)

From the total population of individual records in SPCD, data on patients diagnosed with asthma or COPD visiting the health care centres during the period of 2000–2005 were extracted for the studies. Selection criteria were:
diagnosis of asthma and/or COPD registered during the study period, and with at least one subsequent contact with primary health care during 2004–2005 irrespective of the cause. The selected ICD-codes for case finding were J45 for asthma and J44 for COPD. All individuals with at least one prescription of asthma/COPD medication issued during 2004–2005 were also extracted regardless of diagnoses. Included drugs with respective ATC-code [45] were short-acting β2-adrenergics (SABA; ATC R03AC02 and R03AC03), long-acting β2-adrenergics (LABA; R03AC12 and R03AC13), inhaled corticosteroids (ICS; ATC-codes R03BA01, R03BA02, R03BA05 and R03BA07), and fixed combinations of long-acting β2-adrenergics and glucocorticoids (R03AK06 and R03AK07). Drugs belonging to the R03BB group (anticholinergics) were not included, since the focus from the start was asthma.

3.2.2 Random sample for detailed analysis (study 1 and study 2)

From the extracted SPCD-records a sample of 5 percent (n = 945) was randomly selected for detailed analysis. In the detailed analysis data from the patients’ medical records were manually extracted using a structured form (Appendix). A total of 43 individuals were excluded due to lack of information in their medical records and the final sample for detailed analysis consisted of 902 individuals. A schematic outline of the patient selection is presented in Figure 1.
3.2.3 Analysis of the individual studies

Study 1
In study 1 the patients with recorded diagnoses of asthma and/or COPD, from the total population (n = 12,328) and from the random sample (n = 623), were included. In the detailed analysis the data extracted from their medical records included date of visit, performed diagnostic procedures, performed procedures at follow-up and medication prescribed. For procedures performed in incident (new) cases, data from the initial visits in primary care due to respiratory problems were analysed. Evaluations within six months
were referred to “initial visits”. Patients were considered as prevalent (already ongoing disease) if they had had their initial visits during 2002 or earlier and in the follow-up analysis only prevalent cases were included. Attendance at follow-up was defined as the proportion of the prevalent patients who visited the PHCC at least once during 2004–2005. Mixed cases with diagnosis of both asthma and COPD were categorized into the COPD-group.

Performed procedures were compared with guidelines and quality indicators as recommended by expert committees [20,47-48]. The agreement of applied procedures with recommended procedures was used as a measure of quality. Proposed quality indicators at diagnosis and at follow-up are presented in Table 1. Available quality indicator targets are also included in Table 1.

Table 1. Quality indicators at initial visits and at follow-up visits in asthma and COPD

<table>
<thead>
<tr>
<th>Quality indicators at initial visits</th>
<th>Standard targets³</th>
</tr>
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<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients with spirometry or repeated PEF¹,⁴</td>
<td>-</td>
</tr>
<tr>
<td>Proportion of patients with smoking status recorded¹</td>
<td>-</td>
</tr>
<tr>
<td>Proportion of patients with an allergy testing¹</td>
<td>-</td>
</tr>
<tr>
<td>Proportion of patients with spirometry¹</td>
<td>-</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients with smoking status recorded¹</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality indicators at follow-up</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients attending follow-up¹</td>
<td></td>
</tr>
<tr>
<td>Proportion of patients with an acute/unscheduled visit²</td>
<td>&lt; 10 %</td>
</tr>
<tr>
<td>Proportion of patients with spirometry¹</td>
<td></td>
</tr>
<tr>
<td>Proportion of patients on ICS²,⁵</td>
<td>&gt; 60 %</td>
</tr>
<tr>
<td>Proportion of patients on ICS with spirometry²</td>
<td>&gt; 50 %</td>
</tr>
<tr>
<td>Proportion of patients with smoking status recorded¹</td>
<td></td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients attending follow-up¹</td>
<td>-</td>
</tr>
<tr>
<td>Proportion of patients with spirometry¹,²</td>
<td>&gt; 90 %</td>
</tr>
</tbody>
</table>

¹National Board of Health and Welfare
²The Swedish Association of General Practice: The Standing Committee for Quality Improvement
³Proportion of patients
⁴Peak Expiratory Flow
⁵Inhaled corticosteroids
Study 2
In study 2 patients with asthma/COPD medication from the total population (n = 14,101) and from the random sample (n = 670) were included. Data extracted from their medical records for the detailed analysis included indication for prescription (ICD-code or written free text field when no ICD-code was given), clinical evaluation and type and number of prescriptions. The medication users were categorized into: Asthma recorded diagnosis: ICD-code of asthma recorded in the SPCD. COPD recorded diagnoses: ICD-code of COPD recorded in the SPCD. Patients with both asthma and COPD were included in this group. Provisional diagnoses: Diagnosis of asthma or COPD based on written notes in the text part of the medical records. Trial of medication: The physician was uncertain about the diagnosis, to be confirmed by the response to the medication. Off-label: No information in the medical record of the patient having asthma/COPD or when the medication was prescribed for other non-recommended indications. A prescription issued in Sweden is valid for one year, while for long-term medication prescriptions are commonly issued for the entire year of treatment. Indication for prescription, as well as type and number of prescriptions, as compared to recommended was used as a measure of quality.

3.3 Statistical methods
Descriptive statistics were performed using Statistics Package for Social Sciences (SPSS version 19.0 for PC). Data are numbers (n) and proportions (%) and differences between groups in categorical variables were estimated by Chi-2 tests. Statistical significant differences were assumed when p<0.05. All tests were two-sided.

3.4 Ethics
Regional Ethics Review Board at Gothenburg University (Dnr. 191-07) approved the studies.
4 RESULTS

4.1 Population data (study 1 and study 2)

The first selection of patients from the database generated a total of 18,892 individuals. Asthma diagnosis was recorded for 9,296 individuals, 2,288 had COPD and 744 had both asthma and COPD. The prevalence of asthma and COPD based solely on recorded diagnoses was 3.6 % and 1.2 % respectively for the Skaraborg population. Medication was prescribed to 14,101 individuals in SPCD (corresponding to approximately 6 % of the total population in Skaraborg). Among patients with asthma, medication was prescribed to 5,876 (63 %) individuals, to 1,116 (49 %) with COPD and to 545 (73 %) with both asthma and COPD. No medication had been prescribed to 3,420 of the individuals with diagnosed asthma (37 %), to 1,172 with diagnosed COPD (51 %) and to 199 with both asthma and COPD (27 %). A total of 6,564 individuals were prescribed medication, but lacked a diagnosis of asthma or COPD, corresponding to 47 % of the total population of medication users (n = 14,101). The lack of congruence between medication users and individuals with a recorded diagnosis of asthma or COPD is presented graphically in a Venn diagram in Figure 2.
The total prevalence of asthma/COPD medication users in the SPCD was 5.6%. In the age group 0–9 years the prevalence of medication use was 2.7%. This prevalence increased with age and peaked in the age-groups 60–69 years and 70–79 years (7.1% and 8.3% respectively). The average gap between medication and diagnosis was 2.6 percentage points. It was lowest among the youngest (1.3 percentage points) and increased with age and peaked in age-groups between 60–79 years with a gap of 3.1 percentage points. In the youngest age group asthma was the predominant diagnosis whereas in the older COPD contributed to a large extent.
4.2 Random sample (study 1 and study 2)

The random sample comprised 945 individuals with asthma/COPD or medication prescribed. A total of 43 individuals were excluded due to incorrectly entered diagnoses or lack of information in their medical records. The final sample for analysis thus consisted of 902 individuals. Baseline characteristics of the patients, both the population from the SPCD and the random sample are presented in Table 2.
Table 2. Characteristics of the individuals in the population and from the random sample

<table>
<thead>
<tr>
<th></th>
<th>Total population</th>
<th></th>
<th>Random sample</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Asthma</td>
<td>COPD</td>
<td>Asthma/COPD</td>
<td>Medication only</td>
</tr>
<tr>
<td></td>
<td>n = 9,296</td>
<td>n = 2,288</td>
<td>n = 744</td>
<td>n = 6,564</td>
</tr>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td></td>
<td>Female</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4,066 (44)</td>
<td>1,156 (51)</td>
<td>305 (41)</td>
<td>2,675 (41)</td>
</tr>
<tr>
<td></td>
<td>209 (42)</td>
<td>57 (59)</td>
<td>10 (36)</td>
<td>119 (43)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>5,230 (56)</td>
<td>1,132 (49)</td>
<td>439 (59)</td>
</tr>
<tr>
<td></td>
<td>290 (58)</td>
<td>40 (41)</td>
<td>17 (63)</td>
<td>160 (57)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>0–17</td>
<td>2,095 (23)</td>
<td>3 (0)</td>
<td>5 (1)</td>
</tr>
<tr>
<td></td>
<td>18–70</td>
<td>5,889 (63)</td>
<td>1,149 (50)</td>
<td>382 (51)</td>
</tr>
<tr>
<td></td>
<td>71+</td>
<td>1,312 (14)</td>
<td>1,136 (50)</td>
<td>357 (48)</td>
</tr>
<tr>
<td></td>
<td>102 (21)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>331 (66)</td>
<td>57 (59)</td>
<td>15 (56)</td>
<td>188 (67)</td>
</tr>
<tr>
<td>Asthma/COPD medication</td>
<td>1,312 (14)</td>
<td>1,136 (50)</td>
<td>357 (48)</td>
<td>904 (14)</td>
</tr>
<tr>
<td>All</td>
<td>5,876 (63)</td>
<td>1,116 (49)</td>
<td>545 (73)</td>
<td>All</td>
</tr>
<tr>
<td>All</td>
<td>341 (68)</td>
<td>62 (64)</td>
<td>24 (89)</td>
<td>All</td>
</tr>
</tbody>
</table>

1 Asthma/COPD medication: short-acting adrenergics (ATC-codes R03AC02 and R03AC03), long-acting adrenergics (R03AC12 and R03AC13), glucocorticoids (R03BA01, R03BA02, R03BA05 and R03BA07) and combination of adrenergics and steroids (R03AK06 and R03AK07)
Adherence to guidelines (study 1)
A total of 623 individuals in the random sample had a diagnosis of asthma and/or COPD recorded during 2000–2005. At initial visit among 499 individuals with asthma, 167 (33 %) were evaluated with spirometry or repeated PEF within six months, and thus in agreement with recommendation. An additional single PEF was performed on 95 individuals (19 %), and a total of 262 individuals (53 %) were thus objectively evaluated at initial visit. More adults had their diagnosis based on objective measures compared to children and adolescents (58 vs. 36 %; p< 0.001). For patients with COPD 40 individuals out of 124 (32 %) were objectively evaluated with spirometry.

A total of 462 individuals had prevalent asthma or COPD defined as described in the method section. Among 371 prevalent patients with asthma 217 (58 %) attended the PHCC for follow up. An additional 42 (11 %) had asthma medication prescribed. Attendance was lower among children and adolescents than among adults (46 % vs. 61 %; p = 0.029). Among 91 patients with COPD 77 attended follow-up (85 %) and 81 (89 %) attended follow-up/had a prescription issued. In asthma recommended evaluation with spirometry was performed on 82 individuals (38 %) or with repeated PEF-measurements on 22 (10 %) patients. Spirometry was performed on 35 (45 %) patients with COPD. During follow-up 44 % of the visits due to asthma and 45 % of the visits due to COPD were unscheduled or acute. Inhaled corticosteroids (ICS) (single or in combination with long-acting adrenergics) were prescribed to 167 (77 %) of the patients with asthma who attended follow-up. ICS was more frequently prescribed to adults (150; 79 %) than to children/adolescents (17; 61 %, p = 0.029). Performance procedures at initial visit and performed investigations at follow-up are presented in Table 3 and Table 4 respectively.
Table 3. Performed procedure and fulfilment of quality indicators at diagnosis in asthma and COPD. Table 1 shows quality indicators for asthma and COPD respectively

<table>
<thead>
<tr>
<th>Investigation procedure/ quality indicator</th>
<th>Asthma child/adolescent&lt;sup&gt;1&lt;/sup&gt; n = 125</th>
<th>Asthma adult&lt;sup&gt;1&lt;/sup&gt; n = 374</th>
<th>Asthma all n = 499</th>
<th>COPD and Asthma/ COPD&lt;sup&gt;2&lt;/sup&gt; n = 124</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Spirometry</td>
<td>22 (18)</td>
<td>79 (21)</td>
<td>101 (20)</td>
<td>40 (32)</td>
</tr>
<tr>
<td>Repeated PEF</td>
<td>10 (8)</td>
<td>56 (15)</td>
<td>66 (13)</td>
<td>15 (12)</td>
</tr>
<tr>
<td>Single PEF</td>
<td>13 (10)</td>
<td>82 (22)</td>
<td>95 (19)</td>
<td>21 (17)</td>
</tr>
<tr>
<td>Objective measure&lt;sup&gt;4&lt;/sup&gt;</td>
<td>45 (36)</td>
<td>217 (58)</td>
<td>262 (53)</td>
<td>76 (61)</td>
</tr>
<tr>
<td>Medical history alone</td>
<td>80 (64)</td>
<td>137 (37)</td>
<td>217 (43)</td>
<td>44 (35)</td>
</tr>
<tr>
<td>None of the above procedure</td>
<td>0 (0)</td>
<td>20 (5)</td>
<td>20 (4)</td>
<td>4 (3)</td>
</tr>
<tr>
<td>Smoking status recorded</td>
<td>26 (21)</td>
<td>133 (36)</td>
<td>159 (32)</td>
<td>85 (69)</td>
</tr>
<tr>
<td>Allergy testing</td>
<td>11 (9)</td>
<td>38 (10)</td>
<td>49 (10)</td>
<td>3 (2)</td>
</tr>
</tbody>
</table>

<sup>1</sup>Child/adolescent: age 0–17 years at time of initial visit, adult: age 18 years or older at time of initial visit

<sup>2</sup>Diagnosis of asthma and COPD in 27 individuals

<sup>3</sup>Percentage of the total number of patients

<sup>4</sup>Objective measure: spirometry or repeated PEF or single PEF
### Table 4 Performed investigation and fulfilment of quality indicators at follow-up in asthma and COPD

<table>
<thead>
<tr>
<th>Investigation procedure/quality indicator</th>
<th>Asthma child/adolescent&lt;sup&gt;1&lt;/sup&gt; n = 28</th>
<th>Asthma adult&lt;sup&gt;1&lt;/sup&gt; n = 189</th>
<th>Asthma all n = 217</th>
<th>COPD and Asthma/COPD n = 77</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute/unscheduled visit</td>
<td>6 (21)</td>
<td>90 (48)</td>
<td>96 (44)</td>
<td>35 (45)</td>
</tr>
<tr>
<td>Spirometry</td>
<td>7 (25)</td>
<td>75 (40)</td>
<td>82 (38)</td>
<td>35 (45)</td>
</tr>
<tr>
<td>Repeated PEF</td>
<td>1 (4)</td>
<td>21 (11)</td>
<td>22 (10)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Single PEF</td>
<td>2 (7)</td>
<td>24 (13)</td>
<td>26 (12)</td>
<td>9 (12)</td>
</tr>
<tr>
<td>Objective measure&lt;sup&gt;3&lt;/sup&gt;</td>
<td>10 (36)</td>
<td>120 (63)</td>
<td>130 (60)</td>
<td>45 (58)</td>
</tr>
<tr>
<td>Smoking status recorded</td>
<td>7 (25)</td>
<td>101 (53)</td>
<td>108 (50)</td>
<td>50 (65)</td>
</tr>
<tr>
<td>Patients on anti-asthma medication&lt;sup&gt;4&lt;/sup&gt;</td>
<td>22 (79)</td>
<td>172 (91)</td>
<td>194 (89)</td>
<td>61 (79)</td>
</tr>
<tr>
<td>Patients on ICS&lt;sup&gt;5&lt;/sup&gt;</td>
<td>17 (61)</td>
<td>150 (79)</td>
<td>167 (77)</td>
<td>43 (56)</td>
</tr>
<tr>
<td>Patients on ICS&lt;sup&gt;5&lt;/sup&gt; with spirometry</td>
<td>6 (21)</td>
<td>67 (45)</td>
<td>73 (44)</td>
<td>26 (60)</td>
</tr>
</tbody>
</table>

<sup>1</sup> Child/adolescent: age 0–17 years at time of follow-up, adult: age 18 years or older at time of follow-up

<sup>2</sup> Percentage of the total number of patients

<sup>3</sup> Objective measure: spirometry or repeated PEF or single PEF

<sup>4</sup> Anti-asthma medication: See Table 2

<sup>5</sup> Inhaled Corticosteroids
Diagnosis in relation to prescribing (study 2)
The detailed analysis of the random sample is presented in Table 5. A total of 670 individuals in the random sample were prescribed asthma/COPD medication during 2004–2005. Among these, a recorded diagnosis was found for 391 individuals (58 %); a diagnosis of asthma was present for 320 patients and 71 had COPD. Consequently, 279 (42 %) individuals lacked a recorded diagnosis. Out of these individuals 44 (16 %) had a provisional diagnosis. Among the remaining 235 individuals 85 (30 %) were prescribed medication on trial and 150 (54 %) individuals were prescribed off-label. A statistical non-significant result indicated that more women than men were prescribed off-label (p = 0.061). The most common indications found for off-label prescribing were symptoms of cough, airway obstruction or dyspnoea (n = 21; 14 %), diagnosis of cough (n = 18; 12 %) or acute bronchitis (n = 16; 11 %).
<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Recorded asthma diagnosis</th>
<th>Recorded COPD diagnosis</th>
<th>Provisional diagnosis</th>
<th>Trial by medication</th>
<th>Off-label Prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>n  (%)</td>
<td>n  (%)</td>
<td>n  (%)</td>
<td>n  (%)</td>
<td>n  (%)</td>
</tr>
<tr>
<td>All patients</td>
<td>670</td>
<td>320 (48)</td>
<td>71 (11)</td>
<td>44 (7)</td>
<td>85 (13)</td>
<td>150 (22)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>295</td>
<td>140 (44)</td>
<td>36 (51)</td>
<td>24 (55)</td>
<td>39 (46)</td>
<td>56 (37)</td>
</tr>
<tr>
<td>Female</td>
<td>375</td>
<td>180 (56)</td>
<td>35 (49)</td>
<td>20 (45)</td>
<td>46 (54)</td>
<td>94 (63)</td>
</tr>
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<td>Age groups</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–17</td>
<td>100</td>
<td>59 (18)</td>
<td></td>
<td>8 (18)</td>
<td>11 (13)</td>
<td>22 (15)</td>
</tr>
<tr>
<td>18–70</td>
<td>452</td>
<td>223 (70)</td>
<td>41 (58)</td>
<td>27 (61)</td>
<td>58 (68)</td>
<td>103 (69)</td>
</tr>
<tr>
<td>≥ 71</td>
<td>118</td>
<td>38 (12)</td>
<td>30 (42)</td>
<td>9 (20)</td>
<td>16 (19)</td>
<td>25 (17)</td>
</tr>
<tr>
<td>Number of prescriptions</td>
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</tr>
<tr>
<td>1 prescription</td>
<td>332</td>
<td>135 (42)</td>
<td>22 (31)</td>
<td>25 (57)</td>
<td>34 (40)</td>
<td>116 (77)</td>
</tr>
<tr>
<td>2 prescriptions</td>
<td>196</td>
<td>117 (37)</td>
<td>16 (23)</td>
<td>15 (34)</td>
<td>26 (31)</td>
<td>22 (15)</td>
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<td>≥ 3 prescriptions</td>
<td>142</td>
<td>68 (21)</td>
<td>33 (46)</td>
<td>4 (9)</td>
<td>25 (29)</td>
<td>12 (8)</td>
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<td>Therapy groups(^2)</td>
<td>Number of Prescriptions</td>
<td>Therapy Steps</td>
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<td></td>
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<tr>
<td>SABA only</td>
<td>207</td>
<td>54 (17)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>15 (21)</td>
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<td>14 (32)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>29 (34)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>95 (63)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS and SABA</td>
<td>141</td>
<td>83 (26)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
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<td>7 (10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td>13 (30)</td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>24 (28)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
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<td></td>
<td>14 (9)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>ICS and LABA</td>
<td>91</td>
<td>55 (17)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 (17)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>7 (16)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>6 (7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>11 (7)</td>
<td></td>
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</tr>
<tr>
<td>Fixed combination of</td>
<td>175</td>
<td>102 (32)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS/LABA</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
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<td>8 (18)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>17 (20)</td>
<td></td>
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<td></td>
<td>14 (9)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>ICS only(^3)</td>
<td>56</td>
<td>26 (8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 (4)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>2 (5)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>9 (11)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>16 (11)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Clinical evaluation | Number of Prescriptions | Therapy Steps | |
|---------------------|-------------------------|---------------|
| PEF\(^4\) only     | 36                      | 25 (8)        |
|                     |                         | 1 (1)         |
|                     |                         | 1 (2)         |
|                     |                         | 2 (2)         |
|                     |                         | 7 (5)         |
| Spirometry          | 207                     | 110 (34)      |
|                     |                         | 37 (52)       |
|                     |                         | 16 (36)       |
|                     |                         | 24 (28)       |
|                     |                         | 20 (13)       |

\(^1\) Number of prescriptions = number of occasions where the patient had one or more medications prescribed

\(^2\) Therapy groups according to the treatment steps in the therapy recommendations, SABA = Short acting beta-2-agonists; LABA = Long-acting beta-2-agonists; ICS = Inhaled Corticosteroids

\(^3\) ICS is not recommended as monotherapy

\(^4\) PEF = Peak Expiratory Flow
5 DISCUSSION

This thesis is an extensive survey of the quality of the diagnoses of asthma and COPD in Swedish primary care and its relation to drug prescribing based on individual data of patients of different ages.

The Venn diagram in Figure 2, shows a complex representation of patients with diagnoses of asthma or COPD, and with medication for asthma/COPD. In an ideal scenario the areas of diagnoses and medication should overlap, but that is only partially the case. A considerable proportion of the individuals with asthma did not have any medication prescribed during the study period. Approximately half (47%) of the patients with recorded diagnosis of asthma (study 1) were lacking objective evaluation during their initial visits. Therefore it could be expected that some of them were incorrectly diagnosed with asthma, i.e. over-diagnosing, thus accounting for some of the observed incongruence between diagnosis and medication. Additional explanations could be under-medication, since our data show that among patients with asthma and medication approximately half (42%) of the individuals had only one prescription during the two-year study period. Those patients, along with those with no medication (36%), show that under-medication is common in asthma according to observations also supported by others [48]. Approximately half of the individuals prescribed asthma/COPD medication had no diagnosis of asthma or COPD recorded, which could indicate over-medication. This interpretation is supported by the findings (study 2) that off-label prescribing was common. Under-diagnosing of individuals who actually had asthma or COPD may also contribute, which is supported by the observation of low prevalence of 3.6 percent and 1.2 percent for asthma and COPD, respectively. Thus asthma diagnoses where no drugs were prescribed may be due to over-diagnosing and under-medication whereas prescribed medication with no diagnoses may be due to over-medication and off-label prescribing or under-diagnosing.

5.1 Adherence to guidelines

We found that about one third of the patients with asthma or COPD during initial visits, and approximately half of the patients during follow-up, had a clinical evaluation, including spirometry or PEF, in agreement with recommendations.
There are few studies measuring clinical evaluation in patients with asthma. In the current study the quality of the clinical evaluation was expressed as the agreement between applied and recommended procedure. The results show that during initial visits agreement with recommended procedure was observed for 33 percent of the patients with asthma. In the Netherlands, Schellevis et al found that 58 percent of the patients with obstructive pulmonary diseases were evaluated in full agreement with recommendations [23]. However, in that study there was no separation between patients with asthma and patients with COPD. Among the patients with COPD 32 percent had spirometry performed, which further supports the previous findings of diagnostic shortfalls in COPD. Related data show that in the United States 32 percent and in Denmark 50 percent of the patients diagnosed with COPD had spirometry performed [25-26]. In a Swedish study 53 percent of the patients with COPD had spirometric data in connection to their diagnosis according to their primary care medical record and additional 6 percent in their record from outpatient clinics (secondary care) [50].

During follow-ups approximately half of the patients with asthma were managed in agreement with the recommendations. A majority of the patients were prescribed ICS in accordance with recommendation; 77 percent had a prescription of ICS and the target standard is set at a minimum of 60 percent. In spite of this high level of prescribed ICS almost every second patient made an acute visit during the follow-up period, whereas the target standard is set at a maximum of 10 percent. Thus a large proportion of the patients do not seem to have their disease under control. One of the reasons may be low adherence, i.e. that prescribed medicines are not always dispensed [51] or consumed. A Swedish study showed that patient refill adherence for ICS-treatment was only 34 percent [52].

5.2 Diagnosis in relation to prescribing

The detailed examination of medical records shows that more than half of the undiagnosed medication users (54 %) had the medication prescribed off-label (study 2). Medication was often used as a diagnostic tool (30 %) and 16 percent of the individuals had provisional diagnoses of asthma or COPD.

Approximately half of the medication users without recorded diagnoses of asthma or COPD were prescribed off-label. Our results confirm previous findings of off-label prescribing by indication [43,53]. Many previous studies
have involved only children [54-55]. Our study shows that off-label prescribing of asthma/COPD medication is also common in adults and used to treat patients with diagnoses of acute bronchitis and cough. The Cochrane group found no evidence for such prescribing [56] and in addition, the use of medication off-label may be a waist of resources in health care and the risk of adverse reactions is common in off-label prescribing of asthma medication [57]. Among individuals where medication was used as a diagnostic tool the subjective response to medication might have replaced objective measurements, since fewer were investigated with PEF or spirometry (Table 5), as also shown elsewhere [58].

Among patients with asthma 79 percent of the patients were issued a medication once or twice (Table 5), indicating that patients with asthma have been adequately provided with medication for their treatment. However, when considering also those patients with no prescription (n = 3,420; 37 %) (Figure 2), we conclude that this was not the case. Our results thus support previous findings showing that patients with asthma are sub-optimally treated and that their adherence to medication is low [9,28]. For patients with COPD the situation seems somewhat different. They had more prescriptions issued (Table 5) and almost half of the patients (46 %) with COPD were prescribed medication on three or more occasions during the study period. Assuming one year’s supply for each prescription, our data indicate over-medication. However, since under-detection is common [11], the patients detected and diagnosed may be those with the more severe COPD and therefore in need of more medication. This interpretation is further supported by the more common use of LABA and fixed combination of LABA/ICS among patients with COPD, and the fact that these medications are to be used in the moderate to severe stages of COPD [3,20].

The use of asthma/COPD medication as a proxy for disease prevalence is an on-going debate. Our study confirms previous results of incongruence between diagnosis and prescription [43,53,55]. Others have shown a close resemblance between prevalence of medication and prevalence of disease in asthma/COPD [9,59]. However, in these studies the use of non-linked data sets and the lack of information about diagnoses in databases with dispensed medication are limitations. On the other hand, diagnoses as asthma and COPD are also uncertain, with over-diagnosing and under-diagnosing, leading to validity problems. In the current study, the gap presented in Figure 2 indicates that the levels of asthma/COPD medication cannot be used as a proxy for asthma/COPD disease prevalence.
6 METHODOLOGICAL ASPECTS

The first selection of individuals with asthma, COPD and/or asthma/COPD medication from the SPCD gave an overview of patients and showed the incongruence between diagnoses and prescription. The observed incongruence raised the questions about quality of recorded diagnoses, and quality of prescribing. The detailed analysis, by selection of a random sample and the manual extraction of data from the medical records, gave an opportunity to study each individual in detail, in an attempt to find the answer to the questions raised. The strengths and limitations in respective areas are discussed below.

6.1 Setting and source of data

One of the strengths of this study is the large size of the sample and the coverage of the population in the geographic area, since the database is almost complete for Skaraborg. The data were also considered to be representative not just for the area of Skaraborg but also for Sweden, since the area includes towns as well as rural areas and has an age distribution similar to that of the nation [60]. However, other areas and other countries could deviate.

6.2 SPCD

When using information in medical records from routine care there is always the risk that performed investigations and treatment have not been documented in the patient records. In such cases the observed level of agreement with recommended procedure would be underestimated. There is also a risk that a patient, who has been subjected to a clinical evaluation in agreement with recommended procedure, still does not get the correct diagnosis. However, an evaluation in agreement with the recommendations increases the probability of a correct diagnosis of high quality. The detailed analysis of the free text field in the medical records with manual documentation of performed procedures is also an advantage. Even though this size of sample was restricted for practical reasons (5 %, n = 902) it was considered large enough to give a description applicable to the whole
population, since the characteristics of the complete sample and the random sample were very similar.

6.3 Prescriptions

In this study we are limited to data from primary care. Data from additional caregivers managing the patient and prescribing medicines are not included. We do not know whether the patients really have their medicines dispensed from the pharmacy, and if the patients use the acquired medication. In both cases there is a risk of overestimation of drug use. The medication use was limited to asthma/COPD medication. The treatment with anticholinergics exclusively used in COPD, was not included, since the initial focus was asthma. This probably underestimates the medication use among patients with COPD. Our data is limited to off-label by indication. Off-label use related to age, dosage, duration of time or route of administration was not examined. Medication use was defined as prescribed medication at the patient level. Information about volumes of medication was not included in these studies.
7 CONCLUSIONS

- There is incongruence between diagnoses of asthma or COPD and prescription of medication, consistent in all age-groups, which indicates that the levels of asthma/COPD medication cannot be used as proxy for asthma/COPD disease prevalence.
- Asthma/COPD medication is often prescribed outside recommendations and used both as a diagnostic tool and in an off-label manner.
- Patients with asthma seem to be inadequately treated, since approximately one third of all patients with recorded diagnoses of asthma are non-medicated, one third use medication sparsely and only one third use medication continuously.
- Adherence to recommended guidelines is low since only one third of the patients with diagnoses of asthma or COPD during initial visits, and about half of the patients during follow-up, had a clinical evaluation, including spirometry or PEF, in agreement with recommendations.
- The prescribing of ICS-treatment reaches the quality indicator target, still patients with asthma seem to be uncontrolled in their disease, indicating low adherence to medication.
- There is substantial room for quality improvement in the clinical evaluation of patients with asthma and COPD and there is a need to observe the extent of off-label prescribing in asthma/COPD medication.
8 FUTURE ASPECTS

There is a need to improve the knowledge about the outcome for the patient due to incomplete evaluation in diagnosing diseases and prescribing of medicines off-label. This could be done in studies with a longitudinal design, following patients for several years. SPCD contains medical records from 2000 and is continuously updated. This gives the opportunity for longitudinal studies of patients’ outcome, not only patients with asthma or COPD, but of all patients visiting primary health care. The possibility of extracting patients’ personal identification numbers adds to the possibility of linkage with national registries such as the Swedish Prescribed Drug Register at the National Board of Health and Welfare, giving the opportunity for studies such as adherence to medication and total medication exposure at the individual level. Linkage with other national registries such as the Hospital Discharge Register and the Cause of Death Register gives the opportunity to study a broad range of factors of importance for patient outcomes. An interesting aspect would be to investigate the variation in practice between different clinics and different physicians in order to find out the impact of such variables on the diagnostic procedure and the off-label prescribing of medicines.

For patients to receive a proper treatment of their disease there has to be a proper diagnosis. Therefore the compliance to evidence-based guidelines has to be improved. Objective measurements of lung function with spirometry is worthwhile and necessary for a proper diagnosis; however, the lack of time in a busy schedule might have an impact on how to deal with these issues. The process of diagnosing the disease has to be improved, as well as the management and follow-up of patients with existing asthma or COPD. In order to achieve good control of the disease the patients need to be regularly seen by the doctor or a nurse. Scheduled appointments instead of “calling when you need it” could probably have a large impact on the patient’s adherence to medication and accordingly to their control of the disease.
Målsättning: Den övergripande målsättningen med denna avhandling var att utvärdera kvaliteten vid diagnostik och behandling av patienter med astma och KOL (Kroniskt Obstruktiv Lungsjukdom) i svensk primärvård. De specifika målen var att undersöka hur rekommenderade riktlinjer och kvalitetsindikatorer följs vid diagnostik samt vid läkemedelsförskrivning till patienter med astma och KOL samt att kartlägga sambandet mellan förekomst av diagnostiserad astma/KOL och förskrivna astma/KOL-läkemedel.


Resultat: Bland 499 patienter med astma undersöktes 167 (33 %) med spirometri eller Peak Expiratory Flow (PEF-mätning) under första besöken och i enlighet med riktlinjer. På motsvarande sätt undersöktes 40 utav 124 patienter med KOL (32 %) med spirometri. Under senare uppföljning, utfördes utvärdering i enlighet med riktlinjer på 130 (60 %) av patienterna med astma och på 35 patienter av 77 (45 %) med KOL. Trots att förskrivningen av inhalationssteroider (ICS) nådde uppsatta kvalitetsmål, gjorde varannan patient ett akutbesök under uppföljningen.

Astma/KOL-läkemedel förskrevs i primärvården till ungefär 6 % av hela befolkningen i Skaraborg. Totalt sett registrerades diagnoser för astma, KOL eller både och hos 54 % av läkemedelsanvändarna. Av detta följer att 46 % saknade astma/KOL-diagnos. Inkongruensen mellan registrerad diagnos och förskrivet läkemedel existerade i alla
åldersgrupper. Bland patienter med registrerad astmadiagnos hade 37 % inte någon medicinering ordinerad.

**Slutsats:**

- Astma/KOL-läkemedel förskrivs ofta utanför rekommendationer och används både som diagnostiskt verktyg samt förskrivs off-label.
- Patienter med astma verkar vara ofullständigt behandlade, eftersom närmare en tredjedel av alla patienter med registrerade astmadiagnoser står utan läkemedelsbehandling, en tredjedel använder läkemedel sparsamt och endast en tredjedel använder läkemedel kontinuerligt.
- Följsamheten till rekommenderade riktlinjer är låg vid diagnostik av astma och KOL. Endast en tredjedel av patienterna vid första besöken, samt cirka hälften vid uppföljningen, fick en klinisk utvärdering med spirometri eller PEF, i enlighet med rekommendationer.
- Trots att förskrivningen av inhalationssteroider uppnår uppsatta kvalitetsmål, verkar patienter med astma okontrollerade i sin sjukdom, vilket indikerar låg följsamhet till läkemedelsordination.
- Det finns ett behov av kvalitetsförbättring av den kliniska utvärderingen av patienter med astma och KOL, och det finns behov av att observera omfattningen av off-label förskrivning av astma/KOL-läkemedel.
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11 REFERENCES


12 APPENDIX

Structured form for manual extraction of data from medical record (in Swedish).

DVårdcentral ID:_______

DID:__________

D1. Sjukdomsdebut:
1 = Ej känd
2 = Före 2000
3 = Under 2000–2005
4 = Notat felaktigt infogat i patientjournal enligt beh läkare

D2. Datum för första besök relaterat till astma eller KOL: YYYY-MM-DD
(besvär tas upp eller förskrivning sker)
Om mer än 5 år sedan föregående besök = detta besök räknas som första besök

D2.0 Sjukdomsdebut inom journalgenomgång?
0 = Ej känd
1 = Ja

D2.01 Inget besök inom journalgenomgång
0/missing = Stämmer ej
1 = Stämmer

D2.1 Diagnos registrerad (tillhörande andningsorganen):
0 = Nej
1 = Astma
2 = KOL
3 = Både astma och KOL
4 = Annan sjukdom luftvägarna
D3. Genomförd procedur vid första besök relaterat till astma eller KOL:
D3.1 Ej känd 0 = Nej 1 = Ja
D3.2 Anteckning om astma respektive KOL 0 = Nej 1 = Ja
D3.3 Sjukdomsanamnes 0 = Nej 1 = Ja
D3.4 Enstaka PEF-värde 0 = Nej 1 = Ja
D3.5 PEF-variabilitet 0 = Nej 1 = Ja
D3.6 Spirometri 0 = Nej 1 = Ja
D3.7 Lungröntgen 0 = Nej 1 = Ja
D3.8 Allergiutredning 0 = Nej 1 = Ja
D3.9 Rökanamnes 0 = Nej 1 = Ja

D3.1.A Förskrivning vid detta tillfälle?
0 = Nej
1 = Ja

D4. Återbesök relaterat till astma eller KOL inom 6 månader från första besök?
0 = Nej
1 = Ja

D4.B Diagnos registrerad(tillhörande andningsorganen) vid återbesök:
0 = Nej
1 = Astma
2 = KOL
3 = Astma och KOL
4 = Annan

Genomförd procedur vid återbesök relaterat till astma eller KOL:
D4.1 Ej känd 0 = Nej 1 = Ja
D4.2 Anteckning om astma respektive KOL 0 = Nej 1 = Ja
D4.3 Sjukdomsanamnes 0 = Nej 1 = Ja
D4.4 Enstaka PEF-värde 0 = Nej 1 = Ja
D4.5 PEF-variabilitet 0 = Nej 1 = Ja
D4.6 Spirometri 0 = Nej 1 = Ja
D4.7 Lungröntgen 0 = Nej 1 = Ja
D4.8 Allergiutredning 0 = Nej 1 = Ja
D4.9 Rökanamnes 0 = Nej 1 = Ja

D4.1.A Förskrivning vid detta tillfälle?
0 = Nej
1 = Ja
D5. Datum för senaste besök relaterat till astma eller KOL: YYYY-MM-DD

D5.0 Ej aktuellt pga endast ett besök relaterat till astma eller KOL (=första):
0 = Nej
1 = Ja

D5.1 Diagnos registrerad(tillhörande andningsorganen):
0 = Nej
1 = Astma
2 = KOL
3 = Både astma och KOL
4 = Annan

6. Genomförd procedur vid senaste besök relaterat till astma eller KOL:
D6.1 Ej känd 0 = Nej 1 = Ja
D6.2 Anteckning om astma respektive KOL 0 = Nej 1 = Ja
D6.3 Sjukdomsanamnes 0 = Nej 1 = Ja
D6.4 Enstaka PEF-värde 0 = Nej 1 = Ja
D6.5 PEF-variabilitet 0 = Nej 1 = Ja
D6.6 Spirometri 0 = Nej 1 = Ja
D6.7 Lungröntgen 0 = Nej 1 = Ja
D6.8 Allergiutredning 0 = Nej 1 = Ja
D6.9 Rökanamnes 0 = Nej 1 = Ja

D6.1.A Förskrivning vid detta tillfälle?
0 = Nej
1 = Ja

7. Genomförd procedur någon gång under perioden 2004-2005:
D7.1 Ej känd 0 = Nej 1 = Ja
D7.2 Anteckning om astma respektive KOL 0 = Nej 1 = Ja
D7.3 Sjukdomsanamnes 0 = Nej 1 = Ja
D7.4 Enstaka PEF-värde 0 = Nej 1 = Ja
D7.5 PEF-variabilitet 0 = Nej 1 = Ja
D7.6 Spirometri 0 = Nej 1 = Ja
D7.7 Lungröntgen 0 = Nej 1 = Ja
D7.8 Allergiutredning 0 = Nej 1 = Ja
D7.9 Rökanamnes 0 = Nej 1 = Ja
D7.10 Diagnoser registrerade hos individen under perioden 04-05
0 = Ingen
1 = Astma
2 = KOL
3 = Astma och KOL
4 = Annan luftväggssjukdom

D7.0 Ej aktuellt pga ej besök relaterat till astma eller KOL inom 04-05
0 = Nej
1 = Ja

D8. Vård även vid annan vårdenhet eller vårdnivå under 2004-2005, inkluderat förekomst av ApoDos:
0 = Ej känt
1 = Ja

D9.1 Antal besök på vårdcentralen relaterat eller möjligen (dvs luftväggssymtom som tyder på…) relaterat till astma eller KOL under perioden 2004-2005
0, 1, 2, 3, 4, 5…

D9.2 Varav journalförda akuta besök relaterat eller möjligen relaterat till astma eller KOL under tidsperioden 2004-2005
0 = Ej känt 1, 2,3,4…

D10. Akuta besök vid annan vårdenhet eller vårdnivå under tidsperioden 2004-2005
0 = Ej känt
1,2,3,4,5,6,7,8

D11 Antal förskrivningstillfällen av astma-kol preparat under 2004-2005
0 = Inga
1,2,3,4,5…

D12. Diagnoser hos patienten:
0 = Ingen
1 = Astma
2 = KOL
3 = Astma och KOL
D13. Diagnos avfärdad av läkare efter objektiva fynd?
0 = Ej känt
1 = Ja
2 = Objektiv undersökning aldrig utförd

D14. Patient avliden: dödsorsak:
0 = Stämmer ej eller uppgift ej tillgänglig i journalen
1 = Hjärtsvikt efter pneumoni
2 = UVI med njursvikt
3 = Ingen orsak angiven/dödsorsaksintyg utfärdat av annan vårdgivare
4 = KOL
5 = Cerebral infarkt, hypertoni, pneumoni
6 = Hjärtsvikt

L2. Debut för sjukdom eller besvär:
1 = Ej känd
2 = Före 2000
3 = Under 2000-2005
4 = Läkemedel ej förskrivet till patienten

L2.0 Debut inom journalgenomgång?
0 = Ej känt
1 = Ja

L3. Datum för första besök relaterat till astma respektive KOL: YYYY-MM-DD
(första besök där besvär tas upp eller förskrivning sker)
Om mer än 5 år sedan föregående besök = detta räknas som första besök

L3.0 Inget besök inom journalgenomgång?
0 = Stämmer ej
1 = Stämmer
Om patienten inte har något besök inom journalgenomgång så beskriver denna fråga datum för första förskrivning
4. Genomförd procedur vid första besök relaterat till astma respektive KOL:

L4.1 Ej känd
L4.2 Anteckning om astma respektive KOL
L4.3 Sjukdomsanamnes
L4.4 Enstaka PEF-värde
L4.5 PEF-variabilitet
L4.6 Spirometri
L4.7 Lungröntgen
L4.8 Allergiutredning
L4.9 Rökanamnes
0 = Nej 1 = Ja

L4.0 Förskrivning vid detta tillfälle?
0 = Nej
1 = Ja

L4.1.A Övriga indikationer eller symtom vid vilka förskrivning sker:
0 = Ej aktuellt hos denna individ
1 = J22-P Akut bronkit, ospecificerad nedre luftvägssjukdom
2 = J42 Kronisk bronkit
3 = J20 Akut bronkit
4 = J21 Akut bronkiolitis
5 = J43 Emfysem
6 = R05 Hosta
7 = J30.1-4 Allergisk rinit
8 = J98.-P Annan sjukdom i andningsorganen
9 = Obstruktivitet
10 = Symtom som hosta och liknande
11 = Patienten ber om preparatet utan att någon diagnosprocedur utförs
12 = Patient ber om via telefonkontakt
13 = Annat eller inget angivet
14 = J.06 ÖLI
15 = Mot astma eller KOL
16 = Diagnos Dyspne
17 = Andfåddhet symtom

L5. Återbesök inom 6 månader från första besök relaterat till astma eller KOL
0 = Nej
1 = Ja

Om patient utan besök inom journalgenomgång beskriver denna fråga eventuell andra förskrivning inom 6 mån från första
Genomförd procedur vid återbesök relaterat till astma eller KOL:
L5.1 Ej känd 0 = Nej 1 = Ja
L5.2 Anteckning om astma respektive KOL 0 = Nej 1 = Ja
L5.3 Sjukdomsanamnes 0 = Nej 1 = Ja
L5.4 Enstaka PEF-värde 0 = Nej 1 = Ja
L5.5 PEF-variabilitet 0 = Nej 1 = Ja
L5.6 Spirometri 0 = Nej 1 = Ja
L5.7 Lungröntgen 0 = Nej 1 = Ja
L5.8 Allergiutredning 0 = Nej 1 = Ja
L5.9 Rökanamnes 0 = Nej 1 = Ja

L5.0 Förskrivning vid detta tillfälle?
0 = Nej
1 = Ja

L5.1.A Övriga indikationer eller symtom vid vilka förskrivning sker:
0 = Ej aktuellt hos denna individ
1 = J22-P Akut bronkit, ospecificerad nedre luftvägssjukdom
2 = J42 Kronisk bronkit
3 = J20 Akut bronkit
4 = J21 Akut bronkiolitis
5 = J43 Emfysem
6 = R05 Hosta
7 = J30.1-4 Allergisk rinit
8 = J98.-P Annan sjukdom i andningsorganen
9 = Obstruktivitet
10 = Symtom som hosta och liknande
11 = Patienten ber om preparatet utan att någon diagnosprocedur utförs
12 = Patient ber om via telefonkontakt
13 = Annat
14 = ÖLI
15 = Mot astma eller KOL
16 = Diagnos Dyspne
17 = Andfåddhet symtom

L6. Datum för senaste besök relaterat till astma respektive KOL: YYYY-MM-DD

L6.0 Ej aktuellt pga endast ett besök relaterat till astma eller KOL (= första), eller återbesök:
0 = Nej
1 = Ja
7. Genomförd procedur vid senaste besök relaterat till astma respektive KOL:

(senaste besök där besvär tas upp eller förskrivning sker)

<table>
<thead>
<tr>
<th>L7.1</th>
<th>Ej känd</th>
<th>0 = Nej 1 = Ja</th>
</tr>
</thead>
<tbody>
<tr>
<td>L7.2</td>
<td>Anteckning om astma respektive KOL</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.3</td>
<td>Sjukdomsanamnes</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.4</td>
<td>Enstaka PEF-värde</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.5</td>
<td>PEF-variabilitet</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.6</td>
<td>Spirometri</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.7</td>
<td>Lungröntgen</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.8</td>
<td>Allergiutredning</td>
<td>0 = Nej 1 = Ja</td>
</tr>
<tr>
<td>L7.9</td>
<td>Rökanamnes</td>
<td>0 = Nej 1 = Ja</td>
</tr>
</tbody>
</table>

L7.0 Förskrivning vid detta tillfälle?

| 0 = Nej |
| 1 = Ja |

L7.1.A Övriga indikationer eller symtom vid vilka förskrivning sker:

| 0 = Ej aktuellt hos denna individ |
| 1 = J22-P Akut bronkit, ospecificerad nedre luftvägssjukdom |
| 2 = J42 Kronisk bronkit |
| 3 = J20 Akut bronkit |
| 4 = J21 Akut bronkiolitis |
| 5 = J43 Emfysem |
| 6 = R05 Hosta |
| 7 = J30.1-4 Allergisk rinit |
| 8 = J98.-P Annan sjukdom i andningsorganen |
| 9 = Obstruktivitet |
| 10 = Symtom som hosta och liknande |
| 11 = Patienten ber om preparatet utan att någon diagnosprocedur utförts |
| 12 = Patient ber om via telefonkontakt |
| 13 = Annat |
| 14 = ÖLI |
| 15 = Mot astma eller KOL |
| 16 = Diagnos Dyspne |
| 17 = Andfåddhet symtom |
8. Genomförd procedur någon gång under perioden 2004-2005:

L8.1 Ej känd 0 = Nej 1 = Ja
L8.2 Anteckning om astma respektive KOL 0 = Nej 1 = Ja
L8.3 Sjukdomsanamnes 0 = Nej 1 = Ja
L8.4 Enstaka PEF-värde 0 = Nej 1 = Ja
L8.5 PEF-variabilitet 0 = Nej 1 = Ja
L8.6 Spirometri 0 = Nej 1 = Ja
L8.7 Lungröntgen 0 = Nej 1 = Ja
L8.8 Allergiutredning 0 = Nej 1 = Ja
L8.9 Rökanamnes 0 = Nej 1 = Ja

L8.0 Ej aktuellt pga ej besök relaterat till astma eller KOL inom 04–05:
0 = Nej
1 = Ja

L9. Vård även vid annan vårdenhet eller vårdnivå under 04-05, inkluderat förekomst av ApoDos:
0 = Ej känt
1 = Ja

L10.1 Antal besök på vårdcentralen relaterat eller möjligen relaterat till astma eller KOL under perioden 2004-2005
0, 1, 2, 3, 4, 5…

L10.2 Varav journalförda akuta besök relaterat eller möjligen relaterat till astma eller KOL under tidsperioden 2004-2005
0 = Ej känt
1,2,3,4,5,6,7,8

L11. Akuta besök vid annan vårdenhet eller vårdnivå under tidsperioden 2004-2005, relaterade eller möjligen relaterade till astma eller KOL
0 = Ej känt
1,2,3,4,5,6,7,8

L12. Antal förskrivningar av astma-kol preparat under 2004-2005:
1,2,3,4,5…
L13. Uppgifter om att patienten har en astma eller KOL-diagnos utan att detta registrerats i ProfDoc?
0 = Nej/nej känt
1 = Astma
2 = KOL
3 = Både astma och KOL
4 = Osäker diagnos astma
5 = Osäker diagnos KOL
6 = Osäker diagnos astma och/eller KOL

L14. Patient avliden: Dödsorsak?
0 = Stämmer ej eller uppgift ej tillgänglig i journalen
1 = Hjärtsvikt efter pneumoni
2 = UVI med njursvikt
3 = Ingen orsak angiven/dödsorsaksintyg utfärdat av annan vårdgivare
4 = KOL
5 = Cerebral infarkt, hypertoni, pneumoni
6 = Hjärtsvikt