

**Why are sleep-inducing drugs frequently used in hospitals?
Applying mixed-methods to understand a common practice
and develop a complex intervention to change it**

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1 Introduction

Many hospital doctors and nurses experience a conflict every night when on duty: what to do with patients who have trouble sleeping? For severe cases of chronic insomnia, cognitive behavioral therapy and hypnotic drug treatments are recommended. However, transient sleep problems in the hospital—often linked to environmental factors [1] such as unfamiliar sounds, nursing interruptions, uncomfortable beds and bright lights—are different from a clinical diagnosis of insomnia disorder, which affects sleep onset, duration and/or quality for at least a month [2]. In other words, hospitalized patients who have trouble sleeping regularly receive sleep-inducing drugs, often without an appropriate clinical indication and often without careful and coordinated planning and consultation between doctors and nurses.

An interdisciplinary team combining health services research, medicine, nursing and sociology developed a research project, the so-called Sleeping Pills Project, funded by the German Ministry of Health¹, with the overall goal of changing this common practice. This thesis is an essential part of the project and has two main objectives: First, to explore the use of sleep-inducing drugs in a regional hospital in Germany and understand this practice from the perspectives of doctors, nurses and patients. Second, the knowledge gained should be translated into a new clinical practice by creating a tailored intervention that motivates clinicians to change unquestioned routine behaviors when prescribing/dispensing sleep-inducing drugs.

This thesis lies at the interface of several scientific areas and branches of medicine. Without being a geriatric study, this thesis focuses on the care of older patients, who are at a higher risk for adverse outcomes when taking sleep-inducing drugs. Without being a sleep medicine study, which typically collects polysomnographic data or relevant sleep outcomes such as sleep efficiency, this thesis collects data from patients about their experiences with sleep-inducing drugs. Without being a study of interprofessional relations, this thesis investigates professional differences between doctors and nurses and takes them into account when developing an intervention strategy. Without being a study of hospital medicine, this thesis considers the priorities of hospital organization and administration when trying to understand why sleep-inducing drugs are prescribed/dispensed and when developing a strategy to reduce their use. Without being a pharmacological study about what drugs work best to induce sleep, this thesis looks at the real-

¹ The Sleeping Pills Project (official German title “... da gab es wunderbare Schlaftabletten“ – Verordnungen von Benzodiazepinen und Z-Substanzen an der Schnittstelle von Krankenhaus und Hausarzt) was funded by a research grant from the German Ministry of Health (II A5-2513DSM228). Ethical approval was obtained from University Medical Center Göttingen Ethics Committee (ref number 25/2/15).

world environment surrounding the decision to prescribe, dispense and use specific sleep-inducing drugs to treat hospital-associated sleeping problems.

This thesis uses the techniques of health services research to build on and combine these five areas (geriatrics, sleep medicine, interprofessional relations, hospital medicine, clinical pharmacology) to understand and later change a common practice in hospitals. I first present a short overview about what is known—and what we still need to know—about this subject and about the framework we used to develop an intervention (chapter 2). The main part of the thesis are the six papers in chapter 3 which follow a mixed-methods approach to collect data about the prevalence of sleep-inducing drugs in the hospital under study as well as the perspective of doctors, nurses and patients about the use of sleep-inducing drugs for hospital-associated sleeping problems. In chapter 4, I highlight the main lessons learned from each publication and identify areas with room for improvement. Chapter 5 describes the translation process from the empirical studies to the development of an intervention strategy and to the concrete measures to reduce the use of sleep-inducing drugs. The thesis ends with a discussion of the main results presented in the previous chapters and an outlook of future research in this area (chapter 6).

2 Understanding the use of sleep-inducing drugs in the hospital environment and development of a tailored hospital intervention

Doctors (and nurses) often treat hospital patients who have trouble sleeping with benzodiazepines and newer non-benzodiazepines, so-called Z-drugs [3–5]. While these drugs may help patients to sleep in the hospital environment, they also have adverse effects, such as confusion, falls, fractures and craving [6]. If used over a longer period, sleep-inducing drug use may lead to dependency. In Germany, it is estimated that 1.2 to 1.5 million of its 82 million citizens are dependent upon tranquilizers and sleep-inducing drugs, especially older people [7].

A meta-analysis of studies about of sleep-inducing drug use in older patients comes to the conclusion that the benefits may not justify the increased risk of adverse events [8]. Therefore, guidelines, such as the German PRISCUS list [9] and the German Guideline for Treating Unrestful Sleep and Sleeping Disorders [10] recommend that doctors restrict the prescription of sleep-inducing drugs. Despite such recommendations, the use of sleep-inducing drugs is still high [11–15].

There are some studies about the prevalence of sleep-inducing drug use in hospitals, but not in Germany. Moreover, we know only little about the reasons for their use from the prescriber perspective, which can be characterized by a—more or less unregulated—interplay of different professional groups in the hospital setting. Traditionally, prescribing has been a sign and indicator of the professional power of doctors at the micro level of the consultation and the wider structure of society [16]. Sleep-inducing drugs in the hospital are often prescribed as p.r.n.² drugs. That means that doctors are still responsible for diagnosis and prescription of drugs, but nurses dispense and document the use of these p.r.n. drugs and often decide in the end to whom and when to administer such a drug—a grey area, often not openly discussed [17]. In other words, if we want to better understand why professionals in hospitals prescribe/dispense sleep-inducing drugs, we have to consider multiple perspectives and possible conflicts and tensions between these professional roles.

Another important factor for the use of sleep-inducing drugs may be patient preferences [18]. Although this factor is not well studied in the hospital setting, it can be expected that patients who have had previous positive experiences with sleep-inducing drugs wish to receive such drugs when sleep problems re-occur.

² The term “p.r.n.” originates from the Latin *pro re nata*; meaning “as needed” or “as the situation arises”.

The research presented in this thesis had the ultimate goal of reducing the use of sleep-inducing drugs in hospitals or making their use more appropriate. As a first step, we needed to better understand this drug use in the complex hospital setting. This is important for two reasons:

- (1) The use of drugs in hospitals follows only partly pharmacological criteria; their use is also a matter of non-medical or context factors, as Helman states in his early research [19], or as a matter of games with specific rules and strategies within the habitus of the social world of a hospital, as Bourdieu [20] put it.
- (2) Any attempts to interrupt this smooth-running game begin by showing all relevant stakeholders that we understand what is going on in the hospital and what the reasons for their performance are. Only then will it be possible to develop together with them new and reliable rules of how to cope with transient sleep problems in the hospital.

The Sleeping Pills Project (including the six papers presented in the next chapter of this thesis) follow the Medical Research Council (MRC) framework for designing and evaluating complex interventions to improve health care [21, 22]. One aim of this framework is to ensure that interventions are empirically and theoretically founded. In our case, it seemed essential to explore the real extent of the use of sleep-inducing drugs in the hospital where the intervention should take place and the reasons for their use as well as the experience with these drugs, seen from the perspective of doctors and nurses as well as patients. We chose a mixed-methods approach to collect the data needed, comprising (i) a chart review of the patient hospital files with a quantitative analysis, (ii) a standardized survey and comparison of doctors' and nurses' use of, and experience with, sleep-inducing drugs, (iii) guideline-based interviews with nurses about non-drug treatments of sleep problems in the hospital and barriers to use them and (iv) a standardized patient survey combined with a comparison of the patient's hospital file. The goal of these studies, both individually and collectively, is to understand the current practice and to identify possible changes that could improve this practice.

Reviews showed that formal didactic conferences and passive forms of medical education, such as brochures or printed clinical guidelines are the least effective methods for changing physician behavior [23]. Moreover, stakeholder engagement is essential for moving knowledge into action within healthcare [24]. This is the heart of the MRC framework. Based on our results, presented in chapter 3, we identified several areas with a potential for improvement and worked together with the stakeholders of the hospital to create an intervention strategy and to implement a multi-faceted hospital intervention. The different facets of the intervention correspond to what Michie et al. have identified as domains which influence behavior change, such as knowledge, skills, social/professional role, environmental context and resources [25].

3 Published work

The publications of this thesis encompass the study protocol (**Paper 1**), a review of hospital charts (**Paper 2**), the analysis of a standardized professional survey about benzodiazepines (**Paper 3**) and Z-drugs (**Paper 4**), semi-structured, guideline-based interviews with nurses (**Paper 5**) and a survey of older hospital patients combined with a review of these patient's hospital charts (**Paper 6**). Table 1 gives a brief overview of the research questions and the methods used in these publications.

Table 1. Overview of publications.

Study	Research question (Aim)	Method	Participants
Paper 1 Heinemann et al. 2016 [26]	Description of the project background, goals and the methods used to collect data from several perspectives with multiple methods to understand and (where appropriate) reduce the use of sleep-inducing drugs at the interface of primary and hospital care.	Study protocol	Not applicable
Paper 2 Arnold et al. 2017 [27]	Frequency of benzodiazepines, Z-drugs, antidepressants and neuroleptics; Proportion of potentially inappropriate medication (PIM) according to the PRISCUS list.	Chart review	2130 charts of older hospital patients (≥ 65 years old)
Paper 3 Heinemann and Himmel 2017 [28]	Benefits and risks of benzodiazepines and the risk-benefit ratio for patients, as seen from the doctors' and nurses' perspective.	Standardized survey	Target: all hospital doctors and nurses Participation rate: 65/126 doctors 73/282 nurses
Paper 4 Heinemann et al. 2019 [29]	Benefits and risks of Z-drugs compared to benzodiazepines, as seen from the doctors' and nurses' perspective.	Standardized survey	Target: all hospital doctors and nurses Participation rate: 65/126 doctors 73/282 nurses
Paper 5 Kauffmann et al. 2018 [30]	Experiences of nurses when using non-pharmacological treatments for elderly patients with sleeping problems.	Face-to-face interviews with a semi-structured interview guideline	13 nurses (10 females) from different wards (e.g. internal medicine, geriatrics, and surgery)
Paper 6 Heinemann et al. 2019 [31]	Whether and to what degree do prior experiences with sleep-inducing drugs before hospitalization and positive experiences during hospitalization trigger a patient's wish to continue these drugs after hospitalization.	Computer-assisted personal interview with a standardized survey and chart review	Target (according to sample size calculation): 500 483 patients ≥ 65 years

3.1 **Paper 1: Study protocol for a mixed-methods study**

Heinemann S, Weiß V, Straube K, Nau R, Grimmsmann T, Himmel W et al. Understanding and reducing the prescription of hypnotics and sedatives at the interface of hospital care and general practice: a protocol for a mixed-methods study. *BMJ Open* 2016; 6(8):e011908.

BMJ Open Understanding and reducing the prescription of hypnotics and sedatives at the interface of hospital care and general practice: a protocol for a mixed-methods study

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ABSTRACT

Introduction: Hypnotics and sedatives, especially benzodiazepines and Z-drugs, are frequently prescribed for longer periods than recommended—in spite of potential risks for patients. Any intervention to improve this situation has to take into account the interplay between different actors, interests and needs. The ultimate goal of this study is to develop—together with the professionals involved—ideas for reducing the use of hypnotics and sedatives and then to implement and evaluate adequate interventions in the hospital and at the primary and secondary care interface.

Methods and analysis: The study will take place in a regional hospital in northern Germany and in some general practices in this region. We will collect data from doctors, nurses, patients and a major social health insurer to define the problem from multiple perspectives. These data will be explored and discussed with relevant stakeholders to develop interventions. The interventions will be implemented and, in a final step, evaluated. Both quantitative and qualitative data, including surveys, interviews, chart reviews and secondary analysis of social health insurance data, will be collected to obtain a full understanding of the frequency and the reasons for using hypnotics and sedatives.

Ethics and dissemination: Approval has been granted from the ethics review committee of the University Medical Center Göttingen, Germany. Results will be disseminated to researchers, clinicians and policy makers in peer-reviewed journal articles and conference publications. One or more dissemination events will be held locally during continuous professional development events for local professionals, including (but not confined to) the study participants.

INTRODUCTION

Hypnotic and sedative drugs, especially benzodiazepines and Z-drugs are frequently

Strengths and limitations of this study

- This study makes use of a close cooperation between a university department of general practice, a regional general hospital, a number of primary care practices and a large social health insurer to study the use of hypnotics and sedatives in the hospital and at the primary and secondary care interface.
- The mixed-methods design will combine insurance data, patient chart reviews, standardised surveys of patients and health personnel as well as qualitative interviews to analyse hypnotic and sedative prescriptions and to obtain deeper insight into the attitudes and experiences of hospital staff and general practitioners (GPs).
- Interventions for reducing the use of hypnotics and sedatives will be developed in focus groups with all relevant stakeholders to support compliance.
- The success of the interventions will strongly depend on the willingness of the hospital staff and GPs to change familiar and established workflows and implement new strategies in handling patients with sleeping problems.

prescribed and in many cases for longer periods than recommended—in spite of the potential risks for patients such as addiction, falls, cognitive impairment and depressive symptoms.^{1–4} These drugs are often started during an acute situation, for example, during a personal crisis or hospital stay. It seems that in these cases, drugs such as benzodiazepines and Z-drugs are given because of a perceived lack of alternative treatment options⁵ or because physicians regard other medical issues with higher priority than the restriction of hypnotics and sedatives.⁶

In the hospital setting, different professional groups may play a role in the relatively



high level of hypnotic and sedative prescribing. While doctors are responsible for diagnosis and treatment (ie, prescription of drugs), nurses dispense and document the use of p.r.n.¹ drugs. The decision of when to administer a p.r.n. drug is generally left to the nurse. Once a drug has been given in the hospital setting, it becomes possible that its use is carried over into primary care.⁷ Such chain reactions between primary and secondary care have been described for other drugs, such as proton pump inhibitors,^{8,9} but not hypnotics and sedatives. We only know from a recently published survey that German general practitioners (GPs)¹⁰ complain about hospital discharge letters in which sleeping pills are recommended without any need in the patient's home.

To study the knowledge and attitudes of the professionals involved can give insight into the reasons for high benzodiazepine and Z-drug use. Hoffmann¹¹ surveyed German GPs about the risks and benefits of these drugs, discovering that Z-drugs are perceived to be more effective and less harmful than benzodiazepines, although there is little evidence to support this.¹² However, the attitudes of hospital doctors and nurses towards these commonly used drugs are unknown.

Hypnotic and sedative use could also be influenced by patient preferences. Patient satisfaction and (perceived, short-term) improvement of quality of life may motivate prescriptions. Over 90% of general practice patients taking benzodiazepines reported at least one benefit and 50% of respondents reported that they 'feel better overall'.¹³ Due to this kind of 'magic bullet' potential of benzodiazepines and Z-drugs, GPs might prescribe them because they feel overwhelmed by the psychosocial problems of their patients.¹⁴ However, we do not know whether a positive experience in the primary care setting may motivate patients to ask for a sleeping pill in the hospital and, vice versa, whether a positive experience in the hospital may be a reason why patients ask their primary care physician to continue this drug after discharge.

In Germany, it is possible for doctors to prescribe drugs for social health insurance patients via so-called 'private prescriptions'.^{15,16} In this case, the patient pays the entire cost for the drugs out of pocket. Since social health insurers have no record of these prescriptions, it may be possible that physicians prescribe drugs associated with abuse as private prescriptions to avoid liability issues. Looking at pharmacy data, Hoffmann and Glaeske¹⁷ found that private prescriptions made up nearly half (49%) of all prescriptions for zolpidem, a commonly prescribed Z-drug. However, we know very little about the doctors' reasons and motives for issuing private prescriptions.

¹These drugs are labelled 'p.r.n. drugs' (from Latin: 'pro re nata'; meaning 'as needed' or 'as the situation arises').

Any intervention to reduce the prescription and use of hypnotics and sedatives has to take into account this interplay between different actors, interests and needs. Therefore, we will study

- ▶ The frequency of hypnotic and sedative use during hospitalisation;
- ▶ The continuation or discontinuation of these drugs in primary care;
- ▶ The attitudes of hospital doctors and nurses towards hypnotics and sedatives;
- ▶ The reasons for beginning hypnotic and sedative prescriptions in primary care and in hospital, including the use of private prescriptions; and
- ▶ The experience of hospitalised patients with these drugs.

The ultimate goal of this study is to develop—together with the professionals involved—ideas for reducing the use of hypnotics and sedatives and then to implement and evaluate adequate interventions in the hospital and at the primary and secondary care interface.

METHODS AND ANALYSIS

This 2-year study makes use of a close cooperation between a university department of general practice, a regional general hospital, a number of primary care practices in the region and a large social health insurer. The framework for designing and evaluating complex interventions to improve healthcare from Campbell *et al*¹⁸ will be used in a supporting manner to guide the research and to develop an intervention. Figure 1 shows

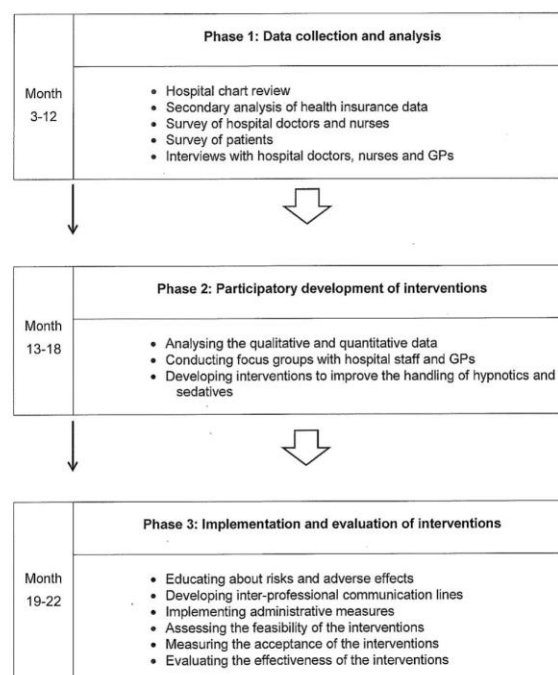


Figure 1 Flow chart of study phases.



the three phases of the project. First, we will collect data from doctors, nurses, patients and a social health insurer to define the problem from multiple perspectives. Second, we will explore these data with relevant stakeholders to develop ideas for an intervention. Third, the intervention will be implemented and evaluated.

Phase 1: data collection and analysis

Five different data sources or groups of informants will be addressed, using both quantitative and qualitative methods of data collection and analysis.

Hospital chart review

Aim: To determine the amount of hypnotics and sedatives administered in a regional hospital and possible patient characteristics associated with administration.

Data source and data collection: This retrospective chart review will include all patients ≥ 65 years who were hospitalised during a defined period of time. Patients of all wards in the hospital (internal medicine, geriatrics, trauma surgery, general surgery, urology, plastic surgery and otolaryngology) will be included. Patients without at least one overnight stay and cases of death will be excluded. Anonymised data will be collected from the clinical records of the patients using a computer-based form. It will be password-secured and stored on the security servers of the University of Göttingen. The data will include the following information:

- ▶ Age and sex of the patient;
- ▶ Duration of hospital stay;
- ▶ Referral from (home, other hospital, rehabilitation or nursing home);
- ▶ Discharge to (home, other hospital, rehabilitation or nursing home);
- ▶ Hospital ward;
- ▶ Actual diagnosis and other diagnoses;
- ▶ Addictive disorders;
- ▶ Prescribed and administered hypnotics and sedatives;
- ▶ Dosages and number of times hypnotic and sedative drugs were taken;
- ▶ Medication on admission;
- ▶ Discharge medication.

Data analysis: The absolute and relative number of patients who receive one or more benzodiazepines, Z-drugs, antidepressants and antipsychotics during their hospital stay will be analysed. Predictors for the prescription of hypnotics and sedatives, such as patient age and gender, condition or the hospital ward will be identified by multivariate logistic regression analyses.

Secondary analysis of health insurance data

Aim: To ascertain the overall influence of hospitalisation on the prescription of anxiolytics and hypnotics and sedatives, especially benzodiazepines and Z-drugs in outpatient care.

Data source and data collection: Our data base comprises primary care prescription data from all patients who (1) live in the federal states of Berlin, Brandenburg and

Mecklenburg-West Pomerania and (2) are insured by one of the largest social health insurers in Germany. We will select all patients who were hospitalised in 2012 and compare their prescriptions before and after hospitalisation. The following data will be available:

- ▶ Pseudonymised identification number of the insured person, including age and sex;
- ▶ Dates of hospital admission and discharge, including the hospital wards;
- ▶ Anatomical Therapeutic Chemical (ATC) classification system code and pack size of each prescription.

As social health insurance claim data in Germany do not contain any information about prescriptions in hospital, the analysis will be restricted to outpatient-dispensed prescriptions.

Data analysis: At the patient level, we will compare the number of benzodiazepines and Z-drugs (ATC codes N05BA, N05CD, N05CF) dispensed in the primary care sector before and after hospitalisation. We will define a prescription of benzodiazepines and Z-drugs as a 'new prescription' if a patient has not received such a drug during 50 days before hospitalisation but receives it during the 50 days following a hospitalisation, and as a 'long-term medication' if repeat prescriptions occur in the second 50 days after hospitalisation. These periods of time were chosen because a normal prescription typically comprises a package of up to 50 units (eg, tablets). Statistical analysis will include, besides others, the McNemar test for dependent samples.

Survey of hospital doctors and nurses

Aim: To understand the knowledge and attitudes of hospital doctors and nurses with regard to hypnotics and sedatives, especially in terms of their risks and benefits.

Data source and data collection: All doctors (~120) and nurses (~260) working in the cooperating general hospital will be invited to participate in the survey. A previously published questionnaire for GPs¹⁹ will be adapted to the hospital situation and distributed to all doctors and nurses together with their pay cheques. The study team will promote the study with informative posters and personally invite employees to participate in the study, for example, during routine meetings.

Data analysis: We will compare doctors' and nurses' points of view about the frequency of use, benefits and harms of hypnotics and sedatives, differentiating between benzodiazepines and Z-drugs. In a multivariate logistic regression, we will analyse whether the likelihood of prescribing or dispensing a hypnotic or sedative drug increases according to medical specialty or ward (surgery, internal medicine, geriatrics), professional group (doctors or nurses) and years of experience. A special focus will be given to contrasting the perceptions of hospital doctors and nurses. First, we will contrast each group's perception of how often benzodiazepines and Z-drugs are prescribed (doctors) and dispensed (nurses). Also, we will look in detail at how each



professional group perceives the benefits and side effects of these drugs.

Survey of patients

Aim: To compare patients' self-reported use of sleeping pills in the hospital with the data from the hospital records, and to survey patients' experiences of effects and side effects, and their attitudes towards use of these drugs at home.

Data source and data collection: Five hundred inpatients ≥ 65 years will be personally interviewed using a standardised format 1 day before or on the day of their hospital discharge. Data from consenting patients will be matched with their patient file information on the use of benzodiazepines, Z-drugs, mirtazapine, melperone or other hypnotics and sedatives. Data will be stored and analysed in a pseudonymised form.

Data analysis: Interview responses will be analysed descriptively. To determine possible predictors for the wish to receive sleeping pills also after discharge, age, gender, hospital ward will be included in multivariate models. Agreement between the patients' reported use of hypnotics or sedatives and the hospital file will be determined by the κ statistics.

Interviews with hospital doctors, nurses and GPs

Aim: To understand the usage of hypnotics and sedatives from the prescriber and dispenser perspective—particularly in hospital care—and to reconstruct the decision-making and prescribing processes at the primary and secondary care interface. Research questions which guide this part of the study are: Why do hospital doctors, nurses and GPs prescribe/dispense hypnotics and sedatives; what are the trigger and reasons? Which factors influence an increased use of hypnotics and sedatives (eg, high workload, lack of time, ambiguous division of labour, pressure to act)? Since these are rather sensitive topics, they will be addressed in an open and unobtrusive way so that our interview partners feel encouraged to talk about them.

Data source and data collection: The sample of interview partners should comprise 10–12 participants from each occupational group (hospital doctors, nurses, GPs). Hospital doctors and nurses will be recruited from the regional general hospital through word-of-mouth and telephone requests. GPs will be recruited by telephone or through face-to-face contacts. Sampling will consider gender, age, job function and length of experience, aiming at maximum variability. The sample of GPs will also consider the practice location. Semistructured interviews (see online supplementary appendices 1–3 for interview guidelines) will last about 30–45 min. The interviews will be recorded and transcribed.

In accordance with recommended principles for conducting qualitative research, the interviews will begin with a narrative opening question; however, a self-developed topic guide will provide a flexible framework

to explore beliefs that were not spontaneously covered in the participants' initial narrative.

The topic guide will be developed on basis of the previous quantitative survey and a literature review. Topics will include experiences and attitudes regarding the prescription and handling of hypnotics and sedatives, external influences such as reimbursement method and physician–patient relations, the possibility of 'private prescriptions', knowledge about the benefits and risks of hypnotics and sedatives, alternative therapies for insomnia, critical incidents and requested support.

Data analysis: The interviews will be analysed according to Mayring's¹⁹ qualitative content analysis. Materials will be coded using an inductive procedure. Categories obtained will be discussed by an interprofessional research team with expertise in hospital geriatrics, family medicine, nursing science, health services research and sociology to validate ratings and achieve consensus.

Phase 2: participatory development of interventions

To take the complexity of the situation into account, we will invite all relevant stakeholders, especially practitioners at the grass roots level, as partners in the research process.²⁰ These partners will join us to discuss and develop interventions with the aim of reducing the prescription and use of hypnotics and sedatives. The most important component of such a participatory approach²⁰ will be a series of focus groups with hospital doctors, nurses and GPs to discuss the phase 1 results. Each group will consist of about 10 participants. Each focus group will start with a short feedback on our previously collected quantitative and qualitative data. We will then try to stimulate a discussion about how to change the situation. Ample opportunity will be given to the multiple views of the problem in order to guarantee that the different needs of the participants can be addressed and considered when developing ideas for interventions. We will reflect on the needs and input from the local stakeholders in light of the current state of research about effective interventions for reducing hypnotics and sedatives.

During the sessions, preliminary results will be compiled following by the knowledge mapping method.²¹ A final synopsis will be circulated among all members.²⁰

Phase 3: implementation and evaluation of interventions

The final phase of the project will be based on the results of the data collection (phase 1) and the focus group discussions (phase 2) and include the implementation and evaluation of interventions.

Implementation of interventions

Successful implementation of interventions depends, besides others, on the target audience's willingness to change behaviour. We will have to consider a variety of attitudes and opinions of nurses, hospital doctors and GPs as well as a variety of organisational structures. For

example, nurses are often the first health professionals to be contacted about sleeping problems in hospitals. In primary care, however, patients typically address their sleep problems directly to their GP. Therefore, it will be necessary to develop interventions which address both the actions and strategies of the individuals involved as well as the organisational structures of their professional working environment.

Interventions may involve the following topics:

- ▶ Discussing the risks and adverse effects of hypnotics and sedatives within the interprofessional team, including how to inform patients about risks and possible alternatives, including non-pharmacological strategies;
- ▶ Improving interprofessional communication lines in challenging situations and developing a team spirit for balancing patient needs and workplace demands;
- ▶ Implementing administrative measures (eg, a standardised care pathway for patients with insomnia, quality management indicators) for handling hypnotics and sedatives.

Evaluation

The evaluation of the interventions will address two aspects: (1) feasibility and (2) effectiveness, including the following questions:

- ▶ Will all target groups accept, and participate in, the interventions?
- ▶ Will the participants be satisfied with the interventions?
- ▶ Can the interventions reduce the amount of hypnotics and sedatives being prescribed in the hospital and in general practice?

The research team will record and analyse quantitative data about the participation rates of the different professional groups in intervention activities, for example, how many nurses participated, from which wards, etc, in order to measure whether all relevant professional groups could be reached. Participants in intervention activities, for example, a workshop about the treatment of sleeping problems, will be asked to fill in a survey form about their satisfaction with the workshop, its relevance and remaining knowledge gaps regarding hypnotic and sedative drugs.

After the interventions, hospital employees will be asked to self-rate their competence in handling hypnotic and sedative drugs within the framework of a regular employee survey. The hospital pharmacy will provide benchmarking data in terms of the type and amounts of hypnotic and sedative drugs dispensed in the different departments before and after the interventions.

A larger, controlled effectiveness trial of the intervention featuring clinical outcomes is outside the scope of this project and requires additional funding.

DISCUSSION

Following the framework for designing and evaluating complex interventions,¹⁸ we will collect data from

various sources (see phase 1) to explore the context and structural surrounding conditions that influence the prescription and use of hypnotics and sedatives and then bring together all professional parties involved to develop interventions (see phase 2) that help to avoid unnecessary prescriptions and use of hypnotics and sedatives in primary and secondary healthcare. The evaluation will focus on feasibility and effectiveness of the interventions (see phase 3).

Strengths and limitations

Due to the close cooperation between a university department and a regional general hospital, this project will have the opportunity to investigate the attitudes and experiences of doctors and nurses concerning hypnotics and sedatives and thus try to reconstruct the prescribing and dispensing process at the primary and secondary care interface. Other studies have concentrated on individual actors of the primary and secondary care interface separately,^{11 13 22} whereas we will look at the interaction between professional groups, patients and settings and include all wards. This design will contribute to a comprehensive description of the problem.

To measure the frequency of hypnotics and sedatives, we will use different data sources and different methods, namely the combination of a hospital chart review and a secondary analysis of social health insurance data. This design will contribute to the validity of our data about the use of hypnotics and sedatives in the hospital and at the primary and secondary interface. Our research will be dependent on well-documented hospital charts and social health insurance records. The analysis of continuation or discontinuation of these drugs on the interface between the hospital and primary care will be dependent on the completeness of discharge letters.

Using the hospital charts, it is, on principle, not possible to exactly determine whether the drugs under study have been administered because of sleeping problems or other reasons. We only know from exploratory discussions with experts in the hospital that the majority of hypnotics and sedatives are described for sleeping problems. Moreover, we will compare the patients' answers about the drugs used in the hospital with the data in the hospital charts. In case of a high agreement, we can conclude that the drugs under study were, indeed, used for sleeping problems.

With regard to the recruitment of interviewees, we expect a selection bias: individuals who are sensitive to the problems and risks associated with hypnotics and sedatives will be more likely to participate. Furthermore, it could be possible that we obtain socially desirable answers in both surveys as well as semistructured interviews.

For the patient survey, we will not consider patients who suffer from severe forms of dementia as interview partners; consequently, we cannot explore the perspectives of these patients, who are often treated with hypnotics and sedatives.

In terms of a sustainable development, it would be desirable to extend the interprofessional intervention created here to other hospitals, family practices and/or quality circles. A further aim will be to develop a larger trial to evaluate the effectiveness of an interprofessional intervention for reducing hypnotic and sedative use in hospitals and/or primary care.

ETHICS AND DISSEMINATION

Patient and staff information sheets will be distributed on the wards and clinical areas before and during the study. Before the study, the researchers will spend time in each ward to make the staff aware of the study, respond to any queries about the study and hand them information sheets. All participants will receive written information sheets to provide written informed consent. All person-related data will be collected and treated according to current data privacy legislation. Medical and nursing staff as well as GPs and patients participating in the study will be assigned a unique participant identifier. Clinical records included will be also assigned a unique participant identifier. The list of clinical records included, participant identifier and associated identification numbers will be kept separate from the data collection in the university department. This data key list will be destroyed at the end of the study.

Results will be disseminated among researchers, clinicians, medicals schools, nursing schools and health planners in peer-reviewed journal articles and conference publications. Additionally, the findings of the research in the hospital setting will be reported in the hospital staff magazine. Local events for continuous professional development will share the research results among local professionals, including (but not confined to) the study participants.

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Contributors All authors contributed to the design of the research. EH-P, RN and WH are the initiators and primary supervisors of the project. SH and VW are two of the main researchers and drafted the manuscript. KS is responsible for the chart review; TG is responsible for the secondary analysis of the health insurance data. All authors contributed to the manuscript and approved the final version.

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Competing interests None declared.

Ethics approval Göttingen University Medical Center Ethics Committee (ref number 25/2/14).

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3.2 **Paper 2: Chart review of psychotropic drugs for older hospital patients**


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RESEARCH ARTICLE

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High prevalence of prescription of psychotropic drugs for older patients in a general hospital

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Abstract

Background: Many elderly patients receive psychotropic drugs. Treatment with psychotropic agents is associated with serious side effects including an increased risk of falls and fractures. Several psychotropic drugs are considered potentially inappropriate for treatment of the elderly.

Methods: A retrospective chart review was conducted covering all patients aged ≥ 65 years who were admitted to Evangelisches Krankenhaus Göttingen-Weende between 01/01/2013 and 03/31/2013. Psychotropic drugs reviewed for included benzodiazepines, Z-drugs, antidepressants and neuroleptics, but not drugs for sedation during artificial ventilation or pre-medication before surgery. Potentially inappropriate drugs were identified according to the PRISCUS list. To assess which factors were associated with the administration of psychotropic drugs, univariate and multivariable logistic regression analyses were performed.

Results: The charts of 2130 patients (1231 women) were analyzed. 53.9% of all patients received at least one psychotropic medication (29.5% benzodiazepines, 12.6% Z-drugs, 22.2% antidepressants, 11.9% neuroleptics). The mean number of psychotropic drugs prescribed per patient with at least one prescription was 1.6. Patients treated in the geriatric department most often received antidepressants (45.0%), neuroleptics (20.6%) and Z-drugs (27.5%). Benzodiazepines and Z-drugs were prescribed mostly as medication on demand (77.7% of benzodiazepines, 73.9% of Z-drugs). Surgical patients most frequently received benzodiazepines (37.1%). Nearly one-third of all patients ≥ 65 years was treated with at least one potentially inappropriate psychotropic medication. The mean number of potentially inappropriate psychotropic medications per patient with at least one psychotropic prescription was 0.69. The percentage of patients with potentially inappropriate psychotropic medication was highest in the surgical departments (74.1%). Female gender (adjusted OR 1.36; 95% CI 1.14 to 1.63), stay in the Department of Geriatrics (2.69; 2.01 to 3.60) or the interdisciplinary intensive care unit (1.87; 1.33 to 2.64) and age ≥ 85 years (1.33; 1.10 to 1.60) were associated with psychotropic drug treatment.

Conclusions: A high percentage of patients aged ≥ 65 years received psychotropic drugs. The chance that a potentially inappropriate psychotropic drug would be administered was highest in the surgical departments. Antidepressants, neuroleptics and Z-drugs were used surprisingly often in geriatric medicine. Educational strategies could reduce the use of psychotropic drugs and the prescription of potentially inappropriate medications.

Keywords: Pharmacoepidemiology, Drug use, Psychotropic drugs, Elderly, Retrospective study, Hospital

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Background

A high percentage of older patients are administered psychotropic drugs, despite the considerable risks associated with their use. Falls, drug-induced cognitive decline and excess mortality during treatment with psychoactive drugs [1–8] are frequent problems in the care of older people. Especially benzodiazepines and Z-drugs are frequently prescribed to older persons with sleeping problems. Medication-related fall risk factors have been identified in previous studies [9]. The risk of falls is evident for psychotropic drugs, but also for antihypertensives and polymedication [4, 10, 11]. The Swedish National Board of Health and Welfare (NBHW) has generated a list of fall-risk increasing drugs (FRID) which includes opioids, neuroleptics, anxiolytics, hypnotics and sedatives, and antidepressants [12].

Benzodiazepines, Z-drugs, antidepressants and neuroleptics contribute to cognitive deficits in patients [13–15]. Chronic use of benzodiazepines is associated with a lower latent cognitive level [16]. Antidepressants or neuroleptics with strong anticholinergic side effects are more likely to induce cognitive decline than less anticholinergic drugs [17]. Excess mortality due to the use of psychoactive drugs has been extensively studied with neuroleptics. Up to one-third of nursing home residents receive at least one neuroleptic drug [17, 18]. Both conventional and atypical neuroleptic drugs increase mortality in the elderly by a factor of approx. 1.5–1.7 [3, 7]. The risk increases with higher dosages and is highest in the first weeks after start of therapy [1, 8]. Moreover, the risk of cerebrovascular events appears to be elevated by 1.3 to 2 in older people taking neuroleptics [19, 20].

In view of the severe potential side effects of psychotropic drugs and the potential for improvement by adhering to guidelines for their use, we conducted a retrospective survey of the current practice in patients older than 65 years. We hypothesized that in some departments sleep disorders very frequently were treated with benzodiazepines, and that not all departments adhered to the PRISCUS list [21], an expert opinion-based list of potentially inappropriate drugs in the elderly that is currently used as a guideline in Germany. Therefore, we assessed the frequencies and average daily doses of treatments with benzodiazepines, Z-drugs, antidepressants and neuroleptics in patients ≥ 65 years in relation to the department, in which the patient was treated, and to the recommendations of the PRISCUS list. The study took place in a regional general hospital with several surgical departments as well as departments of general internal and geriatric medicine.

Methods

Sampling

The study was carried out in a regional hospital in Lower Saxony, Germany, which focusses on basic and standard in-patient care. There are seven departments with a total

of 485 beds: internal medicine, geriatrics (acute geriatrics and geriatric rehabilitation), trauma surgery/orthopedics, general surgery, plastic surgery, urology and otorhinolaryngology. We retrospectively reviewed the paper hospital charts of all patients aged 65 years or older who were admitted to the hospital for at least one night in the time period between 01/01/2013 to 03/31/2013. The period in the past was chosen to ensure that most of the hospital charts were accessible in the hospital archive and not in current use for administrative purposes. In 2016, we began interventions to reduce the consumption of benzodiazepines. We expect that the prescriptions of psychotropic drugs between 2014 and 2016 did not differ substantially from 2013; the effect of the interventions will become apparent in the course of 2017 and 2018. Patients who died were not included in the study, because they often received benzodiazepines in their last days of life as part of their palliative care. Furthermore, psychotropic drugs applied as sedatives for artificial ventilation or premedication before surgery or in the postanaesthesia care unit were not taken into consideration including those used for agitation after surgery, i.e. at the end of sedation.

Data collection

Patients' age, sex, department and duration of stay were retrieved from computerized lists of patients available for the whole hospital. These lists were used to order the paper charts from the archive. The patients' data including diagnoses were gathered from the charts and documented anonymously using a computer-based standardized case report form (CRF). Possible predisposing factors for a treatment with psychotropic drugs were also noted: living place before and after the present hospital stay (own home, nursing home, other department in same hospital, other hospital or unknown), medication or drug addictions (if documented). Intra-hospital transferees (161 patients, 7.6%) were counted as one patient in each department. This was necessary due to the fact that after each intra-hospital transfer, a new prescription plan was set up under the guidance of the physician or surgeon in charge of the patient. Otherwise we would have been unable to calculate department-specific differences.

The use of benzodiazepines, Z-drugs, antidepressants and antipsychotic or sedative neuroleptics during the hospital stay was recorded in detail: the name of the drug, the number of days the drug was administered, and based on this information the average daily dose. Furthermore, we documented whether drug treatments were initiated or stopped or whether there was any attempt to reduce the dosage during the hospital stay. Besides data concerning the hospital period, we also recorded the psychotropic drug medication before and after hospitalization (as documented in the admission

form and the discharge letter). “Discontinued medication” referred exclusively to the drugs a patient had been receiving prior to hospital admission that were stopped during hospital stay. The study was approved by the Ethics Committee of the University Medical Center Göttingen (reference number: 25/2/14).

Statistical analysis

To facilitate data handling and comparisons, several variables were grouped into classes. The departments were categorized into three groups: surgical departments (trauma surgery/orthopedics, general surgery, plastic surgery, urology and oto-rhino-laryngology), general internal medicine and geriatrics. This categorization was based on the different attributes of the departments, which were comparable in all surgery departments (similar intensity of doctor-patient contact, similar drug management procedures, similar processes in admission and discharge) as opposed to the Departments of Internal Medicine (more drug-centered treatment) and Geriatrics (high incidence of depression and dementia, longer time of stay, rehabilitative approach, interest of the staff not only in medical, but also in social conditions, special focus on the medication regime, older patients). This categorization of the departments allowed departments with only few patients (e.g. oto-rhino-laryngology, $n = 2$) to be included in the analysis. Patient age was divided into high age (65-84 years) and very high age (≥ 85 years) for the multivariable logistic regression analysis.

The dependence of patient characteristics and the drugs prescribed on the department category are described in absolute and relative numbers. Furthermore, the prescription frequency of the different psychotropic substances and differences in prescribing between the departments were of main interest. To assess which factors were significantly associated with the administration of at least one psychotropic substance, we performed univariate and multivariable logistic regression analyses and calculated the odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) as measures of effect size [22]. Goodness of fit of the multivariable analysis was assessed by the Hosmer-Lemeshow test, with p -values > 0.05 supporting the model's adequacy.

Potentially inappropriate drugs according to the PRISCUS-list

To identify potentially inappropriate drugs for the elderly, we based our analysis on the German PRISCUS list [21]. This list names substances associated with a high risk of side effects in patients aged ≥ 65 years. For some compounds, the list defines a maximum recommended daily dose, others are classified as potentially inappropriate regardless of dosage. The basis for the classification

as potentially inappropriate was either the administration of the drug at any dose (if the drug was considered potentially inappropriate irrespective of its dose) or the average daily dose determined by the questionnaire (if the drug was considered potentially inappropriate only at high doses). Potentially inappropriate psychotropic drugs according to the PRISCUS list which were used in patients treated at our institution were: benzodiazepines - lormetazepam > 0.5 mg/d, lorazepam > 2 mg/d, brotizolam > 0.125 mg/d, oxazepam > 60 mg/d, diazepam, temazepam, bromazepam, dipotassium clorazepate, flunitrazepam, alprazolam, clonazepam, nitrazepam, flurazepam; Z-drugs - zopiclone > 3.75 mg/d, zolpidem > 5 mg/d; antidepressants - amitriptylin, doxepine, trimipramine, clomipramine, imipramine, maprotiline, fluoxetine; neuroleptics - haloperidol > 2 mg/d, olanzapine > 10 mg/d, levomepromazine, clozapine.

Results

Sample

A total number of 2130 patients aged 65 years or older were included, 57.8% ($n = 1231$) of the patients were women, 42.2% ($n = 899$) men.

The mean age was 79.2 years, and the mean length of stay was 9.1 days. The mean length of stay ranged from 7 days at the Dept. of Internal Medicine and the surgical departments to 23 days at the Dept. of Geriatrics. The longest hospital stay of an individual patient was 72 days. Most patients admitted to the hospital came from their own homes (65.2%). 12.1% came to the hospital from nursing homes, 7.6% from another department of the same hospital, 6.4% from another hospital, and in 8.7% of the patients the previous residence was not documented (most of these patients came probably from their own homes). Demographic and clinical characteristics are presented in Table 1. Two hundred thirty patients (10.8%) had a diagnosis of dementia documented in the discharge letter, and in 124 (5.8%) depression was diagnosed.

Prevalence of in-hospital consumption of psychotropic drugs

Approximately half of the patients (53.9%) received at least one psychotropic drug during their hospital stay, with benzodiazepines being the most frequently prescribed psychotropic drugs. 27.4% of the patients received a psychotropic medication before admission and 29.0% after discharge (Fig. 1). Patients who received at least one psychotropic drug in the hospital ($n = 1149$) had a longer hospital stay than those who did not receive any psychotropic drug ($n = 981$) (10.95 ± 10.07 days versus 6.93 ± 6.90 days, $p < 0.0001$, t -test). The mean number of psychotropic drugs prescribed per patient in patients who received at least one prescription of a psychotropic drug was 1.6.

Table 1 Age distribution of the sample

	Department	n	%	mean	Age			
					SD	median	min	max
Sex								
Female	surgical departments	512	24.0	78.3	7.8	77	65	100
	internal medicine	525	24.7	80.9	7.6	82	65	101
	geriatrics	194	9.1	83.8	6.7	85	67	99
	total	1231	57.8	80.3	7.8	80	65	101
Male	surgical departments	438	20.6	75.7	6.7	75	65	95
	internal medicine	364	17.1	78.7	7.1	79	65	97
	geriatrics	97	4.6	82.4	6.3	83	69	95
	total	899	42.2	77.6	7.2	77	65	97
Department								
	surgical depts.	950	44.6	77.1	7.4	76	65	100
	internal medicine	889	41.7	80	7.5	80	65	101
	geriatrics	291	13.7	83.3	6.6	85	67	99
	total	2130	100	79.2	7.7	79	65	101

Age in years, SD = standard deviation, surgical departments include: trauma/orthopedic surgery, urology, otorhinolaryngology, general surgery and plastic surgery

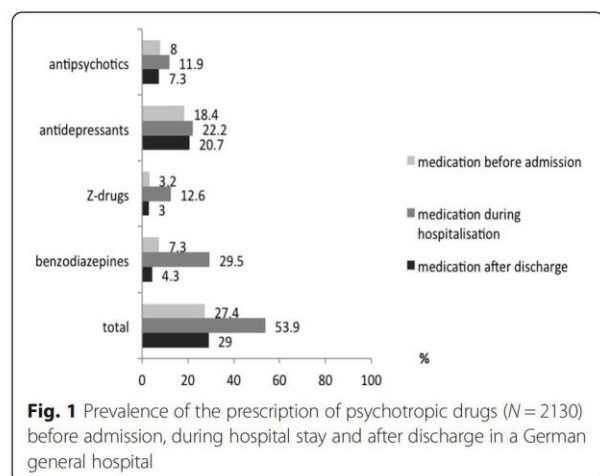
In hospital, antidepressants and neuroleptics with sedative effects were prescribed more often than stimulating or anti-psychotic agents; 14.2% vs. 11.7% for antidepressants and 8.7% vs. 4.9% for neuroleptics. The most frequently prescribed psychotropic drugs were: lormetazepam, lorazepam, zopiclone, mirtazapine, citalopram and melperone (Table 2).

Benzodiazepines and Z-drugs were prescribed mostly as medication on demand (77.7% of benzodiazepines, 73.9% of Z-drugs). Neuroleptics were prescribed both as long-term medication (60.1%) and medication on demand (39.9%), whereas antidepressants were prescribed almost exclusively as long-term medication (99.6%).

Compared to patients treated in the surgical departments (51.3%) and the Dept. of Internal Medicine (50.3%), patients in the Dept. of Geriatrics were more likely to

receive psychotropic drugs (73.9%). All groups of psychotropic drugs were prescribed most frequently to patients in the Dept. of Geriatrics with the exception of benzodiazepines, which were prescribed most frequently to patients in one of the surgical departments (Fig. 2).

In 9.3% of all patients ≥ 65 years at least one new psychotropic drug was started during their hospital stay and recommended in the discharge letter (Table 3). The most frequent newly started psychoactive compounds were the antidepressants mirtazapine ($n = 81$, 3.8%) followed by citalopram ($n = 20$, 0.9%). Melperone ($n = 24$, 1.1%), tetrazepam ($n = 17$, 0.8%) and zolpidem ($n = 10$, 0.5%) were the most frequent newly prescribed neuroleptic, benzodiazepine and Z-drug. In 5.5% of patients a long-term psychotropic medication that the patients had been receiving prior to hospital admission was discontinued. Tricyclic antidepressants (amitriptyline, doxepine, trimipramine, nortriptyline; $n = 22$), citalopram ($n = 20$) and mirtazapine ($n = 13$) were the most frequently discontinued antidepressants, melperone ($n = 11$), risperidone ($n = 7$) and promethazine ($n = 5$) were the most frequently discontinued neuroleptics. The most frequently discontinued benzodiazepines and Z-drugs were zopiclone ($n = 8$, 0.4%), lorazepam ($n = 6$, 0.3%) and lormetazepam ($n = 6$, 0.3%). Overall, geriatricians prescribed a new treatment with psychotropic drugs most frequently, but also most often discontinued other long-term psychotropic medications.



Factors associated with the prescription of psychotropic drugs

Three factors were significantly predictive in the univariate model for the prescription of at least one psychotropic

Table 2 Prevalence of all psychotropic drugs prescribed in the period studied

Psychotropic drugs	n	%	Potentially inappropriate (%)
benzodiazepines			
lormetazepam ^a	403	18.9	> 0,5 mg/d (97.3)
lorazepam ^a	155	7.3	> 2 mg/d (1.9)
tetrazeepam	26	1.2	each dose (100)
diazepam	25	1.2	each dose (100)
oxazepam	25	1.2	> 60 mg/d (0)
temazepam	15	0.7	each dose (100)
bromazepam	12	0.6	each dose (100)
dipotassium clorazepat	10	0.5	each dose (100)
flunitrazepam	9	0.4	each dose (100)
alprazolam	5	0.2	each dose (100)
brotizolam	5	0.2	> 0.125 (80)
clonazepam	3	0.1	each dose (100)
midazolam	3	0.1	n.a.
nitrazepam	2	0.1	each (100)
flurazepam	1	0.1	each dose (100)
neuroleptics			
melperone	119	5.6	n.a.
prothipendyl	58	2.7	n.a.
quetiapine	42	2.0	n.a.
haloperidol	33	1.6	> 2 mg/d (42.4)
promethazine	29	1.4	n.a.
risperidone	20	0.9	n.a.
aripiprazole	6	0.3	n.a.
olanzapine	6	0.3	> 10 mg/d (50)
pipamperone	3	0.1	n.a.
levomepromazine	2	0.1	each dose (100)
clozapine	2	0.1	each dose (100)
flupentixol	1	0.1	n.a.
pimozid	1	0.1	n.a.
sulpirid	1	0.1	n.a.
Z-drugs			
zopiclone	171	8.0	> 3,75 mg/d (60.8)
zolpidem	112	5.3	> 5 mg/d (76.8)
antidepressants			
mirtazapine	228	10.7	n.a.
citalopram	138	6.5	n.a.
duloxetine	47	2.2	n.a.
venlafaxine	34	1.6	n.a.
amitriptyline	31	1.5	each dose (100)
doxepine	22	1.0	each dose (100)
sertraline	14	0.7	n.a.
trimipramine	12	0.6	each dose (100)

Table 2 Prevalence of all psychotropic drugs prescribed in the period studied (*Continued*)

Psychotropic drugs	n	%	Potentially inappropriate (%)
escitalopram	10	0.5	n.a.
opipramol	9	0.4	n.a.
trazodone	5	0.2	n.a.
maprotiline	5	0.2	each dose (100)
fluoxetine	5	0.2	each dose (100)
paroxetine	5	0.2	n.a.
clomipramine	4	0.2	each dose (100)
bupropion	4	0.2	n.a.
agomelatin	2	0.1	n.a.
mianserin	2	0.1	n.a.
imipramine	2	0.1	each dose (100)
fluvoxamine	1	0.1	n.a.

% of potentially inappropriate refers to patients receiving the respective psychotropic drug

^aAverage daily doses [mg] of the psychotropic drugs most frequently prescribed (medians). Lormetazepam: 1.0; lorazepam: 1.0; zopiclone 7.5; zolpidem 10.0; mirtazapine: 15; citalopram: 20; melperone: 25; prothipendyl: 50

drug; staying on an intensive care unit or the geriatric department, female gender and high age (Table 4). Treatment in the intensive care unit and in the Dept. of Geriatrics and gender remained statistically significant predictors of treatment with psychotropic drugs in the multivariable model (goodness of fit by Hosmer-Lemeshow test: $p = 0.16$), with a stay in the geriatric department being the strongest predictor (OR: 2.69; 95% CI: 2.01–3.60). In this multivariable analysis, high age (≥ 85 years) failed to be a significant factor for the prescription of a psychotropic drug.

We repeated the multivariable analysis for benzodiazepines and Z-drugs together (goodness of fit by Hosmer-Lemeshow test: $p = 0.80$). The probability that a patient would receive a benzodiazepine or Z-drug was higher in the Dept. of Geriatrics compared to the surgical departments (OR 1.5; 95% CI 1.14–1.97; $p = 0.004$). This was a

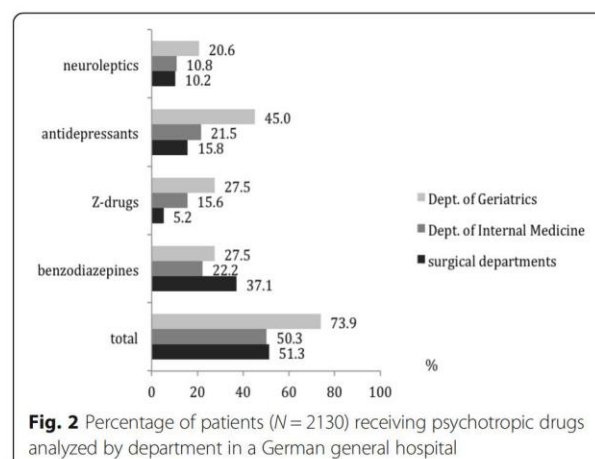
**Fig. 2** Percentage of patients ($N = 2130$) receiving psychotropic drugs analyzed by department in a German general hospital

Table 3 Number of patients receiving a new prescription of psychotropic drugs or a discontinuation of long-term psychotropic medication

	Total (N = 2130)	Benzodiazepines	Z-drugs	Antidepressants	Neuroleptics
new prescription	198 (9.3%)	33 (1.6%)	17 (0.8%)	126 (5.9%)	41 (1.9%)
long-term medication discontinued	118 (5.5%)	27 (1.3%)	15 (0.7%)	61 (2.9%)	31 (1.5%)

New prescription refers to psychotropic drugs newly prescribed during hospital stay and recommended in the discharge letter, long-term medication discontinued refers to medication, which was prescribed prior to hospital admission and discontinued during the hospital stay

consequence of the relatively frequent use of Z-drugs in the Dept. of Geriatrics. Age was inversely correlated with the prescription of benzodiazepines and Z-drugs, i.e., patients ≥ 85 years were less likely to receive these drugs than patients between 65 and 84 years (OR 0.79; 95% CI 0.65–0.97; $p = 0.023$). The multivariate analysis was also repeated with potentially inappropriate psychotropic drugs as dependent variable (goodness of fit by Hosmer-Lemeshow test: $p = 0.50$). Treatment in one of the surgical departments was associated with an increased probability of receiving a potentially inappropriate psychotropic medication compared with treatment in the Dept. of Geriatrics (OR 1.68; 95% CI 1.23–2.29; $p = 0.001$). Age < 85 years was associated with the prescription of potentially inappropriate psychotropics, i.e., younger patients were more likely to receive these drugs than older ones (OR 1.89; 95% CI 1.50–2.36; $p < 0.0001$).

Dementia and the prescription of neuroleptics

Of 230 patients with a diagnosis of dementia, 105 (45.7%) received at least one neuroleptic drug during their hospital stay. Eighty-two patients received one neuroleptic, 14 patients two different neuroleptics and 9 patients three

neuroleptics. The diagnosis dementia was strongly associated with the prescription of at least one neuroleptic drug ($p < 0.0001$, Fisher's exact test). There was no association between the prescription of an anti-dementia drug and a neuroleptic ($p = 0.73$, Fisher's exact test).

Potentially inappropriate psychotropic drugs

Nearly one-third of all elderly patients was treated with at least one potentially inappropriate psychotropic medication or an inappropriately high dosage. More than half of those who were treated with psychotropic drugs received at least one potentially inappropriate psychotropic medication (58.5%).

Differences were observed between the individual departments. Compared to the Dept. of Geriatrics (31.6%) and Internal Medicine (54.6%), patients treated in one of the surgical departments received the highest proportion of potentially inappropriate psychotropic drugs (74.1% of all patients receiving psychotropic drugs). The use of benzodiazepines at inappropriate doses in the surgical departments was most prominent (90.1%) (Fig. 3). The mean number of psychotropic drug prescriptions per patient was 0.88 (0.78 in the surgical departments, 0.80 in

Table 4 Factors associated with the prescription of psychotropic drugs

Influencing variables	%	Univariate model			Multivariable model ^a		
		OR	95%CI	<i>p</i> value	OR	95%-CI	<i>p</i> value
intensive care unit ^b							
no	52.8	1.0					
yes	67.7	1.87	(1.33–2.64)	0.0004	2.08	(1.47–2.96)	0.0001
sex							
male	48.8	1.0					
female	57.7	1.43	(1.20–1.70)	0.0001	1.36	(1.14–1.63)	0.0006
age							
65–84 years	51.9	1.0					
≥ 85 years	58.9	1.33	(1.10–1.60)	0.0036	1.10	(0.90–1.35)	0.33
department							
surgical departments	51.3	1.0					
internal medicine	50.3	0.96	(0.80–1.15)	0.67	0.96	(0.80–1.16)	0.70
geriatrics	73.9	2.69	(2.01–3.60)	0.0001	2.68	(1.99–3.61)	0.0001

P values, odds ratios and confidence intervals from univariate and multivariable logistic regression. (%) refers to patients prescribed psychotropic drugs based on $N = 2130$, OR odds ratio, CI confidence interval

^aGoodness of fit (Hosmer–Lemeshow test: $p = 0.16$)

^bPatients were treated at the intensive care unit (ICU) for part of their hospital stay. Psychotropic drugs administered during the ICU stay were not included in this evaluation

the Dept. of Internal Medicine, 1.46 in the Dept. of Geriatrics). Overall, the mean number of potentially inappropriate psychotropic medication per patient with at least one psychotropic drug prescription was 0.69. It was highest in patients treated in the surgical departments (0.90), intermediate in patients treated in the Dept. of Internal Medicine (0.63) and lowest in patients treated in the Dept. of Geriatrics (0.36). Most patients only received one potentially inappropriate psychotropic drug or an inappropriate dose during their hospital stay, but some patients received different potentially inappropriate psychotropic drugs, one patient was even prescribed 6 different potentially inappropriate psychotropic drugs during his hospital stay (Table 5).

The most frequent potentially inappropriate prescriptions according to the PRISCUS list were high doses of lormetazepam (> 0,5 mg/d, $n = 392$, mostly 1 mg/d), zopiclone (> 3,75 mg/d, $n = 104$, mostly 7.5 mg/d), zolpidem (> 5 mg/d, $n = 86$, mostly 10 mg/d), haloperidol (> 2 mg/d, $n = 14$, 2.5 mg/d or higher) and tricyclic antidepressants (amitriptyline $n = 31$, doxepine $n = 22$, trimipramine $n = 12$, clomipramine $n = 4$, imipramine $n = 2$) at any dose.

Discussion

The proportion of patients ≥ 65 years receiving psychotropic drugs in this hospital was high, i.e., 53.9% of the patients received at least one psychotropic drug during their hospital stay. With interdepartmental variations, this applied to benzodiazepines, Z-drugs, antidepressants and neuroleptic drugs. Especially in the surgical departments, we detected a high proportion of patients treated with potentially inappropriate psychotropic drugs.

In general, the proportion of patients ≥ 65 years treated with psychotropic drugs was highest in the Dept. of

Geriatrics. Several reasons may account for this: 1. Many geriatric patients suffered from geriatric multimorbidity including depression, chronic pain, insomnia, but also agitation during the day or night, hallucinations and delusions. 2. As recommended by the World Health Organization [23], antidepressants were used as adjuvants in analgesic medications at our institution. In a retrospective study, it often is difficult to identify the reason(s), why a drug was started. Often, more than one indication was present for the initiation of therapy, e.g., depression, sleep disturbance and weight loss as the reasons to choose mirtazapine. In the present study, therefore, no attempt was made to evaluate the indication for the prescription of an antidepressant. 3. In part, the antidepressant mirtazapine and the neuroleptics melperone and pipamperone were already used in the Dept. of Geriatrics during the study period as substitutes for benzodiazepines and Z-drugs for sleep induction. 4. The mean hospital stay of geriatric patients was longer than the mean stay in the other departments (23 days versus 7 days in the Dept. of Internal Medicine and in the surgical departments). One reason could be that the chance to develop symptoms necessitating treatment with a psychotropic drug was increased in geriatrics. Alternatively, patients requiring psychotropic drugs needed longer hospital stays to recover than patients who did not need psychotropics. Indeed, in the present study the duration of the hospital stay was longer in patients receiving psychotropic drugs than in those who did not receive any psychotropic medication ($p < 0.0001$).

Our data compare well with recently published data from nursing homes [5, 24, 25]. Residents in nursing homes, particularly those with dementia, often receive psychotropic drugs, among these even a high percentage of neuroleptics which may shorten their lives [1–4, 6–8]. In a recent Swedish study that reviewed all persons living in geriatric care units in Northern Sweden, in 2007 25.4% were reported to have received antipsychotic drugs, and 35.5% anxiolytic, hypnotic, or sedative drugs [24]. In Scotland, 28.4% of the population ≥ 65 years living in a care home received a benzodiazepine or a Z-drug [25].

When the medication prior to admission and the recommendations at discharge were compared (Table 3), 9.3% of all patients studied received a psychotropic drug as a new prescription, and in 5.5% a long-term medication was discontinued, i.e. the difference was 3.8%. Three percent of this difference was caused by antidepressants (5.9% of patients with prescription during hospital stay and recommendation in the discharge letter, 2.9% of patients whose antidepressants were stopped during their hospital stay). Conversely, new long-term prescriptions and discontinuation of long-term medication of benzodiazepines, Z-drugs and neuroleptics were almost equal. Hence, the high benzodiazepine and Z-drug use in in-

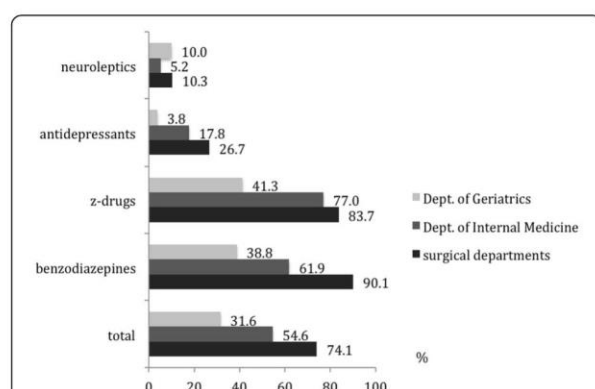


Fig. 3 Percentage of patients receiving at least one potentially inappropriate psychotropic drug analyzed by department. Patients with at least one potentially inappropriate psychotropic drug are given as a percentage of all patients receiving psychotropic drugs. For the definition of potentially inappropriate drugs see Methods and the PRISCUS list [22]

Table 5 Proportion of patients with 0 to 7 psychotropic drugs/ potentially inappropriate psychotropic medication during hospital stay

	Surgical Depts.	Dept. of Internal Medicine	Dept. of Geriatrics	Total (N = 2130)
all psychotropic drugs				
0	463	442	76	981
1	328	284	95	707
2	96	96	62	254
3	42	44	34	120
4	12	11	18	41
5	6	9	3	18
6	1	3	3	7
7	2	0	0	2
potentially inappropriate psychotropic drugs				
0	589	645	223	1457
1	302	212	59	573
2	45	29	9	83
3	11	1	0	12
4	2	2	0	4
5	0	0	0	0
6	1	0	0	1

For the definition of potentially inappropriate psychotropic medication see Methods and Table 2

patients did not result in an increase of the prescription of these drugs at discharge. This might be a result of the fact that the in-house medication of these drugs mostly was a medication on demand, which often was not included in the discharge letter.

In recent years, efforts to reduce the consumption of psychotropic drugs in institutions caring for older people have shown some success. The above mentioned Swedish study on patients living in geriatric care units noted that in 2013 the use of antipsychotic drugs had declined to 18.9%, and the prescription of anxiolytic, hypnotic, and sedative drugs had fallen to 29.4% [24]. Similarly, a mild decrease in the benzodiazepine use was observed in France between 2006 and 2012 in a population-based study [26]. Conversely, the prevalence of people receiving antidepressant drugs remained unchanged at approx. 50%. In the Swedish study, the use of anti-dementia drugs rose from 17.9 to 21.5% [24]. Anti-dementia drugs are often prescribed in an attempt to reduce the use of neuroleptics. In the present study, the prescription of an anti-dementia drug and a neuroleptic were not inversely associated, i.e., we found no evidence that the prescription of anti-dementia medication was associated with a reduced use of neuroleptics. Recently, it was suggested that physicians prescribing benzodiazepines to their elderly patients should educate these patients about the risks of benzodiazepine use and, when appropriate, offer them tapering protocols. A substantial proportion of long-term users appears to be able to taper off

benzodiazepines via low-intensity interventions [27]. The present study was part of a project aiming at the reduction in the consumption of benzodiazepines and Z-drugs in our hospital [28] by developing in-house recommendations for the pharmacological treatment as well as education about alternative options for sleep problems.

The wide use of potentially inappropriate psychotropic medications in all departments was striking. The most frequent reason for this was surpassing the recommended daily doses of drugs considered potentially inappropriate at high doses. One probable reason is that many medical doctors are not familiar with lists of potentially inappropriate drugs for older patients. Another important reason appears to be the wish of the patient to increase the dose of a benzodiazepine or Z-drug above the doses considered appropriate for the elderly [22]. The prescription of potentially inappropriate psychotropic medication was most frequent in the surgical departments. There is evidence that avoiding potentially inadequate medication in the elderly reduces complications, particularly cognitive impairment, falls and all-cause mortality [4, 9, 29–32]. Adherence to the PRISCUS list has been one goal of the interventions started in 2016 in the hospital studied here.

The main strength of this study is the extensive and detailed assessment of all psychotropic medication administered to the entire elderly patient population of a German general hospital in a particular time period. The

medications were classified according to the widely acknowledged PRISCUS list [22], an adaptation of Beer's criteria and their revisions [33, 34] to German conditions, which helped detect shortcomings and a potentially inappropriate or even dangerous use of these drugs. In several instances, the maximum recommended dose according to the PRISCUS list is lower than the maximum dose allowed in the officially approved product label.

One weakness of our study is the assessment of the year 2013. It is known that interventions can reduce the consumption of benzodiazepines in hospitals. Since interventions to reduce the consumption of benzodiazepines were started in 2016, we expect that in the period 2014–2016 the prescriptions of psychotropic drugs were very similar to 2013, and that the interventions of 2016 will begin to show effects in 2017 and 2018. It may be considered a weakness of this study that intra-hospital transferees were counted as one patient in each department. If we had not done this, however, we would not have been able to calculate department-specific differences. The main weakness of our study was the inability to identify the real cause of the prescription of a psychotropic drug. This was a consequence of several shortcomings: 1. We conducted a retrospective study, and the daily comments of the medical doctors in the patients' charts often were not detailed enough to identify the indications for the use of a psychotropic drug. 2. Often, one drug was prescribed for more than one indication (e.g., duloxetine or mirtazapine for depression and as analgesic adjuvants, quetiapine as an antipsychotic and as sleep inductor in patients with Parkinson's disease). 3. Approximately 11% of the patients analyzed in this study suffered from dementia. Patients with dementia often express discomfort, but frequently do not report their complaints in detail, which complicates the diagnosis of pain or depression and may result in an overuse of psychotropic drugs.

Conclusion

In a German general hospital, psychotropic drugs were frequently prescribed to patients ≥ 65 years, and a high percentage of older patients received potentially inappropriate psychotropic medication. Whereas in the Dept. of Geriatrics the proportion of patients receiving psychotropic drugs was highest, the proportion of patients receiving potentially inappropriate psychotropics was highest in the surgical departments. Awareness and the development of hospital-tailored guidelines for the treatment of sleep disturbances, delirium, dementia and depression may reduce the frequency of the use of psychotropic medication in general, and of potentially inappropriate psychotropic drugs or doses in particular.

Abbreviations

CI: Confidence interval; CRF: Case report form; FRID: Fall-risk increasing drugs; NBHW: Swedish National Board of Health and Welfare; OR: Odds ratio; p: Probability; PRISCUS: Literal translation: venerable; Project "Prerequisites for a New Health Care Model for Elderly People with Multi-Morbidity", funded by the German Ministry of Education and Research (BMBF); Z-drugs: A group of non-benzodiazepine drugs with effects similar to benzodiazepines, whose names start with the letter "Z"

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Availability of data and materials

The data sets generated and/or analyzed during the current study are not publicly available due to the rules of the Ethics Committee of the University Medical Center Göttingen, but are available from the corresponding author on reasonable request.

Authors' contributions

KS, IA, WH had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: EHP, WH, RN. Drafting of the manuscript: IA, KS, RN. Critical revision of the manuscript for important intellectual content: All authors. Acquisition, analysis, or interpretation of data: All authors. Statistical analysis: IA, KS, SH, WH. Study supervision: EHP, WH, RN. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the University Medical Center Göttingen (reference number: 25/2/14). Data were stored on a protected server of the University Medical Center Göttingen. The questionnaire was password-protected and taken offline after the completion of the data collection. Since the study was a retrospective chart review, did not comprise any interventions and data were processed anonymously, the Ethics Committee waived the need for consent of the patients to participate.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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3.3 **Paper 3: Survey of hospital doctors and nurses about benzodiazepines**

Heinemann S, Himmel W. Searching for factors that may reduce the use of benzodiazepines in hospitals - a survey of hospital doctors and nurses. *Int J Clin Pharmacol Ther* 2017; 55(12):905–10.



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Searching for factors that may reduce the use of benzodiazepines in hospitals – a survey of hospital doctors and nurses

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Key words

benzodiazepines
– attitudes of health
personnel – drug
utilization – question-
naires – risk perception

Abstract. A chart review at a mid-sized German general hospital found a high usage of benzodiazepines among older patients. Therefore, all doctors and nurses of this hospital were surveyed about the benefits and risks of benzodiazepines that they considered to be the strongest and their own overall assessment of the risk-benefit ratio for their patients. Response rate was 54% (63/116) for doctors and 30% (73/243) for nurses. “Reduced fear or agitation” was perceived by many doctors (71%) and nurses (49%) to be a strong benefit of benzodiazepines. With regards to the overall risk-benefit ratio, doctors who indicated that “falls” and/or “craving” often occur in combination with benzodiazepines were more likely to estimate that the risks of benzodiazepines outweigh the benefits. For nurses, “confusion” strongly influenced their overall assessment of the risk-benefit ratio. The results of this study will be incorporated into interventions for reducing benzodiazepine prescriptions.

Introduction

A hospital chart review found a high usage of benzodiazepines among older patients (28%), especially in those with sleeping problems, including many potentially-inappropriate prescriptions according to the German PRICSUS list [1]. From other studies, we know that hypnotics and sedatives, such as benzodiazepines, are still often administered in primary care, nursing homes, and hospital settings [2] – in spite of well-known safety concerns, such as craving, confusion, and increased falls [3].

Even though there have been calls to reduce the use of benzodiazepines in hospitals [4], there is a lack of evidence-based recommendations about how to reach this aim. In particular, little is known about the reasons for benzodiazepine use from the pre-

scriber perspective, especially in hospitals. Underlying beliefs and values, perceptions of innovation, and an individual’s overall assessment of a drug’s risk-benefit ratio all influence prescribing [5].

Therefore, it is important to know which benefits and risks of benzodiazepines doctors and nurses consider strongest and which of these factors are closely associated with their own individual overall assessment of the risk-benefit ratio of these drugs. This knowledge could help to tailor interventions to reduce the use of benzodiazepines in hospitals.

Materials and methods

Context

In a mixed-methods project, we strive to gain knowledge about the current use of sedatives and hypnotics in hospitals and primary-care settings [6]. The data reported here come from a survey performed between June and September 2014 of doctors and nurses about psychotropic drugs. The study was approved by the Ethics Committee of Göttingen University Medical Center (25/2/14). Parts of the survey results have already been analyzed [7].

Design, participants, and measures

In a cross-sectional survey, all physicians and nurses of a mid-sized to large-sized German general hospital received a paper questionnaire on risks and benefits of benzodiazepines. In order to raise the survey response rate, reminders were sent out, and the hospital staff were informed about the study and encouraged to participate during routine meetings.

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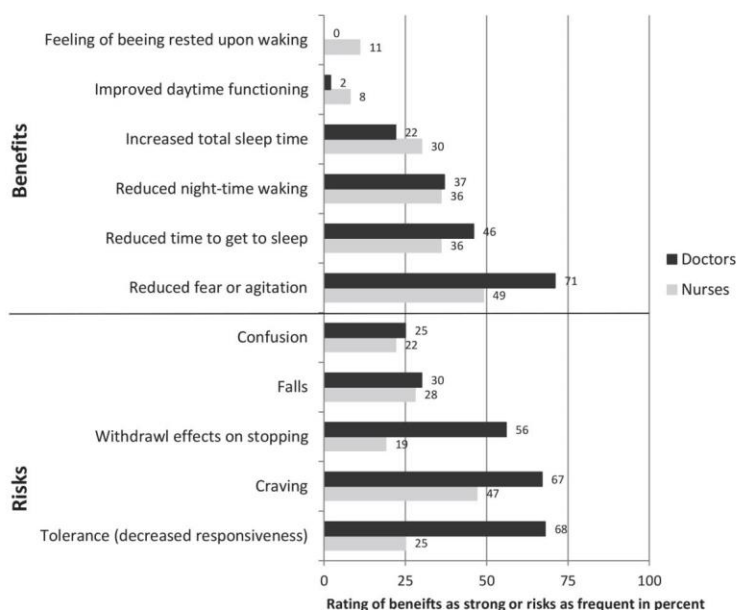


Figure 1. Percentage of hospital doctors and nurses who rated a benefit as strong or a risk as frequent.

The questionnaire was developed by Siriwardena et al. [8] to explore practitioners' beliefs about the benefits and risks of hypnotic prescribing. Hoffmann [9] translated the questionnaire into German for a survey of German general practitioners, and our study group adapted it to the hospital setting.

The questionnaire first requires the respondents to rate their overall assessment of risk-benefit ratio, i.e., whether in their view the benefits of benzodiazepines outweigh the risks or vice versa or whether risks and benefits are equal. Then, they are asked to rate the extent of different benefits ("very small" to "very strong") and the frequency of different risks ("never" to "always") on a 5-point scale.

Statistical analysis

We analyzed how many doctors and nurses rated the different benefits as "strong" or "very strong" and how many rated the frequency of different risks as "often" or "always" on a 5-point scale. Using multivariate logistic regressions, we then determined to what extent each individually-rated risk and benefit influenced the overall perception that the risks of benzodiazepines outweigh their benefits, with adjusted odds ratios (ORs) and their 95% confidence intervals (CI). All analyses were performed using SAS 9.4.

Results

More than half of the doctors (63/116) and approximately one-third of nurses (73/243) filled in and returned the study questionnaire. Many doctors (71%) and nurses (49%) rated "reduced fear or agitation" as a strong or very strong benefit (Figure 1). The majority of doctors perceived "tolerance" (68%), "craving" (67%), and "withdrawal" (56%) to be frequent risks of benzodiazepines. For nurses, the most frequently-perceived risk was "craving" (47%). Approximately one-quarter of participants from both professional groups considered "falls" and "confusion" to be frequent risks of benzodiazepines.

20 (27%) nurses and 30 (48%) doctors perceived the risks of benzodiazepines to outweigh the benefits, while 29 (40%) nurses and 12 (19%) doctors had the opposed perception. The remainder (24 nurses and 21 doctors) assessed that the risks and benefits were equal. In the following, we only compare those respondents who perceived the risks to outweigh the benefits versus all others.

The item "falls" most strongly predicted how an individual doctor assessed the overall risk-benefit ratio of benzodiazepines (Table 1). Of those doctors who rated "falls" as happening often or always, 79% (15/19) perceived the risks of benzodiazepines to outweigh the benefits. Vice versa, of those who did not rate "falls" as happening often or always, only 34% (15/44) did so. This strong association between "falls" and the overall risk-benefit ratio resulted in an adjusted OR of 12.04 (95% CI 1.72 – 84.54). "Craving", too, was a significant and strong predictor for a doctor's assessment that risks outweigh the benefits.

For nurses, "increased sleep time" predicted their individual overall assessment of risk-benefit ratio of benzodiazepines (Table 1). Of those nurses who rated "increased sleep time" a strong benefit, only 13% (3/22) perceived the risks of benzodiazepines to outweigh the benefits. Vice versa, of those who did not rate "increased sleep time" a strong benefit, one-third (17/51) did so. This resulted in a tremendously low OR of 0.08 that is easier to understand if we change the criterion – benefit instead of risk – and use the reciprocal value of the odds – 12.5 instead of 0.08. That means a nurse who rates "increased sleep time" to be a strong benefit

Table 1. Predictors for the global assessment that the risks of benzodiazepines outweigh the benefits.

Predictors	Nurses				Doctors			
	Risks outweigh the benefits				Risks outweigh the benefits			
	Yes (n = 20)		No (n = 53)		Yes (n = 30)		No (n = 33)	
	n	(%)	n	(%)	n	(%)	n	(%)
Benefits								
Reduced time to get to sleep								
Strong*	6	(23)	20	(77)	14	(48)	15	(52)
Not strong	14	(30)	33	(70)	16	(47)	18	(53)
Adjusted OR (95 % CI)**	2.55 (0.51 – 12.71)				1.33 (0.38 – 4.62)			
Reduced night-time waking								
Strong	9	(35)	17	(65)	11	(48)	12	(52)
Not strong	11	(23)	36	(77)	19	(48)	21	(53)
Adjusted OR (95 % CI)	3.45 (0.70 – 17.13)				0.71 (0.19 – 2.66)			
Increased total sleep time								
Strong	3	(14)	19	(86)	9	(64)	5	(36)
Not strong	17	(33)	34	(67)	21	(43)	28	(57)
Adjusted OR (95 % CI)	0.08 (0.01 – 0.72)				3.14 (0.63 – 15.69)			
Reduced fear or agitation								
Strong	7	(19)	29	(81)	20	(44)	25	(56)
Not strong	13	(35)	24	(65)	10	(56)	8	(44)
Adjusted OR (95 % CI)	0.24 (0.05 – 1.22)				0.71 (0.18 – 2.83)			
Risks								
Falls								
Frequent***	10	(50)	10	(50)	15	(79)	4	(21)
Not frequent	10	(19)	43	(81)	15	(34)	29	(66)
Adjusted OR (95 % CI)	1.94 (0.36 – 10.58)				12.04 (1.72 – 84.54)			
Confusion								
Frequent	11	(69)	5	(31)	11	(69)	5	(31)
Not frequent	9	(16)	48	(84)	19	(40)	28	(60)
Adjusted OR (95 % CI)	24.96 (3.40 – 183.00)				0.53 (0.07 – 3.91)			
Craving								
Frequent	13	(38)	21	(62)	24	(57)	18	(43)
Not frequent	7	(18)	32	(82)	6	(29)	15	(71)
Adjusted OR (95 % CI)	2.60 (0.51 – 13.32)				7.51 (1.32 – 42.72)			
Withdrawal effects on stopping								
Frequent	6	(43)	8	(57)	19	(54)	16	(45)
Not frequent	14	(24)	45	(76)	11	(39)	17	(61)
Adjusted OR (95 % CI)	2.36 (0.32 – 17.35)				0.53 (0.10 – 2.87)			
Tolerance (decreased responsiveness)								
Frequent	7	(39)	11	(61)	21	(49)	22	(51)
Not frequent	13	(24)	42	(76)	9	(45)	11	(55)
Adjusted OR (95 % CI)	1.06 (0.16 – 6.98)				0.46 (0.09 – 2.47)			

*„strong“ = those who rated the benefits to be strong or very strong; **OR = odds ratio; 95 % CI = 95 % confidence interval; ***„frequent“ = those who rated the risks to happen often or always; bold type = significant (0.05).

is ~ 12 times more likely than the remainder to perceive the benefits of benzodiazepines to outweigh the risks. “Confusion” was a further significant and strong predictor for a nurse’s assessment that risks outweigh benefits.

Discussion

Doctors rated benzodiazepines as strong drugs – both in benefits, such as “reduced fear or agitation”, and risks, such as “craving”. Nurses estimated the benefits and risks of benzodiazepines to be somewhat weaker

than doctors did. For many doctors, the risks of benzodiazepines outweighed the benefits if they rated “falls” or “craving” as a frequent risk; for nurses, it was “confusion” and if they did not consider “increased sleep” a benefit.

Up to now, hospital doctors and nurses have not been surveyed about their perception of risks and benefits of hypnotics using this instrument. A previous German study using this questionnaire [9] found that for most general practitioners (63%) the risks of benzodiazepines outweighed the benefits, whereas only some hospital doctors (48%) and nurses (27%) in our study shared this opinion.

The item “reduction of fear and agitation” was added to the original questionnaire in order to adapt it to the hospital setting. Some benzodiazepines, e.g., lorazepam, not only help induce sleep, but also have a strong effect in reducing anxiety. Indeed, most hospital doctors and nurses in our study perceived “reduction of fear and agitation” as a strong benefit of benzodiazepines. Only a few participants perceived that patients have a “feeling of being rested upon waking” or “improved daytime functioning”. These results are in line with results from studies surveying British [8] and German [9] general practitioners.

Most hospital doctors in our study perceived “craving”, “tolerance”, and “withdrawal” to be frequent risks of benzodiazepines, corresponding to the above-mentioned surveys with general practitioners in Great Britain [8] and Germany [9]. The nurses in our study did not share this view, however, and rated these risks to be less frequent than doctors did. Since only approximately one-quarter of our study participants perceived “confusion” and “falls” to be frequent risks of benzodiazepines, awareness of these serious effects, which directly reduce the patient’s quality of life, seems to be low.

A limitation of the study is the relatively small sample size, with consequently rather large confidence intervals for the multivariate logistic regression. The results of a single-hospital study are – of course – not generalizable for other settings. However, a strength of the study is that we were able to investigate more deeply within the setting of a single hospital, the prescription patterns in the patients’ charts alongside the beliefs and attitudes of the doctors and nurses who are

responsible for these charts. Also, more than half of the hospital’s doctors participated in the study, even though doctors’ willingness to participate in surveys is generally limited.

We first would like to discuss two topics as explanatory factors for our results 1) doctors’ and nurses’ perception of a strong anxiolytic effect of benzodiazepines and 2) the impact of benzodiazepines on professional workload. We will conclude with some implications for practice.

1) Most doctors and nurses considered “reduction of fear and agitation” as a strong benefit of benzodiazepines. Similarly, interview studies with primary care physicians in the USA [10] and Australia [11] found that primary care physicians appreciated benzodiazepines as a quick-acting, effective treatment for stress and anxiety. Since patients often experience anxiety in the hospital situation, hospital doctors and nurses are also in need of an effective solution for this problem, and benzodiazepines provide a quick – although not harmless – fix.

2) Benzodiazepines can affect the workload of doctors and nurses in different ways. Most doctors who answered that “falls” occur often or always when patients take benzodiazepines also indicated that the risks of benzodiazepines outweigh the benefits. Similarly, a Slovenian study with general practitioners showed that awareness of drug risks, including falls and consecutive hip fractures was associated with low benzodiazepine prescription rates [12]. Fewer falls mean less potential for patient harm and fewer sequelae to treat. Falls also create an additional workload and bureaucracy for hospital doctors, who are often required to examine the patient and fill out a standardized “fall protocol”.

For nurses, getting patients to sleep longer and “confusion” had the strongest impact on their overall assessment of risk-benefit ratio. Both items have a direct but opposing effect upon their workload. Patients who do not sleep ring the bell more often and require more nursing care. Giving a benzodiazepine can relieve this problem and reduce workload. However, patients who are confused and groggy due to hangover effects of benzodiazepines are less self-sufficient and require more attention and care the next day, which in turn increases nurses’ workload.

Conclusion and implications for practice

This study shows, exemplified in a single hospital, a strategy for pinpointing the source of high benzodiazepine prescriptions in a general hospital. Further studies with doctors and nurses in other hospitals are needed in order to see if the factors that we have found are generalizable or if each hospital has a different “culture” with regards to the risks and benefits of benzodiazepines.

For the hospital studied here, a strategy to reduce benzodiazepine use in the hospital should especially take two factors into account:

First, doctors and nurses perceive the reduction of fear or agitation to be the strongest benefit of benzodiazepines. If benzodiazepines are to be reduced, effective nonpharmacological alternatives to curb fear or agitation must in turn be made available and implemented in the hospital setting.

Second, educating healthcare professionals about the risks and benefits of benzodiazepines should focus upon the perception of “falls” and “craving” (in the case of doctors) or “confusion” and “sleep” (in the case of nurses) in order to have a strong impact on the overall assessment of risk-benefit ratio. Stressing other typical risks of benzodiazepines, such as “tolerance” and “withdrawal” would – according to our data – most likely be ineffective in altering benzodiazepine use because doctors already know this and neither they nor nurses are influenced in their overall assessment of risk-benefit ratio by this knowledge.

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Conflict of interest

The authors declare no conflict of interest.

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3.4 **Paper 4: Why Z-drugs are used – a hospital survey of doctors and nurses**

Heinemann S, Brockmüller J, Hagmayer Y, Himmel W. Why Z-drugs are used even if doctors and nurses feel unable to judge their benefits and risks — a hospital survey. *Eur J Clin Pharmacol* (accepted).



Why Z-drugs are used even if doctors and nurses feel unable to judge their benefits and risks—a hospital survey

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Abstract

Background Many patients receive Z-drugs for hospital-associated sleep problems, in spite of well-known risks. The aim of this study was to learn more about the attractiveness of Z-drugs, seen from the doctors' and nurses' perspective.

Methods Using a standardized questionnaire, doctors (63/116) and nurses (73/243) in a German general hospital were surveyed about the risks and benefits of Z-drugs, compared with benzodiazepines.

Result "Reduced time to get to sleep" was perceived by doctors (51%) and nurses (53%) to be a strong benefit of Z-drugs; "confusion" and "falls" were perceived by ca. 10% of doctors and ca. 15% of nurses to be a frequent problem. Compared with benzodiazepines, respondents more often answered "unable to judge" for Z-drugs; e.g. for doctors, 18% (benzodiazepines) vs. 45% (Z-drugs) were unable to judge "improved daytime functioning" and 12% (benzodiazepines) vs. 37% (Z-drugs) were unable to judge "falls."

Conclusion Z-drugs seem to be attractive because experiential knowledge overemphasizes their benefits and fails to take risks such as drug-related falls and confusion into account. Difficulties to judge a drug's risk-benefit ratio do not prevent doctors and nurses from using them. Interventions for reducing Z-drug usage should incorporate local quality assurance data about relevant patient risks.

Keywords Hypnotics and sedatives · Attitudes of health personnel · Drug utilization · Questionnaires · Sleep initiation and maintenance disorders · Perception · Risk assessment

Introduction

Many hospital doctors experience a conflict every night when on duty: what to do with patients who have trouble sleeping? For severe cases of chronic insomnia, cognitive behavioral therapy and hypnotic drug treatments are recommended. However, transient sleep problems in the hospital—often linked to environmental factors such as unfamiliar sounds, nursing interruptions, uncomfortable beds, and bright lights [1]—are different from a clinical diagnosis of insomnia

disorder, which affects sleep onset, duration, and/or quality for at least a month [2]. Guidelines on how to treat transient sleep problems are not helpful in the hospital environment so that doctors and nurses are challenged to manage inpatient sleeping problems.

Chart review studies give us an idea of how hospital doctors usually solve this conflict; they often prescribe benzodiazepines and newer non-benzodiazepines (so-called Z-drugs) for patients who have trouble sleeping [3–5]. While these drugs may help patients to sleep in the hospital environment, they also have adverse effects, such as confusion, falls, fractures, and craving [6] so they are not recommended for the treatment of transient sleep problems in most guidelines [7]. Z-drugs, specifically, have been accompanied with conflicting information ranging from "[Z-drugs are] considered the safest and most effective prescription sleep aids for geriatric patients" [8] to "[Z-drugs are] not necessarily a safer alternative to traditional BZDs" [9].

The goal of this study was to understand why Z-drugs remain an attractive solution for doctors and nurses to

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transient sleep problems. We performed a survey to learn more about how hospital doctors and nurses perceived Z-drugs compared with benzodiazepines. After an initial review of the data of this survey, we became aware that many doctors and nurses in our sample checked “unable to judge” when answering items about the benefits and risks of Z-drugs. Therefore, we were also interested in factors associated with the inability to judge the risks and benefits of Z-drugs.

Method

Context: the sleeping pills project

In a mixed-methods project, we strived to add knowledge about the current use of sedatives and hypnotics in hospital and primary care from multiple perspectives and with several different types of data [10]. For example, a hospital chart review showed that 12% of all patients 65 and older received a Z-drug at least once during their stay [11]. A patient survey in the same hospital revealed that more than half of the older patients who received Z-drugs in the hospital wished to continue taking these drugs at home [12].

The data reported here come from a survey from the professional perspective performed between June and September 2014. The study was approved by the Ethics Committee of Göttingen University Medical Center (25/2/14). Parts of the survey results have already been analyzed and published [13, 14], with a focus on benzodiazepines.

Design, participants, and measures

In a cross-sectional survey, all physicians and nurses of a German general hospital received a paper questionnaire about the risks and benefits of benzodiazepines and Z-drugs. The questionnaire was developed by Siriwardena et al. [15] to explore general practitioners’ beliefs about the benefits and risks of hypnotic prescribing. Respondents are asked to rate the extent of different benefits (on a 5-point scale, ranging from “very small” to “very strong”) and the frequency of risks (from “never” to “always”) for benzodiazepines and Z-drugs. Both scales have an additional answer category, “unable to judge.” Hoffmann translated this questionnaire into German to survey German general practitioners [16]. We used Hoffmann’s translation in this study, making slight adjustments to the questionnaire for use in a hospital setting.

Statistical analysis

The relative frequencies of doctors’ and nurses’ assessments of the six benefits and five risks of Z-drugs and benzodiazepines were analyzed. We combined the two extremes “strong/very strong” for the benefits and “often/always” for the risks

of both Z-drugs and benzodiazepines. We compared doctors’ and nurses’ perspectives about “strong benefits” and “frequent risks” for both Z-drugs and benzodiazepines.

We then explored in more detail the group of respondents who checked the “unable to judge” box when asked about the risks and benefits of Z-drugs. First, we compared the percentage of doctors and nurses who answered “unable to judge” to the items about Z-drugs with the percentage who answered “unable to judge” for benzodiazepines. In a second step, we divided the sample into those who were able to judge the majority of items about Z-drugs (i.e., 0–5 unable to judge answers) versus those who were not (i.e. 6–11 unable to judge answers). In a multivariable logistical regression analysis, we modeled the likelihood for being unable to judge Z-drugs, taking the following five factors into account: sex, profession, length of employment, department, and self-reported frequency of use. We report adjusted odds ratios (ORs) and their 95% confidence intervals (CI). All analyses were performed using SAS 9.4.

Results

More than half of the doctors (63/116) and about one-third of nurses (73/243) participated in the survey. Most doctors were male (66%), about one-third worked either at departments of internal medicine or surgery, half of them for less than 5 years. Nearly 81% of the responding nurses were female; the majority had more than 10 years working experience (Table 1).

With regard to the benefits of Z-drugs, most respondents appreciated “reduced time to get to sleep” (with 51% of the doctors and 53% of the nurses reporting a strong/very strong benefit; Table 2) and “reduced night-time waking” (41% doctors, 63% nurses). Nearly as many doctors reported these advantages for benzodiazepines, but fewer nurses (Table 2). Both groups clearly favored benzodiazepines for “reducing fear or agitation.”

We also found common features of, and differences between, the perceived risks of Z-drugs and benzodiazepines. The order of risks for Z-drugs was nearly the same for benzodiazepines, but far more doctors perceived them as occurring less frequently in Z-drugs than benzodiazepines (Table 2). This difference did not apply to nurses. Both doctors and nurses agreed about the most frequent risk for Z-drugs, 38% of doctors and 45% of nurses rated “craving” as occurring frequently (Table 2). Only few respondents found “confusion” (10% doctors, 15% nurses) and “falls” (10% doctors, 16% nurses) to be frequent problems of Z-drugs.

Interestingly, far more doctors and nurses answered “unable to judge” for the benefits and risks of Z-drugs in comparison with benzodiazepines. For example, 45% (Z-drugs) versus 19% (benzodiazepines) of doctors answered unable to

Table 1 Characteristics of participating hospital doctors and nurses in percent

Baseline characteristics	Hospital doctors (<i>n</i> = 65)*	Hospital nurses (<i>n</i> = 73)*
Sex		
Male	66.2	19.2
Female	33.9	80.8
Type of station		
Internal medicine	36.9	23.9
Geriatrics	16.9	29.6
Surgical departments	30.8	38.0
Other departments (e.g., radiology)	15.4	8.5
Years of working experience		
< 5 years	48.4	22.2
5– 10 years	29.7	20.8
> 10 years	21.9	56.9
Frequency of Z-drugs for sleeping problems		
Often/always	29.7	63.9
Never/seldom/sometimes	70.3	36.1

**n* varies due to missing data

judge for “improved daytime functioning” and 37% (Z-drugs) versus 12% (benzodiazepines) answered unable to judge for “falls.” Similarly, more nurses answered unable to judge “falls” for Z-drugs (18%) than for benzodiazepines (8%).

A total of 33 of the 138 respondents (24%) answered “unable to judge” for 6 or more of the 11 items about Z-drugs compared with 14 respondents (10%) for benzodiazepines.

Table 2 Perceptions of hospital staff about the strong benefits and frequent risks of benzodiazepines (BDZ) and z-drugs (all values in percent)

	Doctors		Nurses	
	BDZ	Z-drugs	BDZ	Z-drugs
Strong benefits				
Reduced time to get to sleep	56.6	51.2	41.3	52.5
Reduced night-time waking	42.6	41.0	42.6	63.2
Increased total sleep time	25.0	26.3	34.4	47.4
Feeling of being rested upon waking	0.0	21.1	13.8	22.2
Improved daytime functioning	1.9	13.9	10.5	12.5
Reduced fear or agitation	75.4	11.9	57.1	25.9
Frequent risks				
Tolerance (decreased responsiveness)	78.2	21.1	30.5	10.0
Withdrawal effects on stopping	62.5	29.3	27.5	18.6
Craving	72.4	38.1	53.1	44.8
Confusion	27.6	9.5	23.9	16.4
Falls	33.3	9.8	30.3	15.3

N for benzodiazepines (doctors and nurses combined) varies from 107 to 125; *N* for Z-drugs varies from 38 to 100 due to the number of “unable to judge” answers

This difference is significant (Fisher exact test, OR = 2.77, $p = .002$). A multivariable logistic regression showed that sex did not play a role in the ability to judge the benefits and risks of Z-drugs (Table 3). However, four other characteristics (profession, length of employment, department, and self-reported frequency of use) had a significant effect upon the likelihood of being able to judge Z-drugs. The strongest predicting factor was being a doctor (adjusted OR 7.79; 95% CI 1.85 to 32.56), followed by infrequent use of Z-drugs on one’s ward (3.99; 1.17 to 13.60).

Discussion

Many respondents in our survey appreciated the potential of Z-drugs to reduce the time to get to sleep; especially nurses saw a strong effect in reducing night-time waking. For many doctors and nurses, Z-drugs are thought to cause less confusion and fewer falls than benzodiazepines. This is surprising since a Canadian meta-analysis of risks and benefits of short-term treatment with sedative hypnotics in older people with insomnia concluded already 14 years ago that the benefits of both benzodiazepines and Z-drugs are only marginal and outweighed by the risk of falls or cognitive impairment, particularly in a high-risk elderly population [17]. Later studies confirmed these results, most recently a review from Canada in which Lee and colleagues [18] plea for a strategy of deprescribing benzodiazepines and Z-drugs for insomnia. How, then, did the doctors and nurses in the hospital under study come to their positive risk-benefit assessment of Z-drugs?

Table 3 Predictors for respondents being “unable to judge” the benefits and risks of Z-drugs

Predictors (<i>N</i>)	%*	Univariate model			Multivariable model		
		OR	(95% CI)	<i>p</i>	OR	(95% CI)	<i>p</i>
Gender							
Male	28.1	1.00			1.00		
Female	21.0	0.68	(0.31–1.50)	0.338	1.91	(0.66–5.51)	0.233
Profession							
Nurses	13.7	1.00			1.00		
Doctors	35.4	3.45	(1.49–7.98)	0.004	7.76	(1.85–32.56)	0.005
Length of employment							
Less than 10 years	19.8	1.00			1.00		
More than 10 years	30.9	1.82	(0.82–4.01)	0.139	3.53	(1.12–11.17)	0.032
Department							
Non-surgical	16.9	1.00			1.00		
Surgical	36.2	2.80	(1.24–6.31)	0.013	3.27	(1.17–9.15)	0.024
Frequency of Z-drugs for sleeping problems**							
Often/always	6.2	1.00			1.00		
Never/seldom/sometimes	39.4	9.93	(3.25–30.37)	< 0.001	3.99	(1.17–13.60)	0.027

*Percentage of respondents who are unable to judge 6 or more of the 11 items about benefits and risks of Z-drugs

**Survey question: “How often are Z-drugs used to treat sleep problems on your ward?”

OR, odds ratio; 95% CI, 95% confidence interval

Values in italics indicate significance ($p < 0.05$)

First of all, they do not stand alone with their positive assessment of Z-drugs. Many surveyed general practitioners also perceived Z-drugs as more effective and safer compared with benzodiazepines [16]. In addition, pharmacoepidemiological studies report a reduction of benzodiazepine prescribing while Z-drug prescribing is increasing [19]. Z-drugs still seem to benefit from the myth that they are similarly effective and safer alternatives to benzodiazepines, although studies show that Z-drugs also carry the same risks of daytime sedation, cognitive impairment, falls, fractures, and accidents [18].

Second, since Z-drugs are hypnotics, i.e., prescribed primarily to treat sleeping problems, they may not have the same value in the eyes of hospital doctors as benzodiazepines, which are prescribed for several other indications in addition to sleeping problems. Interview studies with hospital doctors have shown that doctors regard other medical issues with higher priority than sleep problems during hospitalization [20].

Third, based on meta-analytic data on sleep efficacy reported mostly by younger patients, Rösner et al. [21] could show a 12-min decrease of sleep onset latency, a 17-min decrease of wake time after sleep onset, and a 28-min increase of total sleep time for eszopiclone, compared with placebo. Although the possible benefits of Z-drugs are relatively minor, it seems that it is exactly these minor effects that matter: for doctors and nurses working in night shifts under high stress

and for patients desperately seeking a good night’s sleep in a busy hospital and unfamiliar environment [20].

For a deeper understanding why individuals prefer some risky choices over other options, such as Z-drugs to combat hospital-associated sleep problems, a look at recent research on the role of descriptive knowledge (e.g., official drug information) and experiential knowledge (e.g., seeing benefits and risks of a drug first or second hand) in decision making may be helpful. Research investigating how descriptive and experiential knowledge affect choices between risky options found that people give more weight to experiential knowledge [22, 23]. That is, they are more influenced by the perceived outcomes of their own choices rather than by accurate summary statistics about the outcomes across many decisions taken by many people. Importantly, people rely on experiential knowledge even when it is limited and based on rather small samples [22, 23]. When deciding on Z-drugs, doctors and nurses may also have observed only small samples. For example, data analyses show that “falls” occur more often in older hospital patients treated with Z-drugs [24], but falls themselves are rare adverse events and, therefore, difficult for a doctor or nurse to observe. Even if doctors and nurses were taught differently via descriptive knowledge, the experiential knowledge of regularly giving Z-drugs and seeing no direct harm may lead to the belief that Z-drugs do not increase the risk of falls. Vice versa, doctors who were convinced, for whatever reason, that “falls” and/or “craving” are a frequent adverse

effect of benzodiazepines, believed the risks outweigh the benefits of these drugs [14].

A second result of our survey was no less surprising: despite the fact that 12% of older patients are treated with a Z-drug in this hospital [11], a considerable group of respondents checked the unable to judge answer category for the majority of questions about the risks and benefits of Z-drugs. The above-mentioned description-experience approach for explaining risky choices [23] may also help to explain this result. We know from a chart review in this hospital [11] that Z-drugs are much less commonly used in surgical departments. Consequently, this lack of experience with Z-drugs on surgical departments is a logical explanation why fewer surgeons and nurses on surgical wards were able to answer survey questions about the benefits and risks of Z-drugs.

Most interesting is the strong difference between doctors and nurses in the ability to judge Z-drugs, in spite of the fact that the majority of respondents should have had some contact with Z-drugs (experiential knowledge) during the course of their professional careers. All six benefits and, at least, three of the unwanted drug effects (“confusion,” “falls,” and “craving”) can be directly observed due to the fact that these effects come about (or not) within hours of administering the drug. Although doctors are responsible for diagnosing diseases and prescribing medicines, they often prescribe Z-drugs as p.r.n. (pro re nata; as needed) drugs. Since the “as needed” case often occurs during the night shift, doctors may lack direct experience with the patients who use Z-drugs. Nurses, on the other hand, have direct patient contact day and night and are able to directly observe the benefits and adverse effects of these drugs. This difference in experience may explain why nurses are better able to judge the benefits and risks of Z-drugs, especially for items like “reduced time to get to sleep,” which are immediate, directly observable results of Z-drug use.

Strengths and limitations of the study

The most important limitation of the study is the relatively small sample size. The results of a single-hospital study can only be a starting point for future research and are not—of course—generalizable for other settings.

A strength of the study is that we were able to compare within the setting of a single hospital how doctors and nurses perceived and assessed Z-drugs and the frequency with which these drugs are prescribed [11]. However, quantitative analyses of survey data cannot explain the underlying reasons for behavior. Rather, qualitative data (e.g., interviews) may provide an explanation for the discrepancy between unable to judge survey responses and actual Z-drug prescription practices.

An additional strength of the study is the inclusion of both the doctor and nurse perspectives, since the management of hospital-associated sleep problems is a multi-professional task and any change of the current practice will need multi-professional efforts. A high percentage of the hospital’s doctors participated in the study, even though doctors’ willingness to participate in surveys is generally limited. Given the leading role of hospital doctors in a hospital’s prescribing policy, the high response rate contributes to the internal validity of the study results. We can only speculate why two-thirds of nurses declined to participate in the survey. Perhaps they did not consider sleep-inducing drugs an important issue or were afraid that this survey, although anonymous, might uncover a lack of pharmacological knowledge.

Conclusions and implications for practice

The personal trade-off between the perceived benefits and adverse effects of medicines is essential for deciding on their use [25]. Z-drugs seem to be attractive because experiential knowledge overemphasizes their benefits and fails to take risks such as drug-related falls and confusion into account. Moreover, difficulties to judge a drug’s risk-benefit ratio do not prevent doctors and nurses from using them. In light of the dominance of experiential knowledge over descriptive knowledge, hospitals and clinical pharmacologists should not put too much faith in traditional continuous medical education about the risks of Z-drugs to reduce their usage. Rather, descriptive knowledge about Z-drugs should be accompanied at least by a numerical expression of risks and benefits, similar to a number needed to treat statistic. For example, Lee et al. explain that 13 older patients need to be treated with a benzodiazepine or Z-drug for one person to experience improvement in sleep quality, but only 6 patients need to be treated with these drugs for one person to experience an adverse event [18]. Presenting nurses and doctors with a case series of patients showing these relative frequencies may have similar convincing power as experiential knowledge acquired during practice. In particular, results from local quality assurance data about relevant patient risks resulting from Z-drug use in one’s own hospital (e.g., statistics about falls and craving) could be used as a case series for feedback and, thus, be a key to changing professional behavior.

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Authors' contributions SH and WH developed the study idea, performed statistical analysis, and interpreted data. SH drafted the manuscript. WH, JB, and YH commented extensively and contributed to the expansion of the text including further statistical analyses. SH and WH revised the manuscript. All authors read and approved the final manuscript and are the guarantors.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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3.5 **Paper 5: Nurse interviews about the non-drug treatment of sleeping problems**

Kauffmann L, **Heinemann S**, Himmel W, Hußmann O, Schlott T, Weiß V. Nicht-medikamentöse Maßnahmen bei Ein- und Durchschlafproblemen von älteren Patienten im Krankenhaus – Qualitative Interviews mit Pflegenden. *Pflege* 2018; 31(6):291–300.

Originalarbeit



Nicht-medikamentöse Maßnahmen bei Ein- und Durchschlafproblemen von älteren Patienten im Krankenhaus – Qualitative Interviews mit Pflegenden

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Zusammenfassung: *Hintergrund:* Ältere Patienten leiden im Krankenhaus häufig unter Ein- und Durchschlafproblemen. Nicht selten erhalten diese Patienten trotz der bekannten Risiken ein Schlaf- oder Beruhigungsmittel, obwohl auch nicht-medikamentöse Maßnahmen zur Verfügung stehen. *Ziel:* Die Studie untersucht Erfahrungen und Wahrnehmungen von Pflegenden im Umgang mit nicht-medikamentösen Maßnahmen bei Schlafproblemen älterer Patienten im Krankenhaus. *Methode:* Es wurden semistrukturierte Interviews mit 13 examinierten Gesundheits- und Krankenpflegern/-pflegerinnen aus einem Krankenhaus geführt und inhaltsanalytisch ausgewertet. *Ergebnisse:* Folgende nicht-medikamentöse Maßnahmen werden bei Schlafproblemen älterer Patienten eingesetzt: (1) strukturelle Maßnahmen (Regulierung von Temperatur und Licht), (2) organisatorische Maßnahmen (Zeit für abendliche Rundgänge), (3) pflegerische Maßnahmen (pflegerische Schlafanamnesen, beruhigende Ganzkörperpflegen) und (4) übliche Hausmittel. Die Anwendung dieser Maßnahmen erhöht die Patientenzufriedenheit und entspannt Abläufe im Nachtdienst. Barrieren ergeben sich durch knappe zeitliche und personelle Ressourcen, fehlende Standards, diskrepante Vorstellungen im Pflegeteam und dezidierte Patientenwünsche nach Medikamenten. *Schlussfolgerung:* Pflegende kennen eine Vielzahl nicht-medikamentöser Maßnahmen zur Förderung eines gesunden Schlafes. Das Fehlen eines Konsenses und mangelnde Ressourcen behindern den Einsatz dieser Maßnahmen. Wünschenswert wäre ein Klima, das den Einsatz von Medikamenten bei Schlafproblemen als letzte Möglichkeit vorsieht.

Schlüsselwörter: Insomnien, Schlafprobleme, alternative Behandlungsansätze, Perspektiven von Pflegenden, Krankenhaus, qualitative Studie

Non-pharmacological treatment of hospital patients with sleeping problems – the nurse perspective

Abstract: *Background:* Elderly patients suffer from sleep disturbances during hospitalization. These patients often receive hypnotics and sedatives; despite of the known risks and although non-pharmacological treatments are available. *Aim:* The study investigates the experiences of nurses when using non-pharmacological treatments for elderly patients with sleeping problems. *Methods:* Semi-structured interviews with 13 nurses from a general hospital were analyzed according to Mayring's qualitative content analysis. *Results:* Nurses used a variety of non-pharmacological treatments for elderly inpatients with sleeping problems: (1) structural measures (regulation of temperature and light), (2) organizational measures (more time for conversation during the nightshift), (3) nursing measures (asking about night-time routines) and (4) household remedies. From the nurses' perspective, the more intensive contact required when applying non-pharmacological treatments can lead to higher patient satisfaction and a lower bell frequency during the night shift. Barriers result from limited time and personnel, a lack of standards and individual patient needs. *Conclusion:* Nurses know several kinds of non-pharmacological treatments to help elderly inpatients sleep better. A lack of resources as well as a lack of professional consensus about the treatment of temporary sleeping disturbances can be an obstacle to their use. A professional climate should restrict the use of drugs for sleeping problems as far as possible.

Keywords: sleep irritation and maintenance disorders, complementary therapies, hospitals, nurses, qualitative research

Was ist (zu dieser Thematik) schon bekannt?

Ältere Patienten leiden besonders im Krankenhaus unter Schlafproblemen und erhalten häufig Schlafmittel.

Was ist neu?

Die Umsetzung nicht-medikamentöser Maßnahmen von Pflegenden stößt aufgrund knapper Ressourcen, fehlender Standards und diskrepanter Vorstellungen auf Widerstand.

Welche Konsequenzen haben die Ergebnisse für die Pflegepraxis?

Es sollte ein Klima gefördert werden, das den Einsatz von Medikamenten bei vorübergehenden Schlafproblemen als letzte Möglichkeit sieht.

Ein erholsamer Schlaf ist insbesondere während eines Krankenhausaufenthalts wichtig für Heilungs-/Erholungsprozesse (Gathecha et al., 2016; Morgan, Closs & Kraut, 2000). Schlafmangel oder eine geringe Schlafqualität während eines Krankenhausaufenthalts können das Immunsystem beeinflussen, Wundheilungsprozesse verzögern oder die Schmerzwahrnehmung verstärken (Tamrat, Huynh-Le & Goyal, 2014). Aufgrund der besonderen Gegebenheiten eines Krankenhausaufenthalts sind die Voraussetzungen für einen erholsamen Schlaf im Krankenhaus nicht immer gegeben (Tamrat et al., 2014).

Die subjektiv empfundene Schlafqualität von Patienten/Patientinnen während eines Krankenhausaufenthalts ist schlecht. Eine deutsche Studie aus 2008 hat festgestellt, dass mehr als ein Drittel der befragten Patienten/Patientinnen über Einschlafstörungen und über die Hälfte dieser Patienten/Patientinnen über Durchschlafstörungen klagten (Fietze, Wiesenäcker, Blau & Penzel, 2008). Neuere internationale Studien belegen ebenfalls, dass die Schlafqualität während eines Krankenhausaufenthalts deutlich schlechter als im privaten häuslichen Umfeld bewertet wird (Dobing, Frolova, McAlister & Ringrose, 2016; Ghanbari Jolfaei, Makvandi & Pazouki, 2014). Insbesondere ältere Patienten/Patientinnen haben Schwierigkeiten, sich an veränderte Umgebungen anzupassen, mit dem Ergebnis einer verminderten Schlafqualität während eines Krankenhausaufenthalts (Park & Kim, 2017). Häufig sind Lärmbelastungen für eine verminderte Schlafqualität im Krankenhaus verantwortlich, z. B. störende Geräusche durch Bettnachbarn, Verkehrslärm oder nächtliche Kontrollen durch Pflegenden oder ärztliches Personal. Neben Lärm können aber auch Schmerzen, depressive Verstimmungen, die Dauer eines Krankenhausaufenthalts oder die Atmosphäre der Station die Schlafqualität mindern (Müller, Olschinski, Kundermann & Cabanel, 2017; Park & Kim, 2017).

Anhand einer Analyse von 2.130 Patientenakten konnte unsere Arbeitsgruppe zeigen, dass die Hälfte der älteren Patienten/Patientinnen (≥ 65 Jahre) während eines Krankenhausaufenthalts ein Schlaf- und Beruhigungsmittel erhält. Das Benzodiazepin Lormetazepam zählte zu den am häufigsten eingesetzten Schlaf- und Beruhigungsmitteln ($n = 403/1.231$; 18,9%). Eine Behandlung auf Intensivstationen, auf geriatrischen Abteilungen und das Geschlecht

zählen zu den stärksten Prädiktoren für die Verordnung dieser Medikamente (Arnold et al., 2017). Eine belgische Querschnittstudie aus dem Jahr 2011 kam zu ähnlichen Ergebnissen, allerdings bei einer deutlich jüngeren Patientenpopulation von durchschnittlich 48 (w) bzw. 62 Jahren (m) (Somers et al., 2011).

Zu Schlaf- und Beruhigungsmitteln gehören beispielweise Benzodiazepinhypnotika mit den Wirkstoffen Lormetazepam und Temazepam sowie Benzodiazepinrezeptoragonisten (auch Z-Substanzen genannt) mit den Wirkstoffen Zolpidem und Zopiclon (Lohse & Müller-Oerlinghausen, 2017). Medikamente aus dieser Gruppe zählen aufgrund ihrer Risiken und Nebenwirkungen zu den potenziell inadäquaten Medikamenten bei älteren Patienten/Patientinnen und können zu Stürzen, Abhängigkeit oder Verstärkung bestehender kognitiver Einschränkungen führen (Holt, Schmiedl & Thürmann, 2015).

Gemäß der S3-Leitlinie (LL) „Nicht erholsamer Schlaf/Schlafstörungen“ der Deutschen Gesellschaft für Schlafmedizin sind situativ bedingte und transient auftretende (nicht-organische) Insomnien häufig. Sie bedürfen jedoch „meist keiner Behandlung“ (Riemann et al., 2017; 10). Streng genommen ist daher der Einsatz von Hypnotika bei Schlafproblemen, die nur während eines Krankenhausaufenthalts auftreten und beispielsweise durch fremde Umgebungsbedingungen hervorgerufen werden, medizinisch nicht indiziert. Schlafprobleme sind gemäß ICD-10 krankheitswertig und behandlungsbedürftig, wenn die Beschwerden vier Wochen andauern und mindestens dreimal pro Woche auftreten. In der vorliegenden Studie beziehen wir uns ausschließlich auf situativ auftretende, nicht-organische Schlafprobleme, da die Anwendung nicht-medikamentöser Maßnahmen bei dieser Art von Schlafstörung indiziert ist und zum Aufgabenbereich der Pflegenden zählt.

Der Schlaf ist für die Genesung von Krankenhauspatienten wichtig. Allerdings ist der Einsatz von Hypnotika bei einfachen Schlafproblemen nicht angemessen und führt vor allem bei älteren Patienten/Patientinnen zu hohen Risiken und Nebenwirkungen. Deswegen ist der Einsatz von Alternativen wünschenswert (Schwarz, Fröhlich & Deuschle, 2010; 920). In einer systematischen Übersichtsarbeit über nicht-medikamentöse Maßnahmen zur Behandlung von Patienten/Patientinnen mit Schlafproblemen während eines Krankenhausaufenthalts wurden folgende Möglichkeiten identifiziert: Tageslicht-Lichttherapien, Entspannungstechniken, Maßnahmen zur Schlafhygiene und Programme zur Reduktion von Schlafunterbrechungen (Tamrat et al., 2014). Obwohl nicht für all diese Maßnahmen ausreichende Evidenz zur Verfügung steht, werden Entspannungstechniken und Maßnahmen zur Schlafhygiene gegenwärtig in der S3-Leitlinie „Nicht erholsamer Schlaf/Schlafstörungen bei nicht-organischen Schlafstörungen“ empfohlen (Riemann et al., 2017). In einer quasi experimentellen Pilotstudie zur Förderung der Schlafqualität und -dauer während eines Krankenhausaufenthalts wurden folgende Maßnahmen eingesetzt: Schlafprotokoll zur systematischen Erfassung

von Schlafgewohnheiten, Veränderungen der Umgebungsbedingungen (schlaffördernde Lichtverhältnisse, Regulation der nächtlichen Geräuschkulissen), Ausgabe von Schlafmedikamenten am frühen Abend, Minimierung der Flüssigkeitszufuhr am Abend und auf Wunsch Ohrstöpsel, Schlafmasken, wärmende Decken und Musik zur Entspannung (Gathecha et al., 2016).

Trotz ihrer Vielfältigkeit kommen diese, zumindest gelegentlich auch außerhalb der stationären Versorgung propagierten Maßnahmen (Hauschild, 2015), insgesamt nur selten zum Einsatz. Neben Wissensdefiziten dürften dabei vor allem negative Erfahrungen bei der Anwendung oder schon im Vorfeld der Anwendung von Bedeutung sein. Hierüber wissen wir so gut wie nichts. Anthierens, Gryphonck, Pauw und Christiaens (2009) berichten, dass Pflegende in Einrichtungen der stationären Altenpflege den Einsatz von Benzodiazepinen als unproblematisch ansehen und deren Einsatz bei Schlafproblemen von Bewohnern/Bewohnerinnen oftmals initiieren.

Forschungsziel und Untersuchungsfragen

Ziel dieser Studie ist es, aus der Sicht von Mitarbeitenden des Pflegedienstes die Ursachen für den zurückhaltenden Einsatz von und Umgang mit nicht-medikamentösen Maßnahmen bei vorübergehenden Schlafproblemen älterer Patienten/Patientinnen im Krankenhaus zu erfahren und zu verstehen. Im Besonderen sollen zwei Forschungsfragen beantwortet werden:

Welche nicht-medikamentösen Maßnahmen setzen Pflegende während der Behandlung von Schlafproblemen bei älteren Patienten/Patientinnen im Stationsalltag ein?

Welche positiven und negativen Erfahrungen machen Pflegende vor, während und nach dem Einsatz der nicht-medikamentösen Maßnahmen?

Methode

Kontext

Die vorliegende Studie ist ein Teil des vom Bundesministerium für Gesundheit geförderten Projekts: „... da gab es so wunderbare Schlaftabletten – Verordnungen von Benzodiazepinen und Z-Substanzen an der Schnittstelle von Krankenhaus und Hausarzt“ (Förderkennzeichen: IIA5-2513DSM228). Die Studie hatte zum Ziel, mittels der Anwendung quantitativer und qualitativer Methoden (Mixed-Methods-Design), die Verordnung von Schlaf- und Beruhigungsmitteln vor, während und nach einem Krankenhausaufenthalt zu rekonstruieren und aufbauend auf den Ergebnissen Maßnahmen zur Verbesserung von Kommunikations- und Handlungskompeten-

zen im Umgang mit diesen Medikamenten zu entwickeln (Heinemann et al., 2016).

Die Studie erhielt von der Ethik-Kommission der Universitätsmedizin Göttingen ein positives Votum (AZ 25/2/14). Für die Befragung gab die Mitarbeitervertretung des Krankenhauses ihr Einverständnis.

Studiendesign

Mit einem qualitativen Forschungsansatz sollten die Erfahrungen und das Handeln von Pflegenden im Falle des Einsatzes nicht-medikamentöser Maßnahmen bei Schlafproblemen älterer Patienten/Patientinnen rekonstruiert werden.

Stichprobe

Alle examinierten Gesundheits- und Krankenpfleger/-innen der vollstationären Abteilungen (Intermediate Care Stationen und Intensivstationen eingeschlossen) des kooperierenden Krankenhauses wurden zwischen März 2015 und Oktober 2016 eingeladen, an den Interviews teilzunehmen. Teilnehmende wurden nach Fachabteilung und Geschlecht (maximum variation sampling) rekrutiert (Paly, 2008). Informationen zur Studie wurden während der Stationsleitungssitzungen, per Informationsflyer und über die Mitarbeiterzeitschrift bekannt gegeben. Zusätzlich informierten die Autorinnen (LK, VW) durch regelmäßige Anwesenheit auf den Stationen persönlich die Pflegenden über die Studie, deren Ziele sowie Maßnahmen zum Datenschutz. Die Teilnehmenden erhielten keinerlei finanzielle Entschädigungen.

Datenerhebung

Die Datenerhebung erfolgte durch einen halbstrukturierten Interviewleitfaden mittels offener Fragetechnik (siehe Elektronisches Supplement). Der Leitfaden wurde auf Grundlage von Ergebnissen einer vorangegangenen quantitativen Befragung des medizinischen und pflegerischen Personals zum Umgang mit Schlaf- und Beruhigungsmitteln (Weiß, Heinemann, Himmel, Nau & Hummers-Pradier, 2016) und aufbauend auf dem von Anthierens et al. (2009) verwendeten Interviewleitfaden zur Erfassung der Wahrnehmung des Gebrauchs von Benzodiazepinen von Pflegenden in Alten- und Pflegeheimen entwickelt. Die Interviews wurden zwischen März 2015 und Oktober 2016 geführt. Die Gesprächsdauer variierte zwischen 25 und 47 Minuten. Die meisten Gespräche wurden unmittelbar vor oder nach dem Dienst der Pflegenden durchgeführt.

Mit der erzählgenerierenden Eingangsfrage (Leitfrage) wurden die Pflegenden aufgefordert, sich an konkrete Situationen zu erinnern und zu berichten, welche Erfahrungen sie im Umgang mit Schlaf- und Beruhigungsmitteln und deren Einsatz bei älteren Patienten/Patientinnen ma-

chen. In einem zweiten Teil wurden die folgenden Themenbereiche durch Nachfragen (Helfferich, 2011) angesprochen: Pflegende-Patienten-Beziehung, Umgang mit Schlaf- und Beruhigungsmitteln im interdisziplinären Team, alternative Therapiemöglichkeiten, Wissen über Wirkungen und Nebenwirkungen sowie Verbesserungswünsche. Im Rahmen der vorliegenden Arbeit stand die Auswertung der Frage zu den alternativen Therapiemöglichkeiten im Vordergrund. Fragen zu diesem Themengebiet wurden wie folgt formuliert:

„Anstatt des Einsatzes von Schlaf- und Beruhigungsmitteln gibt es auch alternative und komplementärmedizinische Möglichkeiten. Welche alternativen Möglichkeiten setzen Sie im pflegerischen Alltag bevorzugt ein und warum? Können Sie mir erzählen, welche positiven und negativen Erfahrungen Sie im Umgang mit alternativen Möglichkeiten gemacht haben?“

Die Reihenfolge der Fragen und die Art der Fragestellung orientierten sich an den jeweiligen Gesprächssituationen. Im Vordergrund stand der Aufbau einer gesprächsfördernden Atmosphäre. Der Interviewleitfaden wurde im Vorfeld mit zwei Pflegenden erprobt, validiert und die Ergebnisse im Forschungsteam evaluiert. Datenmaterial aus diesen Probeinterviews wurde nicht in die Analyse aufgenommen.

Datenauswertung

Bis auf ein Interview konnten nach Aufklärung der Teilnehmenden alle Gespräche digital mittels Aufnahmegerät aufgenommen und nach den Transkriptionsregeln von Rosenthal (1995) transkribiert werden. Die Organisation des Datenmaterials erfolgte mit MAXQDA (MAXQDA, 2017). Die Daten wurden mittels qualitativer Inhaltsanalyse in Anlehnung an Mayring (2010) ausgewertet. Die Kategorien wurden induktiv gebildet, das heißt ohne Berücksichtigung von Vorannahmen und theoretischen Konzepten (Mayring, 2010). Nach einer Analyse von ca. 10–20 % des Datenmaterials wurde ein Kategoriengerüst aufgebaut und ein entsprechender Kodierleitfaden entwickelt. Dieser wurde in einem interdisziplinären Team, bestehend aus Gesundheitswissenschaftlern/-wissenschaftlerinnen, examinierten Gesundheits- und Krankenpflegern/-pflegerinnen sowie einem Soziologen auf zwei Transkripte angewendet und weiterentwickelt, bis sich alle Kategorien klar voneinander abgrenzten. Datenerhebung und Analyse erfolgten parallel. Die Ergebnisse aus dem Interview mit einer Pflegenden der Intensivstation konnten nicht in vollem Umfang in die Analyse einbezogen werden. Aufgrund differenzierter Handlungsanforderungen wie Beatmungstherapie mit einhergehender Sedierung der Patienten/Patientinnen sind alternative Therapiemöglichkeiten dort nur eingeschränkt möglich. In der Ergebnisdarstellung werden neben den Kategorien ergänzend prägnante Transkript-Passagen wiedergegeben. Der Satzbau in den hier wiedergegebenen Zitaten wurde zur besseren Lesbarkeit geringfügig bearbeitet; beispielsweise wurden fehlende Endungen ergänzt oder die Satzstellung aufgrund eines besseren Leseflusses behutsam angepasst.

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Ergebnisse

Beschreibung der Stichprobe

Von 20 angefragten examinierten Gesundheits- und Krankenpflegern/-pflegerinnen nahmen 13 (m = 3; w = 10) aus den Abteilungen Urologie, Geriatrie, Unfallchirurgie, Allgemeinchirurgie, Innere Medizin, Pulmonologie, Intermediate Care (IMC) und Intensivstation (ITN) an den Interviews teil. Die teilnehmenden Pflegenden waren 25–44 Jahre alt und inklusive ihrer Ausbildungszeit zwischen 3,5 und 25 Jahren in ihrem Beruf tätig.

Nicht-medikamentöse Maßnahmen aus Sicht der Pflegenden

Im Folgenden werden alternative Maßnahmen mittels Ankerbeispielen aus den Interviews klar voneinander abgegrenzten Bereichen zugeordnet und veranschaulichend dargestellt. Tabelle 1 enthält eine Zusammenfassung dieser Maßnahmen und dazugehörige Beispiele. Im Anschluss daran werden die von den Befragten berichteten positiven und negativen Erfahrungen aufgeführt.

Tabelle 1. Eingesetzte nicht-medikamentöse Maßnahmen von Pflegenden bei Schlafproblemen älterer Patienten

Art der Maßnahmen	Beispiele
Strukturelle Maßnahmen	<ul style="list-style-type: none"> • Regulierung der Raumtemperatur • Dimmen des Lichts zum Abend • Reduktion von Geräuschen im Flur • Verlegung unruhiger Patienten in ein Einzelzimmer
Organisatorische Maßnahmen	<ul style="list-style-type: none"> • Führen von kurzen Gesprächen am Abend • Mehr Zeit für Abendrundgänge einplanen
Pflegerische Maßnahmen	<ul style="list-style-type: none"> • Durchführung von Schlafanamnesen • Durchführung von atemstimulierenden Einreibungen/beruhigenden Ganzkörperwaschungen
Hausmittel	<ul style="list-style-type: none"> • Anbieten von warmen Getränken (Milch mit Honig, Tee) • Anbieten von beruhigender Musik • Möglichkeit fernzusehen

Strukturelle Maßnahmen

Zu den strukturellen Maßnahmen zählt die Gestaltung einer schlaffördernden Umgebung. Beispielsweise berichteten Pflegenden, dass sie die Raumtemperatur regulierten und Licht zum Abend dimmten. Wenn Patienten/Patientinnen unruhig sind, beispielsweise aufgrund eines Durchgangssyndroms, verlegten sie diese auch in Einzelzimmer. Mit dieser Maßnahme sollte für beide Patienten/Patientinnen aus einem Zweibettzimmer eine möglichst schlaffördernde Atmosphäre hergestellt werden.

„Da habe ich gemerkt, dann schaukeln die beide sich gegenseitig hoch. Also trenne ich die. Also der eine kommt hier in den Therapieraum, der eine bleibt alleine im Zimmer, so dass mindesten einer schläft.“ (I: P11, 4, 36–38, w)

Organisatorische Maßnahmen

Pflegende hielten es für sinnvoll und für die nächtliche Ruhe förderlich, sich während der Abendrunden mehr Zeit für die Patienten/Patientinnen zu nehmen. Nach den Angaben der Pflegenden half oftmals schon ein kurzes Gespräch.

„Manchmal reicht es wirklich, einfach nur noch mal vorbeizugehen und zu sagen: ‚Wie war es?‘ oder ‚Wie ist es?‘ oder so. Da sind die Leute einfach ruhiger. Dass sie einfach wissen, dass wer da ist [...]“ (I: P5, 8, 19–22, m)

Pflegerische Maßnahmen

Im Sinne pflegerischer Maßnahmen berichtete eine Pflegende der Unfallchirurgie davon, Schlafanamnesen durchzuführen, um so mögliche Schlafgewohnheiten und Einschlafhilfen erfragen zu können. Sofern möglich, wurden die von den Patienten/Patientinnen berichteten Bedürfnisse in den Stationsalltag integriert. Im Rahmen dieser Gespräche konnten zudem bisherige Erfahrungen mit Schlaf- und Beruhigungsmitteln sowie aufgetretenen Nebenwirkungen thematisiert werden.

„Und oft unterhalten wir uns nachher auch mit dem Patienten und wie schlafen sie denn zu Hause. Wo sie dann einem sagen wie sie zu Hause einschlafen können.“ (I: P8,7, 33–35, w)

Neben einer Schlafanamnese nutzten einige Pflegende im Stationsalltag weitere pflegerische Maßnahmen, wie die basale Stimulation oder eine beruhigende Ganzkörperpflege, zur Schlafförderung. In einigen Fällen tauschten sie sich über Entspannungstechniken aus.

„Ja. Basale Stimulation. Sprich Patienten, die halt sehr, ja, vor allem halt auch ältere, [...] denen tut das manchmal sehr gut, einfach mal gewaschen zu werden. [...] Und dadurch halt tritt ein beruhigender Effekt ein. Das ist mir schon aufgefallen halt. Und dann sind die Patienten danach kaputt. Also müder halt und schlafen halt sehr gut.“ (I: P7, 9, 13–18, m)

„Hausmittel“

Orientiert an den Bedürfnissen der Patienten/Patientinnen werden „Hausmittel“ zur Schlafförderung angeboten. Dazu zählen nach den Aussagen der Pflegenden beispielsweise warme Getränke wie Tee oder heiße Milch mit Honig. Weiterhin werden Patienten/Patientinnen empfoh-

len, abends zur Beruhigung Musik zu hören oder bei Einschlafschwierigkeiten fernzusehen.

Positive Erfahrungen bei der Anwendung nicht-medikamentöser Maßnahmen

Eine wichtige positive Erfahrung der hier geschilderten nicht-medikamentösen Maßnahmen sahen die Pflegenden in einer Verringerung des Einsatzes von Schlaf- und Beruhigungsmitteln. Insbesondere ältere Patienten/Patientinnen mit kognitiven Beeinträchtigungen, z. B. aufgrund demenzieller Erkrankungen oder wegen eines Durchgangssyndroms, würden am meisten von der Anwendung nicht-medikamentöser Maßnahmen profitieren; insbesondere von Ganzkörperwaschungen mit Ölen und Gesprächen. Dadurch erhielten die Patienten/Patientinnen zunehmend ein Gefühl von Nähe und Geborgenheit. Nach den Pflegenden würde sich das dadurch erhaltene positive Körpergefühl und die mentale Entspannung durch mehr Zuwendung, mehr Gesprächs-/Austauschmöglichkeiten seitens der Patienten/Patientinnen, beruhigend auf diese vulnerable Patientengruppe auswirken.

„[...] Da ich von der inneren Station komme und auch angebunden an die Geriatrie war, finde ich es total schön, wenn man abends, kommt halt drauf an, wie die Station aussieht, die Patienten beruhigend wäscht. [...] einfach, weil die Kombination, aus meiner Erfahrung heraus, meistens besser wirkt, als wenn man da ein Beruhigungsmittel nach dem nächsten reinschüttet.“ (I: P8,3, 60–63, w)

Des Weiteren beobachteten die Pflegenden, dass ein adäquater Einsatz von Schlaf- und Beruhigungsmitteln pflegerisch relevante Nebenwirkungen wie Paradoxreaktionen (starke Agitiertheit und Verwirrtheit) vermeiden kann.

Eine weitere wichtige positive Erfahrung sind nach Meinung der Pflegenden die eingesparten zeitlichen Ressourcen im Nachtdienst. Eine intensive Beschäftigung mit älteren Patienten/Patientinnen während des Nachtrundganges steht nach Aussagen der Pflegenden im direkten Zusammenhang mit einer geringeren „Klingelfrequenz“.

„Das überträgt sich ja auch auf die Patienten, [...] wenn ich hier durchschieße im Eiltempo, dann habe ich, dass hinterher ganz oft geklingelt wird, weil irgendwelche Fragen vergessen wurden zu stellen, man sich nicht geäußert hat, [...], und dann klingelt es halt viel häufiger und ist es deutlich unruhiger.“ (I: P3, 7, 25–27, w)

Negative Erfahrungen während der Anwendung nicht-medikamentöser Maßnahmen

Zu den gravierendsten Gründen, nicht-medikamentöse Maßnahmen bei einfachen Schlafproblemen nicht anzuwenden, zählen die geringen zeitlichen und personellen Ressourcen. Pflegende sahen aufgrund von institutionel-

len Vorgaben (hohe Arbeitsverdichtung im Pflegedienst und enge Personalplanung) sowie geringen Besetzungen während des Nachtdienstes medikamentöse Maßnahmen zur Schlafförderung häufig als alternativlos an. Interviewpartner/-innen berichteten, dass im Nachtdienst oftmals eine Person für bis zu 33 Patientinnen und Patienten zuständig ist.

„[...] das ist schlimm für den Patienten, aber seien wir mal ganz ehrlich: Wir haben eine begrenzte Arbeitskraft und eine begrenzte Zeit.“ (I: P5, 5–6, 44–1, m)

Zudem gäbe es im pflegerischen Team keine einheitliche Vorgehensweise im Umgang mit nicht-medikamentösen Maßnahmen. Einige Kollegen würden eine solche Vorgehensweise bei Schlafproblemen belächeln und nicht akzeptieren. Das führe zu Konflikten innerhalb des pflegerischen Teams.

„[...] Die belachen das dann, finde ich. Auch einige Pflegekräfte, also, wenn ich sage, ich habe den abends mit Lavendel abgewaschen [...]“ (I: P6, 11, 9–10, w)

Die Akzeptanz von alternativen Maßnahmen würde nicht nur auf Seiten der Pflegenden fehlen. Auch Patienten/Patientinnen wünschten sich – so die Erfahrung der Pflegenden – oft eher ein Schlaf- und Beruhigungsmittel.

„Es entsteht so schon der Eindruck: [Patient]: ‚Ich möchte eine Schlaftablette, und die will ich auch, egal was man mir sonst anbietet, das nutzt nichts.‘“ (I: P3, 3, 24–26, w)

Diskussion

Im Fokus dieser Studie standen nicht-medikamentöse Maßnahmen bei Schlafproblemen älterer Patienten/Patientinnen im Krankenhaus aus Sicht von Pflegenden. Pflegende berichteten von zahlreichen nicht-medikamentösen Maßnahmen, um Schlafproblemen älterer Patienten/Patientinnen im Krankenhaus zu begegnen. Dazu gehörten strukturelle Maßnahmen wie die Förderung einer schlaffreundlichen Umgebung, organisatorische Veränderungen wie die Anpassung der Dienstabläufe an die Bedürfnisse der Patienten/Patientinnen, spezielle pflegerische Maßnahmen sowie übliche „Hausmittel“. Nach Einschätzung der Pflegenden profitierten insbesondere ältere Patienten/Patientinnen mit kognitiven Einschränkungen von der Anwendung pflegerischer Maßnahmen. Die mit den Maßnahmen verbundene Zuwendung wirkte entspannend und beruhigend. Zudem führte eine intensivere Betreuung schlafgestörter Patienten/Patientinnen zu einer ruhigeren Nacht. Barrieren für diese Maßnahmen ergäben sich durch knappe zeitliche und personelle Ressourcen, fehlende Standards und durch individuelle Patientenbedürfnisse.

Stärken und Schwächen der Studie

Während einer vorangegangenen standardisierten Befragung von Pflegenden (Weiß et al., 2016) wurde sehr deutlich, dass diese sich ungern über die Ausgabe von Schlaf-

und Beruhigungsmitteln äußern. Mangelndes Fachwissen und das Gefühl, etwas Unrechtes oder Falsches zu tun, waren offensichtlich ausschlaggebend für eine geringe Rücklaufquote der Fragebögen. Die methodische Anlage der vorliegenden Studie in Form halbstrukturierter Gespräche machte es Pflegenden leichter, ihre Erfahrungen und Wahrnehmungen im Umgang mit nicht-medikamentösen Maßnahmen bei Schlafproblemen mitzuteilen.

Trotz des Bemühens um eine möglichst angenehme und offene Gesprächsatmosphäre kann sozial erwünschtes Antwortverhalten nicht ausgeschlossen werden, insbesondere um Wissenslücken oder unsachgemäßes Handeln zu verbergen. Im Weiteren ist anzumerken, dass die Ergebnisse auf Aussagen und Erfahrungen und nicht auf Beobachtungen tatsächlichen Handelns beruhen.

Interpretation der Ergebnisse

Über die Evidenz zur Wirksamkeit nicht-medikamentöser Maßnahmen während der Behandlung von vorübergehenden Schlafproblemen besteht nur bedingt Konsens. In der S3-Leitlinie „Nicht-erholsamer Schlaf/Schlafstörungen“ wird angegeben, dass situativ auftretende Insomnien „meist keiner Behandlung bedürfen“ (Riemann et al., 2017; 10). Empfehlungen über nicht-medikamentöse Maßnahmen werden nur zur Behandlung chronischer Insomnien gegeben. In akuten schlaflosen Situationen wird empfohlen, schlafhygienische Maßnahmen zu vermitteln, um schlaffördernde Verhaltensweisen zu fördern. Hierzu zählen beispielsweise regelmäßige körperliche Aktivitäten, das Vermeiden von schweren Mahlzeiten am Abend, das Einführen persönlicher Schlafrituale, die Gestaltung einer angenehmen Schlafatmosphäre und das Vermeiden von koffeinhaltigen Getränken am Abend. Einige dieser Maßnahmen wurden von Pflegenden der Fachabteilungen Geriatrie, Unfallchirurgie und Inneren Medizin benannt. In vorliegender Arbeit wurden diese den Themengebieten „strukturelle Maßnahmen“ und „Anwendung von Hausmitteln“ zugeordnet (siehe Tab. 1).

Hintergrundgeräusche, hervorgerufen durch medizinische und pflegerische Tätigkeiten, zählen zu den Hauptursachen für Durchschlafstörungen im Krankenhaus (Bano et al., 2014; Thomas et al., 2012). Alle Pflegenden dieser Untersuchung, unabhängig von der Zugehörigkeit einer Fachabteilung, ziehen die Möglichkeit, Lärmquellen im Krankenhaus zu reduzieren beziehungsweise zu vermeiden, nur selten in Betracht. Das Bewusstsein, nachts durch pflegerische Tätigkeiten Lärm zu verursachen, scheint nach den Aussagen einer Pflegenden lediglich auf Intensivstationen verbreitet zu sein. Als sehr einfache Maßnahme zur Lärmreduktion konnte nach Aussage der Pflegenden das Anbieten von Ohrstöpseln helfen. Eine prospektiv randomisierte Studie weist den Nutzen von Ohrstöpseln zur Verbesserung der subjektiven Schlafqualität auf postoperativen Stationen nach (Le Guen, Nicolas-Robin, Lebard, Arnulf & Langeron, 2014).

Pflegende der geriatrischen Abteilungen berichteten, dass in einigen Fällen sogar nachts Patienten/Patientinnen aus Doppelzimmern in Einzelzimmer (auch in Therapieräume) oder in „Therapiestühle“ (I: P3, 4, 14–18, w) verlegt bzw. in Sichtnähe der Pflegenden gesetzt werden, vorausgesetzt, die räumlichen Kapazitäten ließen dies zu. Die Erfahrungen der Pflegenden werden überdies durch Hinweise aus der Literatur gestützt (van de Glind, Roode & Goossensen, 2007). Nach Hermann and Flick (2012) kann davon ausgegangen werden, dass es sinnvoll ist, Patienten/Patientinnen mit ähnlichem Bedarf an nächtlichen Pflegehandlungen gemeinsam unterzubringen, um andere Patienten/Patientinnen nicht durch nächtliche Zimmerbegehungen zu stören. Zu berücksichtigen ist jedoch, in welche Räumlichkeiten die Patienten/Patientinnen verlegt werden und wie deren Privatsphäre gewährleistet werden kann.

Um Lichtverhältnisse den zirkadianen Rhythmen der Patienten/Patientinnen anzupassen, erwähnte eine Pflegende der geriatrischen Station die Möglichkeit, das Licht im Patientenzimmer zu dimmen. Die Anwendung von Schlafmasken wurde von den Befragten nicht in Betracht gezogen. Die positiven Auswirkungen von Schlafmasken auf die Schlafqualität bei Menschen im höheren Alter mit akutem Koronarsyndrom konnten in einer randomisiert kontrollierten Studie nachgewiesen werden (Babaii, Adib-Hajbagheri & Hajibagheri, 2015). Grundsätzlich wirkt sich ein 24-h-Lichtmanagement positiv auf die Wahrnehmung der Schlafqualität aus. Das konnte Giménez et al. (2017) mittels einer kontrolliert randomisierten Studie nachweisen. Nach Müller, Olschinski, Kundermann und Cabanel (2017) sollte insbesondere bei Patienten/Patientinnen mit depressiven Erkrankungen, unabhängig vom Alter, während eines Krankenhausaufenthalts der individuelle Schlaf-wach-Rhythmus berücksichtigt werden. So ist es möglich, die Schlafdauer positiv zu beeinflussen und die Symptome der Depression nicht zu verschlechtern.

Eine Befragte der Unfallchirurgie berichtete, im weitesten Sinne unsystematische Schlafanamnesen bzw. Gespräche am Abend zur Erhebung von Schlafgewohnheiten durchzuführen. Die dadurch vermittelte Aufmerksamkeit würde sich positiv auf das Wohlbefinden der Patienten/Patientinnen und auf Belastungen des Nachtdienstes auswirken. Patienten/Patientinnen würden seltener klingeln und besser schlafen. Thomas et al. (2012) bezeichnen Schlafanamnesen zum Abend als „sleeping rounds“ und stellen fest, dass diese Maßnahme einfach und handhabbar in die pflegerische Praxis umzusetzen ist. Zudem konnten sie nachweisen, dass sich die Anwendung der sich daraus ergebenden Maßnahmen positiv auf die subjektive Schlafqualität auswirkt.

Interviewpartner/-innen aus den Fachabteilungen der Unfallchirurgie, Geriatrie und IMC berichteten auch von Hausmitteln als einfache Maßnahmen bei Schlafproblemen. Solche Hausmittel, wie warme Getränke am Abend oder das Hören von klassischer Musik, kennen Patienten/Patientinnen häufig aus ihren normalen Schlafritualen und Routinen im häuslichen Umfeld. Wenn solche Haus-

mittel zu den Schlafritualen der Patienten/Patientinnen gehören, können diese im Rahmen eines Krankenhausaufenthalts ohne großen Aufwand bereitgestellt werden. Umgekehrt fördert der Einsatz von solchen Hausmitteln im Krankenhaus wichtige Strategien zur Entwicklung eines persönlichen Einschlafrituals. Nach Meinung von Irish, Kline, Gunn, Buysse und Hall (2015) ist die alleinige Vermittlung dieser Maßnahmen jedoch nicht ausreichend, sondern lediglich Bestandteil präventiver und therapeutischer Maßnahmen zur Förderung der Schlafqualität.

Die Pflegenden berichteten, dass sich insbesondere während des Nachtdienstes eine intensive Beschäftigung mit älteren Patienten/Patientinnen positiv auf die Klingelfrequenz auswirkt. Beispielsweise plant ein Pflegender der Geriatrie (P5) für den nächtlichen Rundgang bei Patienten mit Schlafproblemen mehr Zeit für Gespräche ein. Seinen Aussagen zufolge würde sich diese Art der Zuwendung positiv auf die Klingelfrequenz auswirken. Für weitreichendere Therapiemöglichkeiten, die mehr Zeit als Gespräche in Anspruch nehmen (wie beispielsweise eine beruhigende Ganzkörperpflege), reiche weder die Besetzung noch die Zeit im Nachtdienst aus, so die Erfahrung von P5. Die Besetzung im Nachtdienst wird in den einzelnen Fachabteilungen unterschiedlich gehandhabt: In den Abteilungen der Inneren Medizin und Geriatrie sind bis 00:00 Uhr zwei Pflegende für den Nachtdienst eingeplant, auf den urologischen und allgemeinchirurgischen Abteilungen werden 33–35 Patienten von einer Person betreut.

Insgesamt äußerten sich die interviewten Pflegenden ambivalent zur Anwendung nicht-medikamentöser Maßnahmen im Nachtdienst. Einerseits scheint den Pflegenden, insbesondere der geriatrischen Stationen, bewusst zu sein, dass Maßnahmen wie eine beruhigende Ganzkörperpflege und Gespräche schlaffördernd und beruhigend wirken. Andererseits werden diese Maßnahmen als zeitaufwendig bewertet und kommen aufgrund mangelnder personeller Ressourcen eher selten zum Einsatz. Dass Hypnotika auf den geriatrischen Abteilungen häufiger als in anderen Fachabteilungen zum Einsatz kommen, wird zudem aus einer Patientenaktenanalyse von Arnold et al. (2017) ersichtlich; begründet u. a. durch Multimorbidität, einhergehend mit Depressionen, Schmerzen und Schlafstörungen.

Dass das Wissen um den Nutzen nicht-medikamentöser Maßnahmen nicht die Anwendung entsprechender Maßnahmen nach sich zieht, erscheint zunächst widersprüchlich. Zieht man die als Mangel erlebten zeitlichen und personellen Ressourcen in Betracht, spiegelt sich hierin der auch in anderen Zusammenhängen nicht unbekanntes Widerspruch zwischen kurzfristig als Belastung erlebten Maßnahmen und deren vermuteten langfristig positiven Effekten wider. Gathecha et al. (2016) empfehlen, während der Durchführung nicht-medikamentöser Maßnahmen bei Schlafproblemen zu berücksichtigen, dass es mehrerer aufeinanderfolgender Nächte bedarf, um eine Verbesserung der Schlafqualität hospitalisierter Patienten/Patientinnen zu erreichen. Nach den Autoren gilt das insbesondere für Maßnahmen zur Vermittlung der Schlafhygiene und für

schlaffördernde Umgebungsveränderungen. Dementsprechend könnten in der pflegerischen Praxis diese Maßnahmen insbesondere für ältere Patienten/Patientinnen mit einer längeren Liegedauer (z. B. geriatrischen Rehabilitationsabteilung) sinnvoll sein. So könnte der Umgang mit knappen Ressourcen vorausschauender geplant und bestenfalls medikamentöse Maßnahmen reduziert werden.

Schlussfolgerung

Bisher scheint es keinen Konsens in der Pflege gegenüber nicht-medikamentösen Maßnahmen bei Schlafproblemen älterer Patienten/Patientinnen zu geben. Eine homogene Problemsicht über den häufigen Einsatz von Schlaf- und Beruhigungsmitteln bei vorübergehenden Schlafproblemen sowie ein von Leitungen befürwortetes Konzept zur Anwendung alternativer Möglichkeiten könnten zu einer höheren Akzeptanz führen.

Wünschenswert wäre ein Klima, das den Einsatz von Medikamenten bei Schlafproblemen zur Ultima Ratio erklärt. Professionell sollte das ärztlich-pflegerische Team ein gemeinsames standardisiertes Vorgehen (im Sinne einer Standard Operating Procedure, SOP) entwickeln und dort vereinbaren, wie man bei vorübergehenden Schlafproblemen vorgeht und Patienten/Patientinnen gemäß ihren individuellen Bedürfnissen berät. Organisatorisch sollten die möglichen nicht-medikamentösen Maßnahmen problemlos verfügbar sein (Anthierens et al., 2009).

Zusammen mit weiteren explorativen Untersuchungen (siehe Heinemann et al., 2016) bildeten die hier beschriebenen Ergebnisse die Basis für die Entwicklung partizipativer Interventionsmaßnahmen in dem betreffenden Krankenhaus (Institut für Allgemeinmedizin, Universitätsmedizin Göttingen, 2017). Unser Vorgehen orientierte sich dabei u. a. an den Empfehlungen von Campbell et al. (2007). Die Interventionsmaßnahmen wurden in mehreren Fokusgruppen-Diskussionen (mono-disziplinär) mit dem pflegerischen und ärztlichen Personal und während weiterer Gespräche und regelmäßiger Arbeitsgruppentreffen – mit dem Ziel der Identifikation von Konflikten und der partizipativen Entwicklung von Kommunikations- und Handlungsstrategien – entwickelt. (Vorgehensweise nachzulesen unter: Institut für Allgemeinmedizin, Universitätsmedizin Göttingen, 2017). Die Erfahrungen der Pflegenden zum Umgang mit nicht-medikamentösen Maßnahmen während der Behandlung von Schlafproblemen älterer Patienten/Patientinnen im Krankenhaus flossen unmittelbar in eine hausinterne SOP „Schlafstörungen im Krankenhaus“ ein. Die SOP und weitere Bestandteile des Maßnahmenpaketes wurden unter der Initiative „Schlaffreundliches Krankenhaus“ eingeführt (www.schlaffreundliches-krankenhaus.de). Durch diese Initiative soll schrittweise eine Kultur zur Förderung einer schlaffreundlichen Umgebung geschaffen werden.

„Ältere Patienten/Patientinnen“ standen – insbesondere aufgrund ihrer erhöhten Risiken für Nebenwirkungen durch Hypnotika und ihrer im Regelfall höheren Anfälligkeit für

Lärm und ihrer größeren Anpassungsprobleme an neue Umgebungen – im Fokus dieser Studie. Von einzelnen Aussagen abgesehen, vornehmlich von Pflegenden aus der Geriatrie, in einem Fall aus der Intensivmedizin, haben die Interviewpartnerinnen und -partner Schlafprobleme und Lösungsmöglichkeiten für Patienten/Patientinnen aller Altersgruppen angesprochen. Aus Sicht der Befragten erscheint dies konkludent, treten ihnen doch auf den einzelnen Stationen Schlafprobleme als ‚einzelne Individuen‘ entgegen, die sich weniger durch ihr Alter als durch ihre jeweiligen Erkrankungen und individuellen Bedürfnisse unterscheiden.

Strukturell würde man sich ein auf die besonderen Belastungen und Vulnerabilität Älterer abgestimmtes Maßnahmenpaket wünschen, mehr noch eine Krankenhausumgebung, die speziell den Bedürfnissen Älterer gerecht wird. Hier ließe sich beispielsweise an „Senior-Friendly- oder Age-Friendly-Hospital-Initiativen und -Programme“ anknüpfen. Zum Beispiel wird im Senior-Friendly-Programm in Ontario/Kanada explizit das Thema Schlafen für ältere Patienten/Patientinnen in einem umfassenden Rahmen des Pflegeprozesses angesprochen und berücksichtigt (Wong, Ryan & Liu, 2014). Auch die Choosing-Wisely-Initiative des American Board of Internal Medicine (ABIM) macht die Schlafprobleme Älterer und den voreiligen Griff zur Schlaftablette zum Thema (ABIM Foundation, 2018).

Wünschenswert wäre, die bisherigen und zukünftigen Interventionsmaßnahmen im Rahmen unserer Initiative „Schlaffreundliches Krankenhaus“ auf ihre Effektivität, Praktikabilität und Akzeptanz zu untersuchen – im Idealfall mittels randomisiert kontrollierter Studien. Dabei stünde nicht nur die Reduktion bzw. der leitliniengerechte Einsatz von Schlaf- und Beruhigungsmitteln im Vordergrund, auch der vorausschauende Umgang mit schlafbeeinträchtigten Patienten/Patientinnen und die Sensibilität gegenüber dem Thema Schlaf und Schlafproblemen wären dabei wichtige Zielgrößen. Während das Projekt bisher auf der Zusammenarbeit von Vertretern aus Pflege und Medizin sowie aus Leitungsebene und Personalrat etc. beruhte, sollte zukünftig auch die Patientenperspektive, z. B. durch Patientenvertreter im Sinne eines Advisory Boards, zum Ausdruck kommen – im Idealfall mit einer frühzeitigen Beteiligung an der Studienplanung (International Collaboration for Participatory Health Research, 2013).

Des Weiteren steht der Nachweis des Nutzens nicht-medikamentöser Maßnahmen bei situativ auftretenden Schlafproblemen älterer Patienten/Patientinnen im Krankenhaus und Wege zu ihrem sinnvollen Einsatz aus (Tamarat et al., 2014).

Elektronische Supplemente (ESM)

Die elektronischen Supplemente sind mit der Online-Version dieses Artikels verfügbar unter <https://doi.org/10.1024/1012-5302/a000639>

ESM1. Halbstrukturierter Interviewleitfaden.

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Was war die größte Herausforderung bei Ihrer Studie?

Die Gewinnung von Teilnehmern. Es mussten viele zeitliche Ressourcen und Fingerspitzengefühl aufgebracht werden.

Was wünschen Sie sich bezüglich der Thematik für die Zukunft?

Ich wünsche mir von meiner Berufsgruppe einen reflektierten Umgang mit Schlaf- und Beruhigungsmitteln.

Was empfehlen Sie zum Weiterlesen / Vertiefen?

Das Buch von Garms-Homolová und Flick (2013): Schlafstörungen im Alter; mit einem Überblick über die Folgen von Schlafstörungen Älterer und Indikationen über Behandlung und Pflege.

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3.6 **Paper 6: Hospital patient survey of older adults about sleep-inducing drugs**

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Patient-reported factors associated with the desire to continue taking sleep-inducing drugs after hospital discharge: A survey of older adults

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Abstract

Purpose: To find out whether any prior experiences with sleep-inducing drugs before hospitalization and positive experiences with these drugs during hospitalization influence a patient's wish to continue taking sleep-inducing drugs after hospitalization.

Methods: We surveyed older hospital patients about use of sleep-inducing drugs before, during, and after hospitalization and compared these answers with their hospital chart using the kappa statistic. The association between the wish to continue these drugs after discharge and the perceived benefits, experience of side effects, and prior experience with sleep-inducing drugs was determined by multivariable logistic regression.

Results: Agreement between patient responses and the hospital file was high ($\kappa = 0.7$). Seventeen percent (83/483) of the participants reported prior experience before their hospital stay; 45% received a sleep-inducing drug during hospitalization; 17% wished to continue taking them after discharge. Of the 400 patients who had no prior experience with sleep-inducing drugs, 147 (37%) became first-time users in the hospital, and 27% (40/147) of these wished to continue this medication after discharged. Strong predictors for this wish were the reduction of sleep onset problems (adjusted odds ratio, 6.26; 95% confidence interval, 2.38-16.44) and any prior experience with sleep-inducing drugs (4.08; 1.97-8.48).

Conclusions: Many older patients become first-time users of sleep-inducing drugs in the hospital. Especially the experience of sleep onset improvements influences the wish to continue sleep-inducing drug use after discharge. Avoiding first-time use should become a goal of hospital policy and be taken into account when weighing the benefits and risks of sleep-inducing drugs.

Stephanie Heinemann and Freya Neukirchen contributed equally to this work.

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KEYWORDS

aged, drug utilization, hospitals, hypnotics and sedatives, pharmacoepidemiology, sleep initiation and maintenance disorders, surveys and questionnaires

1 | INTRODUCTION

Hospitalization significantly affects patients' sleep, both in duration and quality of sleep.¹ Reasons for poorer sleep in the hospital include noise of other patients, medical devices, pain, and toilet visits.¹ Interventions to address such sleep problems during a hospital stay often include the prescription of hypnotic and sedative drugs, especially benzodiazepines and Z-drugs.^{2,3}

These drugs have been shown to improve sleep quality, increase sleep time, and decrease the number of nighttime awakenings. However, there are several potential risks, especially for older patients, such as falls, cognitive impairment, depressive symptoms, and addiction.⁴⁻⁷ In Germany, it is estimated that 1.2 to 1.5 million of its 82 million citizens are dependent upon tranquilizers and sleep-inducing drugs, especially older people.⁸ A review based on epidemiological research⁹ found an overwhelming degree of evidence that benzodiazepines and Z-drugs cause fatal and nonfatal motor vehicle accidents, fractures, and cognitive dysfunction and, at least, weak evidence that these drugs cause dementia. And even if clinical doubt persists regarding the new safety accusations, such as dementia, pancreatitis, or cancer,⁹ the use of these drugs, especially in older persons, needs particular caution. Glass et al⁴ and Treves et al¹⁰ come to the same conclusion, namely, that for persons over 60, the benefits of sedatives and hypnotics may not justify the increased risk.

In spite of these risks and recommendations, more than 40% of older patients receive sleep-inducing drugs during their hospital stay.^{2,11,12} We know some of the reasons for this prescribing behavior: for example, professional knowledge deficits,^{13,14} a perceived lack of alternative treatment options for sleep problems,¹⁵ and the "magic bullet" potential of benzodiazepines and Z-drugs to help patients "feel better overall."¹⁶ Physicians may also regard other medical issues with higher priority than the control and restriction of sleep-inducing drugs.¹⁷

Another important factor for the high use of sleep-inducing drugs in hospitals may be the patients themselves.¹⁸ Although this factor is not well studied, it can be expected that patients who have had previous positive experiences with sleep-inducing drugs wish to receive such drugs when sleep problems reoccur. In interviews, hospital doctors report that patients frequently experience difficulties sleeping in an unfamiliar environment with strange noises and request sleep-inducing drugs.¹⁷ If patients request and use these drugs during hospitalization to deal with sleep problems, a positive experience in the hospital with these drugs may be a reason why patients wish to continue them after discharge.

The aim of this pharmacoepidemiological study was to explore how often older patients use sleep-inducing drugs in the hospital while taking their previous drug experiences into account. Also, the

study aims to explore the consequences of this inpatient drug use after discharge from a patient perspective. We hypothesized that prior experience with these drugs before hospitalization may influence older patients' drug use during hospitalization. We also hypothesized that positive experiences during hospitalization may trigger the wish to continue this use after hospitalization.

2 | METHODS

2.1 | Design

The focus of this study is older patients (65 y and older) who experience nonchronic (transient) sleep problems during their hospital stay. This cross-sectional study was based on a patient survey about the use of sleep-inducing drugs in the hospital and a hospital chart review of the prescribed substances for each surveyed participant. The prescribed sleep-inducing medication classes in this study encompassed the standard medications prescribed for sleep in the hospital studied: benzodiazepines, Z-Drugs, mirtazapine, and baldrian.

2.2 | Context

The study is part of a larger project on the prescription of hypnotics and sedatives in primary care and during hospitalization. The ultimate goal of this project is to develop, implement, and evaluate strategies to reduce the use of hypnotics and sedatives.¹⁹

2.3 | Setting

The study took place in a regional hospital for basic and standard care in a mid-sized city in Lower Saxony. The 485 bed hospital has departments of internal medicine, geriatrics (acute and rehabilitation), trauma surgery/orthopedics, general surgery, plastic surgery, urology, and oto-rhino-laryngology. It should be noted that this hospital has no specialized departments for sleep medicine or psychiatry. Therefore, sleep disorders were not the main indication for a treatment episode in this hospital.

2.4 | Sample size

Our first hypothesis—prior experiences with the sleep-inducing drugs before hospitalization may influence older patients' drug use during hospitalization and subsequently also after hospital discharge—was the basis for a rough estimate of the number of patients needed. We estimated that a high percentage (about 70%) of those who had previous experience received a sleep-inducing drug in the hospital,

compared with those who had no previous experience. A total sample of 2×91 patients would be necessary to detect a significant difference of 20% between both groups, with a power of 80% and a confidence level of 95%. A chart review performed at this hospital³ showed that 27% of hospitalized patients received one or more psychotropic drugs before hospital admission. Of course, not all psychotropic drugs are prescribed for sleep induction and related problems. On the other hand, hospital records cannot capture the indication of prior use of sleep-inducing drugs, especially for patients who are not currently taking these drugs at the time of admission. Taking this into account, we estimated that about 20% of patients will have prior experience with sleep-inducing drugs, at least from time to time. Therefore, we aimed to recruit 500 patients to have, at least, 100 patients in the "prior experience" group.

2.5 | Study population

The study included patients from all departments in the participating hospital. The inclusion criteria was defined as all older inpatients (65 y or older) who were about to be discharged (1 day before or on the day of their hospital discharge). The exclusion criteria were defined as patients who did not speak German, were disoriented in time and space, and/or were diagnosed with dementia. Patients meeting inclusion criteria were identified by the hospital nursing staff and interviewed by one of two trained interviewers (FN and a study assistant).

We recruited study participants successively until 500 patients were included in the study. Computer-assisted personal interviewing (CAPI) was performed by two interviewers who used tablet computers to read questions and corresponding answer categories to older patients personally and to enter the data into a web-based questionnaire.

2.6 | Survey

The survey was based on an instrument adapted by Siriwardena et al¹⁶ to investigate the use, experience, and perceptions of Z-drug and benzodiazepine hypnotics in the community. We translated, pretested, and adapted this instrument for use with the CAPI methodology in a population of older patients in the hospital setting (see Appendix S1).

Patients were asked several questions about prior, current, and future use of sleep-inducing drugs. First, they were asked whether they had ever taken a sleep-inducing drug before being admitted to the hospital at some time in the past (phase 1). Then, patients were asked whether or not they had received a sleep-inducing drug during this hospital stay and, if so, what benefits and/or side effects of sleep-inducing drugs they had experienced. Since not all patients experienced all symptoms and some patients received multiple medications, we offered an additional category "I don't know" for the benefits of sleep-inducing drugs (phase 2). In the regression analysis, "I don't know" was treated as "no." A new aggregate variable "side

KEY POINTS

- Hospitalization significantly affects patients' sleep, both in duration and quality of sleep.
- Forty-five percent of all older hospital patients used sleep-inducing drugs during their hospital stay.
- Of the patients who received sleep-inducing drugs in the hospital, 68% were first-time users.
- Nearly 40% of patients who took sleep-inducing drugs in the hospital wished to continue using them after discharge.
- Further studies should expand our knowledge about how the short-term use of sleep-inducing drugs in the hospital influences patient strategies for dealing with sleeping problems at home.

effect" was created for use in the regression analysis. If a patient answered "yes" to any single question about side effects (see Appendix S1, question #7), the aggregate variable "side effect" was also "yes." Lastly, patients were asked if they wished to continue taking sleep-inducing drugs after their hospital discharge (phase 3). Following the interview, the interviewers consulted the corresponding patient files to record whether or not the patient had received a sleep-inducing drug and, if so, which substance (eg, benzodiazepines, Z-drugs, mirtazapine, or other sleep-inducing drugs; see Appendix S2 for drug details).

2.7 | Data analysis

Differences between patients who have had prior experiences with sleep-inducing drugs and patients without prior experience were tested for significance by the χ^2 test. The association between the wish to continue sleep-inducing drugs after hospitalization and the perceived benefits was analyzed by multivariable logistic regression, controlling for age, gender, department, experience of any side effects, and prior experience with sleep-inducing drugs—with crude and adjusted odds ratios (ORs) and their corresponding 95% confidence intervals (CI) as measures of effect. Agreement between patient responses about receiving sleep-inducing drugs in the hospital and the prescription information from the hospital file (chart review) was determined by Cohen kappa (κ).

To analyze whether the drug(s) received in the hospital had an influence on the wish to continue sleep-inducing drugs at home, we only considered patients that received a sleep-inducing drug according to both the hospital file and the patient survey ($n = 184$). Patients were classified into five groups according to the sleep-inducing drugs they received over the course of the hospital stay: only benzodiazepines, only Z-drugs, only mirtazapine, only plant extracts (such as the

German "baldrian," a popular valerian-hop extract), or a "mix of these 4 groups." It should be noted that type-1 antihistamines, often given to induce sleep in hospital care in other countries, are not commonly used for this purpose in Germany.

3 | RESULTS

3.1 | Recruitment and sample characteristics

Patient recruitment took place from May to September 2014. A total of 957 patients were soon to be discharged during this period. However, 261 patients could not be included because of disorientation in time and space (75%), dementia (13%), and language barriers (6%); 188 patients refused to take part in the study so that 508 patients 65 years and older (59% women) could be surveyed. Their average age was 77.8 years (women) and 76.0 years (men). About half of the surveyed patients were treated in a surgical department (50%), followed by internal medicine (27%) and geriatrics (23%).

For the following analyses, we excluded all patients who were unsure whether or not they had taken sleep-inducing drugs before or during hospitalization, resulting in a valid sample of 483 subjects. Characteristics of these 483 participants in the survey can be found in Table 1.

3.2 | Use of sleep-inducing drugs before and during hospitalization

Seventeen percent (83/483) of the participants reported prior experience with sleep-inducing drugs before their current hospital stay. Of these patients, the majority had prior experience of 1 year or longer (56/83; 67%).

TABLE 1 Characteristics of the study population (N = 483 patients)

Characteristics	N	%
Gender		
Male	198	41.0
Female	285	59.0
Department		
Surgical departments	240	49.7
Internal medicine departments	135	28.0
Geriatric departments	108	22.4
Previous experience with sedatives/hypnotics		
Not at all	400	82.8
Up to 4 wk	9	1.9
Up to 1 y	18	3.7
Longer than 1 y	56	11.6
Age group		
85 y and older	72	14.9
65-84 y	411	85.1

According to the chart review, 20% (96/483) of the respondents had received a benzodiazepine at some point during their hospital stay, 17% baldrian, 12% mirtazapine, and also 12% a Z-drug. A total of 46% (222/483) of the patients had received at least one sleep-inducing drug, 145 (30%) of them received a benzodiazepine or a Z-drug or both.

According to the survey, 45% (217/483) of the older patients received a sleep-inducing drug during their hospital stay, with no differences between men and women. Sleep-inducing drugs were given more often in the geriatric department (55%) than in surgery departments (39%) and departments of internal medicine (47%). Patient survey responses and the information from the hospital files agreed in 84.9% of the cases, resulting in a substantial κ of 0.70.

Of the 217 patients who received a sleep-inducing drug, the vast majority (188/217; 87%) received sleep-inducing drugs multiple times during their hospital stay. A total of 193 patients experienced at least one benefit, most often improvements of sleep onset time (156/217; 72%) and nighttime waking (129/217; 60%); only 2% to 6% of the sample answered "I don't know." A group of 85 patients reported at least one side effect, most often daytime drowsiness (45/217; 21%) and feeling dazed (25/217; 12%).

3.3 | Factors that predicted the wish to continue sleep-inducing drugs after discharge

In total, 82 of 483 (17%) patients wished to take sleep-inducing drugs after discharge. Figure 1 presents the results along the three phases of the study, ie, before, during, and after hospitalization. Of the 83 patients who had previous experience with sleep-inducing drugs (phase 1), 70 (84%) received such a drug in the hospital (phase 2) and 42 (51%) of these patients wished to continue this medication after being discharged (phase 3). Of the 400 patients who had no previous experience (phase 1), 147 (37%) received a sleep-inducing drug for the first time in the hospital (phase 2) and 40 (10%) patients wished to continue this medication after being discharged (phase 3). The difference between patients with and without prior experience with sleep-inducing drugs was highly significant when comparing the rate of drugs received in the hospital (84% vs 37%; $P < .0001$) and the wish to continue the drugs after hospitalization (60% vs 27%; $P < .0001$).

There were several significant predictors for the wish to continue taking sleep-inducing drugs at home (Table 2): two perceived benefits of sleep-inducing drugs, ie, the reduction of sleep onset problems (adjusted OR, 6.26; 95% CI, 2.38-16.44) and lessening of nervousness (2.20; 1.02-4.76) as well as previous experience with sleep-inducing drugs (4.08; 1.97-8.48) and treatment in a nonsurgical department (2.54; 1.24-5.19).

Of those patients who received a sleep-inducing drug according to both the hospital file and the patient survey ($n = 184$), 74 (40%) wished to continue them. In the case of benzodiazepines, it was 17% (10/59), for Z-drugs 45% (9/20), for baldrian 41% (12/29), for

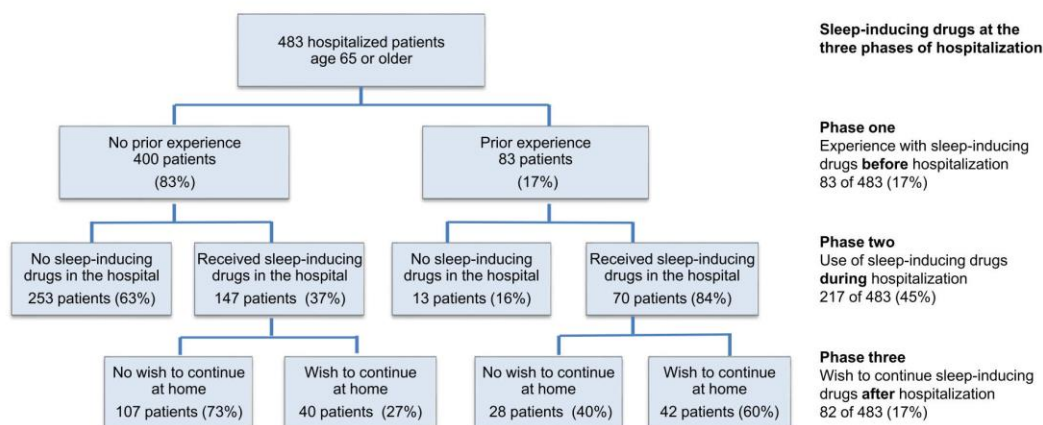


FIGURE 1 Patient-reported use of sleep-inducing drugs before and during hospitalization and the wish to use them after hospitalization [Colour figure can be viewed at wileyonlinelibrary.com]

mirtazapine 70% (16/23), and for a mix of substances from these groups 51% (27/53).

4 | DISCUSSION

4.1 | Summary

Forty-five percent of older hospital patients used sleep-inducing drugs during their hospital stay. The majority of patients who received these drugs in the hospital had no previous experience with sleep-inducing drugs. Of the patients who received sleep-inducing drugs in the hospital, nearly 40% wished to continue using them after discharge. The reduction of sleep onset problems in the hospital most strongly predicted a patient's wish for continued use of sleep-inducing drugs after discharge.

4.2 | Strengths and limitations of the study

To the best of our knowledge, this is the first study that traces the development of the wish to use sleep-inducing drugs as a matter of experiences, first prior to the current hospital stay as a reason to ask for these drugs in the hospital, then in the hospital environment as a predictor for the wish to continue use at home.

The agreement between patient reports about drug use and the hospital files was high, indicating high convergent validity. A further methodological strength of the study lies in the surveying of older patients in the hospital setting using interviewers and a CAPI technique, which lead to complete data collection without missing values.

Limitations include the study design, the study location, and the study sample. First, this is a cross-sectional study so that it is, on principle, impossible to establish a causal relationship between the predictors and our main criterion, ie, the wish to continue sleep-inducing drugs after discharge. For use in a large sample of older patients, the simplicity of yes/no questions in the survey was appropriate. However, such dichotomous data only gives information about the wish to

continue sleep-inducing drugs after discharge and adds no information about why patients wish to (dis)continue these drugs. Second, the survey was conducted in a single hospital, which limits the generalizability of the results. The use of sleep-inducing drugs could vary, according to a hospital's drug policy, size, and specialties. It should be noted that the hospital under study was willing to open its doors and its patient records to our researchers for the explicit purpose of studying sleep-inducing drugs. Therefore, it is possible that the prevalence of the use of sleep-inducing drugs will be even higher in hospitals that would not allow such an in-depth look behind the scenes. Third, all older patients surveyed were able to answer the questions themselves, which excluded, for example, patients with dementia from the sample. Also, we did not record the admission medication or diagnoses of the patients surveyed. Relevant comorbidities such as anxiety, chronic insomnia, and/or depression could have been the reason for the use of psychoactive drugs. However, we know from a chart review of all older patients treated in this hospital that the prevalence of such comorbidities was so low—for example, depression below 6%—that it cannot account for the use of these drugs in 45% of patients.³ A review of admission medication would have allowed us to identify “current users,” ie, those patients who were regularly taking sleep-inducing drugs at the time of hospital admission. Future studies should take these factors (comorbidities and current drug use) into account.

4.3 | Meaning of the study

The study confirmed former results about the high use of sleep-inducing drugs during a hospital stay. According to a study in a Belgian university hospital, more than 40% of patients received a hypnotic drug, mostly but not always as a result of continuation of hypnotics started before admission.¹¹ A more recent Swiss observational study also found a high percentage of patients with sedative drugs at discharge (44%), many of them with a new prescription during hospitalization.² So, the rhetorical question whether anything had changed in the use

TABLE 2 Predictors for the wish to continue taking sleep-inducing drugs after a hospital stay

Predictors	% ^a	Univariate Model			Multivariable Model		
		OR	(95 % CI) ^b	P	OR	(95 % CI) ^b	P
Gender							
Male	31.5	1.00	(0.90-2.81)	.157	1.00	(0.52-2.10)	.905
Female	42.2	1.59			1.04		
Department							
Surgical departments	27.7	1.00	(1.23-3.88)	.003	1.00	(1.24-5.19)	.011
Nonsurgical dept. ^c	45.5	2.19			2.54		
Prior experience with sedatives/hypnotics							
No prior experience	27.2	1.00	(2.20-7.31)	<.001	1.00	(1.97-8.48)	<.001
Prior experience	60.0	4.01			4.08		
Age group							
85 y and older	57.6	1.00	(1.23-5.5)	.005	1.00	(0.82-4.95)	.128
65-84 y	34.2	2.63			2.01		
Side effects							
No side effects	36.4	1.00	(0.67-2.04)	.521	1.00	(0.61-2.44)	.571
At least 1 side effect	40.0	1.17			1.22		
Problems with sleep onset time							
No improvement	13.1	1.00	(2.67-13.40)	<.001	1.00	(2.38-16.44)	<.001
Improvement	47.4	5.98			6.26		
Problems with nighttime waking							
No improvement	29.5	1.00	(1.02-3.25)	.058	1.00	(0.43-1.95)	.822
Improvement	43.4	1.83			0.92		
Problems with pain							
No improvement	33.3	1.00	(1.22-4.61)	.007	1.00	(0.69-3.65)	.280
Improvement	54.4	2.38			1.59		
Problems with nervousness							
No improvement	30.7	1.00	(1.28-3.99)	.008	1.00	(1.02-4.76)	.045
Improvement	50.0	2.26			2.20		
Problems with anxiety							
No improvement	33.3	1.00	(1.22-4.61)	.027	1.00	(0.44-2.65)	.869
Improvement	54.4	2.38			1.08		
Tolerance of hospital environment							
No improvement	29.6	1.00	(1.22-3.74)	.013	1.00	(0.72-2.99)	.297
Improvement	47.5	2.14			1.46		

Note. Numbers in bold are significant at $P < .05$.

^aPercentage of patients who wish to continue taking sleep-inducing drugs after their hospital stay.

^bOR = odds ratio; 95 % CI = 95 % confidence interval.

^c"Nonsurgical departments" include departments of internal medicine and geriatrics (acute and rehabilitative).

of hypnosedative drugs during the last decade¹¹ still remains important.

Our study adds to the present state of knowledge in four respects:

1. The role of prior experience

The fact that especially those patients in our study received sleep-inducing drugs that had already experienced sleep-inducing drugs

before their current hospital stay indicates that prior experience is an important factor for the wish to use sleep-inducing drugs when sleep problems arise. This patient-based factor is a warning not to blame nurses and hospital physicians alone for a too liberal use of these drugs. An interview study reported that hospital doctors felt pressured by patients who demanded hypnotics or sedatives because of the unfamiliar surroundings and strange noises

in the hospital, ie, transient insomnia.¹⁷

2. Sleep onset improvement as the main factor

The hospital environment poses many challenges to patients wishing to sleep, including unfamiliar sounds, smells, lighting, bedding, etc, as well as a situation where nurses may enter the room during the night to perform nursing care duties.²⁰ A quarter of a century ago, a study in an Australian public hospital found that 52% of the patients received a benzodiazepine—mainly due to sleep problems—whereby patients usually reported an improvement in falling asleep, not in the overall quality of sleep.¹² The results of our study confirmed that it is the positive experience of falling asleep soon after taking the drug—but not an improvement in nighttime waking—that patients appreciate. This experience, be it a pharmacological or placebo effect, proved to be a strong factor for the wish to repeat these experiences in other environments.

3. First-time use in the hospital

According to a study from Israel,²¹ older first-time users were almost five times more likely to use sleep medicines in the months after discharge, compared with those that did not receive these medicines in the hospital. To learn more about this knock-on effect of the hospital, we asked patients who received sleep-inducing drugs in the hospital whether or not they wished to continue taking these drugs at home. A considerable proportion of these patients wished to continue the sleep-inducing drugs after discharge. So, while Zisberg et al's²¹ study shows that first-time use of sleep-inducing drugs in the hospital often results in a use of these drugs directly after the hospital stay at home; our study shows the willingness to use these drugs whenever sleep problems arise. Both studies show first-time use of sleep-inducing drugs in the hospital can carry over to the private setting, even if drug management across health care sectors and the role of general practitioners in the prescription and restriction of sleep-inducing drugs differ in both countries. In Germany, for example, p.r.n. drugs—such as sleep-inducing drugs—are often not listed in the recommended medications in the hospital discharge letter. In addition, patients are normally discharged from the hospital with drugs for max. 1 to 3 days and must contact their general practitioner for necessary prescription medication.

Although not every sleep-inducing drug administered and taken in the hospital is the first step into a history of drug abuse or dependency, large studies with insurance claims data in Canada²² and Germany²³ have shown that about 1% of patients who were admitted to the hospital with no recent hypnotic prescriptions received a benzodiazepine or Z-drug over a longer period following a hospital stay. While a rate of 1% looks unimpressive for those unfamiliar with pharmacoepidemiological data processing, our study may raise awareness among hospital nurses and doctors since it is, indeed, a large group of persons who continue using sleep-inducing drugs after hospitalization.

4. Mirtazapine as a sleep-inducing drug

Interestingly, the antidepressant mirtazapine was the sleep-inducing drug that the highest percentage of older patients in our study wanted to continue using at home. So far, mirtazapine has

not played a major role in other hospital-based “sleep” studies. Mirtazapine is appreciated for its fast-acting, positive impact upon sleep latency and sleep quality, whereby weight gain can be a common sequela.²⁴ Although the patients who received mirtazapine in our study reported that they received a “sleep-inducing drug,” we do not know whether these patients were also being treated for depression symptoms. Further research will need to closely examine a strategy of initiating mirtazapine for transient sleep problems in the hospital setting and the potential long-term effects (both benefits and risks) of mirtazapine use to treat sleep problems for nondepressed elderly living at home.

4.4 | Implications of the study

Assuming that most older patients experience nonsevere sleep problems in the hospital, there is little indication for the widespread prescription of sleep-inducing drugs.²⁵ Therefore, doctors and nurses in the hospital setting should take older patients' sleep problems seriously, but respond conservatively, especially when sleep onset problems are communicated. Discussions at the time of hospital admission may present a good window of opportunity to inform patients that sleep onset problems are a normal occurrence in the hospital. Such discussions may be used to proactively curb patients' demands for sleep-inducing drugs.

Since our study shows that many patients become first-time users in the hospital setting, further studies should expand our knowledge about how (if at all) the first-time use of sleep-inducing drugs in the hospital setting affects patient strategies for dealing with sleeping problems in the private setting after hospital discharge.

Nonpharmacological alternatives such as providing ear plugs and eye masks, changing the light and sound environment, and reducing nursing care activities that disrupt sleep²⁶ as a first line treatment for transient sleep disturbances in the hospital environment can reduce the number of patients who experience sleep-inducing drugs for the first time in the hospital. Whether these strategies can also reduce the number of individuals who become long-term hypnotic drug users in old age and how it is possible to reduce the patient wish to continue sleep-inducing drugs after discharge should be topics for future research.

In conclusion, both previous and current experiences with sleep-inducing drugs significantly contribute to the use of these drugs during hospitalization and the wish to continue taking them after hospitalization. Without condemning every sleep-inducing drug as the first step into dependency, we could show that hospitals promote, at least indirectly, interest in these drugs and the wish to use them also after hospitalization. So, avoiding the first-time use of sleep-inducing drugs should become a goal of a hospital's policy and should be taken into account when weighing the benefits and risks of sleep-inducing drugs.

ETHICS STATEMENT

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of the University Medical Center in Göttingen, Germany (ref number 25/2/14).

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interests. R.N. is head physician of the geriatric department of the Evangelisches Krankenhaus Göttingen-Weende.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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4 Summary of Results

In the following, I will briefly summarize those results of the papers of this thesis that helped to inform and implement the multi-faceted intervention in the study hospital.

Paper 1 is a study protocol of the entire Sleeping Pills Project and puts the results of the singularly published papers of this thesis into the context of the larger project.

In **Paper 2**, we showed that sleep-inducing drugs were used often in the hospital under study (29.5% of the patients received at least one benzodiazepine, 12.6% at least one Z-drug). Nearly one-third of all older patients were treated with at least one potentially inappropriate psychotropic medication (PIM), indicating that knowledge about appropriate drugs and dosages for older adults is lacking. An especially frequent PIM in this hospital was lormetazepam. As a consequence, creating a guideline for **appropriate prescribing** including a positive list of sleep-inducing drugs which are recommended by the PRISCUS list became an important goal of the hospital intervention.

Paper 3 focuses on the professionals' perception of the risks and benefits of benzodiazepines (such as lormetazepam, lorazepam and oxazepam). We found that with regards to the overall risk-benefit ratio of benzodiazepines, doctors who answered that "falls" and/or "craving" occur often were more likely to check the statement that the risks of benzodiazepines outweigh the benefits. For nurses, "confusion" strongly influenced the risk-benefit ratio; the frequent perceived occurrence of "confusion" with benzodiazepine use was associated with the statement that the risks of benzodiazepines outweigh the benefits. As a consequence, it became necessary to **communicate the risks of sleep-inducing drugs clearly** and **customize information for doctors and nurses** in the hospital intervention.

In **Paper 4**, we focused upon the professionals' perception of Z-drugs in comparison to benzodiazepines. We discovered that doctors and nurses often answered "unable to judge" when asked to rate the benefits and risks of Z-drugs (e.g. zolpidem and zopiclone). For benzodiazepines, there were far fewer "unable to judge" answers. Nurses estimated the risks to be much less frequent than doctors did. From this study, we learned that **knowledge about the risks and benefits of sleep-inducing drugs (especially Z-drugs) is lacking**, but that this lack of knowledge does not keep such drugs from being regularly prescribed/dispensed in the hospital. As a consequence, we realized that education about Z-drugs is needed but an intervention based solely upon educating professionals will be unlikely to bring about change.

In **Paper 5**, we learned from nurses that lack of resources (time, personnel) and stressful situations during night shifts contribute (at least in part) to the high usage of sleep-inducing drugs.

Nurses also reported that some patients expect to receive sleep-inducing drugs in the hospital and actively request them. Non-drug alternatives (ear plugs, eye masks, herbal teas) were not available on every ward and nurses perceived barriers (e.g. professional criticism both from doctors and nursing colleagues) to using them. As a consequence, we took three important messages into the intervention phase of the project. First, **patients themselves need to be addressed by the intervention directly** to reduce the demand for inappropriate treatment with sleep-inducing drugs. Second, stressful situations in the night should be avoided when possible, for example by **clearly documenting a plan of action** for the case that sleeping problems arise. Third, **non-drug alternatives must be available on every ward** or they cannot be part of the intervention strategy.

In **Paper 6**, we discovered that 37% of patients who had never used sleep-inducing drugs prior to their hospital stay received such drugs in the hospital. Reduction of sleep onset time (72%) and night-time waking (60%) were the most-commonly perceived benefits. Daytime drowsiness (21%) and feeling dazed (12%) were the most commonly perceived side effects. Nearly one-third of older patients who were treated with sleep-inducing drugs in the hospital wished to continue these drugs after discharge. As a consequence, it became important **to reduce the number of older patients who experience sleep-inducing drugs for the first time** in the hospital.

The results of the above-mentioned six papers as well as an additional interview study with hospital doctors (Weiß et al. [17]), were synthesized into six reasons for inappropriate use of sleep-inducing drugs in the hospital setting:

1. Lack of appropriate prescribing knowledge, especially for the elderly population (**Paper 2**)
2. Differences between hospital doctors and nurses in the perception of the frequency and efficacy of sleep-inducing drugs (**Paper 3** and **Paper 4**)
3. Lack of knowledge about (unwanted) drug effects such as falls (**Paper 3** and **Paper 4**)
4. Professional stress and uncertainty in the night (**Paper 5**, Weiß et al. [17])
5. Lack of non-drug alternatives to sleep-inducing drugs (**Paper 5**)
6. Patient demand for sleep-inducing drugs (**Paper 5**, **Paper 6** and Weiß et al. [17])

In the following chapter, I will explain how these reasons for the inappropriate use of sleep-inducing drugs in the hospital setting were communicated to hospital stakeholders (5.1) and how these stakeholders worked together with the research team to create a hospital-wide strategy to improve the use of sleep-inducing drugs (5.2). This strategy was then translated into components of a complex intervention, explained in chapter 5.3 and Box 1. It should be noted here that additional studies in the Sleeping Pills Project (described in **Paper 1** but not included in this thesis) provided important insight, which also contributed to the participatory development of the complex intervention.

5 Using empirical evidence to create a drug reducing strategy

The focus of this thesis is to identify the reasons for the inappropriate use of sleep-inducing drugs in the hospital setting and translate these results into a multi-faceted, tailored intervention embedded in a participatory approach. In this section, I will describe the participatory process (5.1), the intervention strategy (5.2) and how the results of the papers were translated into intervention components to reduce the use of sleep-inducing drugs in the hospital setting (5.3).

5.1 Participatory and interdisciplinary development of the intervention

The Sleeping Pills Project team was made up of researchers³ from the Department of General Practice and the Evangelisches Krankenhaus Göttingen-Weende, where the study was carried out. Therefore, the fact that practicing clinicians worked as part of the research team meant that the makeup of the research team facilitated participation and cooperation between research and daily practice. In addition, two members of the research team (SH, VW) regularly presented study results to leading doctors and nurses (explained in more detail in chapter 5.7) and used these presentations to reach key opinion leaders within the hospital.

A central component of the participatory approach was moderated discussion groups with hospital doctors and nurses. Two members of the research team (SH, MvM) presented and discussed the results of the first phase of the project (**Papers 2-6**) in three group discussions. The aim of the group discussions was to generate possible solutions to the problem of over-prescribing of benzodiazepines and Z-drugs that would be accepted by doctors, nurses, patients and, of course, the hospital administration itself.

The participants of the discussion groups represented the three major departments of this hospital: internal medicine, geriatrics and surgery. The group discussions revealed five areas suitable for intervention:

- Knowledge of pharmacology
- Aspects of professional responsibility
- Time management
- Environmental factors
- Non-drug strategies for dealing with hospital-associated sleeping problems.

³ Researchers who performed field work included: Inken Arnold, Anna Kaspar-Deußen, Stephanie Heinemann (SH), Laura Heyden, Lea Kauffmann, Freya Neukirchen, Katharina Schmalstieg-Bahr, Kati Straube, Matthias von Müller (MvM), Fabian Wedmann, Vivien Weiß (VW).

In a following step, these researchers (SH, MvM) summarized the results from the group discussions and prepared intervention suggestions based on these five areas. The members of the interdisciplinary research team carefully considered these ideas. Some ideas from the group discussions, such as changes to the sleep environment (e.g. different beds, dimmable lighting, more single rooms) were deemed too difficult or too expensive to put into practice. Promising targets for an intervention were identified as: increasing knowledge and awareness of nurses and physicians about pharmacology (e.g. by providing information about appropriate prescribing for the elderly), explicitly communicating an inter-professional strategy (e.g. to reduce ad-hoc nighttime decision-making) and implementing non-drug strategies to induce sleep (e.g. ear plugs, eye masks, herbal tea).

The researchers from the Department of General Practice then presented these ideas to an interdisciplinary and multi-professional team from the hospital (physicians, nursing director, managing director, chief of staff, head physician of the geriatric department, quality management director) at a large project meeting. The goal of this meeting was to weigh the practicability of these suggestions and come to a consensus about the basic intervention strategy (5.2) and the components of the intervention itself (5.3 – 5.11).

5.2 Intervention strategy

The following basic strategy for dealing with hospital-associated transient sleeping problems was agreed upon by all hospital stakeholders. This strategy, which consists of four parts, is the basis of all activities in the tailored intervention.

- Part 1: Patients who normally sleep well at home **should not receive sleep-inducing drugs** in their first night in the hospital.
- Part 2: When possible, decisions about sleep-inducing drugs (which drug and which dosage) **should be made during the day** by the physician responsible for the patient's treatment.
- Part 3: Alternatives to sleep-inducing drugs (ear plugs, eye masks, herbal tea) **should be available on every ward** and offered to patients when appropriate.
- Part 4: When prescribing sleep-inducing drugs: **avoid benzodiazepines** when possible due to the risk of falls and next-day drowsiness.

5.3 The components of the Sleep-friendly Hospital Initiative

On the basis of the results summarized in chapter 4 of this thesis, we created a complex intervention for reducing sleep-inducing drugs in the hospital setting, consisting of several components (Box 1). We named the intervention the "Sleep-friendly Hospital Initiative" [in German "Schlaffreundliches Krankenhaus"] to make clear that the hospital will make every attempt to welcome the patient and make his/her sleep there as comfortable as possible.

Box 1. Components of the Sleep-friendly Hospital Initiative.

Problem	Strategy	Implementation
High rate of sleep-inducing drugs, especially potentially inadequate medications for older patients (Paper 2)	Find a consensus about the appropriate prescription of sleep-inducing drugs (incl. dosage) and make it available to all employees	<ul style="list-style-type: none"> ▪ Prescription assistance positive list (Fig. 1) ▪ SOP (Fig. 2 & Fig. 3) ▪ Staff training
Differences between hospital doctors and nurses (Paper 3, Paper 4)	Create and implement an action strategy where the responsibilities of doctors and nurses are clear	<ul style="list-style-type: none"> ▪ SOP (Fig. 2 & Fig. 3) ▪ Staff training
Lack of knowledge about unwanted drug effects (Paper 3, Paper 4)	Compile and communicate information about common unwanted effects of sleep-inducing drugs	<ul style="list-style-type: none"> ▪ Poster "Why should you avoid using sleep-inducing drugs" (Fig. 4) ▪ Staff training
Professional stress and uncertainty in the night (Paper 5)	Avoid (when possible) stressful, ad hoc situations during the night shift by taking a short sleep history at admission	<ul style="list-style-type: none"> ▪ SOP (Fig. 2 & Fig. 3) ▪ Staff training
Lack of non-drug alternatives to sleep-inducing drugs (Paper 5)	Communicate available non-drug alternatives (e.g. ear plugs, eye masks, herbal tea) and strategies	<ul style="list-style-type: none"> ▪ SOP (Fig. 2 & Fig. 3) ▪ Staff training ▪ Alternatives available on every ward
Patients demand for sleep-inducing drugs (Paper 5, Paper 6)	Provide information for patients about getting to sleep in the hospital setting without sleep-inducing drugs	<ul style="list-style-type: none"> ▪ Homepage (Fig. 5) ▪ Poster campaign (Fig. 6)

5.4 Backbone of the intervention: brief sleep history and action strategy

We knew from **Paper 2**, that older patients often received a sleep-inducing drug at least once during their hospital stay – often a potentially inadequate medication (PIM). Interviews with nurses (**Paper 5**) and with doctors (Weiß et al. [17]) revealed that some doctors and nurses felt uncomfortable with the way sleep problems were handled in the hospital but nearly all professionals appreciated that the current practice ensured a smooth running of the hospital especially in the night with limited personnel. Any interventions in this situation would be treated with great skepticism, accompanied by the fear that changes will increase workload. Especially nurses expressed this fear in the participatory discussion groups—directly or indirectly—because they often felt left alone when dealing with patients' sleeping problems during the night.

Considering these attitudes, experiences and fears, we built the intervention around a very simple question about the patient's sleep history and a clear action strategy (Figure 1). The doctor who admits the patient should ask: "How do you normally sleep at home?" If the patient responds with "I usually sleep well at home," then the patient should only be offered non-drug strategies such as ear plugs, an eye mask or herbal tea in the first night of his/her hospital stay.

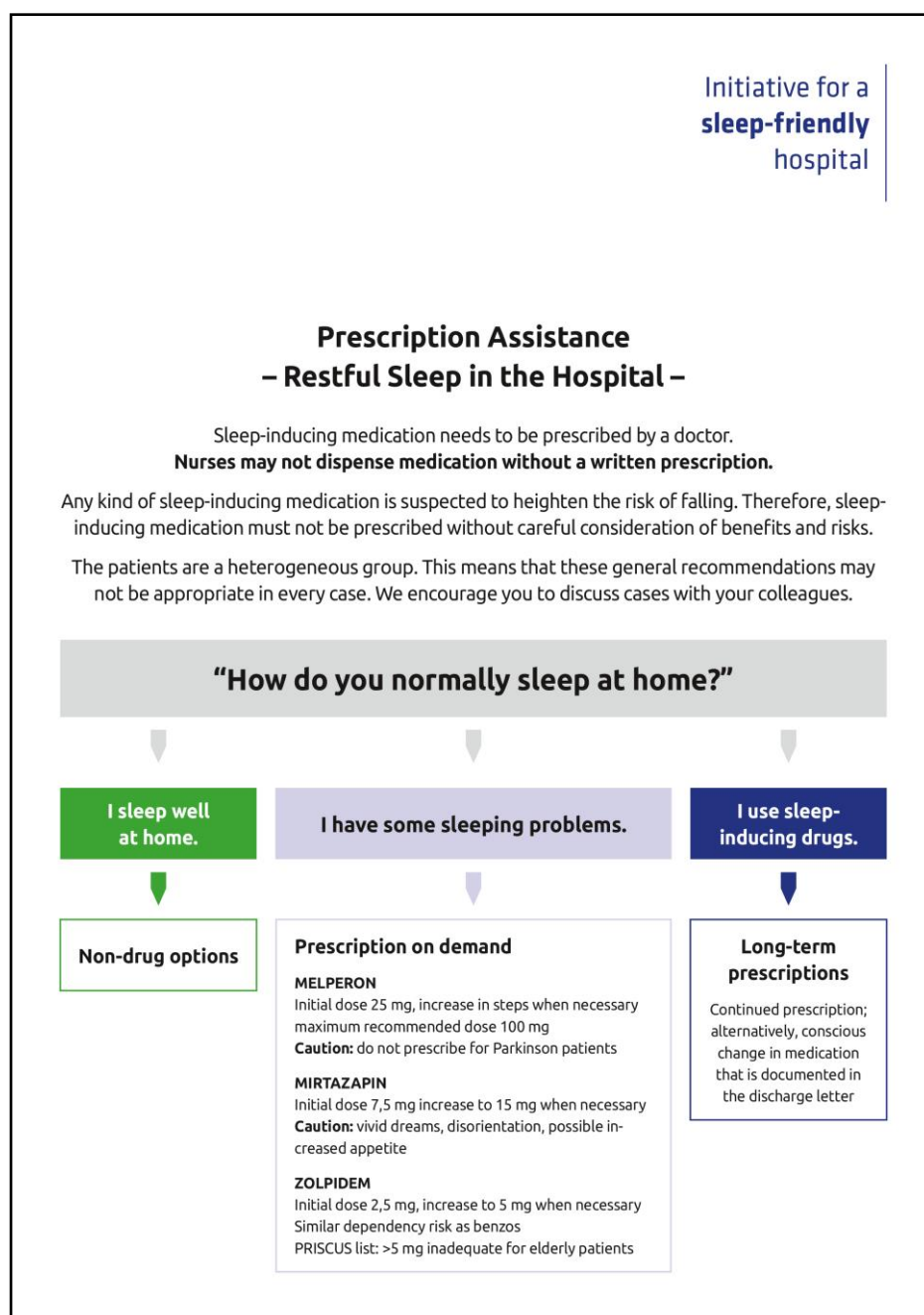


Figure 1. Hospital doctors' prescription assistance (translation SH).

If the patient responds to the question with “I have trouble sleeping at home” then the doctor should make an order in the patient’s chart, explaining how the night nurse should respond in the event that the patient complains about not being able to sleep, e.g. with a p.r.n. (*pro re nata*; as needed) prescription. The thinking behind this strategy is that the ward doctor is most familiar with the patient, his/her health history, current symptoms and treatments. A p.r.n. prescription in the patient’s chart (e.g. baldrian, mirtazapine, melperone or low-dose zolpidem) should ease stress in the night, since the plan of action when hospital-associated sleeping problems arise is

clear to both doctors and nurses. Also, the prescription assistance (Figure 1) gives clear recommendations of drugs which are deemed appropriate for older adults according to the PRISCUS list [9].

If the patient responds to the question with “I take sleep-inducing medications nightly,” the ward doctor should weigh the pros and cons of keeping or changing this medication in light of the current treatments and make a clear order in the patient’s chart. It is important to consider the patient’s entire situation and recognize that an abrupt change may cause withdrawal symptoms [32].

5.5 **Standard operating procedure for newly admitted patients**

The results from **Paper 5**, Weiß et al. [17] and the participatory group discussions showed that both nurses and doctors missed a clear communication of responsibilities. Therefore, we developed a first proposal for the handling of sleep-inducing drugs, especially for newly admitted patients. This proposal aimed to clarify responsibilities between doctors and nurses, offer non-drug options for patients with sleeping problems and help doctors to prescribe adequate sleep-inducing drugs, if necessary, including the appropriate dosage for older persons. This proposal was first presented to senior physicians and, after a further revision, was discussed in the respective team meetings of the ward physicians. After a final agreement with the corresponding persons, we drew up the procedure as a standard operating procedure (SOP), applied the corporate design and entered it into the in-house document management system, available to all employees. Even though the document was accessible via all hospital computers, the visibility of the SOP was rather low. Therefore, the research team worked together with a graphic artist to create a laminated pocket-sized version (Figure 2 and Figure 3) depicting the action strategy and prescription assistance. This pocket card was disseminated to all doctors and nurses, as the two most important target groups. Also, all newly hired staff received the SOP at an introductory seminar to assure that new employees were aware of the SOP.

Initiative for a sleep-friendly hospital

POCKETCARD to SOP "SLEEPING PROBLEMS IN THE HOSPITAL"

SOP "Sleeping problems in the hospital" regulates the non-drug and medication-based treatment of sleeping problems.

AIMS

1. Reduction of/more appropriate prescription of sleep-inducing drugs.
2. For patients who sleep poorly at home, doctors and nurses should have a plan in place (e.g. medication on demand), should sleeping problems in the hospital setting arise.
3. Avoidance of stressful situations at night.

APPLICATION

At admission, all patients are to be asked in detail about their sleep history (phase 1). Depending on this, doctors will prescribe no medication, medication on demand, or long-term medication (phase 2).

When patients complain during their first night about new sleeping problems and do not have current prescriptions, nurses will act according to non-drug recommendations (phase 3). If this strategy fails, other (possibly drug-based) solutions will be discussed on the next day with the doctor responsible for the patient's direct care.

NOTE

Sleep-inducing medication must be prescribed by a doctor. Any kind of sleep-inducing drugs may increase the risk of falling. Never prescribe or dispense sleep-inducing drugs without carefully weighing risks and benefits.

Doctor's Tasks

- Sleep history
- Appropriate prescription of sleep-inducing drugs, as required
- Detecting possible dangerous developments

Nurse's Tasks

- Sleep history
- Prompt notification of doctors as required
- Offer non-drug options

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Practice, University
Medical Center,
Göttingen, Oct. 2016

Figure 2. Front side of the hospital SOP in pocket card format (translation SH).

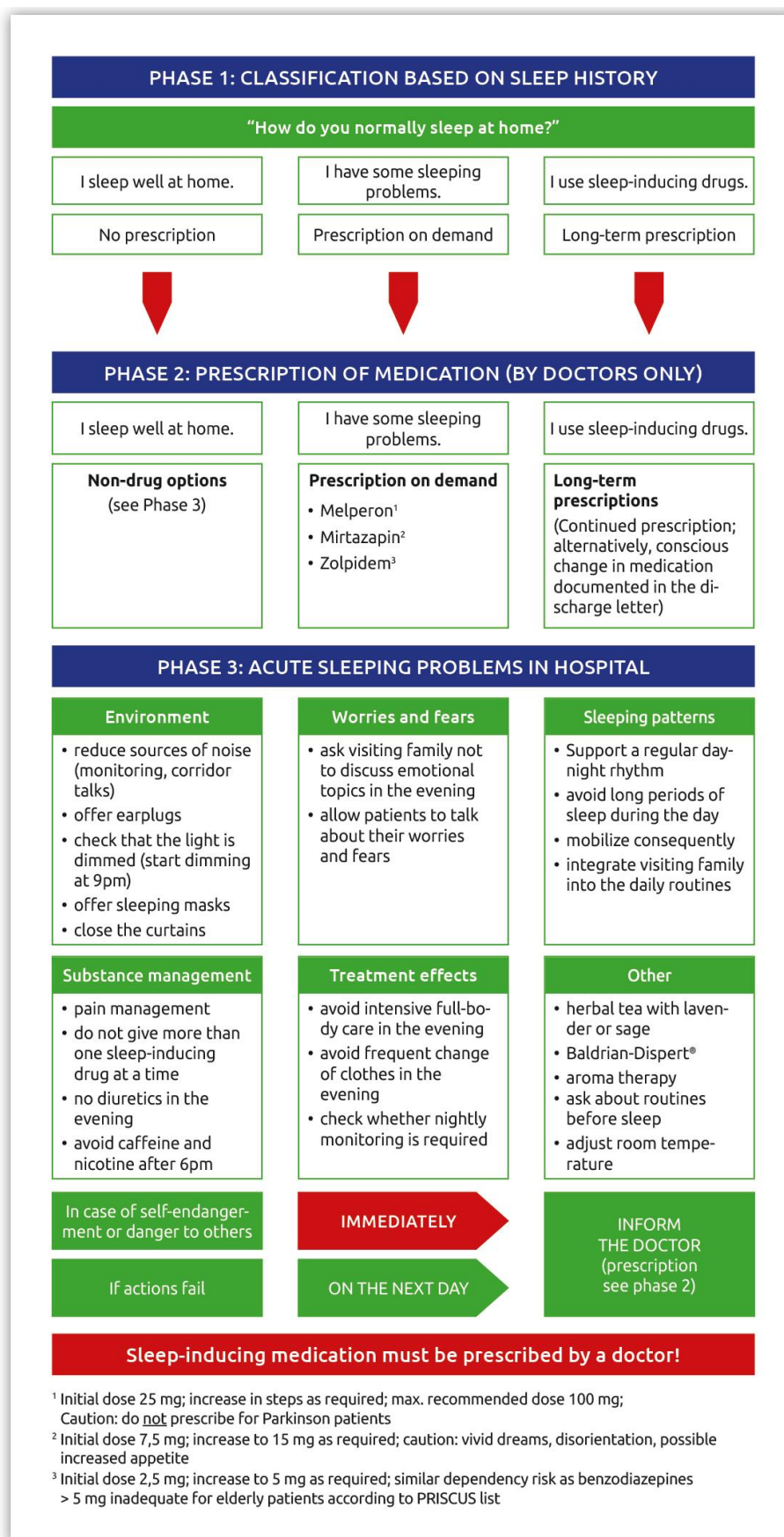


Figure 3. Back side of the hospital SOP in pocket card format (translation SH).

5.6 Poster depicting adverse effects of sleep-inducing drugs

Due to the fact that the doctors and nurses in our study had difficulty weighing the risks and benefits of sleep-inducing drugs (**Paper 3** and **Paper 4**), explicit information about these risks was needed. For the purpose, we created a poster with the title “Why should sleep-inducing drugs be avoided?” (Figure 4). In cooperation with the nursing administrator, the head nurse on each ward received a laminated poster to be prominently displayed in the nursing station, preferably on or near the door of the cupboard where sleep-inducing medicines are kept.






Initiative for a
sleep-friendly
hospital

Why should you avoid using sleep-inducing drugs?

Sleepiness has its price

In addition to the desired effects (falling asleep fast, sleeping through the night), side effects may occur. It depends on the medication you take which undesirable side effects are triggered. Some substances are exclusively used to induce sleep. Other medications are mainly used for depression or epilepsy and induce sleepiness as a side effect. Some unwanted side effects are frequent and/or significant.

Frequent side effects

Disorientation/dizziness
Concentration and cognition can be significantly reduced.

Drowsiness during the day
Sleep-inducing drugs lead to an increased risk of accidents because their effects may continue the next day and remain undetected. You should therefore not drive a car or work with machines after taking sleep-inducing drugs.

Risk of falling
Balance and strength may be negatively affected. This may lead to falls and serious injuries.






Increased tolerance
The desired effects may become weaker over time. This means that some people need to take a higher dose of the drug to get the same effect.

Addiction
Some sleep-inducing drugs are addictive – similar to other drugs, such as alcohol.

Withdrawal symptoms
If you suddenly stop taking sleep-inducing drugs, it may cause problems such as new sleeplessness, night sweats, restlessness and anxiety.

Paradoxical effects (in particular in elderly patients)
Instead of inducing drowsiness, the drug may cause restlessness, inner tension and irritability.

Other possible side effects

Nausea
Stomach pains
Dry mouth

Increased appetite
Weight gain

Reduction in libido
Impotence

Headaches

Allergies
Eczema

Conclusion

Poor sleep can have many causes. Sleep-inducing drugs make you drowsy, but they may also cause serious side effects. If you suffer from sleeping problems, your first plan of action should be implementing simple rules and changes in behavior (i.e. sleep hygiene) that will help you get to sleep.

Icons:
Confused by Andrew Doane, Sleeping by Hadi Davodpour, Falling by Andrea Novoa, Injured by Christopher Anderson, Car crash by Myly
Man Vomits into Toilet Bowl by Gan Khoon Lay, Impotence by Luis Prado, Obesity by Hea Poh Lin, Headache by Gan Khoon Lay, Eczema by Luis Prado

Contact: allgemeinmedizin@med.uni-goettingen.de | January 2017

Figure 4. Poster about adverse effects of sleep-inducing drugs (translation SH).

5.7 Staff training

At several meetings with leading doctors and nurses, we explained health risks associated with benzodiazepines and Z-drugs and informed them about some misconceptions we found in the survey data (**Paper 3, Paper 4**). We talked about the principles of rational pharmacotherapy (as little as possible, as much as necessary) and stressed the use of non-drug alternatives as a first-line treatment for transient sleep problems. These doctors and nurses are a valuable group of opinion leaders within the existing hierarchy of the hospital.

The research team offered 10-minute staff training sessions for doctors to each hospital department on site. Two departments (internal medicine and geriatrics, ca. 20 participating doctors) allowed us to train their staff about the usage of the prescription assistance, the action strategy and the SOP. For nurses, the research team offered a 90-minute training session within the existing, weekly on-site continuing education format [so-called "Pfleger Forum"] with a special focus on increasing pharmacological knowledge, explaining the alternatives to sleep-inducing drugs and understanding and using the SOP. The goal was to empower the nurses to find ways to implement non-pharmacological alternatives in the everyday routine of the ward, as some of them had suggested in **Paper 5**. Additional staff training was provided by members of the research team (SH, KS, VW, MvM) to nursing students in a 120-minute seminar focused around the activity of daily life "being awake and sleeping".

5.8 Alternatives available on every ward

In the SOP and the staff training, non-drug sleep aids (**Paper 5**) are the recommended first line treatment of transient, hospital-associated sleeping problems. Ear plugs were available prior to the intervention, but through the work of the project, eye masks and sleep-inducing herbal tea were added to the list of materials which can be regularly ordered through the hospital procurement office. Especially key to accomplishing this goal was the support of the head nurses on each ward and the nursing administrator's office.

5.9 Homepage

To avoid or interrupt a negative learning process that may carry over after discharge (**Paper 6**), we informed patients about hospital-associated sleeping problems with a project homepage. The website (www.schlaffreundliches-krankenhaus.de) provides information about hospital-associated sleeping problems, practical tips for sleeping better (Fig. 5) in the hospital environment and basic information about the project.

The screenshot shows the homepage of the Sleep-friendly Hospital Initiative. At the top, there is a banner image of daisies. To the right of the banner, the logos for 'UNIVERSITÄTSMEDIZIN GÖTTINGEN UMG' and 'EVANGELISCHES KRANKENHAUS GÖTTINGEN' are displayed. Below the banner is a navigation menu with the following items: 'Gesund schlafen', 'Initiative', 'Maßnahmen', and 'Ansprechpartner'. The main content area is titled 'Schlaffreundliches Krankenhaus' and includes a 'Zurück | Home' link. The text is organized into several sections:

- Was können wir tun, was können Sie tun – Welche Alternativen gibt es?**
 - Schlafprobleme in der ersten Nacht: Kein Grund zur Beunruhigung!**

Es ist ganz normal, in einer fremden Umgebung nicht gut schlafen zu können. Diese „evolutionsbedingte Hab-Acht-Stellung“ hat die Natur eingerichtet. Deswegen sollen Sie nicht beunruhigt sein, wenn Sie im Krankenhaus nicht sofort gut schlafen.
 - Langes Schlafen am Tag möglichst vermeiden**

Sie sollten am Tag möglichst wach bleiben und keine langen Ruhezeiten im Bett (z. B. aus Langeweile) verbringen. Wenn es Ihnen möglich ist, bewegen Sie sich tagsüber und nehmen Sie die Mahlzeiten am Tisch, nicht im Bett ein.
 - Liebgewordene Gewohnheiten können helfen**

Viele Menschen haben bestimmte Gewohnheiten, bevor sie zuhause ins Bett gehen: z. B. einen Tee trinken, ein Hörbuch hören oder ähnliches. Versuchen Sie, wenn möglich, solche Rituale auch im Krankenhaus beizubehalten.
 - Ohrenstöpsel und Schlafbrille**

Viele Patienten tun sich mit den ungewohnten Geräuschen im Krankenhaus schwer. Ohrenstöpsel sind eine gut bewährte Lösung – ohne Risiken und Nebenwirkung. Wenn Sie sich durch veränderte Lichtverhältnisse im Zimmer gestört fühlen, könnten Sie auch eine Schlafbrille aufsetzen. Fragen Sie auf Ihrer Station nach diesen Hilfsmitteln.
 - Medikamente nur in letzter Instanz**

Bei schwerwiegenden Schlafstörungen werden sogenannte „Schlaf- und Beruhigungsmittel“ verordnet. Das sind stark wirksame Medikamente. Das Risiko unerwünschter Wirkungen ist nicht zu unterschätzen. Deswegen soll ein solches Medikament – unter Abwägung von Nutzen und Risiken – erst in letzter Instanz vom Arzt verordnet werden!

At the bottom of the main content area, there are links for 'Druckversion', 'Zurück', and 'Seitenanfang'. On the right side of the page, there are two posters titled 'Schlafprobleme? statt einnehmen aufsetzen.' and 'Schlafprobleme? statt einnehmen einsetzen.'

Figure 5. Screen shot of the Sleep-friendly Hospital Initiative homepage (English version available in the Appendix).

5.10 Poster campaign

We developed two posters (Figure 6) together with a marketing company, with the aim of increasing awareness about the non-drug treatment of sleeping problems during hospitalization. The results from **Paper 5**, **Paper 6**, Weiß et al. [17] and the participatory group discussions were decisive for the development process and the ‘message’ of the posters. The research staff ordered the posters and delivered them to the hospital technical crew. The hospital’s own carpen-

ter installed the posters on each ward (26 posters in total) in close consultation with the respective staff nurse, at places where the target groups, i.e. nurses, patients and doctors spend extended amounts of time, e.g. next to the nurse station.



Figure 6. Posters, highlighting alternatives to sleep-inducing drugs, which were hung on every hospital ward (translation SH).

5.11 Other measures

In addition to the above-mentioned intervention activities, we also reported our results at multi-professional hospital gatherings and through the employee magazine and the regional newspaper. The purpose of these activities was to keep the project visible and keep lines of communication open between the research team and the hospital stakeholders.

6 Discussion

In this final chapter, I will discuss our intervention strategy in comparison to other such interventions (6.1), the transferability of the Sleep-friendly Hospital Initiative to other settings (6.2) and the strengths and limitations of my (our) work (6.3). I will follow this discussion with a personal reflection about my thesis project (6.4) and conclude by explaining the next steps of our research project (6.5).

6.1 Sleep-friendly Hospital Initiative compared to similar programs

It is necessary to emphasize that we were not the first who started an intervention with the aim to reduce the inappropriate use of sleep-inducing drugs in hospitals. In a recently-published review, Soong et al. give an overview of thirteen intervention projects for inpatients with the goal of promoting sleep while reducing the amount of inpatients who receive a sedative-hypnotic drug for the first time [33]. Therefore, I will present some lessons learned from other projects and thereby put our results and the developed components of the Sleep-friendly Hospital Initiative into perspective.

Creating a positive sleep environment for inpatients has been the focus of several interventions in hospitals. For example, Bartick et al. describe a program in the UK to decrease noise and nursing care interruptions for a period of 8 hours, called the “Somerville Protocol” [34]. Chung et al. developed a program of sleep-hygiene education for professionals and patients in South Korea with the goal of sleeping-pill reduction for hospitalized patients (the i-sleep program) [35]. In both of these examples, the focus on sleep hygiene was implemented through interventions that targeted (mainly) professionals.

Many projects trust in the effect of interventions that educate the prescribers [33]. Education, especially verbal information, is a common component of intervention strategies to reduce sleep-inducing drug prescriptions. For example, Del Giorno et al. [36] provided, besides other, educational sessions among medical and nursing staff in several Swiss hospitals and promoted some key messages on sleep hygiene or alternatives to sleeping pills. They also distributed printed pocket-forms and electronic versions of internal guidelines on benzodiazepine prescriptions. Two interventions in Australian and Swedish nursing homes also comprised educational strategies, implemented especially by pharmacists with information on drug use, management of challenging behavior in sleep disturbance and communication skills [37, 38].

In addition to education, a further clinician-based strategy is the review and evaluation of prescriptions by pharmacists in order to optimize the use of sedative/hypnotic drugs. Badr et al. [39] report an intervention whereby pharmacy residents evaluated newly prescribed drugs and recommended that certain drugs could be discontinued. Another intervention strategy is to use

prescribing data of the own hospital(s) to produce audits of prescribed medicines, benchmarked against other hospitals or own targets [36, 37]. The presentation of such data by persons outside the hospital to inform doctors and nurses of inappropriate prescribing in their hospital, may cause participants to feel uncomfortable, as Batty et al. observed in their intervention in England and Wales [40]. Soong et al. come to the conclusion that education alone is unlikely to produce behavior change but that interventions should combine education with other components to create an effective multifaceted intervention [33].

We incorporated many of these strategies into the Sleep-friendly Hospital Initiative. For example, we gave feedback in the form of prescription benchmarking (data collected in **Paper 2**) to key opinion leaders. We organized changes such as a hospital-wide policy of conservative treatment of sleeping problems paired with the availability of eye masks, ear plugs and herbal tea on every ward. This strategy was visualized in the hospital-wide poster campaign. We trained doctors, nurses and nursing students to use the decision aids in pocket format. We created a project homepage with additional sleep hygiene information for patients.

6.2 The transferability of the Sleep-friendly Hospital Initiative

The Sleep-friendly Hospital Initiative met great approval among the hospital employees and we expect positive outcomes in our final evaluation of the project in 2020. Therefore, I would like to discuss the idea of transferring this project to other settings. It may seem like we could take the components introduced in Chapter 5 and easily transfer them to other hospital settings. However, our experience showed that the combination of primary data collection and participatory intervention development brought the topic of unnecessary usage of sleep-inducing drugs onto the hospital agenda and was one of the most important components that made this project possible and the intervention successful. Not only did these steps require several years, it is open to discussion whether this preliminary data collection and interpretation phase of the project is indeed part of the intervention itself. If so, the export of the Sleep-friendly Hospital Initiative instruments into similar hospital settings would not be effective in reducing the prescription of sleep-inducing drugs and increasing non-drug treatment of sleeping problems without prior data collection in each new hospital.

It may be possible, however, to shorten this phase and ‘simulate’ the stage of data collection by presenting data from our project. However, the participatory development of an intervention and the regular involvement of opinion leaders seems to be vital for the success of the intervention—especially since it addresses a problem that does not stand at the top of most hospitals’ agendas. Regarding data collection, I believe that it is necessary to measure relevant endpoints before and after the intervention. First, knowing the amount of sleep-inducing drugs being prescribed/dispensed in the hospital is the first step to realizing that there is a problem. Especially

the measurement and communication of potentially inadequate medications for elderly in the form of benchmarking across departments was a large motivator for change among the stakeholders in the hospital under study. Due to the experiences gained over the course of this project, we have been able to develop a methodology for efficiently measuring sleep-inducing prescriptions and relevant co-morbidities. Second, short surveys of the hospital staff are, in my opinion, also necessary both as a relatively cost-effective way to attract attention to the problem before the intervention starts as well as to measure any changes in the attitudes and perceptions of hospital personnel over time.

In short, a hospital must not completely re-do the entire Sleeping Pills Project in order to implement the Sleep-friendly Hospital Initiative, but it should be willing to fund this kind of basic data collection in order to track both the problem and the results. Any intervention to improve the quality of care in a hospital requires an investment. In this case, the data collection and analysis itself is time and resource-consuming, however the intervention components and materials (posters, pocket cards, homepage, training sessions) are not.

6.3 Strengths and limitations

The project, which started with an investigation of “hypnotics and sedatives at the interface between primary and hospital care” (**Paper 1**) has grown and developed into a large, interdisciplinary, multi-professional research endeavor. Mixed-method research was necessary to better understand the reasons for the inappropriately high usage of sleep-inducing drugs, both in the hospital as well as in general practice. During the course of the project, previous ideas were discarded and new research questions were formulated. For example, we realized that the interface between these levels of care is unproblematic from a professional point of view. There is little to no communication about sleep-inducing drugs either personally (on the telephone) or via discharge letter between these levels of care. Any efforts to get hospital doctors and general practitioners to meet and talk about sleep-inducing drugs (as originally described in the grant proposal; **Paper 1**) would have been an inefficient usage of time and resources. Rather, the context and problems with these drugs in the hospital proved to be much different than in general practices, as explained in the work of Weiß et al. [17].

Subsequently, the project was split up into two separate areas: primary care and hospital care. Some colleagues studied the problematic usage of out-of-pocket prescriptions for benzodiazepines and Z-drugs for publically-insured patients [41, 42]. The lessons learned from interviews with general practitioners about the prescription of sleep-inducing drugs was used to create and implement a multi-professional workshop during the annual continuing education event of the Göttingen Department of General Practice as well as a community outreach event during the bi-annual Göttingen “Night of Knowledge” (in German: “Nacht des Wissens”).

A striking feature of our project is the close co-operation between health services researchers of our team and the regional general hospital where the project took place. We had nearly unlimited access to investigate hospital prescription data (“chart reviews”, see **Paper 2**) as well as the attitudes and experiences of doctors, nurses and patients concerning sleep-inducing drugs in the hospital setting (**Papers 3 – 6**). Consequently, we based the components of Sleep-friendly Hospital Initiative upon intimate knowledge of the handling of sleep-inducing drugs in the hospital under study and the attitudes of the actors involved. Thus, we were able to explain current professional practice, define reasons for resisting new practices and then to offer a multi-faceted, tailored intervention (23) to reduce inappropriate usage of sleep-inducing drugs. This intimate knowledge gave us credibility and acceptance among the staff and hospital management so that we could frankly discuss needed changes within the organizational framework of a hospital where sleep problems were not especially high on the agenda until we introduced the Sleep-friendly Hospital Initiative.

Vice versa, we became aware that the main barrier to the project in all of its facets (development, implementation and evaluation) was the attitude of many hospital doctors and nurses. Hospital-associated sleeping problems did not have a high priority for most of them and did not rank high on the hospital agenda. As a result, the recruitment of participants for surveys, interviews, discussion groups and staff training measures was challenging. Personal relationships between three members of the research team and the doctors and nurses on staff were instrumental for us to gain knowledge about the reasons for and solutions to the over-use of sleep-inducing drugs.

6.4 Personal reflection

The field work portion of the project was very extensive (**Papers 2-6**), including multiple phases of data collection and analysis over a period of more than three years, conducted by multiple researchers under the supervision of Prof. Wolfgang Himmel, Prof. Eva Hummers and Prof. Roland Nau. I did not do it alone and it would be grossly unfair to the team of hard-working individuals involved to pretend that I did. Each person’s work contributed to understanding one more piece of the puzzle. This thesis synthesizes this large base of empirical work to understand the problem and create an intervention, which is the first step of the MRC framework [21, 22].

One particular challenge for me lay in the analysis of data about Z-drugs from the professional perspective (**Paper 4**). Due to the large number of “unable to judge” answers, it was impossible to perform the same kind of analyses with the Z-drugs data as with the data about benzodiazepines (**Paper 3**). It soon became clear that “unable to judge” is not the same as “missing” and that this data is an important piece for understanding the overall puzzle of professional behavior. However, it took quite some time, multiple impulses from congresses and continuing education,

reading in the literature about clinical decision-making as well as discussions with my advisor and other colleagues to finally come up with and execute the idea for **Paper 4**.

The intervention activities of the project were concentrated solely in the hospital setting, which have been presented in the previous chapters of this thesis. The challenge of my work was to seek a well-rounded understanding of a complex problem, keep lines of communication open between research and practice, identify the keys to changing unwanted behaviors, take context and motivation of all actors into account, synthesize all of this information into a manageable, practical, cost-effective intervention strategy and work together with all partners to put this strategy into practice. This has been quite a challenge for me personally and a chance to grow and expand upon both my research and interpersonal skills which are required for a career in health services research.

Looking back upon the entire project, one of the largest limitations of our research is the fact that we collected data solely in one hospital. Concentrating the data collection on a single hospital made it possible to tailor the intervention precisely to context of this hospital, but – at the same time – minimizes the transferability of the research results and the intervention to other locations. Following the evaluation of the Sleep-friendly Hospital Initiative, the next step (as mentioned above) is to test this intervention strategy in other hospitals, refine the intervention strategy and ultimately formulate recommendations and materials for reducing the prescription of sleep-inducing drugs in hospitals across Germany and beyond.

6.5 Further research

In summary, this thesis looked at a common clinical practice—prescribing/dispensing sleep-inducing drugs for hospital-associated sleeping problems—from multiple perspectives and through the eyes of several different disciplines. The focus of this “health services drug research” is on collecting real world data to understand a real world practice and using this understanding to develop an effective strategy to positively change a real world problem. Health services drug research combines multiple perspectives (doctors, nurses, patients and hospital administrators), multiple data sources (prescription data, surveys, interviews, discussion groups) and multiple medical and health science disciplines (sleep medicine, geriatrics, internal medicine, surgical specialties, nursing, sociology, public health) at multiple levels (patient, professional, organizational) to understand how drugs are used in everyday practice and to make recommendations for improvements.

Where do we go from here? The next step in the MRC framework [21, 22] is to evaluate the project by measuring the success of the intervention. This evaluation will include a professional survey before and after the intervention about self-reported drug knowledge, patient demand for

sleep-inducing drugs and treatment of sleep problems. In addition, patient charts will be evaluated to capture any changes in prescription frequency and/or drug appropriateness. Following this evaluation phase, the last step in the MRC framework is to create a randomized controlled trial to test the effectiveness of the intervention across multiple organizations.

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8 Abstract in German

Hintergrund. Viele ältere Patienten können in der ungewohnten Krankenhausumgebung schlecht ein- oder durchschlafen. Trotz bekannter Nebenwirkungen erhalten sie häufig schlaffördernde Medikamente, z.B. Benzodiazepine oder sog. Z-Substanzen.

Ziele. Eine passgenaue Intervention sollte zu einem geringeren, vor allem rationaleren Einsatz schlaffördernder Medikamente führen. Als Vorbereitung und ersten Schritt einer solchen Intervention empfiehlt das Medical Research Council (MRC) in seinem Aktionsplan zur Entwicklung und Evaluation komplexer Interventionen im Gesundheitsbereich eine gründliche Exploration des Problems aus verschiedenen Perspektiven. Ziel dieser Arbeit war es daher, das Ausmaß schlaffördernder Medikamente im Krankenhaus, den Bedarf von Patienten und die Erfahrungen des ärztlichen und pflegerischen Personals zu erheben.

Methode. In einem Mixed-Methods-Ansatz wurden Daten zur Verordnung von schlaffördernden Medikamenten in einem Krankenhaus der Regelversorgung sowie die Sichtweise und Erfahrungen der Ärzte, Pflegenden und Patienten erhoben und verglichen. Zum Einsatz kamen quantitative Verfahren (z. B. Analyse von Verordnungsdaten, standardisierte Befragungen) und qualitative Methoden (z. B. Interviews).

Ergebnisse. Die in dieser kumulativen Doktorarbeit eingebundenen sechs Publikationen kommen zu folgenden Ergebnissen: die Gabe potential inadäquater Medikamente (PIM) zur Schlafförderung im Krankenhaus ist häufig; ca. 30% der älteren Patienten haben mindestens einmal ein PIM erhalten. Ärzte und Pflegende schätzten die Wirkung und Nebenwirkungen von schlaffördernden Medikamenten unterschiedlich ein und haben insbesondere bei Z-Substanzen erhebliche Wissenslücken. Pflegende berichteten über fordernde Patienten, Stress in der Nachtschicht und Barrieren zur Anwendung von nicht-medikamentöse Maßnahmen bei Schlafproblemen. Fast jeder zweite ältere Patient erinnerte sich daran, zumindest einmal während des Krankenhausaufenthaltes ein schlafförderndes Medikament erhalten zu haben. Etwa ein Drittel dieser Patienten könnte sich eine Weitereinnahme dieser Medikamente bei ähnlichen Problemen zu Hause gut vorstellen.

Diskussion. Die Ergebnisse belegen das Ausmaß des Problems und Gründe hierfür, wie z. B. Patientenerwartungen, beruflicher Stress während der Nachtschichten, Mangel an Alternativen und mangelndes pharmakologisches Wissen. Die Erörterung dieser Ergebnisse z.B. in Diskussionsgruppen legten u. a. folgende Maßnahmen für eine Initiative „Schlaffreundliches Krankenhaus“ nahe: eine standardisierte, interdisziplinäre Schlafanamnese bei Krankenhausaufnahme, Vorhalten von Ohrenstöpseln, Schlafmasken, Kräutertees etc. auf Station, eine Posterkampagne für Patienten und gezielte Fortbildungen für Mitarbeiter. Der nächste Schritt im MRC-Aktionsplan ist die Evaluation der Interventionsmaßnahmen sowie die Erprobung der Intervention in einem kontrollierten Studiendesign.

9 Abstract in English

Background. In spite of well-known adverse effects, sleep-inducing drugs, such as benzodiazepines and Z-drugs, are frequently prescribed for patients who have trouble sleeping in the unfamiliar environment of a hospital.

Aims. A tailored intervention should lead to a reduced and more appropriate use of sleep-inducing drugs. To prepare such an intervention, the Medical Research Council (MRC) recommends gathering the best available evidence as the first step of its framework for designing and evaluating complex interventions. The goal of this thesis is to collect data from multiple perspectives to better understand the extent of sleep-inducing drug use in the hospital, the needs and experiences of patients and the perceptions and experiences of doctors and nurses.

Methods. In a mixed-methods approach, data was collected about the prescription of sleep-inducing drugs in a regional general hospital as well as about the perceptions and experiences of doctors, nurses and patients. We used quantitative methods (e.g. chart reviews, standardized surveys) and qualitative methods (e.g. interviews) to gather a wide base of evidence about the use of sleep-inducing drugs in the hospital setting.

Results. The results of six published articles as basis for this cumulative PhD thesis are as follows: the prescription of potentially inappropriate medications (PIM) to induce sleep in hospital patients is a common practice; nearly 30% of older patients received at least one PIM during their hospital stay. Doctors and nurses have differing perceptions of the effects and side effects of sleep-inducing drugs and lack – especially with regards to Z-drugs – basic pharmacological knowledge about these drugs. Nurses report several factors that increase the inappropriate use of sleep-inducing drugs: patient demand, professional stress and uncertainty in the night, and barriers to the use of non-drug alternatives. Nearly 50% of all older hospital patients could remember receiving a sleep-inducing drug at least once during their hospital stay and one-third of these patients wished to continue taking these drugs to induce sleep after discharge.

Discussion. These articles of the cumulative thesis document the extent of – and the reasons for – the problems with sleep-inducing drug use in the hospital setting. The discussion of these results with representatives from all hospital departments and professions stimulated several measures for a Sleep-friendly Hospital Initiative: this complex intervention included a standardized, interprofessional short sleep history at hospital admission, the provision of non-drug alternatives such as sleeping masks, herbal tea and ear plugs, a poster campaign for patients and continuing education courses for hospital employees. The next steps, according to the MRC framework, should be a thorough evaluation of the intervention and to test the effectiveness of the intervention in other settings with a controlled study design.

10 Acknowledgement

As readers of this document will have realized, this thesis is not the work of one individual. Rather, I was fortunate to have the support of and scientific contributions from several people throughout the course of this project including co-authors and other colleagues who helped to make this project a success.

I would like to mention two such persons by name, Vivien Weiß and Matthias von Müller. Vivien and Matthias were important members of the Sleeping Pills Project team. Together, we gathered and analyzed data and reflected on these results in order to develop the components of the Sleep-friendly Hospital Initiative. Their positive attitude, boundless energy and creativity made working on this project a real joy for me.

The Sleep-friendly Hospital Initiative was only possible because the administration, staff and patients of the Evangelisches Krankenhaus Göttingen-Weende opened their doors to our research team. We were always treated kindly and received the upmost cooperation throughout the entire project. I especially want to thank the doctors, nurses and patients who took the time to participate in the study by answering questionnaires, giving interviews and/or participating in discussion groups.

I sincerely thank my family, especially my husband Jens and children Larissa, Tobias and Rebecca. Their love and support has both rooted and uplifted me when my professional path took twists and turns.

I would like to thank the two members of my Thesis Committee who joined me from outside the Department of General Practice. Wolfgang Körber brought the clinical perspective into our discussions about daily practice and clinical decision-making in the case of sleep problems. Friedemann Nauck provided invaluable advice about the project design and scientific rigor of my thesis and the related single studies. My work especially benefitted from his comments on the pharmacological and non-pharmacological management of sleep problems, seen from both the perspective of general hospital care and specialized palliative care.

Finally, I would like to thank my advisor, Wolfgang Himmel, for his good advice and his scientific contributions to this thesis project. Even more so, however, I thank him for his steady encouragement and habitual good humor throughout the past 15 years. It has been a pleasure and a privilege to work with him.

11 Declaration of Authorship

I, Stephanie Heinemann, declare that this dissertation titled, “Why are sleep-inducing drugs frequently used in hospitals? Applying mixed-methods to understand a common practice and develop a complex intervention to change it” and the work presented in it are my own. It was written independently with no other sources and aids than quoted.

Stephanie Heinemann

12 Appendix

Translation of the project homepage “Gesund schlafen” (“Healthy sleep”), Figure 5.

Healthy Sleep

What can we do, what can you do – what alternatives are there?

Sleeping problems in the first night: No cause for worry!

It is absolutely normal to have trouble sleeping in a strange environment. This natural 'standby mode' prepares us to flee if necessary when sleeping in an uncommon place. Therefore, you shouldn't worry if you can't immediately sleep well in the hospital.

Avoid long sleeping periods during the day

Try to stay awake as much as possible and avoid long periods of resting in bed (e.g. due to boredom). If possible, move around as much as you can during the day and eat your meals sitting at a table, not in bed.

Familiar routines can help

Many people routinely do certain things before going to bed at home: e.g. drinking a cup of tea, listening to a book on tape, etc. Try – as much as possible – to keep up your bedtime routine in the hospital.

Ear plugs and sleeping masks

Many patients feel disturbed by the unfamiliar sounds in the hospital when trying to sleep. Ear plugs are a tested and proven solution – without any unwanted side effects. If you feel disturbed by the lighting in your hospital room, a sleeping mask may help. Ask at the nurses' station for these articles.

Hypnotic drugs only as a last resort

By severe sleeping problems, sleep-inducing hypnotic drugs are prescribed for a short period of time. These drugs are very powerful. The risk of unwanted side effects should not be underestimated. That is why such drugs are only prescribed – after carefully weighing the risks and benefits – as a last resort.