Aims, design and methods of the Smoking and Nicotine Dependence Awareness and Screening (SNICAS) study

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ABSTRACT *The objectives of the Smoking and Nicotine Dependence Awareness (SNICAS) study are to provide nationally representative data on the prevalence of smoking and smoking dependence of primary care patients and the frequency in which smoking cessation interventions are offered and provided in primary care. With the inclusion of both providers' (doctor) and patients' perspectives, the study also attempts to identify the needs and motivational status for smoking cessation as reported by the patients and as perceived by the doctor.*

The Smoking and Nicotine Dependence Awareness study uses a two-stage epidemiological design. Stage 1 consists of a pre-study characterization of a nationwide sample of 889 primary care doctors (conservative response rate: 50%). Stage 2 consists of a cross-sectional assessment of unselected consecutive patients (n = 28,707, conservative response rate: 52.8%) on the study's target day, by means of patient questionnaire and a structured clinical appraisal of each patient by the doctor.

This paper provides an overview of the design and methods of the study, informs about sampling and response rates, and examines whether the study sample could be considered representative of German primary care doctors.

Key words: epidemiology, smoking, nicotine dependence, smoking cessation, primary care

Introduction

Numerous studies have documented the persistently high prevalence of cigarette smoking worldwide, and have provided an increasingly broad characterization of core risk factors and correlates, as well as public health implications and the associated economic burden (Cohen et al., 1998; de Wit et al., in press; Fiore et al., 2000; Haustein, 2001; John, 2001; Loddenkemper et al., 2000; Murray et al., 1997; Ruff et al., 2000; World Health Organization, 1997; Nelson et al., 1998a; Schön et al., 2002; Sonntag, 2001; Welte et al., 2000; Wittchen et al., 2003).

Although reducing smoking rates is a top public health priority in most countries, international and national campaigns have enjoyed quite modest success to date (Junge et al., 2003; Pierce et al., 1989; World Health Organization, 2002). Despite the more recent availability of a number of effective drug and non-drug treatments (Fiore et al., 2000; American Psychiatric Association, 1996), considerable prevention efforts, awareness campaigns, and stricter anti-smoking policies, prevalence rates of smoking have not shown a corresponding significant decline (World Health Organization, 2002). For instance, recent regional and nationwide community surveys in Germany have shown that 37% of the male and 28% of the female population aged 18 to 79 years are smokers (Bellach et al., 1998; Junge et al., 2003; Perkonigg et al., 1998; Sonntag et al., 1998; Wittchen et al., 1998). Furthermore, considerably higher prevalence among adolescents and young adults has been observed, together with increasing rates for females (14–24 years old: 47%; Nelson et al., 1999; Nelson and Wittchen, 1998; Wittchen and Nelson, 1998).

Given the extensive literature on the topic and the size, breadth and scope of smoking in the community, it is important to highlight two particular deficits:

- the lack of epidemiological data on nicotine dependence according to DSM-IV or ICD-10 criteria (APA, 1994; Colby et al., 2000), and
- the lack of epidemiological data on smoking and nicotine dependence in primary care (Dennis, 1998; US-DHHS, 1990; WHO, 2002).

Specifically, in sharp contrast to the wide range of prevalence studies on smoking, up to now relatively few studies have addressed the epidemiology of nicotine dependence as the presumably more severe and chronic, clinically relevant manifestation of regular smoking (Samet et al., 2003). Such data on dependent smokers could be regarded as essential for better planning of clinical services because they allow a more precise assessment of the needs for intervention in the most problematic group and the subsequent allocation of resources. The few available community studies for nicotine dependence have estimated rates of 24% (life time prevalence) for the US (Breslau et al., 2001), and of 14% to 17% (point prevalence) for Germany (Bundesgesundheitssurvey 1997/1998). This suggests that nicotine is a drug with considerable dependence risk; at least one out of two smokers can be regarded as dependent smokers according to modern diagnostic classification systems such as the ICD-10 (1992) or DSM-IV (1994).

Given the high prevalence of smoking and nicotine dependence and the tremendous public health implications, the significant lack of epidemiological studies about smoking and nicotine dependence in primary care is remarkable. In fact, a systematic literature search revealed no primary care study that has addressed the question of frequency of smoking and nicotine dependence in primary care with a rigorous epidemiological strategy. Data from such a study may be of critical importance for the following reasons:

- Generally, epidemiological data from primary care settings can be regarded as a prerequisite for designing and implementing improved smoking cessation interventions in primary care and for the allocation of appropriate resources.
- Primary care doctors are of core importance as 'gatekeepers' for recognition, referral and intervention in this respect. In most Western healthcare systems more than two-thirds of the entire population see their primary care doctor at least once in any given year. Further, patients see their primary care doctors over long periods of time in most cases. Thus they can be expected to know their patients' individual short- and long-term risks, as well as their motivational stage, better than specialists. Consequently, most healthcare systems in developed countries regard smoking cessation interventions as a primary task of primary care physicians.
- Visits to primary care doctors usually do not carry the same stigma as visits to mental health specialists.
- Numerous clinical studies have suggested that primary doctors are able to implement a range of established smoking-cessation strategies in their offices. Thus, few data are available as to what degree suggested first-line smoking cessation treatments, established in controlled studies, can be applied with sufficient integrity, feasibility, and success to routine conditions in primary care.

Despite the existence and availability of promising interventions for smoking cessation (American Psychiatric Association, 1996; Batra et al.1995; Buchkremer et al., 1989; 1991; Fagerström 1994; Fagerström et al., 1993; Fiore et al., 2000; Jorenby et al., 1999; Hurt et al., 1997; Prochaska et al., 1993; Silagy et al., 1994; Sonntag et al., 1998; Zimmer et al., 1993), it has been estimated that only a minority of people in Germany, and worldwide, receive any form of smoking cessation treatment in primary care (Fowler, 1997; Jarvis, 1997; Sonntag et al., 2003; Wittchen et al., 2002). Due to the lack of systematic research on this issue, the reasons for this unfortunate situation remain unclear (Sonntag et al., 1998). Possible reasons include: doctors' lack of awareness of the size and range of the smoking problem, time constraints, inaccurate knowledge about the treatment options, inadequate skills to manage smoking cessation, unwillingness on the part of doctors to offer such treatments, and patients' inability or unwillingness to accept smoking cessation treatment offers.

Furthermore, it remains unclear whether and to what degree the results of randomized controlled

trials (RCT) on the first-line treatments – even those conducted in primary care – can be generalized to routine care in primary care settings. Randomized controlled trials need to be performed under standardized and 'artificial' conditions. Consequently, most of them have been conducted in highly selected settings and with possibly highly compliant subjects. Moreover, controlled clinical studies – even in primary care – usually imply a considerable degree of training for the doctor that is atypical of routine care. Training implies knowledge and skills with regard to recruiting patients, motivation enhancement procedures, structured patient counselling skills, and performing complex smoking cessation interventions.

Due to the lack of epidemiology-based evaluation research in this field, there is also a lack of data with regard to effective procedures to transfer the results of clinical trials into health care routines. No findings are available about the core doctors' predictions for successful implementation of established smoking cessation interventions (for example, in terms of office setting, doctor's specialization, attitudes and motivation, experience, knowledge and skills). Similarly, we also lack data from the patient's perspective about predictors for good response to smoking cessation interventions offered by primary care doctors (for example, age, severity, extent and type of smoking-related somatic problems, comorbidity, initial motivation, what type of primary care patients might profit the most from treatment).

Objectives and aims

In an effort to address these research deficits, we developed an epidemiological research programme in primary care. Within the framework of the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung) research initiative 'Allocating substance abuse treatments to patient heterogenity (ASAT)' (www.asat-verbund.de), we designed a complex study, labelled the Smoking and Nicotine Dependence Awareness and Screening' study (SNICAS). The general aim of the SNICAS study was to obtain information about the current smoking cessation interventions in primary care, from both the doctors' and patients' perspectives. This paper describes the design, including the assessment strategies and instruments as well as the field work procedures and completion rates, the objectives, and the specific aims of SNICAS. The embedded intervention component of SNICAS conducted subsequently as an extension to this epidemiological study will not be presented in detail in this paper.

Based on an epidemiological design (nationwide random primary care sample) with a target day assessment of unselected primary care attendees and a subsequent embedded intervention study component in primary care, the aims of SNICAS are as follows.

Stage I: prestudy – provider characteristics

1. To assess doctors' attitudes towards smoking and smoking cessation treatments, and their knowledge and skills in recognizing, diagnosing and treating such patients in a large random sample of primary care doctors.
2. To describe patients' past and current experiences with a wide range of smoking cessation interventions as well as their perceived barriers to using smoking-cessation treatments.

Based on this initial characterization of primary care physicians, stage II of the SNICAS study consists of a cross-sectional assessment of all patients attending their doctor's office on the study target day using a patient questionnaire, and a standardized doctor appraisal of each patient by the doctor.

Stage II: target day assessment of all patients by patient questionnaire and doctor clinical appraisal aims

3. To provide point and lifetime prevalence estimates of occasional, regular and dependent (patients meeting criteria for DSM-IV nicotine dependence) use of nicotine in primary care patients.
4. To characterize the bio-social and clinical characteristics, impairment and disabilities, smoking behaviour, diagnostic features (dependence syndrome, Fagerström), severity and associated health-related problems among primary-care patients who smoke.
5. To describe attempts to quit, smoking cessation treatment history and treatment problems among primary care patients.
6. To assess patients' awareness of smoking as problematic, willingness to quit (stages of motivation), and willingness to become involved immediately in a structured smoking cessation programme offered by their treating primary care doctor.

Embedded intervention component

7. The final stage of SNICAS consists of a randomized assignment of patients willing to quit smoking to one of four smoking cessation options offered by their doctor. This component of SNICAS is only carried out in a smaller subsample of patients in two catchment areas (site 1: Dresden; site 2: Munich). This additional component will not be dealt with in greater detail in this paper, except for a description of the two intervention sites.

Design and methods

The SNICAS study is based on a two-stage epidemiological design of unselected, consecutive patients attending primary care settings, recruited from a nationwide sample of primary care physicians. Figure 1 provides an overview of the design and core components of the study. The core design elements, described in greater detail below, are:

- Defining and recruiting a sample of primary care doctors that could be regarded as representative of Germany.
- The assessment of primary care doctor characteristics with a focus on smoking cessation practices (SNICAS prestudy: Stage I).
- Screening and assessing on one single day (target day) all patients (unselected, consecutive) attending these primary care settings using a patient questionnaire with subsequent clinical appraisal by the doctor (SNICAS target day: Stage II).
- Embedded intervention component. In two regional sites, immediately after the target day assessment, all patients with nicotine use were invited to participate in a randomized smoking cessation trial, offered and conducted by the primary care doctor (not described in detail in this paper).

Figure 1 reveals that SNICAS attempted to base the entire project on a representative sample of primary care physician practices and subsequently on a sample of unselected consecutive patients in these settings. Subsequent to the recruitment of a nationwide sample of primary care physicians and an enrichment in two intervention sites, this design allows the prestudy to characterize the participating doctors fairly comprehensively with regard to their background (experiences and training), number of

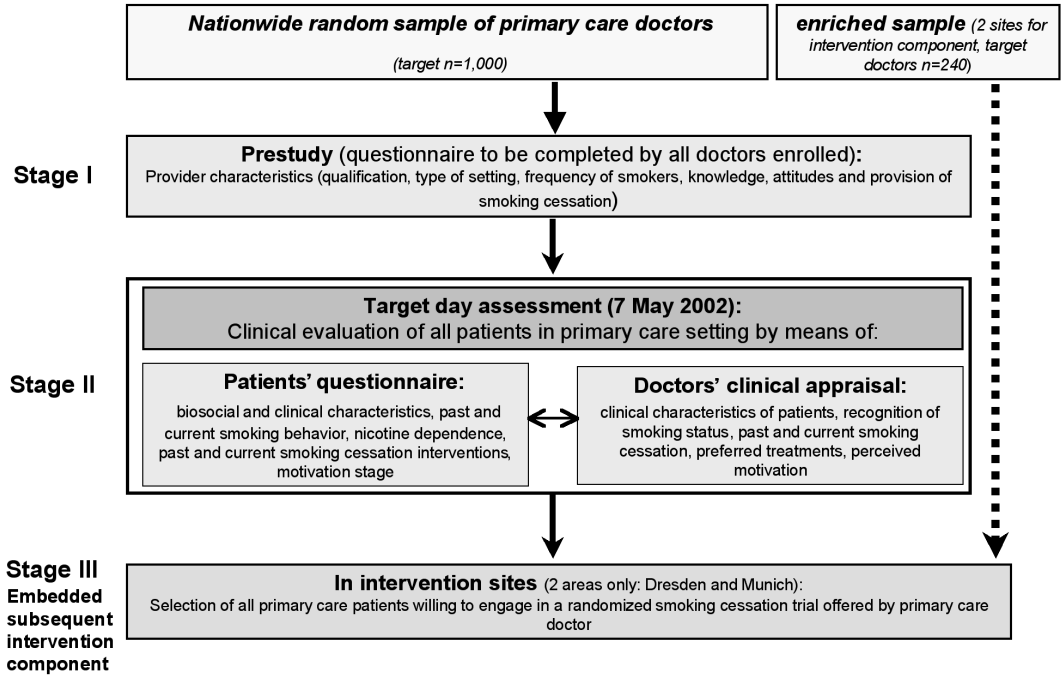

Figure 1: SNICAS study design.

patients seen per day, past and current involvement in smoking cessation intervention and attitudes.

The *target day assessment* was scheduled to take place on 7 May 2002. The choice of this day was critical, due to holiday schedules in the various regions, and established practice patterns of doctors. Other days of the week are either characterized by a high proportion of emergencies (Mondays), administrative and postgraduate courses (Wednesdays) or special services or early weekend arrangements. The special feature and challenge for the doctors is that, on one single day, ideally all patients meeting the inclusion criteria should be approached and invited to participate in the study. Patients were asked to fill out a questionnaire (*patient* questionnaire) and doctors subsequently evaluated each patient with a standardized doctors' *clinical appraisal form*. Study participation constituted a considerable extra burden for participating doctors, given their high workload of approximately 60 or more patients a day in routine care.

In addition, in two intervention sites, participating doctors were required to directly approach their smoking patients to enrol in a smoking cessation treatment offered at this point to the patient, by the treating physician.

Defining and recruiting a sample of primary care doctors (stage 1 for the prestudy)

Heterogeneity of primary care doctors

In the year the study sampling took place (2001), in Germany over 68,000 doctors were registered as primary care doctors (including interns). Unlike other countries, primary care doctors constitute a relatively heterogeneous group and include general practitioners ('Allgemeinarzt'), family doctors ('Praktischer Arzt') and interns with primary care functions (also labelled with the acronym 'API'). Each of these types of doctor might differ in several respects, so the sample should be sufficiently large to allow for subgroup analyses of each of these groups, while retaining the representatives of the overall sample

The need for study monitors

Due to the level of clinical detail and the complexity of the assessment strategy, the study could not be conducted simply by phone or mailed questionnaires. The assessment procedures require the support of local monitors for most steps throughout the study to train, supervise, and assist the doctors as well as to distribute and collect the assessment forms and to supervise the data collection and adherence to the protocol. Because of the scope of work and, in particular, the assessment of patients on one single day (target day), the sampling strategy needed to take into account:

- the fact that each monitor could only manage a maximum of five doctors a day;
- the geographical distribution of both doctors and putative monitors; and
- the fact that due to financial restrictions only a limited number of monitors could be funded by the study.

Sampling strategy

Theoretically, it is possible to use the respective local/regional health authorities doctor registries to perform a series of simple random sampling steps to ultimately obtain a nationally representative study sample. In practice, however, this strategy is not feasible within the usual duration of a research project and, thus, has rarely been used for research purposes, except for smaller regional studies. On a national level, the reliance on existing health authorities has considerable restrictions:

- it is too time consuming, due to the number of registries and varying regional regulations and procedures; and
- it does not allow for adjustment of the sampling frames to the availability of monitors in particular regions.

The possible solution to invite the doctors selected initially by mail for study participation was discarded because mailed study invitations would have resulted in a considerably lower response rate compared to personal invitations.

Alternatively, we decided to base the sampling of doctors using the register segments of the Institute of Medical Statistics (IMS) and the designation of monitors to these respective segments. According to this register (2001) a total of 68,583 API doctors were listed in Germany, of which internists represent 19,583 doctors. This strategy has previously been used in various nationwide primary care studies previously (Krause et al., 2001; Winter et al., 2000;

Wittchen et al., 1999; Wittchen, Höfler, Meister, 2001; Wittchen et al., 2000, 2001, 2001a). The 'IMS' segmentation register clusters all German doctors' offices by type into 1,060 regional units (segments), each containing a number of doctors' practices in a certain geographical area, for which addresses were available. These segments are regularly updated with the health authorities' registries and thus perfectly represent the overall population of API doctors.

Since the operation areas of the field staff of pharmacological companies generally follow this IMS segmentation, for evaluative and logistical reasons we decided to recruit our monitors almost entirely from the respective sales representatives responsible for the API doctors in all of these segments. We approached GlaxoSmithKline (GSK), the cosponsor of parts of the SNICAS study, for cooperation, by asking them to assign their sales representatives to our field force in order to act temporarily as study monitors for SNICAS. GlaxoSmithKline is a suitable candidate because its API sales representatives field force is large enough to cover all segments (N > 200 potential monitors). This strategy has several advantages:

- monitors know the region they are responsible for well – in particular they know where most of the doctors' offices are;
- they even might know potential study doctors personally;
- travel costs associated with the field work could be optimized, and
- these monitors have considerable skills and knowledge concerning how to approach doctors and win their collaboration for a study.

A potentially critical disadvantage might be that GSK, being a core producer of smoking cessation therapies, might introduce some bias in the recruitment and monitoring process, by promoting their drugs. Therefore several quality assurance measures were implemented in both the sampling as well as the field process of the study (see below).

Based on these considerations, 194 field staff members of GlaxoSmithKline (GSK) were initially contracted to serve as monitors and to assist in the sampling process and recruitment. According to their operation profile, these field work monitors took responsibility for each of the 1,060 segment clusters; thus, each monitor took responsibility for three to seven segments depending on the size of the segment, and the number of doctors in each. Of these monitors, 16 were assigned for the two areas, in which the later randomized intervention study was planned. These sites were the greater Dresden area (eight monitors) and the greater Munich area (eight monitors). Eleven of the GSK monitors dropped out during the study because of vacation or illness, leaving a total of 183 monitors available for the fieldwork. In all but two cases of dropping out, the monitoring tasks of respective sampling segments were reassigned to other monitors from the neighbouring segments. In addition, seven study monitors from our research team, all of them clinical psychologists, served as supervisors and later on as field work coordinators with focus on the coordinating study centres in Dresden and Munich.

Sampling process (doctors' offices)

In order to prevent the use of monitors, who were at the same time sales representatives of GSK, from resulting in systematic biases, the sampling process was conducted stepwise. Such biases could be expected to be important; for example, one might assume, that doctors who were known or frequently visited by our monitors might be an atypical subgroup, for example, by being more interested in smoking cessation in general or having preferences for use of drug interventions.

Initial sampling

In preparing the actual recruitment process, the study centre randomly selected 20 doctors' addresses from the total of all doctors in the respective area for each of the participating 183 monitors. Although we ultimately expected the monitors to manage only up to five doctors, this higher number of 20 doctors was chosen in light of the expectation that only 50% to 60% of doctors would agree to participate, as well as to allow additional control of potential systematic biases (see above). Because of the embedded regional intervention component in the later stage of the project, the 16 monitors responsible for the greater Munich and Dresden areas (intervention studies 1 and 2) received 40 addresses instead of 20. This higher number in these two sites should ensure, that a sufficiently high number of doctors could be

recruited for the randomized intervention study, later on. Thus, this initial random nomination list contained a total of 3,980 (5.8% of all API doctors in Germany) doctor addresses (see Tables 1 and 4).

Stratification

In order to control for potential biases introduced by the monitors, all of them and the GSK field force coordinators were requested to indicate, for each doctor setting on this list, whether they knew this doctor personally and whether this doctor was visited by them frequently. This information allowed us to stratify the sample into two strata of

- doctors known or frequently visited by the sales force; and
- doctors not yet known by monitors.

Second random sampling with stratification

The amended list of 20 doctors, which was stratified by the degree to which the monitors knew each doctor, was reported back to the study centre. The study centre then randomly selected five doctors out of each list for each monitor (primary list), of which no more than two should have been known by the monitor. Monitors were instructed to approach each of the five doctors in this primary list to obtain their participation. The outcome of this recruitment process constitutes the overall response rate for this study.

Moreover, each monitor received a secondary list of additional five randomly selected doctors (supplementary list). Again not more than two doctors were allowed to be known personally by the monitor. This supplementary list was meant as a replacement list and was only to be used if any of the five doctors from the primary list refused to participate. In this way, assuming a successful recruitment rate of at least 50%, we ensured that each monitor would recruit a total of about five randomly chosen doctors in his region. At the same time, by means of stratification, we ensured that any systematic selection effect or bias could be avoided, or at least controlled for, in the final analyses. Monitors in the two intervention sites (Dresden and Munich) received an enriched list containing 15, rather than five, addresses. Because of the stratification it turned out that in one site (Munich) there were not sufficient addresses left for the supplementary list. Therefore Munich received six cases less than expected (see Table 1). As a result of this stepwise procedure, monitors received a total of 1,075 doctors' addresses on the primary list, and an additional 1,069 on the supplementary list.

Table 1. Stage I: target n, numbers of doctors recruited (by 183 monitors), and doctors' response rate.

	Primary list	Supplementary list	Total enrolled
Germany w/o intervention sites			
Target of doctors (no. monitors × no. of doctors)	835 (183 × 5)	835 (183 × 5)	–
No. recruited	422	263	685
Response rate	50.5%	–	–
Intervention site 1 Dresden			
Target of doctors (no. monitors × no. of doctors)	120 (8 × 15)	120 (8 × 15)	–
No. recruited	66	44	110
Response rate	55.0%	–	–
Intervention site 2 Munich			
Target of doctors (no. monitors × no. of doctors)	120 (8 × 15)	114* (8 × 15*)	
No. recruited	42	52	94
Response rate	35.0%	–	–
Total			
No. of doctors	1,075	1,069	–
No. recruited	530	359	889
Response rate	49.3%	–	–

* Note: six doctors dropped out after recruitment for technical reasons, therefore only 114 doctors were eligible

Recruitment of doctors and response rate (stage II of prestudy)

Recruitment process

After training and instructing the monitors in one central and two regional workshops the recruitment period started in October 2001 and lasted for approximately two months. Monitors were supervised to follow the protocol strictly and the instruction to first approach the doctors on the primary list. For recruitment of doctors, the monitors received a standardized recruitment package, consisting of:

- a personalized invitation letter;
- a leaflet instructing about the background of the study and its goals;
- a description of the study procedures;
- an enrollment and honorarium form, that needed to be signed. Doctors were offered a honorarium of 5€ for each fully documented patient.

Doctors agreeing to participate received the prestudy questionnaire (see below), which was to be returned within 14 days in a sealed pre-addressed envelope to the study centre. No financial compensation was offered for filling out the prestudy questionnaire.

For all doctors, monitors had to record whether they were willing to participate or not. Further, a telephone hotline was established for both the doctors as well as the monitors to resolve ongoing issues throughout the course of the study.

It should be noted that, for the intervention site, the recruitment was more complex because primary care doctors needed to agree to participate on all subsequent elements to the target day study, which implied:

- willingness to participate in the intervention training session;
- willingness to approach all patients for treatment;
- willingness to instruct and motivate patients according to the study protocol and remain in the study for at least 6 months, until the final follow-up was completed; and
- willingness to fill out the extensive patient documentation throughout the intervention study.

Thus these requirements were far more challenging than in the non-intervention sites.

Doctors' response rate

As shown in Table 1, during the recruitment period (October–December 2001), monitors were able to recruit from the primary list in the non-intervention group 422 (response rate: 50.5%) of the doctors. In the intervention sites, rates were slightly higher in Dresden with a response rate of 55.0%, but considerably lower in Munich with 35%. Due to the limited time range for recruitment, monitors were unable to work through all doctors on the supplementary list. Therefore no response rate can be calculated for the supplementary list. However the additional n = 263 replacement doctors in the non-intervention sites and n = 52, and n = 44 doctors respectively in the intervention sites, indicate that the target N of 1,075 was nearly reached (n = 889). It should be noted that not all doctors enrolled returned a fully completed prestudy questionnaire (see below). From the total of 889 doctors willing to participate, 76 questionnaires were incomplete, so n = 813 could be used for the final analyses.

Assessment: instrument development, training, core constructs and variables

The study involves the administration of four separate assessment components:

- prestudy questionnaire;
- patient questionnaire;
- doctor clinical assessment; and
- the intervention material (not dealt with in this paper).

All instruments were developed and adapted to fit the special requirement for this project, namely the patient and doctor instruments in the pre- and target day component should be structured in a way that they could be applied in routine care without major interruptions of the routine work of the primary care doctor. The intervention component, in contrast, is much more complex and only partially reflects primary care doctors everyday practice, due to the longitudinal assessment and the use of standardized intervention material.

In designing the assessment tools, we attempted to use previously established instruments, which have been tested for reliability and validity, or at a minimum, those for which the feasibility has been explored, to the extent that this was possible. Most

of the items and the assessment instruments employed – if not empirically validated and published along with their psychometric properties (diagnostic issues: Cottler et al., 1990, 1991; Dennis, 1998; Etter et al., 1999; Heatherton et al., 1986; Jäkle et al., 1999; Lachner et al., 1996, 1998; Üstün et al., 1992) – have already been field-tested in smoking and/or primary care research. The instruments have been used in studies of smoking cessation programs, epidemiological research (Lieb et al., 2000; Wittchen et al., 1998) or in previous primary care studies by our workgroup (Krause et al., 2001; Winter et al., 2000; Wittchen et al., 1999; Wittchen et al., 2001; Wittchen et al., 2000, 2001; Wittchen et al., 2001a). Also, the feasibility of the variables assessed as part of the doctors' or the patients' questionnaires, as well as of all instruments employed, has been shown in our previous primary care studies listed above (Wittchen et al., 1999, 2000).

The doctors' appraisal form in the target study was kept short and could be administered within approximately 5 minutes. The patients' questionnaire could be completed within approximately 15 minutes during the waiting time for the doctors' visit.

Training and distribution of study instruments

Training in the use of these instruments and the preparation of all logistical aspects on the target day assessment was performed by the monitors using a standardized manual. Monitors received a group training session run by the principal investigators one month prior to the target day.

The monitors distributed a personalized study package for the target day assessment to each doctor, before the target day for personal implementation in each setting consisting of:

- 100 patient and doctor assessment instruments;
- informed consent patient leaflets informing about the study;
- posters to be placed in the doctors' office, creating general awareness about the study;
- instruction manuals for the doctor and the staff, explaining the logistical flow and a checklist for them to verify that all preparatory steps were completed.

Further, monitors supervised the target day assessment on the assessment day by assisting the staff in the hand-out, and collection of instruments. The study centre provided a telephone hotline to offer backup support.

Monitors had approximately three to four weeks in which to distribute and implement the protocol individually in the five doctors offices for which they were responsible. Doctors' in the intervention sites also received training in the three standardized smoking cessation treatments, as well as all evaluation forms.

The assessment instruments (see Table 2)

The *prestudy questionnaire* was applied for participating doctors to collect data on their personal characteristics and their offices' settings (see Table 2a). The primary aim was to identify factors that might predict the doctors' ability and success in diagnosing nicotine dependence and offering first-line smoking cessation treatments.

The *patients' questionnaire* (target-day assessment) was used to survey a variety of patient-related variables concerning current physical and mental health status, smoking-related attitudes and behaviours and other variables (see Table 2b). In addition, it served to describe the patients' past and current smoking behaviour, as well as their motivational stage for smoking cessation.

The *doctor's clinical appraisal* included ratings of the patients' current smoking status (regular/occasional), nicotine dependence, as well as their motivation and compliance concerning smoking cessation. By considering the patients' self-reported information on their own smoking status as the gold standard it was also possible to determine the doctors' recognition rates of current smoking. In addition, the presence of 20 other specific somatic and mental disorders was rated using the Clinical Global Impression Scale (CGI: present/not present, borderline, mild, moderate, severe). In this context, the doctors had to assess physical complaints related to smoking and patients' awareness of this association. Further, information on prior smoking cessation attempts and previous smoking cessation treatments as well as possible difficulties and reasons for unsatisfactory treatment results were collected. Finally, doctors were asked about their personal treatment preferences, the need for current interventions regarding smoking, and expected difficulties in conducting smoking cessation programs among individual patients (see Table 2).

Table 2. SNICAS parameters and assessment instruments

A. Prestudy: primary doctor's evaluation questionnaire	
Domains	Examples of variables
Settings	Geographical location, provider characteristics (i.e. number of patients per day; Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Doctor's qualification	Medical and postgraduate specialization, continued education in smoking management, diagnostic competence (nicotine dependence) (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Awareness and attitudes towards smoking	Knowledge and attitudes regarding smoking and smoking cessation; nicotine dependence and associated diseases, (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Treatment practice	Previous experiences in various smoking cessation methods, efficacy ratings, willingness to offer smoking cessation, perceived barriers, informational needs (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al, 2000; Wittchen et al., 2001a; Krause et al., 2002)
Doctor's smoking status	Non-smoker, ex-smoker, current smoker, smoking behaviour, attempts and strategies used to stop smoking
B. Target day assessment	
a) Patient self-report variables	
Domains	Examples of variables
Biosocial	Day of birth, gender, body size and weight, occupation, family status, health insurance company (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Main reason for visit (complaints)	Pain, heart diseases, circulatory disorders, symptoms of cold or flu, anxiety disorders, depression or other psychic problems, problems related to smoking, problems related to alcohol, routine visit, sleeping problems, injuries/accident/emergency, other physical problems and diseases, other reason (e.g., prescription) (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al, 2000; Wittchen et al., 2001a; Krause et al., 2002)
Physical and mental health rating	Current physical and mental health (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Impairment and disability days past month	Number of sick days caused by physical and/or mental impairment, number of days with some physical and/or mental impairment (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al, 2000; Wittchen et al., 2001a; Krause et al., 2002)

Continued

Table 2. Continued

B. Target day assessment	
a) Patient self-report variables	
Domains	Examples of variables
Frequency of doctor visits/hospitalization days	Number of visits to physician/general practitioner, specialist, psychiatrist/neurologist, psychotherapist, hospitalisation (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al, 2000; Wittchen et al., 2001a; Krause et al., 2002)
Smoking habits	Lifetime/past month smoking (Q and F) (CIDI/DIA-X; Wittchen and Pfister, 1997)
Nicotine dependence:	Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker and Fagerström, 1991); DSM-IV nicotine dependence syndrome criteria by Composite International Diagnostic Interview - Module Nicotine Dependence (Cottler et al., 1990; 1991) and CIDI/DIA-X (Wittchen and Pfister, 1997)
Treatment history	Number, type and success of previous attempts to quit with and without treatment
Motivation	Stages of change (Prochaska and DiClemente, 1992; Jäkle, Keller, Baum and Basler, 1999) and attitudes towards quitting smoking; rating for immediate motivation to quit, motivation to enrol in the intervention study
Health risk behaviours and attitudes	Health Behavior Index
Current somatic and mental disorders, severity, and their treatment status	Heart and circulatory diseases, cerebral blood circulation disorders, blood circulation disorders in the legs (varicose veins), infections/flu/cold, pulmonary diseases/asthma, neurological disorders (seizures), depression, anxiety disorders, problems with alcohol, problems caused by smoking (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al, 2000; Wittchen et al., 2001a; Krause et al., 2002)
b) Doctor's clinical appraisal	
Domains	Examples of variables
Biosocial and sociodemographic data	Age, gender, sickness days (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Current medical diagnoses and severity	Somatic and mental disorders (Clinical Global Impression – CGI), severity, days being on sick leave (Winter et al., 2000; Wittchen et al., 2000; 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002)
Lifetime and current smoking status according to doctor (recognition)	Ever smoked, smoking currently; occasional or regular smoker; mild versus heavy smoking
Perceived needs for smoking cessation interventions	Three items (severity smoking, somatic health, risks)
Perceived motivation for smoking cessation interventions	Patient's willingness to accept smoking problem, readiness for smoking cessation
Doctors' past, current and future smoking cessation interventions (incl. treatment preferences)	Type and success rating for various smoking cessation interventions

Continued

b) Continued

Domains	Examples of variables
Patient motivation and compliance	Rating of patients' willingness to become involved immediately in a smoking cessation treatment
Assumed difficulties/barriers for smoking cessation (for those in the intervention sites only.) In an exclusion criteria checklist, patients' consent and drop out reason list	List of obstacles for successful treatment Medicine intolerability, insufficient motivation, stress/life crisis, smoking partner, strong enticements at work, strong enticements during leisure time/at social gatherings, gaining weight, applicational problems of therapy (too complicated), other reasons

Response rates patients on the target day assessment (stage II)

Inclusion and exclusion criteria for patients

The target day assessment was launched on 7 May 2002. Primary care doctors had received visits from study monitors before and during the target day. On the target day, the doctor and his or her staff were requested to inform each patient by using posters and asking for informed consent. Further they received detailed instructions about the logistic aspects in addition to the patient questionnaires and doctors' forms. Doctors were instructed not to change their routine care behaviour. Ideally all patients – irrespective of their presenting complaints – visiting the doctor's office that day should have been approached and asked for their willingness to participate. The doctor and the staff were further informed to avoid any systematic choice of patients (for example, the doctor should not focus on patients believed to be smokers).

However, for ethical and validity reasons we applied the following exclusion criteria:

- age younger than 16 (no upper limit!);
- not fluent in German language (not being able to read or fully understand the questionnaire items);
- severe cognitive (for example, dementia) or sensumotoric disabilities (for example, visual impairments, glasses forgotten) making valid answers on the questionnaire unlikely;
- physical emergencies, acute suffering, or severe pain, so that filling out the questionnaire would be a major burden;
- no personal contact with the doctor (patients coming for prescription renewals or laboratory checkups only).

We were aware from the outset that the task of approaching and enrolling all patients would be a major challenge to the primary care settings in light of the fact that many doctors have more than 60 patients a day, and thus have only a few minutes time on average for each patient. Each setting was instructed, that the patient recruitment and data collection could be interrupted for half an hour or so, if the burden on patients and data collection was too much. Thus, although we expected ideally about 50 eligible patients per setting, we estimated that only half of the patients eligible would actually be assessed.

Target day patients response rate

The upper portion of Table 3 summarizes the estimated total number of patients seen by the doctor per practice day, as indicated in the prestudy questionnaire. Overall a total of 64,853 patients were estimated to be seen by the 889 participating doctors on the target day, including 5,592 in site I and 6,617 patients in site II respectively.

Of these, 54,412 (100%) patients were eligible, as defined by the inclusion criteria. The lower portion of Table 3 summarizes the number and patients who either refused to participate, for whom only incomplete data were received (either incomplete patients' or doctors' questionnaires or problems in their correct identification) and the number of patients not approached by the doctor or the nurse, primarily because of work load and logistical problems. The total refusal rate (1.8%) was low in all segments (1.7%–2.4%). The proportion of incomplete data was considerably higher (5.7%).

The total completion rate across all sampling segments was 52.8%. There was a striking difference in completion rates in site II (71.9%) as compared to site I (51.2%) and the remaining federal area (50.6%).

Completion rates should be regarded as lower bound estimates of the true completion rate, because almost 40% of non-response is related to non-systematic factors, namely that the patient was not asked for participation due to logistical reasons in the setting.

How representative is the SNICAS doctor sample? To evaluate the representativeness of the doctors' sample we examined:

- the distribution of doctors by geographical factors (called 'Laender' or states) in the federal register with that of SNICAS doctors;
- the effects resulting from our nomination and sampling strategy; here, we focused on the question of whether doctors that were frequently visited by our monitors revealed different characteristics in terms of selected setting and patient characteristics. For this analyses we used the actual data freeze from the target day assessment.

Distribution of doctors in the Germany and in SNICAS
The distribution of all API doctors in Germany (2001) compared with both the primary sampling list of n = 1,075 doctors and the final sample of 889 SNICAS doctors enrolled revealed no remarkable differences. Overall, there is a fairly good concordance. Deviations are evident for the two 'Laender' that incorporated the interventions sites; these 'Laender' reveal – as expected – a considerably higher number of doctors enrolled (see Table 4).

We also examined whether the distribution of general practitioners and internists differed considerably in the national register as compared with the SNICAS study and found no remarkable differences (28.6% federal register; 24.6% SNICAS).

Do doctors previously known and visited by monitors reveal different characteristics than those unknown to monitors?
As noted above, it could have been expected that doctors who were known and visited previously by our monitors, who have also marketed smoking cessation treatments, reveal a number of systematic differences such as for example: a higher willingness of doctors to practise or become involved in smoking cessation with their patients, resulting in a higher number of patients who smoke or have nicotine dependence. As Table 5 reveals, for most doctor variables examined, no such remarkable differences, except for a slightly higher proportion of doctors (32.9% among known versus 26.4% among unknown doctors) visiting continued education seminars on smoking and smoking cessation

4.3. Other inquiries
Furthermore, we investigated to what extent patients' and doctors' characteristics differed between the two

Table 3. Stage II: total and eligible patient population and completion rates of patients on the target day assessment

	Overall	In site I Munich	In site 2 Dresden	Nationwide w/o sites
Total target day patient population n = 889 participating settings				
• mean patients/ setting	73.0	59.5	60.2	76.5
• SD	(34.0)	(28.0)	(21.5)	35.3
• Total number of patients	64,605	5,592	6,617	52,396
Total number of patients eligible (exclusion criteria) n (%)	54,412 (100%)	4,714 (100%)	5,578 (100%)	43,969 (100%)
• n (%) refusal	970 (1.8%)	80 (1.7%)	135 (2.4%)	755 (1.7%)
• n (%) (incomplete data set)	3,073 (5.7%)	249 (5.3%)	443 (7.9%)	2,381 (5.4%)
• n (%) not approached	21,662(39.9%)	1,945 (41.3%)	988 (17.7%)	18,578 (42.3%)
Completion: n and rate (%)	28,707 (52.8%)	2,440 (51.8%)	4,012 (71.9%)	22,255 (50.6%)

Table 4. Distribution of primary care offices and qualification across German states (*Laender*).

States (*Laender*)	API-doctors in Germany (reference population based upon IMS-register)		SNICAS initial sample (prestudy) (n = 1,075)		SNICAS final sample (target day) (n = 889)	
	n	%	n	%	n	%
Bayern*	12,388	18.1	203	18.9	152	17.5
Baden-Wuerttemberg	8,797	12.8	103	9.6	86	9.9
Hessen	5,314	7.7	48	4.5	43	4.9
Saarland	997	1.5	3	0.3	2	0.2
Rheinland-Pfalz	3,485	5.1	42	3.9	40	4.6
NRW	13,579	19.8	217	20.2	179	20.6
Niedersachsen	6,360	9.3	95	8.8	71	8.2
Schleswig-Holstein	2,407	3.5	14	1.3	9	1.0
Bremen	544	0.8	4	0.4	2	0.2
Hamburg	1,579	2.3	16	1.5	8	0.9
Berlin	2,691	3.9	51	4.7	44	5.1
Sachsen*	3,369	4.9	120	11.2	105	12.1
Sachsen-Anhalt	1,870	2.7	37	3.4	33	3.8
Mecklenburg-Vorpommern	1,434	2.1	38	3.5	27	3.1
Thueringen	1,926	2.8	13	1.2	9	1.0
Brandenburg	1,843	2.7	71	6.6	64	7.4
Total	68,583	100.0	1,075	100.0	871**	100.0

* Bayern (Munich) and Sachsen (Dresden) samples were enriched for the intervention component

** For 18 doctors offices missing values (prestudy questionnaire)

focal areas and the *other German regions*; this topic is very important for the generalizability of the results of the subsequent intervention study. Since doctors from the focal areas were over-sampled, potential differences between these regions might have introduced a bias into the final sample. To address this possibility, we compared the un-weighted results on some core outcomes with the results that were weighted according to the different sampling probabilities. Accordingly, the study parti-cipants from the Dresden area were down-weighted with factor 1/3.35 and the offices in the Munich area with factor 1/2.09. Results of this comparison revealed that rates of smokers are slightly lower in both intervention areas. The difference, however, is marginal (0.7%). Given that similarity, no consistent differences occurred in comparisons with other variables (quit attempts, motivational status and so forth). Therefore, we concluded that data should not be weighted to adjust for the different sampling strata. Further, because there were no significant differences, we decided to report the SNICAS finding for the overall total sample including all subjects and doctors from the intervention areas.

Another initial concern was that doctors who had examined only a smaller number of patients on the target day might introduce a systematic bias, for example by selecting smokers for the study with a higher probability than doctors with a higher number of patients enrolled. To examine this issue, the number of questionnaires per primary care setting was categorized into four groups (1–10, 11–30, 31–50, and 51+ patients assessed). Cross-tables were calculated with selected patients' core variables and outcomes (sex, age, reasons for consulting the doctors, general physical and mental health, current smoking status) as well as the doctor's questionnaire (current illnesses). Again, we could not identify any relevant systematic differences in these group comparisons (Table 6).

Discussion and conclusion

The objectives of the Smoking and Nicotine Dependence Awareness (SNICAS) study were to provide nationally representative data on the prevalence of smoking and smoking dependence of primary care patients and the frequency in which smoking

Table 5. Do recruited doctors previously known by monitor differ from those not known previously? Selected doctor and patient variables from pre-study and target day assessment

	Doctors personally unknown by monitors		Doctors personally known by monitors		Total	
	n	%	n	%	n	%
Setting characteristics (pre-study questionnaire)						
Patient load per day						
< 20	4	1.11	6	1.36	10	1.25
20–39	40	11.08	32	7.26	72	8.98
40–59	95	26.32	97	22	192	23.94
60–79	87	24.1	102	23.13	189	23.57
80+	135	37.4	204	46.26	339	42.27
Total	361	100	441	100	802	100
Doctor's own smoking status						
Non-smoker	296	85.3	384	89.3	680	87.52
Smoker	51	14.7	46	10.7	97	12.48
Total	347	100	430	100	777	100
Visited continued education seminars on smoking last year by the doctor						
No	265	73.61	300	67.11	565	70.01
Yes	95	26.39	147	32.89	242	29.99
Total	360	100	447	100	807	100
Used any methods of smoking cessation last year by the doctor						
No	53	15.54	43	10.29	96	12.65
Yes	288	84.46	375	89.71	663	87.35
Total	341	100	418	100	759	100
Doctor's willingness towards smoking cessation issues						
Not at all	1,631	38.61	2,147	40.12	3,778	39.45
Somewhat	1,812	42.9	2,301	42.99	4,113	42.95
Strongly	781	18.49	904	16.89	1,685	17.6
Total	4,224	100	5,352	100	9,576	100
Doctor's prior experiences with smoking cessation treatments (ever tried?)						
No	3,928	88.45	4,935	87.87	8,863	88.13
Yes	513	11.55	681	12.13	1,194	11.87
Total	4,441	100	5,616	100	10,057	100
Patients' characteristics						
Patients' current smoking status as assessed by doctors' clinical appraisal on target day						
Non-smoker	8,545	68.65	10,890	68.34	19,435	68.48
Occasional smoker	583	4.68	763	4.79	1,346	4.74
Regular 'light' smoker	1,735	13.94	2,267	14.23	4,002	14.1
Regular 'heavy' smoker	1,584	12.73	2,014	12.64	3,598	12.68
Total	12,447	100	15,934	100	28,381	100
Proportion of patients with DSM-IV nicotine dependence as assessed by patients' questionnaire						
No	10,864	86.07	13,851	86.12	24,715	86.09
Yes	1759	13.93	2,233	13.88	3,992	13.91
Total	12,623	100	16,084	100	28,707	100

cessation interventions are provided in primary care. The study also makes an attempt to identify the needs and motivational status for smoking cessation from both patients' and providers' perspectives.

As outlined in the literature review, such primary care-based data are currently unavailable, either nationally or internationally (see above). This deficit could be a serious obstacle for understanding the size and the breadth of this problem, thereby hindering improved concerted primary care, public health, and specialist service provider action. Further, the subsequent embedded regional SNICAS intervention component, only briefly mentioned in the current paper, can be expected to provide additional benefits, with regard to poorly studied clinical research issues, and in particular to final outcome research and practice transfer.

This paper provides an overview of the design and background consideration for the study, as well as the methods and procedures of the SNICAS project, focusing especially on sampling, field procedures and the assessment strategies and instruments.

Recruiting a nationally representative sample of primary care doctors

To address the broad range of study goals appropriately, the SNICAS study uses a complex three-stage epidemiological design. In stage I, the challenge was to select and recruit a sufficiently large and representative sample of primary care doctors and to describe their characteristics for use in predictor analyses.

A core critical question that should be addressed first is the integrity of the sampling procedure, namely, did we succeed in recruiting a nationally representative sample of routine primary-care doctors? The most straightforward strategy, using a simple random nationwide sampling of doctors, was not feasible in our case, due to time, financial and logistical restrictions and its inefficiency. Further, this approach would have required a mailed invitation for participation, usually resulting in extremely poor response rates. Additionally, as the study required the use of monitors that were able to provide individual training and support for the primary care physicians in all stages of the study, we needed to adopt a regionally clustered sampling strategy that was compatible in a way that was cost-efficient with respect to the availability of potential study monitors. Based on these considerations, we took advantage of an existing total and regularly updated national register of primary care doctors, which clusters doctors' offices in regional segments. Most pharmaceutical companies in Germany organize their sales force according to these segments. This solution has the advantage that we could use the sales field force of GlaxoSmithKline, the co-sponsor of the study, to assist us in our fieldwork needs.

This sampling strategy was found to work reasonably well for various reasons. The initial unconditional and conservative response rate among randomly selected primary care doctors approached for participation by these study monitors was 51%. As almost 15% of the doctor settings approached did not participate for reasons not related to the study (vacation, group practices, closed office on the target day, part-time employment and so forth), the actual less conservative response rate might be closer to 66%. This rate could be judged as being quite high, given that the participation involved a considerable time commitment for the doctor. The work

Table 6. Number of complete questionnaires at the target day by region and number of patients/day reported at the prestudy (n = 889)

No. of patients per doctor's office	Total		Germany w/o sites		Dresden		Munich	
	n	%	n	%	n	%	n	%
≤10	59	6.64	41	5.99	8	7.27	10	10.64
11–20	186	20.92	142	20.73	19	17.27	25	26.6
21–30	208	23.4	172	25.11	14	12.73	22	23.4
31–40	178	20.02	132	19.27	22	20	24	25.53
>40	258	29.02	198	28.91	47	42.73	13	13.83
Total	889	100	685	100	110	100	94	100

programme participants agreed to be involved, for example, the completion of an eight-page pre-study questionnaire, participation in training for the study procedures, willingness to devote a full, pre-set practice day for the study and the inclusion of all consecutive patients, who needed to be assessed by means of patients' questionnaire and a separate doctor appraisal. Further, the two intervention sites with an enriched doctor sample needed selected patients to be willing to be involved in an additional longitudinal assessment requiring them to quit over 6 months. In fact, the additional long-term workload associated with the additional intervention component seems to have considerably diminished willingness to participate in one site (response rate site 2: 35%). We are, however, unable to explain, why this effect occurred in only one of the two sites (response rate site 1: 55%).

Given these considerations, the fact that more than 50% of the doctors across Germany agreed to participate is remarkable. Whether the response rate is higher or lower than in other studies of this type is difficult to judge, as we are unaware of other studies using this approach.

Of course, one might wonder whether our study sample, and ultimately the overall study, could be still regarded as nationally representative for all German primary care doctors. We are unable to exclude fully the possibility that participating doctors are characterized by a higher motivation to deal with the issue of smoking cessation in primary care. However, at least three pieces of indirect evidence suggest that this is unlikely. First, as mentioned above, 15% of the doctors were simply unable to participate for objective reasons or because they did not meet inclusion criteria (see above), increasing the conditional response rate to 66%. Second, detailed comparisons of our final SNICAS sample of doctors with the total population of primary care doctors, in terms of their distribution by states and in terms of their distribution of professional specialisation, revealed no remarkable differences. Thirdly, by means of comparisons with selected patient and doctor variables we could also exclude the possibility that the use of monitors having had previous contact with some of the doctors related to smoking cessation drugs may have led to a distortion of the representativeness of the study.

In conclusion, we believe that the sampling strategy chosen was successful in recruiting a national sample of primary doctors, which could be considered as being sufficiently representative of the total population of primary care doctors

Is the patient sample representative?

Taking into account that most of the eligible patients not participating on the target day were not approached by the doctor or nurse at all due to logistical problems of handling over 60 patients/day in routine primary care work, we have no serious concerns that the patient sample was biased in a systematic way. Refusal or missing informed consent was surprisingly rare and occurred in less than 2% of all patients. Thus, despite the seemingly low conservative lower bound estimate of 52.8% completion rate, it is extremely unlikely that it reflects diminished representativeness of the patient sample. Furthermore, we could not identify any significant difference in characteristics of patients in practices with lower patient completion rates, testing the hypothesis that some doctors might have systematically selected patients with special characteristics.

Assessment instruments

Despite the finding that almost 6% of all questionnaires and doctors' clinical appraisals were incomplete or grossly inadequate and could not enter the final analyses, our study instruments were well received by both doctors and patients. Even older patients only rarely complained about difficulties filling in the four-page questionnaire.

This unexpectedly positive finding can be attributed to the fact that we relied heavily on established scales and questions and items that have gone through extensive field testing in other studies (Winter et al., 2000; Wittchen et al., 2000, 2001; Krause et al., 2001; Winter et al., 2000; Wittchen et al., 2001a; Krause et al., 2002). However, one needs to take into account the limitation that, except for the diagnostic screening instrument – the CIDI module for nicotine dependence and its associated quantity-frequency questions (Hezler et al., 1991) – the Fagerström questionnaire (Heatherton et al., 1991) and some factors to assess motivational stages (Jäkle et al., 1999), neither the remaining single

items nor the total assessment questionnaire was examined for reliability and validity.

Conclusion

The SNICAS findings can be expected to give a fairly precise cross-sectional picture of the current situation of smokers in primary care settings in Germany. Furthermore, this study is the first to describe the prevalence of smokers in primary care with a dependence syndrome along with a description of their characterization in terms of health risks and motivation to quit and including doctors' advice to become involved in smoking cessation treatments. The SNICAS study also provides greater detail about how well primary-care doctors recognize patients who could benefit from smoking cessation intervention strategies and how frequently and successfully they offer and deliver state-of-the-art treatments. Such data might ultimately allow for more appropriate and efficient strategies for smoking cessation in primary care.

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References

Anda RF, Williamson DF, Escobedo LG, Mast EE, Giovino GA, Remington P L. Depression and the dynamics of smoking: a national perspective. JAMA 1990; 264: 1541–5.

Brandon TH. Negative affect as motivation to smoke. Current Directions in Psychological Science 1994; 3: 33–7.

Breslau N, Johnson EO. Predicting smoking cessation and major depression in nicotine-dependent smokers. American Journal of Public Health 2000; 90 (7): 1122–7.

American Psychiatric Association (APA). Diagnostic and Statistical Manual of Mental Disorders. 4 edn. Washington: American Psychiatric Association, 1994.

American Psychiatric Association. Practice guideline for the treatment of patients with nicotine dependence. American Journal of Psychiatry 1996; 153 (suppl. 10): S1–S31.

Arbeitskreis Rauchen und Gesundheit: Consensus Statement. Eching/München: ÄARG, 1998.

Batra A, Buchkremer G. Raucherentwöhnung mit dem Nikotinpflaster. Zeitschrift für Ärztliche Fortbildung 1995; 89: 505–9.

Bellach B-M, Knopf H, Thefeld W. Der Bundes-Gesundheitssurvey 1997/1998. Das Gesundheitswesen 1998; 60 (suppl. 2): S59–S68.

Breslau N, Johnson EO, Hiripi E, Kessler R. Nicotine dependence in the United States – prevalence, trends, and smoking persistence. Arch Gen Psychiatry 2001, 58: 810–16.

Buchkremer G, Bents H, Horstmann M, Opitz K, Tölle R. Combination of behavioral smoking cessation with transdermal nicotine substitutution. Addictive Behavior 1989; 14: 229–38.

Buchkremer G, Minneker E, Block M. Smoking-cessation treatment combining transdermal nicotine substitution with behavioral therapy. Pharmacopsychiatry 1991; 24: 96–102.

Bühringer G, Körger C, Küfner H, Lieb R, Schütz C, Soyka M, Wittchen H-U. Suchtforschungsverbund ASAT: Entwicklung von Zuordnungsmodellen für Interventionen bei Substanzstörungen. Sucht 2002; 48 (3): 200–8.

Bundesgesundheitssurvey 1997/1998. Das Gesundheitswesen, Schwerpunktheft 1998, Stuttgart: Thieme, 1998, 60 (suppl 2).

Colby SM, Tiffany ST, Shiffman S, Niaura R. Review: are adolescent smokers dependent on nicotine? A review of the evidence. Drug and Alcohol Dependence 2000, 59 (suppl. 1): 83–95.

Cohen D, Barton G. The cost of society of smoking cessation. Thorax 1998; 53 (suppl. 2): S38–S42.

Cottler L, Robins LN, Babor T, Helzer J, Towle L, Grant B, Blaine J, Wittchen H-U, Sartorius N, Burke J, Regier D, Tipp J, Altamura AC, Andrews G, Dingemann R, Droux A, Essau CA, Farmer A, Halikas J, Ingebringsten, Issac M, jenkins P, Kuehne GE, Krause J, Lepine PP, Lykepsos G, Maier W, Pull C, Rubio-Stipic M, Sandanger I, Smeets R, Tachini G, Tihram M, Torres de la Miranda C. Cross-cultural reliability and acceptability of the CIDI-core substance abuse and dependence questions. In CN Stefans, AD Rabavilas, CR Soldatos (eds), Psychiatry: A World Perspective. Amsterdam: Excerpta Medica, 1990, pp. 144–52.

Cottler L, Robins LN, Grant B, Blaine J, Towle L, Wittchen H-U, Sartorius N, Burke J, Regier D, Hezler J, Janca A. The CIDI-core substance abuse and depen-

dence questions: cross cultural and nosological issues. British Journal of Psychiatry 1991; 159: 653–8.

Dennis ML. Integrating research and clinical assessment. Measuring client and program needs and outcomes in a changing service environment. NIDA Resource Center for Health Services Research.

De Wit DJ, Aguilar-Gaziola S, Bijl R, Borges G, Caraveo-Anduaga JJ, Kessler RC, Kolody B, Merikangas KR, Molnar BE, Vega WA, Walters EE, Wittchen H-U. Cross-national comparisons of drug use and drug-related problems. Addiction (in press).

Etter J-F, Perneger TV. A comparison of two measures of stage of change for smoking cessation. Addiction 1999; 94(12): 1881–9.

Fagerström KO, Schneider NG, Lunell E. Effectiveness of nicotine patch and nicotine gum as individual versus combined treatment for tobacco withdrawal symptoms. Psychopharmacology 1993; 111: 271–7.

Fagerström KO. Combined use of nicotine replacement products. Health Values 1994; 18: 15–20.

Fiore MC, Bailey WC, Cohen SJ, Dorfmann SF, Goldstein HG, Gritz ER, Heyman RB, Holbrook J. Treating tobacco use and dependence. Clinical practice guideline. Rockville MD: U.S. Department of Health and Human Services. Public Health Services, 2000.

Fowler G. Smoking cessation: the role of general practitioners, nurses and pharmacists. In CT Bolliger, KO Fagerström (eds) The Tobacco Epidemic. Progress in Respiratory Research. Basel: Karger, 1997, pp. 165–77.

Haustein K-O. Pharmacotherapy of nicotine dependence. International Journal of Clinical Pharmacology and Therapeutics 2000; 38: 273–90.

Haustein K-O. Tabakabhängigkeit – Gesundheitliche Schäden durch das Rauchen. Köln: Deutscher Ärzte-Verlag, 2001.

Heatherton TF, Kozlowski LT, Frecker RC, Fagerström KO. The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. British Journal of Addiction 1991; 86(9): 1119–27.

Hurt RD, Sachs DPL, Glower ED, Offord KP, Johnston JA, Dale LC, Khayrallah MA, Schroeder DR, Glover PN, Sullivan CR, Croghan IT, Sullivan PM. A comparison of sustained-release bupropion and placebo for smoking cessation. New England Journal of Medicine 1997; 337: 1195–202.

Jäkle C, Keller S, Baum E, Basler H-D. Skalen zur Selbstwirksamkeit und Entscheidungsbalance im Prozess der Verhaltensänderung von Rauchern. Diagnostica 1999; 45(3): 138–46.

Jarvis MJ. Patterns and predictors of smoking cessation in the general population. In CT Bolliger, KO Fagerström (eds) The Tobacco Epidemic. Progress in Respiratory Research. Basel: Karger, 1997, pp. 115–64.

John U, Hanke M. Tabakrauch-attributable Mortalität in deutschen Bundesländern. Gesundheitswesen 2001; 63: 363–9.

Jorenby DE, Leischow SJ, Nides MA, Rennard SI, Johnston JA, Hughes AR, Smith SS, Muramoto ML, Daughton DM, Doan K, Fiore MC, Baker TB. A controlled trial of sustained-release Bupropion, a nicotine patch, or both for smoking cessation. The New England Journal of Medicine 1999; 340: 685–91.

Junge B, Nagel M: Das Rauchverhalten in Deutschland. Gesundheitswesen 1999; 61 (suppl. 2): 121–5.

Junge B, Thamm M. Jahrbuch Sucht 2003, Tabak – Zahlen und Fakten zum Konsum. Geesthacht: Neuland-Verlag, 2001, pp. 34–61.

Krause P, Wittchen H-U, Höfler M, Winter S, Spiegel B, Pfister H. Generalisierte Angst und Depression in der Allgemeinarztpraxis (GAD-P). Studiendesign und Methodik. MMW Fortschritte der Medizin 2001; 119 (suppl. 1): 5–12.

Krause, P, Wittchen H-U, Küpper B, Sharma AM, Ritz E, Göke B, Lehnert H, Unger T, Kirch W, Pittrow D, Tschöpe, D. The Hypertension and Diabetes Screening and Awareness Study (HYDRA): aims, design and methods of an innovative epidemiological approach. European Journal of Public Health 2002; 12 (suppl.): 70.

Lachner G, Wittchen H-U, Perkonigg A, Holly A, Schuster P, Wunderlich U, Türk D, Garczynski E, Pfister H. Structure, content and reliability of the Munich-Composite International Diagnostic Interview (M-CIDI). Substance use sections. European Addiction Research 1998; 4(1–2): 28–41.

Lachner G, Wittchen H-U. Das Composite International Diagnostic Interview Substance Abuse Module (CIDI-SAM). In K Mann, G Buchkremer (eds) Sucht. Grundlagen, Diagnostik, Therapie. Stuttgart: Gustav Fischer, 1996, pp. 147–56.

Lieb RB, Isensee B, Von Sydow K, Wittchen H-U. The Early Developmental Stages of Psychopathology Study (EDSP): a methodological update. European Addiction Research 2000; 6(4): 170–82.

Lieb R, Schuster P, Pfister H, Fuetsch M, Höfler M, Isensee B, Müller N, Sonntag H, Wittchen H-U. Epidemiologie des Konsums, Mißbrauchs und der Abhängigkeit von legalen und illegalen Drogen bei Jugendlichen und jungen Erwachsenen: Die prospektiv-longitudinale Verlaufsstudie EDSP. Sucht 2000; 46(1): 18–31.

Loddenkemper R, Sybrecht GW. Health care costs of smoking. European Respiratory Journal 2000; 16: 377–8.

Murray CJL, Lopez AD. Mortality by cause for eight regions of the world: global burden of disease study. Lancet 1997; 349: 1269.

Nelson CB, Wittchen H-U. Smoking and nicotine dependence: Results from a sample of 14 to 24 year olds in Germany. European Addiction Research 1998a; 4(1–2): 42–9.

Nelson CB, Wittchen H-U. Editorial: The EDSP: Setting the Stage! European Addiction Research 1998b; 4 (1–2): 5–7.

Perkonigg A, Lieb R, Wittchen H-U. Substance use, abuse and dependence in Germany: a review of selected epidemiological data. European Addiction Research 1998; 4(1–2): 8–17.

Pierce JP, Fiore MC, Novotny TE, Hatziandreu EJ, Davis RM. Trends in cigarette smoking in the US: projections to the year 2000. JAMA 1989, 261: 61–5.

Prochaska JO, DiClemente CC. The transtheoretical approach. In Norcross JC, Goldfried MR (eds) Handbook of Psychotherapy Integration. New York: Basic Books, 1992.

Prochaska JO, DiClemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. Health Psychology 1993; 12: 399–405.

Ruff LK, Volmer T, Nowak D, Meyer A. The economic impact of smoking in Germany. European Respiratory Journal 2000; 16 : 385–90.

Samet JH, Larson MJ, Horton NJ, Doyle K, Winter M, Saitz R. Linking alcohol- and drug-dependent adults to primary medical care: a randomized controlled trial of a multi-disciplinary health intervention in a detoxification unit. Addiction 2003; 98 (4): 509–16.

Schön S, Nowak D. Medikamentöse Verfahren zur Raucherentwöhnung. Suchtmedizin in Forschung und Praxis 2002; 3 (suppl.).

Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. Lancet 1994; 343: 139–42.

Sonntag H. Epidemiologie des Rauchens und der Nikotinabhängigkeit bei Adoleszenten und jungen Erwachsenen - Eine 5-Jahres prospektiv-longitudinale Entwicklungsstudie an 3021 Personen aus der Allgemeinbevölkerung. Dissertation, München, 2001.

Sonntag H, Hoch E, Jahn B, Spiegel B, Pfister H, Wittchen H-U. Tabakentwöhnungsmaßnahmen in der allgemeinärztlichen Versorgung: Implementierung, Effektivität und Wege einer optimierten Allokation. *Suchtmedizin in Forschung und Prakis* 2003, 5: 137–41.

Sonntag H, Kröger C, Shaw R. Setting up an information system on smoking cessation programmes. IFT Berichte. Band Nr. 96. München: IFT Institut für Therapieforschung, 1998.

Sonntag H, Pfister H, Wittchen H-U. Rauchen und Nikotinabhängigkeit in Deutschland. Ergebnisse des bundesweiten Zusatz-Surveys, Psychische Störungen' im Rahmen des Bundes-Gesundheitssurveys, 1998.

Sonntag H, Wittchen H-U, Höfler M, Kessler RC, Stein MB. Are social fears and DSM-IV social anxiety disorder associated with smoking and nicotine dependence in adolescents and young adults? European Psychiatry 2000; 15 (1): 67–74.

US Department of Health and Human Services. People Health: National Health Promotion and Disease Prevention Objectives. Full Report. Washington: Department of Health and Human Services, 1990.

Üstün TB, Wittchen H-U. Instruments for the assessment of substance use disorders. Current Opinion in Psychiatry 1992; 5: 412–19.

Welte R, König HH, Leidl R. The costs of health damage and productivity losses attributable to cigarette smoking in Germany. Eur J Public Health 2000;10: 31–8.

Winter S, Wittchen H-U, Höfler M, Spiegel B, Ormel H, Müller N, Pfister H. Design und Methoden der Studie 'Depression 2000'. MMW Fortschritte der Medizin 2000; 118 (suppl. 1): 11–21.

Wittchen H-U (ed). Depression 2000. Eine bundesweite Depressions-Screening-Studie in Allgemeinarztpraxen. MMW Fortschritte der Medizin 2000; 118 (suppl. I/2000).

Wittchen H-U (ed.) NISAS 2000: Die Nationwide Insomnia Screening and Awareness Study (NISAS). Prävalenz und Verschreibungsverhalten in der allgemeinärztlichen Versorgung. MMW Fortschritte der Medizin 2001; 119 (suppl. I/2001).

Wittchen H-U (ed.) GAD-P-Studie. Bundesweite Studie 'Generalisierte Angst und Depression im primärärztlichen Bereich'. MMW Fortschritte der Medizin 2001; 119, (suppl I/2001).

Wittchen H-U (ed). Die Hypertension and Diabethes Awareness and Screening-(HYDRA)-Studie GAD-P-Studie. Bundesweite Studie 'Generalisierte Angst und Depression im primärärztlichen Bereich'. MMW Fortschritte der Medizin 2003; 121 (suppl I/2003).

Wittchen H-U, Höfler M, Krause P, Riemann D. The Nationwide Insomnia Screening and Awareness Study (NISAS): Aims, methods and first findings. Abstract P.21.24. International Journal of Neuropsychopharmacology 2000; 3 (suppl. 1): 392.

Wittchen H-U, Höfler M, Meister W. Prevalence and recognition of depressive syndromes in German primary care settings: poorly recognized and treated? International Clinical Psychopharmacology 2001; 16 (3): 121–35.

Wittchen H-U, Krause P, Höfler M, Winter S, Spiegel B, Hajak G, Riemann D, Pittrow D, Steiger A, Pfister H. NISAS-2000 – die Nationale Insomnie Awareness und Screening Studie. Insomnien und Schlafstörungen in der allgemeinärztlichen Versorgung. Nervenheilkunde 2001b; 20 (1): 4–16.

Wittchen HU, Nelson CB. Early developmental stages of substance abuse. European Addiction Research 1998; 4: 1–84.

Wittchen H-U, Perkonigg A, Lachner G, Nelson C B. Early developmental stages of psychopathology study (EDSP) – objectives and design. European Addiction Research 1998; 4 (1–2): 18–27.

Wittchen H-U, Pfister H (eds) DIA-X-Interviews: Manual für Screening-Verfahren und Interview. Frankfurt: Swets & Zeitlinger, 1997.

Wittchen H-U, Schuster P, Pfister, H, Müller N, Storz S, Isensee B. Depressionen in der Allgemeinbevölkerung –

schlecht erkannt und selten behandelt. Nervenheilkunde 1999; 18: 202–9.
Wittchen H-U, Sonntag H, Nowak D, Kröger C, Schmidt LG. Raucherentwöhnung beim Hausarzt – Illusion oder Perspektive? Der Hausarzt 2002; 6: 49–53.
World Health Organization (WHO). The Composite International Diagnostic Interview (CIDI). Geneva: World Health Organization, Division of Mental Health, 1990.
World Health Organization (WHO). Tobacco or health: a global status report. Geneva: World Health Organization, 1997.
World Health Organization (WHO). Gemeinsam handeln – Tabakkonsum reduzieren: Dokumentation der Abschlusskonferenz des WHO-Partnerschaftsprojektes Tabakabhängigkeit (1999-2002). WHO-Konferenzband. pdf in: www.1who-nichtrauchertag.de, 2002.
Zimmer D, Lindinger P, Mitschele U. Neue Wege in der verhaltenstherapeutischen Behandlung des Rauchens. Verhaltenstherapie 1993; 3: 304–11.

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