Reimbursement Restriction and Moderate Decrease in Benzodiazepine Use in General Practice

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ABSTRACT

PURPOSE To limit misuse and save costs, on January 1, 2009, benzodiazepines were excluded from the Dutch reimbursement list when used as anxiolytic, hypnotic, or sedative. This study aims to assess the impact of this reimbursement restriction on benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorder in general practice.

METHODS Was conducted a retrospective observational database study deriving data on diagnoses and prescriptions from the electronic health records–based Netherlands Information Network of General Practice (LINH). We looked for patients aged 18 years and older with an incident diagnosis of sleeping disturbance (*International Classification of Primary Care* code: P06) or anxiety (P74, P01) between January 2008 and December 2009. Incidence of these diagnoses, benzodiazepine use, and initiation of selective serotonin reuptake inhibitor (SSRI) treatment was compared between 2008 and 2009.

RESULTS In total, we identified 13,596 patients with an incident diagnosis of anxiety (3,769 in 2008 and 3,710 in 2009) or sleeping disorder (3,254 in 2008 and 2,863 in 2009). The proportion of patients being prescribed a benzodiazepine after a diagnosis was lower in 2009 than in 2008 for both anxiety (30.1% vs 33.7% $P < .05$) and sleeping disorder (59.1% vs 67.0%, $P < .05$), as was the proportion of patients with more than 1 benzodiazepine prescription for both anxiety (36.4% vs 42.6%, $P < .05$) and sleeping disorder (35.0% vs 42.6%, $P < .05$). We found no increase in the use of alternative treatment for anxiety with SSRIs.

CONCLUSIONS The reimbursement restriction has led to a moderate decrease in the number of incident diagnoses and initiation of benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorder. This finding indicates that in settings where no such reimbursement opportunities exist, physicians have room to reduce benzodiazepine prescribing.

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INTRODUCTION

Benzodiazepines are widely used in the treatment of anxiety, panic disorders, and insomnia, as well as of neurologic and rheumatologic conditions.[1-3] Long-term use of benzodiazepines is associated with an increased risk of abuse, misuse, and adverse events.[4-6] Expert bodies, such as the Netherlands College of General Practitioners, have long advised that use of benzodiazepines should be limited to short courses for acutely distressed patients and generally be avoided in elderly people.[7] Nevertheless, about 30% of the patients using benzodiazepines are chronic users, predominantly for insomnia.[2,8]

In the Netherlands, after consultation with patient and professional organizations, a change was made in the reimbursement status of benzodiazepines that was announced mid 2008 and came into force on January

1, 2009. From that date on, benzodiazepines were excluded from the Dutch reimbursement list (full reimbursement regardless of diagnosis or other restrictions) when used as anxiolytic, hypnotic, or sedative.[9,10] Coverage remained for a limited number of indications, such as epilepsy, palliative sedation, or multiple psychiatric disorders, if no alternative treatment was available.[11] The rationale for this restriction was to reduce the use of these medicines to a few specific patient subpopulations, to avoid irregular (chronic) use of benzodiazepines, and to limit the health care costs. Although costs per prescription are €12 to €16, macro-level costs were high because of the volume of benzodiazepine use.

Several studies have shown the importance of studying the effects of restrictions on reimbursement for pharmaceuticals.[12-14] Policy measures may not always be successful if patients shift to other (costly) treatments or measures do not necessarily lead to clinical benefits, as shown by Wagner et al.[15] The Dutch Foundation for Pharmaceutical Statistics showed a 16% reduction in overall use of benzodiazepines and 14.5% fewer chronic users in 2009 compared with previous years.[16] Nevertheless, it is unknown whether this decline was the result of a decrease in initiating or an increase in discontinuation of benzodiazepines or a decrease in the number of patients given a diagnosis for which a benzodiazepine may be prescribed. To our knowledge, no studies have assessed the impact of the reimbursement restriction on specific diagnoses and initiation of benzodiazepines. Previous studies concluded that it is particularly important to limit the number of patients starting with benzodiazepines, as approximately 30% of all new patients continue use for a longer period and may display inappropriate use.[17,18]

The objective of this study was to assess whether general practitioners made fewer new diagnoses of either sleeping disorder or anxiety and whether fewer benzodiazepines were prescribed for those patients once their condition was diagnosed. Furthermore, we aimed to study the possible unintended consequences of the reimbursement restriction by assessing whether patients with newly diagnosed anxiety were given prescriptions for selective serotonin reuptake inhibitors (SSRIs) instead. Finally, we assessed whether new users of benzodiazepines discontinued their medication earlier after the regulatory change in January 2009 or added or shifted more frequently to treatment with SSRIs when anxiety was diagnosed.

METHODS

Setting

General practice data were derived from the electronic health records–based Netherlands Information Network of General Practice (LINH), a network of general practices across the country.[19,20] LINH practices register standardized information on all health problems reported within a consultation, including information on prescribed medicines. Each patient is identified with an anonymous unique patient identification code. Patients are representative of the Dutch population with respect to age and sex. LINH observational studies, which are carried out according to Dutch legislation on privacy, are not obligated to obtain written informed consent. The LINH database includes information on patient sex, year of birth, and clinical diagnoses, which are coded using the *International Classification of Primary Care (ICPC)* scheme.[21] LINH general practitioners register every prescription, which is coded according to the *Anatomical Therapeutical Chemical (ATC) Classification Index*.[22] Only general practices with complete data during the study period were included (n = 95 practices).

Study Population and Measures

All patients aged 18 years and older with incident diagnoses of sleep disturbance (*ICPC* code P06) and anxiety disorder (*ICPC* codes P74, P01) in 2008 and 2009 were identified. Incident was defined as not having had this diagnosis in the 365 days before the diagnosis of interest. Patients were included only when they were continuously registered between January 2007 and December 2009 and had complete information on sex and year of birth. For each patient with an incident diagnosis, we assessed whether the patient was given a prescription for a benzodiazepine (*ATC* codes N05BA, N05CD, N05CF), either on the same date or within 7 days from the diagnosis date. The duration of each prescription was set at 30 days, which is the standard policy in the Netherlands. We assessed treatment persistence for patients receiving more than 1 benzodiazepine prescription. Patients were considered to have discontinued treatment when no new benzodiazepine prescription was issued in 90 days after the theoretical end date of the previous prescription (30 days). Furthermore, we assessed whether there was a change in the number of patients actually initiating SSRIs (*ATC* code N06AB) after an incident diagnosis of anxiety between 2008 and 2009 and whether patients were switched to a SSRI (in case of discontinuation of benzodiazepine use) or had an SSRI added to their treatment.

Data Analysis

Incidence rates per quarter were calculated by dividing the number of patients with incident diagnoses by the population at risk to assess incident diagnoses of sleeping disorder and anxiety over time. Risk differences

in corresponding quarters in 2008 and 2009 and 95% confidence intervals (CIs) were calculated. We defined population at risk as patients not having or having had a diagnosis of anxiety or sleeping disorder in the 365 days before inclusion. Rates were stratified by sex and age-group (18 to 44 years, 45 to 65 years, 66 to 75 years, and older than 75 years). Differences in proportion of patients who started with a benzodiazepine prescription and proportion of patients with 1 benzodiazepine prescription between 2008 and 2009 were calculated using the Pearson χ^2 test.

Kaplan-Meier survival curves were constructed for patients with more than 1 benzodiazepine prescription, to visualize the difference in time to discontinuation between patients starting with benzodiazepine use in 2008 (before policy change) and those starting with benzodiazepine use in 2009 (after policy change). Because discontinuation could be evaluated only if at least 120 observation days were available between the date of treatment initiation and the end of the calendar year (fixed prescription duration of 30 days and a 90-day allowable gap between prescriptions), only patients who started benzodiazepine use in the first 8 months of 2008 and 2009 were included in this analysis. Cox regression analysis was applied to estimate the strength of the association between calendar year and the risk of discontinuation among patients with more than 1 benzodiazepine prescription, and was expressed as a hazard ratio (HR) with 95% confidence intervals. Age and sex were considered potential confounders.

Because patients may be using concurrent benzodiazepine medications for indications other than anxiety or sleeping disorder, a sensitivity analysis was conducted to assess whether there was a difference between patients using benzodiazepines for sleeping disorder or anxiety only or using concurrent benzodiazepines for other indications. A sensitivity analyses was conducted to assess the influence of our definition of benzodiazepine discontinuation by expanding the 90-day period to 180 days and by defining incident as not having had this diagnosis in the 180 days before. Beforehand, multilevel analyses were conducted to test for clustering effects within general practices; because intraclass correlation coefficients were low (<1.5%), we decided not to use a multilevel approach. Analyses were performed in SPSS 16.0.2 (SPSS Inc, Chicago, Illinois) and MLwiN 2.11 (multilevel) (Centre for Multilevel Modeling, University of Bristol, Briston, United Kingdom).

RESULTS

In total, we identified 13,596 patients with an incident diagnosis of anxiety (n = 7,479) or sleeping disorder (n = 6,117) in the period 2008-2009. Figure 1 shows the incidence of both diagnoses for each quarter in 2008 and 2009. There was a statistically significant lower incidence of sleeping disorders in the first 3 quarters of 2009 compared with these respective quarters in 2008. For anxiety, diagnoses in the first and third quarter of 2009 were significantly lower compared with diagnoses in the first and third quarter of 2008.

Figure 1. Incident diagnoses for anxiety and sleeping disorder in 2008 (■) and 2009 (Δ) and their 95% confidence intervals.

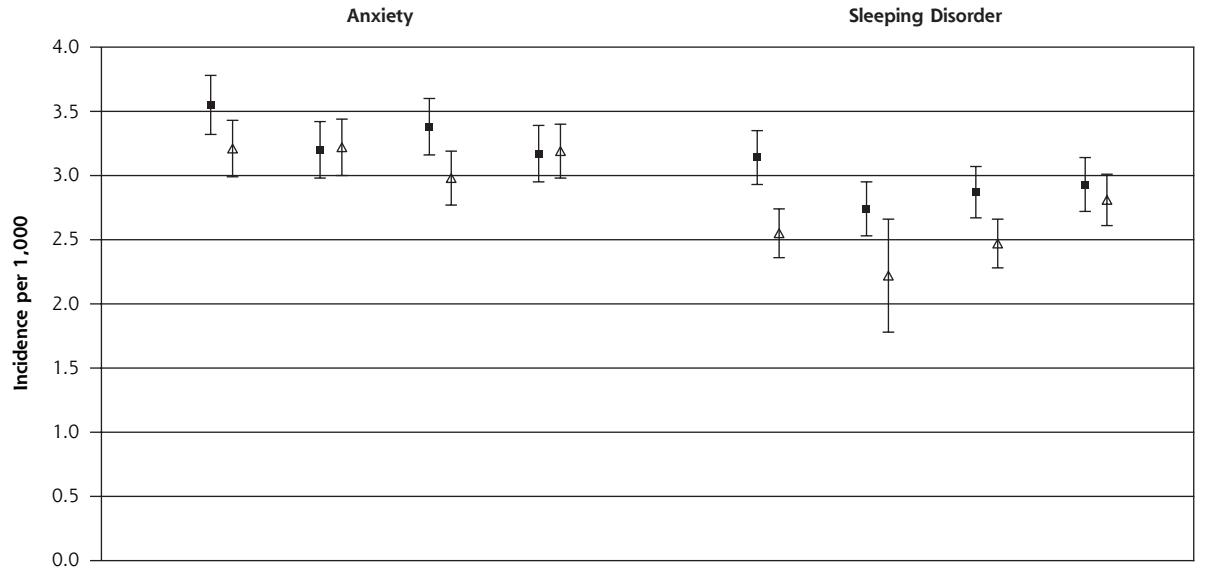


Table 1. Initiation of Benzodiazepine Treatment Among Patients With Incident Diagnoses of Anxiety or Sleeping Disorder

	Anxiety				Sleeping Disorder			
	2008		2009		2008		2009	
Characteristic	Diagnoses No.	Benzodiazepine Prescribed No. (%)	Diagnoses No.	Benzodiazepine Prescribed No. (%)	Diagnoses No.	Benzodiazepine Prescribed No. (%)	Diagnoses No.	Benzodiazepine Prescribed No. (%)
Overall	3,769	1,270 (33.7)	3,710	1,116 (30.1)[a]	3,254	2,181 (67.0)	2,863	1,691 (59.1)[a]
Sex,								
Men	1,205	410 (34.0)	1,209	359 (29.7)[a]	1,171	709 (60.5)	1,048	551 (52.6)[a]
Women	2,564	860 (33.5)	2,501	757 (30.3)[a]	2,083	1,472 (70.7)	1,815	1,140 (62.8)[a]
Age, y,								
18 -44	1,721	419 (24.3)	1,716	378 (22.0)	1,025	639 (62.3)	836	442 (52.9)[a]
45-65	1,418	566 (39.9)	1,330	471 (35.4)[a]	1,399	969 (69.3)	1,222	750 (61.4)[a]
66 -75	331	161 (48.6)	358	151 (42.2)	419	296 (70.6)	380	238 (62.6)[a]
>75	293	124 (42.3)	306	116 (37.9)	411	277 (67.4)	425	261 (61.3)

[a] Statistically significant at $P < .05$ for 2008 vs 2009.

Table 1 displays the characteristics of patients with incident diagnoses for anxiety and sleeping disorder in 2008 and 2009. For both disorders, the proportion of women was higher than men. The proportion of patients being prescribed a benzodiazepine following a diagnosis was slightly lower in 2009 than in 2008 for both anxiety (33.7% vs 30.1%, $P < .05$) and sleeping disorder (67.0% vs 59.1%, $P < .05$). Stratification by sex and age showed similar results. A sensitivity analysis restricted to patients with a first diagnosis in the index year with no previous diagnosis within the previous 180 days, showed similar results (data not shown). The decrease in patients being prescribed a benzodiazepine for anxiety was mostly seen in patients with *ICPC* code P01 (54.1% vs 45.9%, $P < .05$). For *ICPC* code P74, prescriptions decreased from 50.3% to 49.7% ($P > .05$)

Table 2 shows that for patients with benzodiazepine prescriptions after a diagnosis, the proportion of patients being prescribed more than 1 benzodiazepine was lower in 2009 than in 2008 for both anxiety (36.4% vs 42.6%, $P < .05$) and sleeping disorders (35.0% vs 42.6%, $P < .05$).

The Kaplan-Meier curves for the years 2008 and 2009, illustrating the time to discontinuation after initiation of at least 2 benzodiazepine prescriptions, are shown in Figures 2a and 2b. Cox proportional hazards analysis was used to compare the risk of discontinuation between patients starting benzodiazepine use in 2008 and patients starting benzodiazepine use 2009. For patients with newly diagnosed anxiety, no difference in discontinuation rates was observed (HR = 0.87; 95% CI, 0.68-1.11). Patients with newly diagnosed sleeping disorder in 2009 had a lower risk of discontinuation than did patients with newly diagnosed sleeping disorder in 2008 (HR = 0.63; 95% CI, 0.52-0.76). Similar results were seen when analyzing a subcategory; patients with benzodiazepines prescriptions for only the indication of interest (for anxiety, HR = 0.85; 95% CI, 0.64-1.13; for sleeping disorder, HR = 0.59; 95% CI, 0.47-0.75). Adjustment for age and sex had no effect on the risk estimates.

The number of patients actually starting SSRI treatment after a diagnosis of anxiety was low. In 2008 and 2009, only 232 (6.2% of patients with new diagnosis) and 196 patients (5.3%) started SSRI treatment, respectively ($P > .05$). The addition of an SSRI treatment was also infrequent: 57 (1.5%) of the patients who had anxiety newly diagnosed in 2008 added a SSRI to their current treatment of anxiety compared

Table 2. Patients With More Than 1 Benzodiazepine Prescription for Newly Diagnosed Anxiety or Sleeping Disorder

	Anxiety, No. (%)		Sleeping Disorder, No. (%)	
Characteristic	2008	2009	2008	2009
Overall	541 (42.6)	406 (36.4)[a]	930 (42.6)	592 (35.0)[a]
Sex				
Men	181 (44.1)	129 (35.9)[a]	289 (40.8)	195 (35.4)
Women	360 (41.9)	277 (36.6)[a]	641 (43.6)	397 (34.8)[a]
Age categories				
18-44 y	152 (36.3)	113 (29.9)	218 (34.1)	119 (26.9)[a]
45-65 y	236 (41.7)	165 (35.0)[a]	383 (39.5)	235 (31.3)[a]
66-75 y	71 (44.1)	69 (45.7)	148 (50.0)	89 (37.4)[a]
>75 y	82 (66.1)	59 (50.9)[a]	181 (65.3)	140 (53.6)[a]

[a] Statistically significant at $P < .05$ for 2008 vs 2009.

Figure 2a. Kaplan-Meier curves for the years 2008 and 2009, illustrating time to discontinuation after initiation of at least 2 benzodiazepine prescriptions in patients with newly diagnosed anxiety.

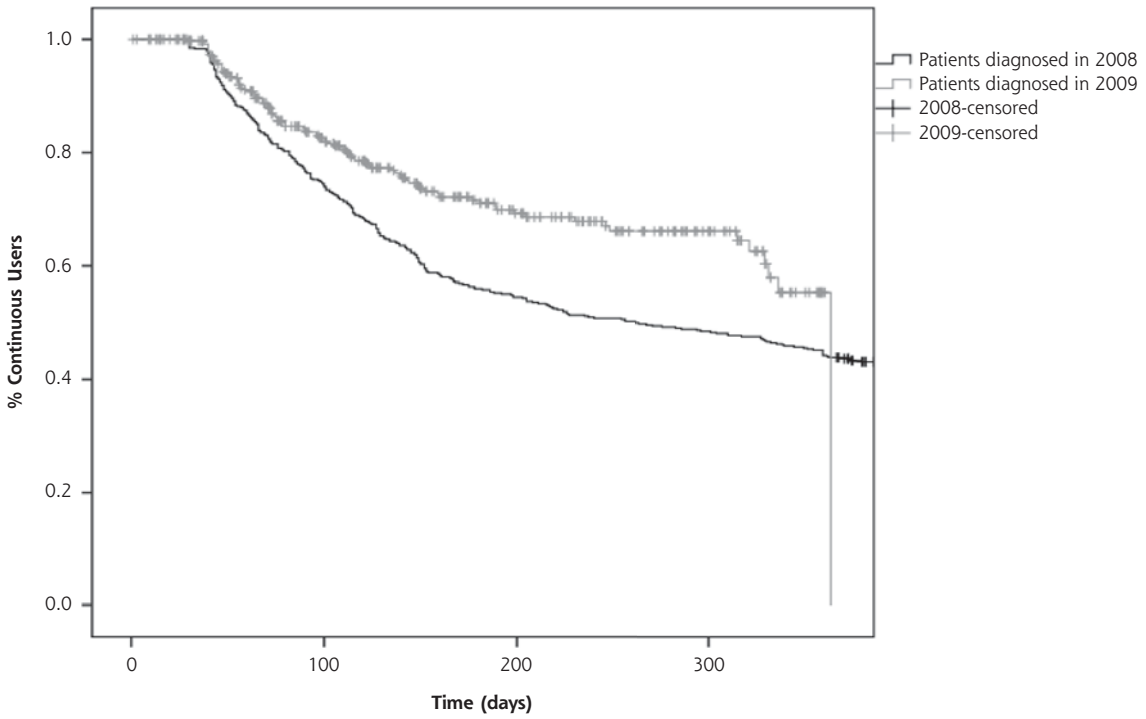
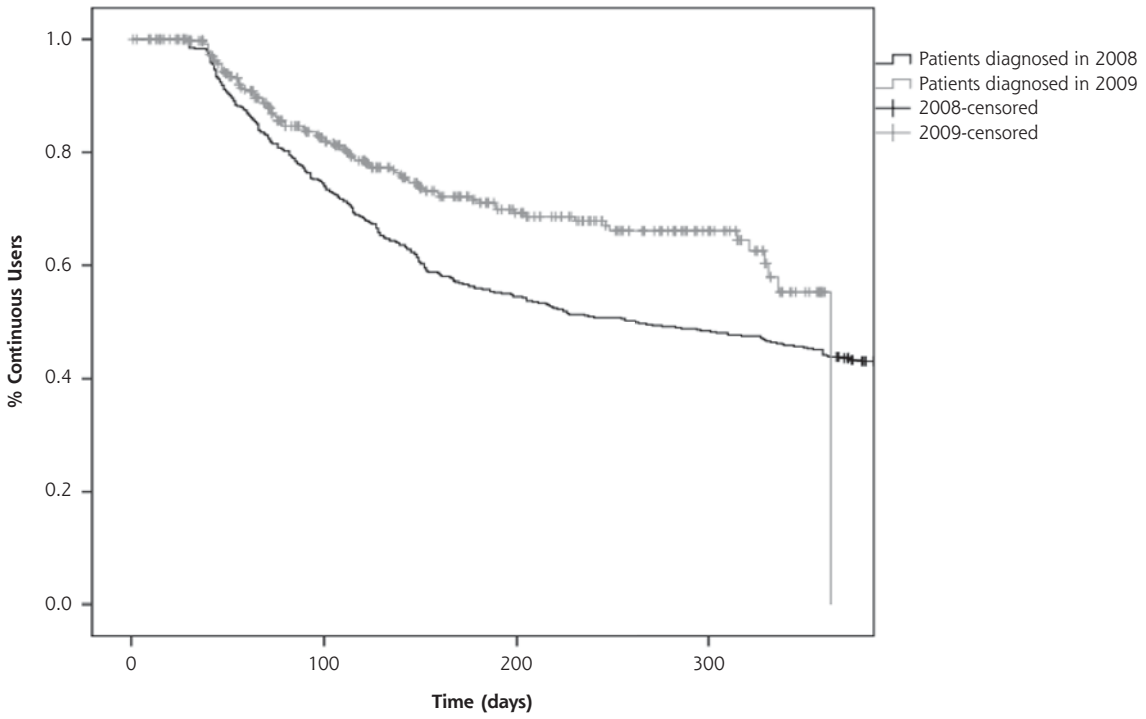


Figure 2b. Kaplan-Meier curves for the years 2008 and 2009, illustrating time to discontinuation after initiation of at least 2 benzodiazepine prescriptions in patients with newly diagnosed sleeping disorder.



with 29 (0.8%) in 2009. The reimbursement restriction had no effect on switching to SSRI treatment among patients discontinuing benzodiazepine treatment when anxiety was diagnosed. Only 12 (0.3%) patients with newly diagnosed anxiety in 2008 who stopped using benzodiazepines switched to treatment with SSRIs. In 2009, only 2 patients switched (0.1%).

DISCUSSION

We evaluated the impact of the reimbursement restriction on benzodiazepines use in patients with newly diagnosed anxiety or sleeping disorder and found that the incidence of sleeping disorders and anxiety was lower in the first 2 to 3 quarters after the policy change. Additionally, the probability of receiving a benzodiazepine prescription was, although modest, significantly lower in 2009 than in 2008. The decrease was most prominent in patients with newly diagnosed sleeping disorder. Among those treated with benzodiazepines, more patients received only 1 prescription in 2009. Patients with newly diagnosed sleeping disorder who received more than 1 benzodiazepine prescription discontinued their treatment earlier in 2008 than in 2009. This phenomenon was not observed in patients with newly diagnosed anxiety. No shifts to treatment with SSRIs have been observed.

We found that the number of consultations for incident diagnoses of sleeping disorders dropped in 2009. An explanation may be that problems with sleeping are often brought up by patients while they are visiting their general practitioner for other complaints. It may be that in such cases the doctor does not register the diagnosis unless a medication is prescribed. Another explanation is that the reimbursement measure was widely announced during the half-year before its introduction. Even patients who did not have a sleeping problem before may have heard that their benzodiazepine medications would no longer be reimbursed and decided not to consult their doctor for troubles with sleeping. We also found a decrease in initiation of benzodiazepine use. An explanation could be that doctors were prescribing benzodiazepines more consciously or that those who were using benzodiazepines were not willing to pay for the medicines themselves.

Furthermore, we found that approximately 50% of the patients received only 1 benzodiazepine prescription. The higher proportion of patients being prescribed only 1 prescription in 2009 indicates that physicians and patients might have become more conscious about the duration of intake, especially in case of sleeping disorder and mild anxiety. The high percentage of single prescriptions for benzodiazepines in patients with sleeping disorder is in line with the national guideline recommendations of the Dutch College of General Practitioners, which advises that benzodiazepine use should be limited to short courses.[7] That discontinuation rates in patients with sleeping problems were lower in 2009 than in 2008 may be because new users were more determined to have sleeping pills and were willing to pay for them themselves. Patients who were less determined may have chosen not to begin with the sleeping pills at all, whereas in 2008 they may have gone to fill 1 prescription. In addition, it may well be that in 2009 relatively more patients with more severe sleeping problems received a prescription for benzodiazepines.

Two-thirds of the patients had newly diagnosed anxiety coded with *ICPC* P01, "feeling anxiousness, nervousness or tense"; many of these patients might have had mild complaints and most likely would benefit from a short treatment with benzodiazepines. All other patients had their diagnoses coded with *ICPC* P74 "anxiety disorder/anxiety state." Treatment guidelines for anxiety recommend that treatment of anxiety should be supported by 2 to 4 weeks of concomitant benzodiazepine use, accounting for a single prescription of benzodiazepines.[23] Furthermore, treatment of anxiety is normally a complex process that requires a strong collaboration between the physician and psychologist. In many cases, general practitioners refer these patients directly to a mental health agency, which would explain the relatively high number of patients having just 1 prescription of benzodiazepines and the low number of patients initiating SSRIs treatment in this study.[24] The 16% reduction in overall use of benzodiazepines published by the Dutch Foundation for Pharmaceutical Statistics[25] is in line with the reduction that was found within the LINH database (approximately 18%, data not shown).

Overall, the number of reimbursed prescriptions for benzodiazepines in the Netherlands increased in 2009 by 4.1%. Even so, benzodiazepines disappeared from the top 10 most-prescribed medicines and were among the top 10 medications with the steepest decrease in number of prescriptions (http://www.sfk.nl; www.gipdatabank.nl). This change in ranking suggests that the policy measure has had an effect on the total use of benzodiazepines in the Netherlands.

Careful attention is needed before and after implementing a new policy when determining the effects of regulatory changes. The outcomes of policy changes should be seen in a broader perspective. A regulatory change may lead to public cost savings, but may increase private expenditures or may lead to undertreatment of certain populations. Patients who actually discontinue benzodiazepine use may still need benzodiazepines but may not be capable of paying for

these medicines out of pocket, although in the case of daily treatment, costs are low (approximately €12 to €16 per month).[25] Furthermore, regulatory measures will not always lead to the desired effects.[26] Barbui et al showed that classifying benzodiazepines in reimbursement class C, which means 100% out-of-pocket payment for all patients, was not enough to discourage their widespread use.[13] A study by Wagner et al showed that policies leading to substantial reductions in the use of benzodiazepines did not necessarily lead to other clinical benefits, such as a decrease in hip fractures in elderly.[15]

The strength of our study is the large sample size and that we had complete data for each individual patient, including all physicians' diagnoses and prescription data. Our study focused on the short-term outcomes of the policy. Van Hulten et al showed that 40% patients generally reinitiate benzodiazepine use within 1 year of discontinuation.[17] Because of the limited follow-up time, we were not able to take prescription restarts into account in this study. Although data for a longer period would be desirable, it would be difficult to attribute changes during a prolonged period to a single intervention, because many patient- and system-level factors change in time.

We did not study prescription patterns for patients with diagnoses for which benzodiazepines were still reimbursed, such as major psychiatric disorders and epilepsy, as a control group, because treatment is often initiated in secondary care, and the number of patients in our database with these diagnoses was limited. Moreover, we were not able to calculate the exact treatment duration. In our study, the duration of each benzodiazepine prescription was set at 30 days. We cannot ignore, however, that some patients might have been using benzodiazepines for a longer or shorter period, which might have influenced the outcomes, especially when looking at discontinuation. The standard treatment duration policy for the first benzodiazepine prescription usually is approximately 14 days. Because we excluded patients with only 1 prescription from our discontinuation analysis, and because the standard treatment duration policy in the Netherlands for each second or consecutive prescription is 30 days, we assume that our results were not influenced significantly. We wanted to observe unwanted effects of the policy, such as substitution effects and effects on health care utilization. Our primary care database did not include hospital admissions, and with regard to referrals, too many practices had incomplete data. We therefore assessed whether patients with anxiety shifted to treatment with SSRIs. Nevertheless, other treatment options for anxiety and sleeping disorder that are available without prescription were not taken into account and should be investigated. Finally, the proposed regulations for benzodiazepines were released in mid 2008, which gave patients and prescribers time to seek alternative medications and start weaning patients off benzodiazepine use. If we would have been able to take into account only discontinuation based on the regulatory change, we might have found a higher difference in discontinuation rate between 2008 and 2009.

Lessons learned from the evaluation of the effects of pharmaceutical policies in one country may provide important information for policy makers and regulators in other countries. This study showed the effects of the policy on patients with newly diagnosed anxiety and sleeping disorder were (partly) associated with a decrease in benzodiazepine use after the policy change, during which time SSRIs were not substituted for benzodiazepines. Albeit prices for benzodiazepines are low, that benzodiazepines are among the few medications no longer reimbursed may have had a signaling function for patients not to use them.

Reimbursement restriction has led to a moderately positive effect on the decrease in the number of incident diagnoses and initiation of benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorder. At the same time, the proportion of patients receiving prescriptions for benzodiazepines decreased moderately. These findings indicate that in health care settings where no such reimbursement settings exist, physicians have room to reduce benzodiazepine prescribing.

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Key words: Benzodiazepines; reimbursement mechanisms; anxiety; sleep initiation and maintenance disorders; health policy

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CORRECTION

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