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PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

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# Detailed postal feedback about prescribing to asthma patients combined with a guideline statement showed no impact: a randomised controlled trial

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**Abstract** *Objective*: To evaluate the effects of postal feedback with clinically relevant data on general practitioners' prescribing compared with feedback with aggregate data on prescribing patterns of asthma drugs.
*Methods*: The study was a randomised, controlled trial. The general practitioners (GPs) in the County of Funen, Denmark (292 GPs representing 178 practices) were randomised to one of three groups receiving different forms of prescriber feedback. The first group received detailed and clinically relevant data on asthma drug prescribing patterns and a guideline statement. These data included tables with counts of asthma patients following classification of each individual's consumption of inhaled $\beta$2-agonists and use of inhaled steroids. The second group received aggregate data on asthma drug prescribing patterns and a guideline statement, and the third group received feedback on an unrelated subject and served as control for the other groups. Each GP received prescriber feedback three times within a 6-month period. The last two letters with prescriber feedback had updated information with the purpose of showing changes in prescribing patterns. Effects were followed for a period of 1 year. The main outcome measures were change in fraction of asthmatics treated with inhaled steroids and incidence rate of treatment with inhaled steroids.
*Results*: The three groups had similar baseline characteristics. None of the two types of feedback on prescribing of asthma drugs had a statistically significant impact on GPs' prescribing patterns.
*Conclusion*: Mailed prescriber feedback of detailed and clinically relevant data with a guideline statement, without revealing patient identities, has little or no impact on prescribing patterns.

**Keywords** Feedback · Physician's practice patterns · Family practice

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## Introduction

Postal feedback to physicians on their prescribing patterns is widely used for quality improvement because it is inexpensive and can be carried out on a large scale [1, 2]. In contrast, prescriber feedback on its own has not proved to produce substantial improvements in practice [3, 4]. Perhaps this is because the feedback information has often been clinically unimportant [2]. It has, therefore, been proposed that prescriber feedback is more useful if the information presented is of greater clinical relevance. For example, for several years there has been a wide consensus that optimal treatment of asthma consists of a combination of inhaled $\beta$2-agonists and inhaled corticosteroids [5]. Preventive anti-inflammatory treatment with inhaled corticosteroids is recommended even for mild asthma. Many asthma patients, however, are not treated with inhaled corticosteroids [6, 7, 8]. Feedback with aggregated data on total amounts of inhaled $\beta$2-agonists and inhaled corticosteroids prescribed per practice might be difficult for general practitioners (GPs) to relate to the quality of care of individual asthmatics. In contrast, data on individual patients' consumption of inhaled $\beta$2-agonists and inhaled corticosteroids are more clinically relevant, even when presented so that patients are not identifiable (patient-count data). We hypothesised that feedback of patient-count data might motivate GPs to improve their prescribing of corticosteroids. The aim of this trial was to evaluate in a randomised, controlled trial the effects

of prescriber feedback presenting clinically relevant patient-count data compared with prescriber feedback presenting aggregated data.

## Methods

The study comprised 178 practices (68 partnerships and 110 solo practices) with 292 GPs and 445,577 listed patients. From a total of 186 practices in the County of Funen we excluded eight practices (three new practices and five practices which closed down during the study period). To avoid the biases arising from possible time trends we used a randomised, controlled study design. The 178 practices included were randomly allocated to one of three groups that received different prescriber feedback: 47 practices (77 GPs) received patient-count data (explained below), 45 practices (74 GPs) received aggregated data and 86 practices (141 GPs) acted as controls for the other groups. The allocation was performed in blocks to ensure an equal distribution of solo and partnership practices in the three groups. We informed GPs about the trial in advance in the local medical journal [9], but there was no information on the topic of the interventions. The regional ethics committee was notified.

### Databases

Data for the interventions and outcome measures were retrieved from Odense Pharmaco-Epidemiologic Database (OPED) and from the Billing Database of the Health Administration of The County of Funen [10]. For every purchase of subsidised drugs, the following data are recorded in OPED: identity of the patient, the date the prescription was redeemed, the brand, quantity and form of the drug and the prescribing general practice. The Billing Database has information on number and type of subsidised services provided, the identities, gender and age of the physicians and the identities, age and gender of persons listed with each practice.

### Interventions

All three groups of general practitioners received mailed prescriber feedback every 3 months from 1 June 1998 to 1 December 1998 in the form of three letters. The two intervention groups received information about their prescribing of inhaled $\beta$2-agonists and inhaled corticosteroids for patients aged 6–45 years. It was clearly stated (referring to the Drug Index published by the Danish Medical Association) that inhaled steroids should be prescribed to asthmatics using more than two to three puffs of inhaled $\beta$2-agonists per week [11].

The first intervention group received feedback as a one-page, large-font letter with a simple table of patient-count data in the middle of the page. For every patient listed with each practice, we calculated the average number of puffs per week of inhaled $\beta$2-agonists during two years (fewer than 3 puffs per week, 3–10 puffs per week, more than 10 puffs per week) and whether inhaled steroids were never used versus used once or more. This information was presented in a table in which patients listed with the practice were classified according to their consumption of inhaled $\beta$2-agonists and inhaled corticosteroids (patient-count data, Table 1). The second and third letters were similar in format except that the table showed changes in prescribing patterns during the intervention period.

The second intervention group received feedback with aggregated data showing total amounts of inhaled $\beta$2-agonists and inhaled corticosteroids purchased by the group of patients listed with each practice. The GPs were given no information about the number of patients they treated with one or both types of drugs. The first letter to this group of GPs showed the consumption of inhaled $\beta$2-agonists and inhaled steroids as the number of packages purchased in 1 year per 100 patients in each practice (Fig. 1). The number of inhaled steroid packages divided by the number of inhaled $\beta$2-agonist packages was used as a crude indicator of the quality of care [12]. These data were, for the sake of comparison, presented together with prescribing data for other practices. The second and third letters presented the aggregated data in a slightly different way in order to keep the GPs' attention to the subject. Major changes in prescribing patterns could, however, be seen by comparing the three letters. The control group received feedback about another subject not related to asthma treatment and no mention of asthma medication or asthma-treatment guidelines.

### Outcome measures and statistics

We evaluated the impact of the interventions on GPs' prescribing patterns for a period of 1 year (1 June 1998 to 1 June 1999) by means of two outcome measures:

1. The fraction of asthmatics treated with inhaled steroids
2. The incidence of treatment with inhaled steroids among persons receiving inhaled $\beta$2-agonists

The fraction of asthmatics treated with inhaled steroids was calculated as a period prevalence for each practice during

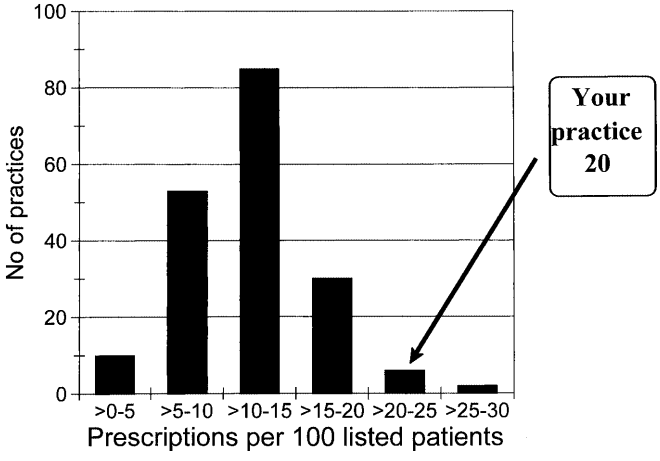


**Fig. 1.** Example of aggregated data on one practice's prescribing of inhaled $\beta$2-agonists compared with other practices' prescribing in the County of Funen sent to general practitioners (GPs) in the second intervention group that received aggregate data on their prescribing of asthma medicine

**Table 1.** Example of clinically relevant detailed information (patient-count data) about treatment of asthma patients sent to general practitioners (GPs) in the first intervention group. Calculated as the number of puffs used on average per week during 2 years

| Consumption of inhaled $\beta$2-agonists | Number of patients treated with both inhaled $\beta$2-agonists and inhaled corticosteroids | Number of patients treated with inhaled $\beta$2-agonists, but not inhaled corticosteroids |
|---|---|---|
| < 3 puffs per week* | 20 | 20 |
| 3–10 puffs per week* | 20 | 10 |
| > 10 puffs per week* | 20 | 10 |

consecutive 3-month periods. The numerator was the number of patients who purchased inhaled β2-agonist in the 3-month period and inhaled steroids at any time since 1 June 1996. The denominator was the number of patients who purchased inhaled β2-agonist in the 3-month period. All these persons purchased inhaled β2-agonists more than once within the 2 years before the last day of each 3-month period.

The incidence of treatment with inhaled steroids among persons receiving inhaled β2-agonists was analysed using survival analysis methods [13]. Patients were included in the analysis if they had not used inhaled steroid in a period of 2 years prior to the trial. The outcome event was each patient's first purchase of inhaled steroid. Incidence rates for each group and hazard ratios (estimated relative "risk" of steroid prescribing) were obtained by means of Cox regression models with confidence intervals (CIs) based on robust variance estimates taking into account patients clustering within practices. These analyses were made on two separate groups of patients: the repeat users and the first-time users of inhaled β2-agonists. The repeat users purchased inhaled β2-agonists in the year before the first letter of prescriber feedback, and they purchased inhaled β2-agonists more than once in the previous 2 years. The first-time users purchased inhaled β2-agonists for the first time in the year after the first letter of prescriber feedback. Person-time for the repeat users was time elapsed from the date of first intervention to the event, and person-time for the first-time users were time elapsed from the date of each person's first purchase of inhaled β2-agonists to the event.

Patients in the outcome analysis were aged 6–45 years. We performed additional analyses stratified on practice or patient characteristics including consumption of inhaled β2-agonist (calculated as each person's average consumption per week between first and last date of purchase).

Results are presented with 95% confidence intervals. Power calculations based on data from 1996 indicated that a trial with 50 practices in each group and on average 20 patients with a need for inhaled steroids per practice had a power of 90% in detecting a 20% reduction in the number of patients not treated with inhaled steroids.

## Results

In the year before the trial, 6437 persons aged 6–45 years (2.8% of 231,282 persons aged 6–45 years listed with the included practices) purchased inhaled β2-agonists and had purchased inhaled β2-agonists more than once within 2 years. Among these repeat users 1650 (26%) had not purchased inhaled steroids in the previous 2 years. Of these non-steroid-using repeat users, 1420 (86%) had a consumption of inhaled β2-agonists that on average exceeded three puffs, and 414 (25%) used more than 21 puffs per week. There were no statistically significant differences between the intervention and control groups as to prescribing patterns for asthma medicine or practice characteristics at the onset of the trial. During the trial 17% (274 persons) of the repeat users purchased inhaled steroids for the first time (Table 1). The first-time users of inhaled β2-agonists comprised 3704 persons of whom 1053 (28%) purchased inhaled steroids before the end of the trial (Table 2).

Neither type of prescriber feedback had a statistically significant impact on prescribing patterns. Figure 2 shows the lack of impact on the fraction of asthma patients treated with inhaled steroids. Three months after the GPs received the first letter, the change in the fraction was –0.01 (95% CI –0.04, 0.02) for the group that received patient-count data, 0.01 (–0.03, 0.05) for the group that received aggregated data and –0.02 (–0.05, 0.00) for the control group. Likewise we found no long-term effects on prescribing patterns measured using the fraction of asthma patients treated with inhaled steroids.

For the 1650 non-steroid-using repeat users of inhaled β2-agonists the incidence rate (number of initial steroid purchases per person-month) was 0.013 (0.011, 0.017) for the patient-count data group, 0.014 (0.011, 0.018) for the aggregated data group and 0.018 (0.015, 0.021) for the control group (Table 2). For the first-time users of inhaled β2-agonists the incidence rate was 0.064 (0.054, 0.076) per person-month for the patient-count data group, 0.054 (0.045, 0.066) for the aggregated data group and 0.060 (0.052, 0.069) for the control group (Table 3).

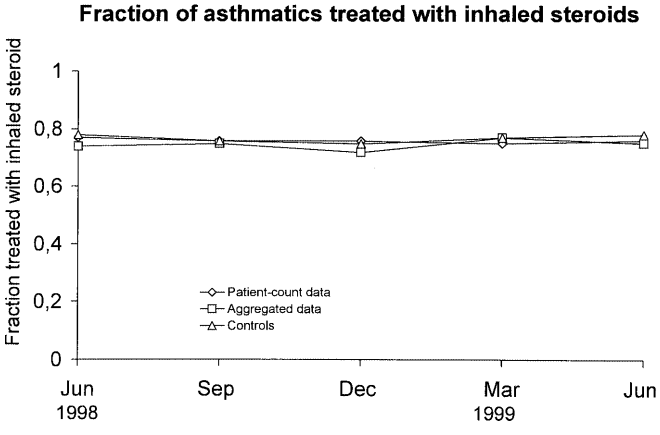


**Fig. 2.** Fraction of asthmatics treated with inhaled steroid. *diamonds* practices receiving patient-count data, *squares* practices receiving aggregated data, *triangles* practices in the control group

**Table 2.** Incidence of initiation of inhaled steroids among 1650 repeat users of inhaled β2-agonists. Data in brackets are 95% confidence interval values

| | Feedback with patient-count data | Feedback with aggregated data | Control group |
|---|---|---|---|
| Number of persons | 457 | 442 | 751 |
| Number of events | 67 | 67 | 140 |
| Mean time at risk of an event (days) | 332 | 333 | 324 |
| Incidence rate (outcome events per person-month) | 0.013 (0.011, 0.017) | 0.014 (0.011, 0.018) | 0.018 (0.015, 0.021) |
| Hazard ratio[a] | 0.77 (0.59, 1.01) | 0.79 (0.59, 1.07) | 1.00 |

[a]Wald test, $P = 0.11$. A hazard ratio $> 1$ indicates an intervention effect

**Table 3.** Incidence of initiation of inhaled steroids among 3704 first-time users of inhaled $\beta$2-agonists. Data in brackets are 95% confidence interval values

| | Feedback with patient-count data | Feedback with aggregated data | Control group |
|---|---|---|---|
| Number of persons | 1000 | 868 | 1836 |
| Number of events | 305 | 229 | 519 |
| Mean time at risk of an event (days) | 144 | 148 | 143 |
| Incidence rate (outcome events per person-month) | 0.064 (0.054, 0.076) | 0.054 (0.045, 0.066) | 0.060 (0.052, 0.069) |
| Hazard ratio[a] | 1.08 (0.90, 1.30) | 0.92 (0.75, 1.13) | |

[a]Wald test, $P = 0.35$. A hazard ratio $> 1$ indicates an intervention effect

The fraction of persons who purchased an inhaled steroid on the same day they purchased inhaled a $\beta$2-agonist for the first time (among all first-time users who purchased inhaled steroids) did not differ between the intervention and the control groups: 0.54 (0.48, 0.59) for the patient-count data group, 0.51 (0.44, 0.58) for the aggregated data group and 0.52 (0.48, 0.56) for the control group. We did not identify any subgroups among patients (age, consumption of inhaled $\beta$2-agonists) or GPs (practice characteristics) that showed any effect of the interventions.

## Discussion

This study indicates that unsolicited prescriber feedback in the form of data on individual patients' consumption of inhaled asthma medicine (patient-count data) without patient identifiers does not have a significant impact on GPs' prescribing patterns. This result must be considered in relation to (1) the statistical precision of the estimates, (2) absence of information on the indication for each prescription, (3) the outcome measures, (4) masking of the groups and (5) a possible ceiling effect. Our findings of a less-frequent initiation of corticosteroids among repeat users in the patient-count group [hazard ratio 0.77 (0.59, 1.01)] are compatible with no effect of the interventions or a weak effect opposite to that intended. Our findings of an only marginally increased frequent initiation of corticosteroids among first-time users in the patient-count group [hazard ratio 1.08 (0.90, 1.30)] are compatible with no effect or a weak effect in the direction intended. Taking the statistical precision into account, we conclude that there is no positive effect among the repeat users and no relevant positive effect among the first-time users.

The use of existing prescription databases does represent a step forward in the evaluation of interventions aimed at improving physicians' performance. It is a way to avoid the possible bias in estimated self-reported behaviour [14]. Furthermore, self-reported behaviour may sensitise the physicians to the desired practice and thus introduce change. The databases used in this study have a high degree of validity and completeness, but the absence of indication for each prescription is definitely a weakness [10]. Did the included patients really suffer from asthma? Chronic bronchitis is rare in younger people [15]. Therefore, by including only 6- to 45-year-olds, we excluded most persons suffering from chronic bronchitis. Only patients who purchased inhaled $\beta$2-agonists more than once were included in the group of repeat users, and we presume that most of these patients suffered from asthma. As to the first-time users of inhaled $\beta$2-agonists, there is presumably a large fraction representing the first appearance of asthma where treatment with inhaled steroids is indicated.

Choice of appropriate outcome measures in intervention studies is often not straightforward. Outcome measures should reflect what we are trying to achieve. The main objective of the intervention was to influence the GPs to treat their asthmatics with inhaled steroids. Therefore, all persons who purchased inhaled steroids once or more were classified as steroid users. Dose of inhaled steroids was not included in the guideline statements and therefore not used as an outcome measure. For one particular GP some patients are treated according to the recommendations and some are not, and this we have chosen to measure with a proportion. Using a dichotomous categorisation would involve an arbitrary limit (e.g. greater than 75% of the GP's patients treated according to guidelines), and this would be a less sensitive measure.

How masked was the control group in reality? Masking is an important issue in rigorous evaluations of interventions aimed at improving performance. All GPs were informed that we launched a large-scale randomised controlled trial evaluating effects of an intervention aimed at improving performance, but they were not informed about the issues for the interventions. Based on the remarks from the GPs we believe that the masking was quite successful. In general the GPs seemed to be unaware that they received feedback information about different health problems.

Another important issue is a possible ceiling effect. If there is no room for improvement (ceiling effect), even the best intervention will have no impact. We considered a ceiling effect, because only approximately 25% of the repeat users had not been treated with inhaled steroids at start of the interventions. The majority of these patients (86%), however, had usage of inhaled $\beta$2-agonists that exceeded three puffs on average per week, and it seems likely that they could benefit from using inhaled

steroids. Some of these patients may have received a prescription for inhaled steroids, but never redeemed it. However, in general the non-redemption rate is low in the County of Funen [16], which indicates that the non-redemption rate is also low for asthma drugs [17].

One reason for lack of impact of interventions may be the way the information is presented. In this study, the layout was developed in collaboration with other GPs and carefully tested in a pilot study, and therefore it was not the layout of the feedback letters that were responsible for the lack of impact.

Only a few rigorous randomised, controlled studies have evaluated the effects of feedback systems on prescription patterns in general practice [18, 19, 20, 21, 22, 23, 24, 25]. Impact ranged from nil to modest. None of these trials addressed the importance of clinical relevance of the information provided. A major reason for lack of impact of prescriber feedback might be that the information given is clinically irrelevant and therefore ignored by the GPs [2]. The patient-count data in our study, being on individual patients' treatment, were clinically relevant, but still there was no impact. Perhaps this is because we anonymised the patients' identities. Even if the GPs were determined to optimise treatment of patients with a need for inhaled steroids, they had to wait until they were contacted by those patients, alternatively the GPs had to go through their patient records.

Some features are thought to be necessary for impact of prescriber feedback. In this trial the prescriber feedback did offer clear alternatives to current practice [2], it was given repetitively [26, 27] by a supposedly recognised authority [27], and local GPs participated in the planning and execution. As the intervention was unsolicited, the participants had not agreed to review their practice [28, 29], and the information might not have been presented close enough to the time of decision-making [28]. Evidence concerning the importance of these features is, however, sparse. In conclusion, unsolicited mailed prescriber feedback of clinically relevant patient-count data with a guideline statement, without revealing patient identities, has little or no impact on prescribing patterns.

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