

Qualitative Research

General practitioners' concepts on issuing out-of-pocket prescriptions for hypnotics and sedatives in Germany

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Abstract

Background. In Germany, almost 50% of prescriptions for benzodiazepines and drugs as Zolpidem and Zopiclone are as out-of-pocket (OOP) prescriptions—requiring patients to buy the drug at their own expense—although almost 90% of the population has statutory health insurance covering medication costs.

Objective. To understand why general practitioners (GPs) choose this prescribing method since needed medications are insurance covered, and unnecessary drugs should not be prescribed at all. **Methods.** In this qualitative study, 17 semi-structured interviews with GPs were conducted, audio recorded and transcribed verbatim. Transcripts were analysed with grounded theory to extract a model explaining the described behaviour.

Results. Knowing the significant medical risks and insecurity about regulations makes GPs wish to avoid hypnotics and sedatives. They achieve this by 'Creating a barrier' (central phenomenon) and employing the strategy 'Using an out-of-pocket prescription', which not only generates costs for the patient but also reduces the physicians' legal and financial accountability. The perceived patient type, expected problem duration and diagnosis influence the decision about the prescription form: patients with an alcohol or drug addiction or those with 'uncomplicated' insomnia are more likely to receive an OOP prescription. Patients with any psychiatric diagnosis will likely receive a statutory health insurance prescription.

Discussion. Current regulations do not provide guidance to GPs regarding hypnotics and sedatives. A clear regulatory framework and guidelines could possibly reduce physicians' defensive attitudes about these drugs and their use of OOP prescriptions. The approach to use OOP prescriptions as a barrier to reduce patients' medication use lacks evidence regarding effectiveness.

Key words: Attitude of health personnel, decision-making, general practice, health expenditures, hypnotics and sedatives, substance-related disorders.

Background

The unwanted effects of benzodiazepines, especially their abuse and addiction potential are well known and have been described many times (1–4). Although some doctors still consider the newer Z-drugs, such as Zolpidem or Zopiclone, as less harmful (5), evidence shows that it is a false belief (6). This is also reflected by updated guidelines

(7–9). That might explain why in many countries, the overall number of prescribed benzodiazepines and Z-drugs (BenzoZ) has decreased over the last decades (10,11). Currently the German board that determines the statutory health insurance (SHI) coverage (Gemeinsamer Bundesausschuss) applicable to 90% of the population limits the use of hypnotics and sedatives to 4 weeks—with the annotation that in some individual cases, a longer use might be

KEY MESSAGES

- General practitioners (GPs) feel ambivalent about benzodiazepines and Z-drugs.
- Many GPs use out-of-pocket prescriptions for these drugs to create a barrier.
- This barrier is intended to prompt the patient to reduce the medication intake.
- GPs try to reduce unnecessary drugs but offer an escape lane for cases of need.
- Data are missing to prove that the barrier strategy is successful.
- GPs perceive current guidelines regarding hypnotics and sedatives as unhelpful.

justified (12,13). Usually any SH prescription implies that the drug can be collected at a pharmacy either with no costs at all for the patient or requiring a very small co-pay of 5-10 Euro (~£ 4.45-8.90) depending on the individual constellation. The SHI will reimburse the pharmacy but will deduct the costs from the prescribing doctor's medication allowance that is granted according to the overall number of patients treated. If the allowance is exceeded, the excess amount can be deducted from the doctors' income, unless each prescription can be justified in a way that the SHI deems acceptable. Also, if the SHI deems a prescription has not been issued according to regulations or is not indicated, the entire costs can (potentially) be deducted from the doctor's income. German doctors could theoretically choose to prescribe many medications including BenzoZ as out-of-pocket (OOP) prescriptions, which allow SH-insured patients to buy the product at a pharmacy but at their own expense and without any form of reimbursement. Drugs that are dispensed this way are not being monitored by the SHI and thus are very hard to track. This practice presents a juridical grey area since SH-insured patients are entitled to receive a SH prescription for any drug that is medically indicated (14).

Therefore, in Germany the described decrease of BenzoZ use is smaller than it seems, because it is estimated that almost 50% of prescriptions are OOP prescriptions (15).

But why do physicians choose an OOP prescription if a medically indicated hypnotic or sedative is covered by the SHI? One survey among general practitioners (GPs) and pharmacists suggests that this prescription form is used when patients requested the drug rather than having a valid medical reason according to the prescribing physician's judgement. The reduction of the financial burden on the doctors' medication allowance was considered less important. Pharmacists and physicians disagreed about whether or not the fact that these prescriptions will not show up in any SHI data influenced the decision to prescribe BenzoZ with OOP prescriptions; 40% of the pharmacists believed that this factor influenced physicians' prescribing behaviour, whereas 40% of the physicians claimed that this was not relevant (16).

The goal of the study was to identify reasons and motives of GPs to choose an OOP prescription when prescribing a benzodiazepine or Z-drug to an SH-insured patient, to identify beliefs and concepts that may influence the decision and to develop a theory that explains this particular prescribing behaviour.

Methods

Study design

This was a qualitative interview study with a regional sample of GPs analysed by grounded theory.

Sampling and recruitment

A cluster-like sampling was used with the initial aim to recruit all GPs willing to cooperate in a defined study area in a rural part of

Southern Lower Saxony. The area was chosen to avoid a recruitment overlap with another practice-based research project. Some practices in Hannover (\sim 500 000 inhabitants) were included to add an urban perspective. Between December 2015 and January 2017, 43 GPs (23 men, 20 women) in 29 practices were invited to participate via telephone, respectively, all GPs from the initial study area (n = 35) and 8 from a rather deprived neighbourhood of Hannover. The telephone numbers were obtained from pre-existing lists within the Department of General Practice matched with telephone book information. Recruitment was continued until the interviews reached theoretical saturation, which means that no new aspects or ideas were found (17).

Participants

Seventeen GPs (10 men, 7 women) from 14 practices agreed to be interviewed. All participants received detailed information about the study by the main author and signed the informed consent. The majority of the participants were either trained GPs (7 men, 3 women) or internal medicine doctors (1 man, 2 women). One person was still specializing (1 woman) and some of the older physicians had practiced for many years without completing a specialty training (2 men, 1 woman)—as this was possible when they started to work. On average, the female physicians who had specialized finished their training 10 years ago (range 5–18 years), the male physicians had finished 14.4 years ago (range 3–33 years). The participants either practiced alone (n = 8) or in a small group practice (1–3 partners). Three physicians practiced in a city with more than 500 000 inhabitants; the other physicians practiced in rural communities.

Data collection

A single, face-to-face semi-structured interview was conducted with each participant by the primary author. The interview took place either in the participant's practice or home or at the authors' office—according to the participant's choice. A guide, which was developed beforehand, was used during each interview to assure that no important aspect was missed but also to allow the physician to emphasize points that he or she considered important. The primary author took field notes after each interview. The interviews were audiotaped, transcribed verbatim and pseudonymized. The transcripts were recompared to the recordings as a measure to assure data quality. Interviews lasted between 28 minutes and 72 minutes (mean 42.5 minutes).

Approach and data analysis

The data was analysed following a grounded theory approach (17–19). The three analysis steps (open coding, axial coding and selective coding) occurred mainly after each other but also in parallel. Categories were formed and arranged using a paradigm model. The centre of such a model, known as the central phenomenon, represents the core of the theory explaining the behaviour under investigation (issuing OOP prescriptions for SHI patients). It is influenced

by a broader context as well as more specific or direct causes, as depicted in Figures 1 and 2. Participants deal or react to this phenomenon by employing one or more strategies. The use of a strategy is influenced by intervening factors and will then lead to results or consequences. MAXQDA software Version 12 was used to support the analysis process (20).

Since the first and last authors are both GPs, it was important to discuss the pseudonymized data with other researchers outside of the health care setting. For this purpose, the data was presented and discussed within the framework of a sport science research colloquium. The assumption was that this group would see the material with less predetermined ideas than the authors and, therefore, help to improve theoretical sensitivity of the analysis.

The authors followed the consolidated criteria for reporting qualitative studies checklist for presenting qualitative data (21). Any information that is not mentioned in the article text can be found under Supplementary material.

Ethical aspects and data security

Approval of the University Medical Center Göttingen ethics committee was obtained prior to starting the study. The audiotapes and the transcripts were securely stored according to German data privacy rules. Only pseudonymized data was used for the analysis.

Results

Overall, the results showed two interrelated paradigm models. The first one can be seen as a superordinate model addressing the general use of BenzoZ (Fig. 1). The second model is nested within the first one and takes a closer look at the strategy 'Using an out-of-pocket prescription' (Fig. 2). The results reported in this article focus on the second model in more detail.

The first, superordinate model showed the central phenomenon of ambivalence with regard to BenzoZ prescriptions: GPs are not

only well aware of the risks and the addiction and abuse potential but also perceive them as useful and effective drugs.

Well, it is not that I could imagine to have worked without benzodiazepines and related substances, because there is a real benefit and a real need, and the abuse that is a different cup of tea. That is something we see with a lot of scientific topics. (I13,75)

To cope with this ambivalence, GPs use several strategies that can be divided into two main groups: using alternatives such as non-pharmaceutical therapies (e.g. sleep hygiene) and non-BenzoZ medications (e.g. antihistamines) on the one hand or using BenzoZ in spite of the risks, on the other (Figure 1). In both groups, several substrategies can be identified. One very important substrategy when using benzodiazepines and Z-drugs is to give out an OOP prescription.

A closer look at this strategy 'Using an out-of-pocket prescription' showed the second, nested paradigm model that is displayed in Figure 2. This model is centred around the phenomenon 'Creating a barrier', which is influenced by the context that 'BenzoZ cause addiction and should be avoided'.

Well, that if possible you need to be restrictive with those[medications], because in my opinion they [the patients] quickly develop an addiction and then permanently depend on that, and I actually talk to them to seek alternatives. Well, I rarely do that [prescribing BenzoZ] but it happens... (I8,4)

The central phenomenon is also influenced by 'Uncertainty in regards to current regulations' as a more specific cause. Some participants admitted that they did not know the current regulations at all. Most GPs stated that they had an idea about the content, for example, one should only use BenzoZ for a short time, but were unsure about regulation details, such as maximal length of therapy or exact indications expressed as an International Classification of Diseases code that would justify a BenzoZ prescription.

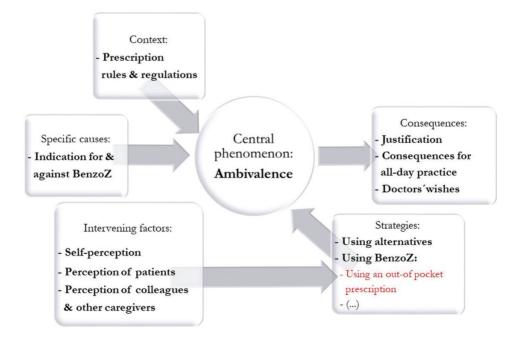


Figure 1. The overview model: When analyzing the data from the physician interviews (2015–17), two main strategies were identified to react to the central phenomenon of ambivalence—using alternatives to BenzoZ or using a BenzoZ hypnotic anyway. The most important substrategy (red) when using BenzoZ was to choose an OOP prescription. Other substrategies are not listed in the figure and symbolized by (...).

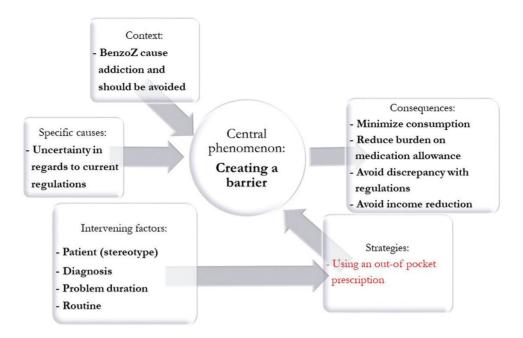


Figure 2. The nested model: When focussing on the strategy 'Using an out-of-pocket prescription' this paradigm model emerged. The context and the specific cause generate the central phenomenon. To archive the latter, the interviewed GPs applied the before-mentioned strategy, which then led to multiple consequences. The application of the strategy was influenced by several intervening factors.

In the end I have to say, one could discuss within the quality circle how others do it [prescribing BenzoZ]. I don't know if you could justify a SHI prescription. (I2, 36)

Since the German SHI may decline covering off-label use, doctors are uncertain as to whether or not the insurance will pay for the medication or if they will be held liable for the costs themselves. In combination with the notion that BenzoZ should be avoided, the idea of creating a permeable barrier—that will still permit consumption if needed—emerges. The strategy 'Using an out-of-pocket prescription' is expected to generate this barrier, thus, to achieve the central phenomenon (Fig. 2). The GPs hope that the barrier will curtail medication consumption while still offering an escape lane for cases of need.

Oh yes, if you have to pay yourself, the barrier is even a little higher than if you would always get that through your insurance. (14,54)

In general, if you want to say it in a mean way, it should hurt a little to treat yourself to this sleeping pill and they [the patients] should not be tempted to take that stuff like candy, because by that they would have certain costs. These are actually my thoughts behind that. (I3,58)

The barrier serves different purposes at the same time. It is not only a reaction to the known drug side-effects and the uncertainty, but just declining a prescription would interfere with one side of the ambivalence. Doctors perceive BenzoZ as more effective than alternatives and want to prescribe something to their patients that they themselves consider helpful. GPs using the strategy believe that an OOP prescription will hold the patient co-responsible and lead to a reduced and more careful medication intake. GPs also use the barrier defensively with regard to their own legal and financial accountability as they know that OOP prescriptions will not be covered by the patients' SHI and are much more difficult to trace in any routine data, meaning an off-label use will most likely not be noticed. OOP prescriptions are not subject to control by the SHI review board with regard to adherence to regulations nor are such prescriptions debited

from the doctors' medication allowance. However, not all participants considered it crucial as BenzoZ are inexpensive drugs. More important was to avoid discrepancy with current regulations, which (if detected by the SHI) would mean to be held financially accountable for not entirely correct prescriptions and—as a result of that—a potential need for detailed justification and potential loss of income.

The barrier strategy is influenced not only by the perception of patient types but also by the perceived diagnosis and duration of the problem. Patients with a history of or a current alcohol or other drug addiction are more likely to receive an OOP prescription, if any; whereas the ones that play according to the doctor's rules, for example, do not request an early refill and do not take more than prescribed, are more likely to receive a SHI prescription.

I always say, the good ones – I have two in my mind that show up every half year to get Zopiclone – those I could actually give an SH prescription. (I4,98)

If the diagnosis is insomnia, most of the time an OOP prescription is issued. Patients with any psychiatric diagnosis including a depression are more likely to receive an SHI prescription—regardless of the fact that BenzoZ are not first line medications for depression.

Yes, generally in over 80 percent of the patients we handle it this way, that if it is just isolated sleep disturbance sensitivities we use an out-of-pocket prescription, no matter if it is for Lorazepam or Zopiclone. Zopiclone almost up 90 to 95 percent, I think. (I7,46)

Whether [it is a] proven anxiety disorder or with a psychiatric diagnosis, they get an SHI prescription from me. The others just get an OOP prescription. (I4, 54)

In regards to the duration of the problem, the chosen approach varied: some doctors used an OOP prescription for short-term problems, for example, if a patient was afraid to travel by aircraft.

I would, even if it is doable [to give out an SHI prescription] with these short-term things we talked about, bereavement, funeral or air travel, prescribe an out-of-pocket prescription. (I7,78)

Others followed the opposite strategy and prescribed a 2-week supply on an SHI prescription, followed by an OOP prescription if the medication was still needed.

Finally, the fact that the use of an OOP prescription has become a routine for many physicians influenced the strategy 'Using an out-of-pocket prescription' by making it a normal practice and its continuous application easier.

Discussion

GPs' ambivalence when prescribing BenzoZ substances emerged as the central phenomenon, giving a theory as to why GPs issue OOP prescriptions to SHI patients—this is a common strategy to deal with the ambivalence. A closer look at physicians' motives for choosing this strategy reveals the nested core category of 'Creating a barrier' serving a dual purpose: attempting to reduce patients' consumption by sharing responsibility for the prescription with the patient through a financial burden while still keeping the drugs available. The barrier does justice to the GPs' ambivalence about prescribing BenzoZ and protects them from liability.

Strength and weaknesses

To the knowledge of the authors this is the first interview study addressing the GPs view of OOP prescriptions for hypnotics and sedatives. The exploratory nature of the grounded theory approach allowed to find unexpected concepts that were not addressed in prior studies (16,22,23). With the help of the paradigm model, we were able to generate a theory explaining why GPs choose this prescription form. Another strength was that contact was established and interviews were conducted physician to physician. This improved the willingness among candidates to participate and most likely increased their willingness to speak freely as well.

One weakness of the study was that theoretical sampling could not be integrated from the beginning, as in Germany objective data about the prescribed BenzoZ amount of individual practices are not available for research in contrast to other countries (24). Regarding the findings of the interviews, theoretical saturation and conceptual density was achieved. However, a selection bias could not be completely avoided since it is likely that only GPs who felt relatively competent about BenzoZ prescribing or had a special interest in the topic took part in the study. The study is limited by the fact that the strategy 'Using an out-of-pocket prescription' is closely linked to the German health care system. However, the wish to avoid these medications and to control the consumption seems international when compared with other studies.

Comparison with literature

That GPs feel ambivalent about BenzoZ but prescribe them nonetheless as has been described before (25). Anthierens et al. identified the initiation of a prescription as a crucial moment: either GPs considered addiction not a problem for first-time users or felt helpless and saw limited alternatives to BenzoZ (26). The idea to control the intake—once the decision to prescribe has been made—by using on OOP prescription seems to be a new finding that is tied to the German health care system (16,22,23); other international studies have focussed on the financial barrier approach and assessed the correlation between hypnotic prescriptions and insurance coverage. These showed a moderate reduction of prescriptions if patients had to pay for the medication themselves (27,28). On the other hand, the changes in US Medicare insurance rules did not result in a reduction of benzodiazepine-related complications such as hip fractures (29) and an OOP payment did not reduce the widespread use of hypnotics in an Italian study (30). Furthermore, the thought of controlling the consumption of an addicting substance through financial costs has been researched in regards to cigarette smoking—with the result that smokers would rather buy bigger packages or order online to make up for the increased costs rather than to stop smoking (31). In Germany, objective numbers of drugs sold or dispensed in pharmacies are not available for research and, therefore, it is impossible to prove or refute that the described strategy is successful in reducing problematic BenzoZ use.

Although legal allegations are not common—since the patient depends on the doctor's goodwill to prescribe the medication—there have been malpractice case reports addressing an iatrogenic opioid addiction (32). Therefore, Fishbain *et al.* recommend obtaining the patient's written consent

Most participating GPs were not aware that the current regulations permit the use of a BenzoZ hypnotic and sedatives for up to 4 weeks (12) but generally stated that these medications should only be prescribed short term. Whether or not the exact time frame is known, this leads to the problem of how to treat patients that have prolonged problems or have developed an addiction and are not candidates for withdrawal—a problem that the regulations only vaguely address with the statement that longer use could be justified in single cases without giving any specifications (12). Therefore, even knowing current regulation details would not completely eradicate the uncertainty. This feeling in regards to BenzoZ and the lack of constructive advice to overcome the gap between regulations and everyday practice needs have also been discussed in other studies (26,33).

Implications for research, policies and patient care

Further interview studies should be conducted to access the patient's perspective of OOP prescriptions since the group of non-health care professionals who were involved in the analysis perceived an OOP prescription as less valuable than a SHI 'real' prescription. They associated self-paying for BenzoZ with the purchase of over the counter drugs, such as cough-and-cold remedies. From this perspective, an OOP prescription rather conveys the message that the substance is harmless. Patients' self-reported intake might be helpful in determining whether paying for a medication leads to a more careful and reduced consumption. Simple and clearly communicated guidelines and regulations might reduce physicians' ambivalence and perceived need to create a barrier. Regulations should specifically address common clinical scenarios including a pre-existing addiction. Alternative treatment options for insomnia, including cognitive behavioural therapy, should be available. If feasible, GPs should choose alternatives to BenzoZ and-in case of use-clearly communicate to the patient for how long the drug will be prescribed and that the medication has a significant addictive potential.

Supplementary material

Supplementary material is available at *Family Practice* online.

Declaration

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Ethical approval: Approval of the University Medical Center Göttingen ethics committee was obtained prior to starting the study.

Conflict of interest: None declared.

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