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Saxon Epidemiological Study in General Practice - 6 (SESAM-6) - Study protocol

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Saxon Epidemiological Study in General Practice - 6 (SESAM-6) - Study protocol

[Sächsische Epidemiologische Studie in der Allgemeinmedizin - 6 (SESAM-6) - Studienprotokoll]

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ABSTRACT

Introduction:

General practitioners (GP) are mostly the first point of contact for patients with health problems in Germany. There is only a limited epidemiologic overview data that describes the GP consultation hours based on other than billing data. Therefore, the aim of SESAM-6 is to examine the frequencies of reasons for encounter, prevalence of long-term diagnosed diseases, and diagnostic and therapeutic decisions in general practice. This knowledge is fundamental to identify the health care needs and to develop strategies to improve the GP care. The results of the study will be incorporated into the undergraduate, postgraduate and continuing medical education for GP.

Methods and analysis:

This cross-sectional study SESAM-6 is conducted in general practices in the state of Saxony, Germany. The study design is based on previous SESAM studies. Participating physicians are assigned to one week per quarter (over a survey period of 12 months) in which every fifth doctor-patient contact is recorded for one half of the day (morning or afternoon). To facilitate valid statements, a minimum of 50 GP is required to document a total of at least 2500 doctor-patient contacts. Univariable, multivariable and subgroup analyses as well as comparisons to the previous SESAM data sets will be conducted.

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Ethics and dissemination:

The study was approved by the Ethics Committee of the Technical University of Dresden in March 2023 (SR-EK-7502023). Participation in the study is voluntary and will not be remunerated. The study results will be published in peer-reviewed scientific journals, preferably with open access. They will also be disseminated at scientific and public symposia, congresses, and conferences. A final report will be published to summarise the central results and provided to all study participants and the public.

Strengths and weaknesses of this study:

- *12-month study period* to capture the reality of GP consultation hours (incl. epidemiological data) considering seasonal influences
- *Randomised survey times* to avoid confounding based on predetermined practice procedures
- *Longitudinal comparison with previous SESAM studies* to demonstrate trends in GP activity over the last 20 years
- *Generalisability* of the results is partly limited due to the regional data collection in the state of Saxony, Germany
- *Data collection* direct after the consultation might be challenging in GPs everyday practice

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1. Introduction

As the first point of contact for health problems of all kinds, general practitioners (GP) provide primary care for the population in Germany. In Germany, 82% of adults were treated at least once by a GP in 2019-2020 (1). The patient population of the GP is unselected and includes people of all ages and social classes. The scope of general practice includes the prevention, detection, treatment and rehabilitation of diseases as well as the maintenance and promotion of health (2). The usual episode of care in general practice includes the reasons for encounter (RFE) and the diagnostic and therapeutic decisions, which does not necessarily include a confirmed diagnosis based on ICD-10.

The RFE in general practice are usually determined by a specific patient concern (3). Internationally and in Germany, the most common RFE in general practice are headache, abdominal and back pain, respiratory complaints (i.e. coughs) and fever (4–10). The RFE determines the content of consultation and the consultation decision. The most common contents of consultations in general practice in Germany and internationally are hypertension, diabetes, myalgia or bronchitis (7, 8, 10, 11). Discussions about test results, medication-related consultations as well as psychosocial problems and lifestyle issues complement the spectrum of consultation contents in the general practice (3, 4, 10–12). The consultation decisions include referrals to further specialists, therapeutic measures, prescription of medication and watchful waiting.

The Saxon Epidemiological Studies in General Practice (Sächsische Epidemiologische Studie in der Allgemeinmedizin: SESAM) were designed to collect data in general practices in Saxony. The SESAM studies 1 (1996-1997), 2 (1999-2000) and 4 (2008-2009) examined consultation hours and the SESAM 3 (2009) and 5 (2014-2015) examined home visits. The SESAM studies focus on the frequency of RFE, the prevalence of long-term diagnoses, the diagnostic and therapeutic decisions (13–21). The present SESAM-6 study is intended to study the consultation hours of general practitioners in Saxony and to address the following research questions:

- What are the most common RFE in general practice?
- How do the RFE differ according to patient demographic characteristics such as age, gender and practice location (urban/rural)?
- What is the prevalence of known long-term conditions in general practice?

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- What diagnostic and therapeutic actions and decisions are made by GP?

The SESAM-6 study is conducted to provide up-to-date data and evidence for GP practice in Germany. The previous SESAM studies 2 and 4 are the only published studies that have investigated consultation hours and RFE in GP practice in Germany. The CONTENT study (2008-2010) provides an overview of the ICPC-2 coded RFE in Germany (10, 22) .

RFE describe the reality of care in general practice more accurately than health insurance data or billing data that only depict confirmed diagnoses and do not directly reflect the episodes of care in general practice. Evidence regarding the frequencies of RFE, prevalence of long-term diagnosed diseases, and diagnostic and therapeutic decisions is fundamental for identifying health care needs and to develop strategies to improve GP care in Saxony and also for the requirements planning for the German healthcare system.

The results of SESAM-6 will be incorporated into the undergraduate, postgraduate and continuing medical education for GP. The evidence is also needed to plan studies in primary care. In addition, potential changes in GP practice over the last 20 years can be made visible through comparisons with previous SESAM studies. Besides, examining the reality of care in Saxony and the corresponding workload of the GPs will provide a basis for professional policy discussions, e.g. for the distribution of remuneration.

2. Methods and analyses

The SESAM-6 study is being carried out in general practices in Saxony, Germany. It is a cooperative project between the general practice departments of the Technical University of Dresden (TU Dresden), the University of Leipzig and the Martin Luther University Halle-Wittenberg.

2.1. Study design

SESAM-6 is a cross-sectional study. The study was designed in collaboration with the Saxon Society for General Practice (SGAM e. V.) and its Scientific Advisory Board. The study design is based on the previous SESAM studies (SESAM-2 (13) and SESAM-4 (17)), which also investigated the consultation hours of general practitioners in Saxony. As part of the study, GP will participate for 12 months (October 2023 - September 2024) and document the consultations for one week per quarter (∑4 weeks per GP). The consultation of every fifth doctor-patient contact will be recorded using the patient documentation form. The study will

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be conducted on half days (either in the morning or afternoon) on the selected recording days. The study weeks allocated to a physician and the corresponding half days were randomised by the study team prior to the start of the study. Randomization was performed using a random number generator[1]. If the participating GP will be absent during the recording period (vacation, illness, etc.), the next possible week will be documented. Half days were not randomised if the participating GP only work half days.

Only actual doctor-patient contacts during consultation hours (including video and telephone consultations) will be documented. Patients who come to the GP practice without any doctor-patient contact, e.g. for a prescription, a blood sample or similar, will be excluded from the documentation. Home visits will also not be recorded. Each patient can only be documented once in the study. To avoid duplication, the participating physicians keep an internal patient list or note the recording of patients in the practice software. There are no further exclusion criteria. At the start of the study, the participating physicians receive an individual document from the study team with their respective recording periods. Additionally, the study team contacts the physicians one week prior to the recording period to remind them.

2.2. Expected results

The main outcomes of the study are the frequency of RFE and the resulting decisions and actions. In addition, an overview of the spectrum and prevalence of chronic diseases in GP practices will be given. Structural characteristics of the physicians (age, gender, urban-rural) will be recorded to allow analysis of group differences. Comparison with previous SESAM studies will facilitate longitudinal analysis, identifying changes in GP activity over the last 20 years.

2.3. Pretest

In June 2023, a 3-week pretest phase of the study was conducted with general practitioners in Saxony-Anhalt (the federal state directly neighbouring the main study region of Saxony). This preliminary study was conducted by the Institute of General Practice at Martin Luther University Halle-Wittenberg (Saxony-Anhalt). The pretest simulated the planned study procedure and included all the study documents (1. physician documentation form to record the characteristics of the participating practices and GP; 2. patient documentation form to

[1] https://www.zinsen-berechnen.de/zufallszahlen.php

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record the respective consultation). Nine GP were recruited for the pretest, but only five took part (3 female, 2 male; mean age = 48 years). The pretest was used to check the feasibility of the study design including randomization of the survey periods and the implementation of the study procedure in everyday practice, as well as the content and comprehensibility of the questionnaires. The participating physicians were allocated a study week and the time of the day (morning or afternoon) for collecting patient data for every fifth doctor-patient contact within the allocated recording period. For the pretest, the following question was added to the physician questionnaire and the patient documentation form: "What comments do you have about the questionnaire or the study design?". In addition, five semi-structured telephone interviews (duration approx.. 30 minutes) were conducted with the participating GP to record any problems with the study implementation. The obtained data were used to review and revise the study procedures and materials. The pretests confirmed the feasibility of the study design for everyday GP practice.

2.4. Case number calculation

In the previous study SESAM-2, 209 participating GPs documented about 8877 doctor-patient contacts (14), and in SESAM-4, 73 GPs documented 2529 doctor-patient contacts (23). In order to allow longitudinal analyses, SESAM-6 aims to have a similar minimum number of cases as SESAM-4. Due to the modified study design in SESAM-6, a recruitment target of at least 50 GPs is required. Each of them should document about 75 doctor-patient contacts, so that a total number of at least 3750 doctor-patient contacts can be achieved. Approximately 25% of the 3750 doctor-patient contacts are imputed for missing values and unpredictable events, aiming a complete and analyzable data set of 2800 doctor-patient contacts in total.

2.5. Recruitment

The SESAM-6 study was first presented to the members of SGAM e.V. via newsletter in March 2023. In the following months, the study was promoted at events organised by TU Dresden and at the annual SGAM congress for GP of the region. An additional joint letter campaign by TU Dresden and Leipzig University reached around 2,700 GP in Saxony. With reference to this letter campaign, a reminder was sent out in August 2023. In addition, further physicians were invited word of mouth. The main criterion for participation in the SESAM-6 study is working as a GP in Saxony. The study allows for the participation of several physicians from GP practices, including GP in advanced training in general practice.

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Following the recruitment measures, a total of 119 physicians were enrolled in the study, which started in October 2023. Prior to the start of the study, the participating physicians received their personalised study documents by mail from the study team: document with randomised four survey weeks in each quarter of the next 12 months, as well as a physician ID, a brief explanation of the study, instructions for the questionnaire, a patient list and two patient documentation forms to serve as a backup for the digital patient documentation form. Two voluntary, digital training sessions in September 2023 were scheduled to inform the participating GP about the study procedures and study documents and to allow discussion regarding the study. 27 GP have participated in the digital training session.

2.6. Data collection

GPs were instructed to complete the physician documentation form before the start of the study, which collected sociodemographic characteristics and practice characteristics. Questionnaire is based on the physician questionnaire of the SESAM-5 study and was revised for the SESAM-6 study by the study team with the support of the SGAM Scientific Advisory Board and based on the results of the pretest.

The patient documentation form is completed by the GP after the consultation with the respective patient. The patient documentation form records the patient's socio-demographic characteristics (sex, age group, familiarity with the patient) and the reason for the encounter, diagnosis and medical decisions made.

The respective questionnaires are completed digitally using the free and open source online statistical survey web app LimeSurvey (provided by Bildungsportal Sachsen GmbH). Once the patient´s data have been entered online, they are immediately available to the study team. If digital processing of the questionnaires by the GP is not possible, the questionnaires can be completed in paper form (for this case, GP have respective examples in their documents). Paper questionnaires will be sent by post to the study team at the TU Dresden at the end of the data collection week and subsequently digitised.

2.7. Data management

Data management is carried out by the TU Dresden study team. The data from the incoming patient documentation forms are exported quarterly by LimeSurvey during the 12-month data

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collection period and initially checked for plausibility. At the end of the data collection period, the final data set is checked for plausibility using a project-specific syntax.

Subsequent coding of the RFEs and results will be performed by the study team (2 coders independent of each other) based on the coding from SESAM-2 and SESAM-4. The RFEs are coded according to the ICPC-2 (International Classification of Primary Care) (24). Consultation results and long-term diagnoses are coded using the ICD-10 classification (25). This approach allows comparability with the previous SESAM studies and the possibility of excluding individual medical coding habits as a source of error.

2.8. Statistical analysis

Data will first be analysed descriptively using IBM SPSS Statistics (version 29.0 or later). Univariable and multivariable statistical analyses will then be carried out to assess changes compared to previous SESAM datasets and for subgroup analyses. Test procedures will be specifically chosen based on the research questions and the level and distribution of the relevant data.

2.9. Declaration on patient and public relations work

GPs from Saxony-Anhalt and Saxony were involved in the iterative development process of the SESAM study. In particular, the opinions of the GP were considered in the development of the questionnaires and their feasibility as well as in the conception of the study design. Patients were not involved in the development process of the study, as the study will be conducted exclusively by GP and will collect anonymous patient data in the GP practice.

3. Ethics and dissemination

The study was approved by the Ethics Committee of the Technical University of Dresden on March 31, 2023 (SR-EK-7502023). Participation in the study is voluntary and will not be remunerated.

3.1. Data protection

The study is conducted in accordance with the Declaration of Helsinki. The legal basis for the storage and processing of the data is Art. 6 para. 1 and Art. 9 para. 2a EU GDPR. The collection, processing, storage, and analysis of the data is therefore subject to the voluntary consent of the participating GP as part of the declaration of consent prior to participation in the study.

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The patient questionnaire is anonymous, as the items contained in the questionnaire do not allow the identification of individual patients. To maintain patient anonymity, identifiers such as patient code and year of birth are not collected. In addition, the anonymity of the patient information is enhanced by the large case number of at least 2800 doctor-patient contacts. As the anonymity is ensured, there is no need for patient consent.

In addition to the patient documentation form, the physician questionnaire collects structural data on GP practices (e.g. type of practice, number of employees, regional allocation, number of invoices). These data relate to the participating GP. The participating GP therefore give their consent to data processing by means of a declaration of consent and have the option of withdrawing their consent at any time. In the event of revocation, the data already collected will be deleted, unless the data have already been processed. In this case, the data processing carried out until the revocation remains lawful.

The responses to the anonymous patient documentation form and the responses to the personalised physician questionnaires are stored in separate data sets. To answer specific research questions (e.g. urban-rural differences), parts of the data sets are linked together. After completion of the survey, the raw data sets (and later the cleansed data sets) are stored on the computers of the Department of General Practice at the Technical University of Dresden. The computers of the Department of General Practice and the group drive of the Department of General Practice are subject to the security concept of the University of Technology Dresden and the University Hospital Dresden. The relevant data structure is secured by passwords that are only known to the respective authorised project members. The final data sets are transmitted to the cooperating institutes via zip encryption. The computers of the cooperating institutes and their drives are subject to respective security concepts and are protected by passwords that are only known to the respective authorised project staff.

The data collected is used to answer scientific questions in the field of epidemiology and health services research. As longitudinal comparisons and time series analyses are of particular interest, an unlimited storage period is planned.

3.2. Possible risks and benefits

As the study only collects patient-related data on the health status and does not involve medical interventions, there are no associated medical risks for the patients whose data are

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collected anonymously. Furthermore, there are no risks, impairments, burdens, or disadvantages for physicians to participate in this study. The results of this study will help to improve the evidence based on documentation of GP consultation hours in general practice and the work of GP. Based on the results, training and continuing education for GP can be supplemented with current data from GP practice. The results of the study will also be incorporated into medical education at universities.

3.3. Dissemination plan

The study results will be published in peer-reviewed scientific journals and, where possible, open access. It is also planned to disseminate the results at scientific and public symposia, congresses, and conferences. In the frames of the study, young scientists will be supported to write their dissertations as part of the study. A final report on the study will summarise the main findings.

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5. Contributions by the authors

Willy Gräfe conceptualized and wrote the manuscript as the first author.

Lukas Liebig developed the data protection concept, contributed to questionnaire development, study design and pretest evaluation, set up the online questionnaire.

Jeannine Schübel contributed to questionnaire development and study design.

Tobias Deutsch contributed to questionnaire development, study design, pretest evaluation and organized recruitment of GPs.

Markus Bleckwenn contributed to questionnaire development, study design and pretest evaluation.

Antje Bergmann contributed to questionnaire development and study design.

Thomas Frese recruited some of the GPs for the pretest in Saxony-Anhalt. Contributed to questionnaire development and study design.

Christine Brütting recruited some of the GPs for the pretest in Saxony-Anhalt, carried out the pretest and evaluated the interviews conducted. Contributed to questionnaire development and study design.

Henna Riemenschneider is the project coordinator. She contributed to questionnaire development, study design and pretest evaluation.

All authors were involved in the preparation of this manuscript and have critically reviewed it.

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7. Financing

The SGAM is part-financing the study. The funding is used for personnel costs (research assistants, study assistance) and material costs. Costs not covered by the funding amount (study preparation, project coordination, supervision and consulting) are financed by own funds of the participating departments. In addition, members of SGAM support the implementation of the study on a voluntary basis.

8. Conflicts of interest

All authors declare that there are no conflicts of interest.

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Saxon Epidemiological Study in General Practice - 6 (SESAM-6) - Protocol of a cross-sectional study

[Sächsische Epidemiologische Studie in der Allgemeinmedizin - 6 (SESAM-6) – Studienprotokoll einer Querschnittsstudie]

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ABSTRACT

Introduction:

General practitioners (GP) are mostly the first point of contact for patients with health problems in Germany. There is only a limited epidemiologic overview data that describes the GP consultation hours based on other than billing data. Therefore, the aim of SESAM-6 is to examine the frequencies of reasons for encounter, prevalence of long-term diagnosed diseases, and diagnostic and therapeutic decisions in general practice. This knowledge is fundamental to identify the health care needs and to develop strategies to improve the GP care. The results of the study will be incorporated into the undergraduate, postgraduate and continuing medical education for GP.

Methods and analysis:

This cross-sectional study SESAM-6 is conducted in general practices in the state of Saxony, Germany. The study design is based on previous SESAM studies. Participating physicians are assigned to one week per quarter (over a survey period of 12 months) in which every fifth doctor-patient contact is recorded for one half of the day (morning or afternoon). To facilitate valid statements, a minimum of 50 GP is required to document a total of at least 2500 doctor-

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patient contacts. Univariable, multivariable and subgroup analyses as well as comparisons to the previous SESAM data sets will be conducted.

Ethics and dissemination:

The study was approved by the Ethics Committee of the Technical University of Dresden in March 2023 (SR-EK-7502023). Participation in the study is voluntary and will not be remunerated. The study results will be published in peer-reviewed scientific journals, preferably with open access. They will also be disseminated at scientific and public symposia, congresses, and conferences. A final report will be published to summarise the central results and provided to all study participants and the public.

Strengths and weaknesses of this study:

- *12-month study period* to capture the reality of GP consultation hours (incl. epidemiological data) considering seasonal influences
- *Randomised survey times* to avoid confounding based on predetermined practice procedures
- *Longitudinal comparison with previous SESAM studies* to demonstrate trends in GP activity over the last 20 years
- *Generalisability* of the results is partly limited due to the regional data collection in the state of Saxony, Germany
- *Data collection* direct after the consultation might be challenging in GPs everyday practice

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1. Introduction

As the first point of contact for health problems of all kinds, general practitioners (GP) provide primary care for the population in Germany. In Germany, services listed in the health insurance benefit catalogue and provided by a registered GP are covered for patients with statutory health insurance (ca. 90% of patients). Although it is recommended to consult a GP first, free access to other specialists is also available. In Germany, 82% of adults were treated at least once by a GP in 2019-2020 [1]. The patient population of the GP is unselected and includes people of all ages and social classes. The scope of general practice includes the prevention, detection, treatment and rehabilitation of diseases as well as the maintenance and promotion of health [2].

The usual episode of care in general practice includes the reasons for encounter (RFE) and the diagnostic and therapeutic decisions, which does not necessarily include a confirmed diagnosis based on ICD-10 (International Statistiscal Classification of Diseases and Related Health Problems). The RFE refer usually a specific patient concern and describe the symptoms presented by the patient, usually not using medical terms and documented using ICPC-codes (International Classification of Primary Care). In contrast, the resulting diagnosis of the presented problem is documented in medical terms (ICD-10) and defined by the GP [3]. Internationally and in Germany, the most common RFE in general practice are headache, abdominal and back pain, respiratory complaints (i.e. coughs) and fever [4–10]. The RFE determines the content of consultation and the consultation decision. The most common contents of consultations in general practice in Germany and internationally are hypertension, diabetes, myalgia or bronchitis [7, 8, 10, 11]. Discussions about test results, medication-related consultations as well as psychosocial problems and lifestyle issues complement the spectrum of consultation contents in the general practice [3, 4, 10–12]. The consultation decisions include referrals to further specialists, therapeutic measures, prescription of medication and watchful waiting.

The Saxon Epidemiological Studies in General Practice (Sächsische Epidemiologische Studie in der Allgemeinmedizin: SESAM) were designed to collect data in general practices in Saxony. The SESAM studies 1 (1996-1997), 2 (1999-2000) and 4 (2008-2009) examined consultation hours and the SESAM 3 (2009) and 5 (2014-2015) examined home visits. Consultation hours only refer to the actual GP-patient contact, not the GP's administrative tasks that occur during

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consultation hours. The SESAM studies focus on the frequency of RFE, the prevalence of long-term diagnoses, the diagnostic and therapeutic decisions [13–21]. The present SESAM-6 study is intended to study the consultation hours of general practitioners in Saxony and to address the following research questions:

- What are the most common RFE in general practice?
- How do the RFE differ according to patient demographic characteristics such as age, gender and size of municipality?
- What is the prevalence of known long-term conditions in general practice?
- What diagnostic and therapeutic actions and decisions are made by GP?

The SESAM-6 study is conducted to provide up-to-date data and evidence for GP practice in Germany. The previous SESAM studies 2 and 4 are the only published studies that have investigated consultation hours and RFE in GP practice in Germany. The CONTENT study (2008-2010) provides an overview of the ICPC-2 coded RFE in Germany [10, 22]. Further comparable studies include the BEACH provides data about GP activity in Australia from 1998 till 2016 [23] and the National Ambulatory Medical Care Survey (NAMCS) that provides annual data about patient visits to physicians in the USA [24, 25]. The NatMedCa Survey describes the primary health care in New Zealand [26], another study examined the RFE managed by GP in China [27]. Another Australian study (ReCEnT) focus on encounters of medical residents and patients [28]. The SESAM-6 study enables an international comparison of GP activity between Germany and other countries and allows global trends to be identified.

RFE describe the reality of care in general practice more accurately than health insurance data or billing data that only depict confirmed diagnoses and do not directly reflect the episodes of care in general practice. Evidence regarding the frequencies of RFE, prevalence of long-term diagnosed diseases, and diagnostic and therapeutic decisions is fundamental for identifying health care needs and to develop strategies to improve GP care in Saxony and also for the demand planning for the German healthcare system.

The results of SESAM-6 will be incorporated into the undergraduate, postgraduate and continuing medical education for GP. The evidence is also needed to plan studies in primary care. In addition, potential changes in GP practice over the last 20 years can be made visible through comparisons with previous SESAM studies. Besides, examining the reality of care in

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Saxony and the corresponding workload of the GPs will provide a basis for professional policy discussions, e.g. for the distribution of remuneration.

2. Methods and analyses

The SESAM-6 study is being carried out in general practices in Saxony, Germany. It is a cooperative project between the general practice departments of the Technical University of Dresden (TU Dresden), the University of Leipzig and the Martin Luther University Halle-Wittenberg.

2.1. Study design

SESAM-6 is a cross-sectional study. The study was designed in collaboration with the Saxon Society for General Practice (SGAM e. V.) and its Scientific Advisory Board. The study design is based on the previous SESAM studies (SESAM-2 [13] and SESAM-4 [17]), which also investigated the consultation hours of general practitioners in Saxony. As part of the study, GP will participate for 12 months (October 2023 - September 2024) and document the consultations for one week per quarter (∑4 weeks per GP). The consultation of every fifth doctor-patient contact will be recorded using the patient documentation form. The study will be conducted on half days (either in the morning or afternoon) on the selected recording days. The study weeks allocated to a physician and the corresponding half days were randomised by the study team prior to the start of the study. Randomization was performed using a random number generator[1]. If the participating GP will be absent during the recording period (vacation, illness, etc.), the next possible week will be documented. Half days were not randomised if the participating GP only work half days.

Only actual doctor-patient contacts during consultation hours (including video and telephone consultations) will be documented. Patients who come to the GP practice without any doctor-patient contact, e.g. for a prescription, a blood sample or similar, will be excluded from the documentation. Home visits will also not be recorded. Each patient can only be documented once in the study. To avoid duplication, the participating physicians keep an internal patient list or note the recording of patients in the practice software. There are no further exclusion criteria. At the start of the study, the participating physicians receive an individual document

[1] https://www.zinsen-berechnen.de/zufallszahlen.php

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from the study team with their respective recording periods. Additionally, the study team contacts the physicians one week prior to the recording period to remind them.

2.2. Expected results

The main outcomes of the study are the frequency of RFE and the resulting decisions and actions. In addition, an overview of the spectrum and prevalence of chronic diseases in GP practices will be given. Structural characteristics of the physicians (age, gender, size of municipality) will be recorded to allow analysis of group differences. Comparison with previous SESAM studies will facilitate longitudinal analysis, identifying changes in GP activity over the last 20 years.

2.3. Pretest

In June 2023, a 3-week pretest phase of the study was conducted with general practitioners in Saxony-Anhalt (the federal state directly neighbouring the main study region of Saxony). This preliminary study was conducted by the Institute of General Practice at Martin Luther University Halle-Wittenberg (Saxony-Anhalt). The pretest simulated the planned study procedure and included all the study documents (1. physician documentation form to record the characteristics of the participating practices and GP; 2. patient documentation form to record the respective consultation). Nine GP were recruited for the pretest, but only five took part (3 female, 2 male; mean age = 48 years). The pretest was used to check the feasibility of the study design including randomization of the survey periods and the implementation of the study procedure in everyday practice, as well as the content and comprehensibility of the questionnaires.

The participating physicians were allocated a study week and the time of the day (morning or afternoon) for collecting patient data for every fifth doctor-patient contact within the allocated recording period. For the pretest, the following question was added to the physician questionnaire and the patient documentation form: "What comments do you have about the questionnaire or the study design?". In addition, five semi-structured telephone interviews (duration approx. 30 minutes) were conducted with the participating GP to record any problems with the study implementation.

The GP reported that the time required was generally acceptable (2-3 minutes for each questionnaire). Only the listing of long-term diagnoses was found to be rather time-

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consuming. Nevertheless, the study team decided to include the long-term diagnoses listed as ICPC, as the ICD coding is not exhaustive enough. The pretest led to minor changes in the documentation forms: “Rehabilitation” was added under “Regulation(s)” and a field “Other” was added under “Therapy”. The “new long-term” and “acute” medication was specified in the instructions and it was added that the information on the number of patients in the practice who are older than 65 years is sufficient as an estimate.

The obtained data were used to review and revise the study procedures and materials. The pretests confirmed the feasibility of the study design for everyday GP practice.

2.4. Case number calculation

In the previous study SESAM-2, 209 participating GPs documented about 8877 doctor-patient contacts [14], and in SESAM-4, 73 GPs documented 2529 doctor-patient contacts [29]. In order to allow longitudinal analyses, SESAM-6 aims to have a similar minimum number of cases as SESAM-4. Due to the modified study design in SESAM-6, a recruitment target of at least 50 GPs is required. Each of them should document about 75 doctor-patient contacts, so that a total number of at least 3750 doctor-patient contacts can be achieved. Approximately 25% of the 3750 doctor-patient contacts are imputed for missing values and unpredictable events, aiming a complete and analyzable data set of 2800 doctor-patient contacts in total.

2.5. Recruitment

The SESAM-6 study was first presented to the members of SGAM e.V. via newsletter in March 2023. In the following months, the study was promoted at events organised by TU Dresden and at the annual SGAM congress for GP of the region. An additional joint letter campaign by TU Dresden and Leipzig University reached around 2,700 GP in Saxony. With reference to this letter campaign, a reminder was sent out in August 2023. In addition, further physicians were invited word of mouth. The criterion for participation in the SESAM-6 study is working as a GP in Saxony. In Germany, physicians who work as a GP are specialized in internal/general medicine or general practice/family medicine. Physicians in advanced training in general medicine or internal medicine, who are working in a GP practice, are also admitted to participate in the study. The study allows for the participation of several physicians from GP practices. If several GP from one GP practice take part in the study, each GP will receive personalised study documents and individual randomised study weeks. There are no further exclusion criteria.

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Following the recruitment measures, a total of 119 physicians were enrolled in the study, which started in October 2023. This equals to a response rate of approximately 4.4% based on the ca. 2700 GP who were contacted by post. Prior to the start of the study, the participating physicians received their personalised study documents by mail from the study team: document with randomised four survey weeks in each quarter of the next 12 months, as well as a physician ID, a brief explanation of the study, instructions for the questionnaire, a patient list and two patient documentation forms to serve as a backup for the digital patient documentation form. Two voluntary, digital training sessions in September 2023 were scheduled to inform the participating GP about the study procedures and study documents and to allow discussion regarding the study. 27 GP have participated in the digital training session.

2.6. Data collection

Physician documentation form

GP were instructed to complete the physician documentation form before the start of the study, which collected sociodemographic characteristics and practice characteristics (gender, age, size of municipality[2]). The questionnaire can be found in appendix 1. Questionnaire is based on the physician questionnaire of the SESAM-5 study and was revised for the SESAM-6 study by the study team with the support of the SGAM Scientific Advisory Board and based on the results of the pretest.

Patient documentation form

The patient documentation form is completed by the GP after the consultation with the respective patient. The patient documentation form records the patient's sociodemographic characteristics (gender, age group, familiarity with the patient) and the reason for the encounter, diagnosis and medical decisions made (referral to a specialist, inpatient referral, watchful waiting). The questionnaire can be found in appendix 2.

The respective questionnaires are completed digitally using the free and open source online statistical survey web app LimeSurvey (provided by Bildungsportal Sachsen GmbH). Once the

[2] A rural municipality is defined as a municipality with a population of less than 5000, while towns with a population of between 5000 and 20.000 are referred to as small towns. Between 20.000 and 100.000 inhabitants are medium-sized towns and towns with more than 100.000 inhabitants are called large towns.

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patient´s data have been entered online, they are immediately available to the study team. If digital processing of the questionnaires by the GP is not possible, the questionnaires can be completed in paper form (for this case, GP have respective examples in their documents). Paper questionnaires will be sent by post to the study team at the TU Dresden at the end of the data collection week and subsequently digitised.

2.7. Data management

Data management is carried out by the TU Dresden study team. The data from the incoming patient documentation forms are exported quarterly by LimeSurvey during the 12-month data collection period and initially checked for plausibility. At the end of the data collection period, the final data set is checked for plausibility using a project-specific syntax.

Subsequent coding of the RFEs and results will be performed by the study team (2 coders independent of each other) based on the coding from SESAM-2 and SESAM-4. The RFEs are coded according to the ICPC-2 (International Classification of Primary Care) [30]. Consultation results and long-term diagnoses are coded using the ICD-10 classification [31]. This approach allows comparability with the previous SESAM studies and the possibility of excluding individual medical coding habits as a source of error.

2.8. Statistical analysis

Data will first analysed using IBM SPSS Statistics (version 29.0 or later). The frequencies and distribution of RFE, chronic diseases, diagnostic and therapeutic decisions will be analysed and presented descriptively. The distribution of the data will be tested for significance using a Shapiro-Wilk test or Anderson Darling test. Group-specific differences in mean values of metric data (such as age) will be tested for significance using a t-test for independent samples. Group-specific differences in means of ordinal scaled data (such as size of municipality) will be tested for significance with a chi²-test. Group-specific differences in means between more than 3 groups will be calculated with a one-factor analysis of variance (ANOVA). Linear regression models will be used to determine associations between two metric variables whereas multiple regression models will be used to explain relations between more than two variables. To explain changes compared to previous SESAM datasets a chi²-test will be used. Cofactors (such as age, gender or size of municipality) will be considered based on the existing

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literature and adjusted for depending of data level, data distribution and the employed test method.

Further topic-specific analyses are carried out in the form of doctorates in order to promote young scientists.

2.9. Patient and Public Involvement

None

3. Ethics and dissemination

The study was approved by the Ethics Committee of the Technical University of Dresden on March 31, 2023 (SR-EK-7502023). Participation in the study is voluntary and will not be remunerated.

3.1. Data protection

The study is conducted in accordance with the Declaration of Helsinki. The legal basis for the storage and processing of the data is Art. 6 para. 1 and Art. 9 para. 2a EU GDPR. The collection, processing, storage, and analysis of the data is therefore subject to the voluntary consent of the participating GP as part of the declaration of consent prior to participation in the study.

The patient questionnaire is anonymous, as the items contained in the questionnaire do not allow the identification of individual patients. To maintain patient anonymity, identifiers such as patient code and year of birth are not collected. In addition, the anonymity of the patient information is enhanced by the large case number of at least 2800 doctor-patient contacts. As the anonymity is ensured, there is no need for patient consent.

In addition to the patient documentation form, the physician questionnaire collects structural data on GP practices (e.g. type of practice, number of employees, regional allocation, number of invoices). These data relate to the participating GP. The participating GP therefore give their consent to data processing by means of a declaration of consent and have the option of withdrawing their consent at any time. In the event of revocation, the data already collected will be deleted, unless the data have already been processed. In this case, the data processing carried out until the revocation remains lawful.

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The responses to the anonymous patient documentation form and the responses to the personalised physician questionnaires are stored in separate data sets. To answer specific research questions, parts of the data sets are linked together. After completion of the survey, the raw data sets (and later the cleansed data sets) are stored on the computers of the Department of General Practice at the Technical University of Dresden. The computers of the Department of General Practice and the group drive of the Department of General Practice are subject to the security concept of the University of Technology Dresden and the University Hospital Dresden. The relevant data structure is secured by passwords that are only known to the respective authorised project members. The final data sets are transmitted to the cooperating institutes via zip encryption. The computers of the cooperating institutes and their drives are subject to respective security concepts and are protected by passwords that are only known to the respective authorised project staff.

The data collected is used to answer scientific questions in the field of epidemiology and health services research. As longitudinal comparisons and time series analyses are of particular interest, an unlimited storage period is planned.

3.2. Possible risks and benefits

As the study only collects patient-related data on the health status and does not involve medical interventions, there are no associated medical risks for the patients whose data are collected anonymously. Furthermore, there are no risks, impairments, burdens, or disadvantages for physicians to participate in this study. The study-related workload for the participating GP is low and amounts to about 1 hour per survey week. The results of this study will help to improve the evidence based on documentation of GP consultation hours in general practice and the work of GP. Based on the results, training and continuing education for GP can be supplemented with current data from GP practice. The results of the study will also be incorporated into medical education at universities.

3.3. Dissemination plan

The study results will be published in peer-reviewed scientific journals and, where possible, open access. It is also planned to disseminate the results at scientific and public symposia, congresses, and conferences. In the frames of the study, young scientists will be supported to

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write their dissertations as part of the study. A final report on the study will summarise the main findings.

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[30] WONCA International Classification Commitee. Internationale Klassifizierung der medizinischen Primärversorgung ICPC-2 [International Classification of Primary Care ICPC-2]: Ein Codiersystem der Allgemeinmedizin [A coding system for general practice] Wien: Springer-Verlag 2001.
[31] BfArM. ICD-10-GM Version 2024 Systematisches Verzeichnis [CD-10-GM Version 2024 Systematic index]: Internationale statistische Klassifikation der Krankheiten und verwandter Gesundheitsprobleme, 10. Revision, German Modification [International Statistical Classification of Diseases and Related Health Problems]

5. Contributions by the authors

Willy Gräfe conceptualized and wrote the manuscript as the first author.

Lukas Liebig developed the data protection concept, contributed to questionnaire development, study design and pretest evaluation, set up the online questionnaire.

Jeannine Schübel contributed to questionnaire development and study design.

Tobias Deutsch contributed to questionnaire development, study design, pretest evaluation and organized recruitment of GPs.

Markus Bleckwenn contributed to questionnaire development, study design and pretest evaluation.

Antje Bergmann contributed to questionnaire development and study design.

Thomas Frese recruited some of the GPs for the pretest in Saxony-Anhalt. Contributed to questionnaire development and study design.

Christine Brütting recruited some of the GPs for the pretest in Saxony-Anhalt, carried out the pretest and evaluated the interviews conducted. Contributed to questionnaire development and study design.

Henna Riemenschneider is the project coordinator. She contributed to questionnaire development, study design and pretest evaluation.

All authors were involved in the preparation of this manuscript and have critically reviewed it.

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8. Conflicts of interest

All authors declare that there are no conflicts of interest.

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Description of documenting physician and associated medical practice SESAM-6

Study ID _ _ _ _

Gender: Male ☐ Female ☐ diverse ☐

Age (years): _ _

Professional status:
established ☐
employed full-time ☐
employed part-time with _ _ hours per week ☐
other, namely _ ☐

Specialist title:
General medicine ☐
Internal medicine ☐
Doctor in further training ☐
Other: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ☐

Practising as a GP since: _ _ _ _ _ (year)

Type of medical practice:
Individual practice ☐
Joint practice/group practice ☐
Medical care centre (MVZ) ☐
other, namely _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ☐

Total number of medical staff incl. salaried doctors: _ _ _ _

Number of employed non-medical staff:
Total number: _ _ of which are MFA _ _ Nurses and health care assistants _ _

Other, namely: _ _ _ _ _ _ _ _ _ _ + Number (other): _ _

Size of the municipality in which your medical practice is located:

<5000 ☐ 5000-20.000 ☐ 20.001-100.000 ☐ >100.000 ☐

Has at least one of your medical assistants/nurses been trained as a VERAH® and/or NäPaH (care assistant in the GP practice/non-medical practice assistant)?
yes ☐ no ☐ aspired to ☐

Your estimated personal average number of notes per quarter: _ _ _ _

Your personal average number of home visits per week: _ _ _

What is the estimated percentage of patients over 65 years of age in the total patient population? _ _ %

How many nursing home patients per quarter do you care for? _ _ _

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Does your practice delegate the performance of home visits (HB)? *(multiple answers possible)*

no ☐ Yes, to:

- ☐ Doctors in further training
- ☐ Non-medical staff without additional qualifications
- ☐ Non-medical staff with additional qualifications (e.g. VERAH®)
- ☐ Home nursing care
- ☐ other, namely _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

How do you organise home visits in your practice? *(multiple answers possible*)

There are fixed days for HB, namely: ☐

Mo ☐ Tue ☐ Mi ☐ Do ☐ Fri ☐ Sat ☐ So ☐

There are fixed HB times: ☐

in the morning ☐ before midday ☐ midday ☐ in the afternoon ☐ in the evening ☐

according to requirement ☐

Other _ ☐

In which of the SESAM studies mentioned have you already participated?

SESAM-1 ☐ SESAM-2 ☐ SESAM-3 ☐ SESAM-4 ☐ SESAM-5 ☐ at none ☐

Are you ...

Member of SGAM	yes	☐	no	☐
Member of the General Practitioners' Association	yes	☐	no	☐
Teaching practice	yes	☐	no	☐
Research practice	yes	☐	no	☐

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Patient documentation form SESAM-6

Physician ID: ☐

Date of the utilisation: ☐ morning ☐ afternoon ☐

Gender of the patient: male ☐ female ☐ diverse ☐

Age group:
0-4 ☐ 5-9 ☐ 10-14 ☐ 15-18 ☐ 19-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐
51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 85-90 ☐ 91-95 ☐ >95 ☐

Mother tongue: german ☐ other ☐ don't know ☐

Language barrier: present ☐ partially present ☐ not present ☐

Familiarity: patient known ☐ patient new ☐

Scheduling: acute appointment ☐ scheduled appointment ☐

Contact initiation: independent ☐ care service ☐ relatives ☐
control date/routine date ☐ does not know ☐

Type of GP-patient contact: Presence ☐ Phone ☐ Video ☐

Chronically ill: yes ☐ no ☐

Already known .....

long-term diagnoses: .....

.....

.....

.....

Existing prescribed long-term medication: none ☐ 1-3 ☐ >3 ☐

Reasons for encounter: 1 ☐ 2 ☐ 3 ☐ >3 ☐

		known	new
Main reasons for the utilisation	.....	☐	☐
(Reasons for encounter):	.....	☐	☐
	.....	☐	☐

Current new "Diagnosis" .....

(Consultation results): .....

.....

Please turn

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GP diagnostics:

- none ☐
- symptom-related ☐
- wohle-body investigation ☐
- laboratory/PoCT investigation ☐
- long-term RR ☐
- Sono ☐
- ECG ☐
- Long-term ECG ☐
- Check-up ☐
- LuFu ☐
- Other: ..... ☐

Decisions:

- wait-and-see approach ☐
- referral ☐
- inpatient referral ☐
- Re-order
  - long-term ☐
  - short-term ☐
- DMP first prescribed ☐
- DMP following ☐
- Certificate of incapacity for work ☐

Other: ☐

.....

Therapy in practice:

- Surgical measures ☐
- Vaccination ☐
- psychosom. primary care ☐
- Counselling ☐

Other: .....

Regulation(s):

- medication
  - leave ☐
  - changed ☐
  - cancelled ☐
  - new - acute therapy ☐
  - new - long-term medication ☐
- Physiotherapy ☐
- Occupational therapy ☐
- Speech therapy ☐
- Podiatry ☐
- Aids ☐
- Home nursing care ☐
- Rehabilitation measures ☐
- ÜW Psychotherapy ☐
- Other: .....

Which long-term medication(s) was (were) newly prescribed today? .....

.....

Which acute medication(s) was (were) newly prescribed today? .....

.....

Duration of GP-patient contact (in min): .....

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Saxon Epidemiological Study in General Practice - 6 (SESAM-6) - Protocol of a cross-sectional study

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Saxon Epidemiological Study in General Practice - 6 (SESAM-6) - Protocol of a cross-sectional study

[Sächsische Epidemiologische Studie in der Allgemeinmedizin - 6 (SESAM-6) – Studienprotokoll einer Querschnittsstudie]

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ABSTRACT

Introduction:

General practitioners (GP) are mostly the first point of contact for patients with health problems in Germany. There is only a limited epidemiologic overview data that describes the GP consultation hours based on other than billing data. Therefore, the aim of SESAM-6 is to examine the frequencies of reasons for encounter, prevalence of long-term diagnosed diseases, and diagnostic and therapeutic decisions in general practice. This knowledge is fundamental to identify the health care needs and to develop strategies to improve the GP care. The results of the study will be incorporated into the undergraduate, postgraduate and continuing medical education for GP.

Methods and analysis:

This cross-sectional study SESAM-6 is conducted in general practices in the state of Saxony, Germany. The study design is based on previous SESAM studies. Participating physicians are assigned to one week per quarter (over a survey period of 12 months) in which every fifth doctor-patient contact is recorded for one half of the day (morning or afternoon). To facilitate valid statements, a minimum of 50 GP is required to document a total of at least 2500 doctor-

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patient contacts. Univariable, multivariable and subgroup analyses as well as comparisons to the previous SESAM data sets will be conducted.

Ethics and dissemination:

The study was approved by the Ethics Committee of the Technical University of Dresden in March 2023 (SR-EK-7502023). Participation in the study is voluntary and will not be remunerated. The study results will be published in peer-reviewed scientific journals, preferably with open access. They will also be disseminated at scientific and public symposia, congresses, and conferences. A final report will be published to summarise the central results and provided to all study participants and the public.

Strengths and weaknesses of this study:

- *12-month study period* to capture the reality of GP consultation hours (incl. epidemiological data) considering seasonal influences
- *Randomised survey times* to avoid confounding based on predetermined practice procedures
- *Longitudinal comparison with previous SESAM studies* to demonstrate trends in GP activity over the last 20 years
- *Generalisability* of the results is partly limited due to the regional data collection in the state of Saxony, Germany
- *Data collection* direct after the consultation might be challenging in GPs everyday practice

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1. Introduction

As the first point of contact for health problems of all kinds, general practitioners (GP) provide primary care for the population in Germany. In Germany, services listed in the health insurance benefit catalogue and services provided by a registered GP are covered for patients with statutory health insurance (ca. 90% of patients). Although it is recommended to consult a GP first, free access to other specialists is also available. In Germany, 82% of adults were treated at least once by a GP in 2019-2020 [1]. The patient population of the GP is unselected and includes people of all ages and social classes. The scope of general practice includes the prevention, detection, treatment and rehabilitation of diseases as well as the maintenance and promotion of health [2].

The usual episode of care in general practice includes the reasons for encounter (RFE) and the diagnostic and therapeutic decisions, which does not necessarily include a confirmed diagnosis based on ICD-10 (International Statistiscal Classification of Diseases and Related Health Problems). The RFE refer usually a specific patient concern and describe the symptoms presented by the patient, usually not using medical terms and documented using ICPC-codes (International Classification of Primary Care). In contrast, the resulting diagnosis of the presented problem is documented in medical terms (ICD-10) and defined by the GP [3]. Internationally and in Germany, the most common RFE in general practice are headache, abdominal and back pain, respiratory complaints (i.e. coughs) and fever [4–10]. The RFE determines the content of consultation and the consultation decision. The most common contents of consultations in general practice in Germany and internationally are hypertension, diabetes, myalgia or bronchitis [7, 8, 10, 11]. Discussions about test results, medication-related consultations as well as psychosocial problems and lifestyle issues complement the spectrum of consultation contents in the general practice [3, 4, 10–12]. The consultation decisions include referrals to further specialists, therapeutic measures, prescription of medication and watchful waiting.

The Saxon Epidemiological Studies in General Practice (Sächsische Epidemiologische Studie in der Allgemeinmedizin: SESAM) were designed to collect data in general practices in Saxony. The SESAM studies 1 (1996-1997), 2 (1999-2000) and 4 (2008-2009) examined consultation hours and the SESAM 3 (2009) and 5 (2014-2015) examined home visits. Consultation hours only refer to the actual GP-patient contact, not the GP's administrative tasks that occur during

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consultation hours. The SESAM studies focus on the frequency of RFE, the prevalence of long-term diagnoses, the diagnostic and therapeutic decisions [13–21]. The present SESAM-6 study is intended to study the consultation hours of general practitioners in Saxony and to address the following research questions:

- What are the most common RFE in general practice?
- How do the RFE differ according to patient demographic characteristics such as age, gender and size of municipality?
- What is the prevalence of known long-term conditions in general practice?
- What diagnostic and therapeutic actions and decisions are made by GP?

The SESAM-6 study is conducted to provide up-to-date data and evidence for GP practice in Germany. The previous SESAM studies 2 and 4 are the only published studies that have investigated consultation hours and RFE in GP practice in Germany. The CONTENT study (2008-2010) provides an overview of the ICPC-2 coded RFE in Germany [10, 22]. Further comparable studies are the BEACH study, which provides data about GP activity in Australia from 1998 till 2016 [23] and the National Ambulatory Medical Care Survey (NAMCS) that provides annual data about patient visits to physicians in the USA [24, 25]. The NatMedCa Survey describes the primary health care in New Zealand [26], and another study examined the RFE managed by GP in China [27]. Another Australian study (ReCEnT) focus on encounters of medical residents and patients [28]. The SESAM-6 study enables an international comparison of GP activity between Germany and other countries and allows global trends to be identified.

RFE describe the reality of care in general practice more accurately than health insurance data or billing data that only depict confirmed diagnoses and do not directly reflect the episodes of care in general practice. Evidence regarding the frequencies of RFE, prevalence of long-term diagnosed diseases, and diagnostic and therapeutic decisions is fundamental for identifying health care needs and to develop strategies to improve GP care in Saxony and also for the demand planning for the German healthcare system.

The results of SESAM-6 will be incorporated into the undergraduate, postgraduate and continuing medical education for GP. The evidence is also needed to plan studies in primary care. In addition, potential changes in GP practice over the last 20 years can be made visible through comparisons with previous SESAM studies. Besides, examining the reality of care in

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Saxony and the corresponding workload of the GPs will provide a basis for professional policy discussions, e.g. for the distribution of remuneration.

2. Methods and analyses

The SESAM-6 study is being carried out in general practices in Saxony, Germany. It is a cooperative project between the general practice departments of the Technical University of Dresden (TU Dresden), the University of Leipzig and the Martin Luther University Halle-Wittenberg.

2.1. Study design

SESAM-6 is a cross-sectional study. The study was designed in collaboration with the Saxon Society for General Practice (SGAM e. V.) and its Scientific Advisory Board. The study design is based on the previous SESAM studies (SESAM-2 [13] and SESAM-4 [17]), which also investigated the consultation hours of general practitioners in Saxony. As part of the study, GP will participate for 12 months (October 2023 - September 2024) and document the consultations for one week per quarter (∑4 weeks per GP). The consultation of every fifth doctor-patient contact will be recorded using the patient documentation form. The study will be conducted on half days (either in the morning or afternoon) on the selected recording days. The study weeks allocated to a physician and the corresponding half days were randomised by the study team prior to the start of the study. Randomization was performed using a random number generator[1]. If the participating GP will be absent during the recording period (vacation, illness, etc.), the next possible week will be documented. Half days were not randomised if the participating GP only work half days.

Only actual doctor-patient contacts during consultation hours (including video and telephone consultations) will be documented. Patients who come to the GP practice without any doctor-patient contact, e.g. for a prescription, a blood sample or similar, will be excluded from the documentation. Home visits will also not be recorded. Each patient can only be documented once in the study. To avoid duplication, the participating physicians keep an internal patient list or note the recording of patients in the practice software. There are no further exclusion criteria. At the start of the study, the participating physicians receive an individual document

[1] https://www.zinsen-berechnen.de/zufallszahlen.php

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from the study team with their respective recording periods. Additionally, the study team contacts the physicians one week prior to the recording period to remind them.

2.2. Expected results

The main outcomes of the study are the frequency of RFE and the resulting decisions and actions. In addition, an overview of the spectrum and prevalence of chronic diseases in GP practices will be given. Structural characteristics of the physicians (age, gender, size of municipality) will be recorded to allow analysis of group differences. Comparison with previous SESAM studies will facilitate longitudinal analysis, identifying changes in GP activity over the last 20 years.

2.3. Pretest

In June 2023, a 3-week pretest phase of the study was conducted with general practitioners in Saxony-Anhalt (the federal state directly neighbouring the main study region of Saxony). This preliminary study was conducted by the Institute of General Practice at Martin Luther University Halle-Wittenberg (Saxony-Anhalt). The pretest simulated the planned study procedure and included all the study documents (1. physician documentation form to record the characteristics of the participating practices and GP; 2. patient documentation form to record the respective consultation). Nine GP were recruited for the pretest, but only five took part (3 female, 2 male; mean age = 48 years). The pretest was used to check the feasibility of the study design including randomization of the survey periods and the implementation of the study procedure in everyday practice, as well as the content and comprehensibility of the questionnaires.

The participating physicians were allocated a study week and the time of the day (morning or afternoon) for collecting patient data for every fifth doctor-patient contact within the allocated recording period. For the pretest, the following question was added to the physician questionnaire and the patient documentation form: "What comments do you have about the questionnaire or the study design?". In addition, five semi-structured telephone interviews (duration approx. 30 minutes) were conducted with the participating GP to record any problems with the study implementation.

The GP reported that the time required was generally acceptable (2-3 minutes for each questionnaire). Only the listing of long-term diagnoses was found to be rather time-

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consuming. Nevertheless, the study team decided to include the long-term diagnoses listed in their own words, as the ICD coding is not exhaustive enough. The pretest led to minor changes in the documentation forms: “Rehabilitation” was added under “Regulation(s)” and a field “Other” was added under “Therapy”. The “new long-term” and “acute” medication was specified in the instructions and it was added that the information on the number of patients in the practice who are older than 65 years is sufficient as an estimate.

The obtained data were used to review and revise the study procedures and materials. The pretests confirmed the feasibility of the study design for everyday GP practice.

2.4. Case number calculation

In the previous study SESAM-2, 209 participating GPs documented about 8877 doctor-patient contacts [14], and in SESAM-4, 73 GPs documented 2529 doctor-patient contacts [29]. In order to allow longitudinal analyses, SESAM-6 aims to have a similar minimum number of cases as SESAM-4. Due to the modified study design in SESAM-6, a recruitment target of at least 50 GPs is required. Each of them should document about 75 doctor-patient contacts, so that a total number of at least 3750 doctor-patient contacts can be achieved. Approximately 25% of the 3750 doctor-patient contacts are imputed for missing values and unpredictable events, aiming a complete and analyzable data set of 2800 doctor-patient contacts in total.

2.5. Recruitment

The SESAM-6 study was first presented to the members of SGAM e.V. via newsletter in March 2023. In the following months, the study was promoted at events organised by TU Dresden and at the annual SGAM congress for GP of the region. An additional joint letter campaign by TU Dresden and Leipzig University reached 2678 GP in Saxony. With reference to this letter campaign, a reminder was sent out in August 2023. In addition, further physicians were invited word of mouth. The criterion for participation in the SESAM-6 study is working as a GP in Saxony. In Germany, physicians who work as a GP are specialized in internal/general medicine or general practice/family medicine. Physicians in advanced training in general medicine or internal medicine, who are working in a GP practice, are also admitted to participate in the study. The study allows for the participation of several physicians from GP practices. If several GP from one GP practice take part in the study, each GP will receive personalised study documents and individual randomised study weeks. There are no further exclusion criteria.

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Following the recruitment measures, a total of 119 physicians were enrolled in the study, which started in October 2023. This equals to a response rate of approximately 4.4% based on the 2678 GP who were contacted by post. This rather low response rate is a limitation of the external validity of the study. However, the number of GP calculated in the case number planning was achieved.

Prior to the start of the study, the participating physicians received their personalised study documents by mail from the study team: document with randomised four survey weeks in each quarter of the next 12 months, as well as a physician ID, a brief explanation of the study, instructions for the questionnaire, a patient list and two patient documentation forms to serve as a backup for the digital patient documentation form. Two voluntary, digital training sessions in September 2023 were scheduled to inform the participating GP about the study procedures and study documents and to allow discussion regarding the study. 27 GP have participated in the digital training session.

2.6. Data collection

Physician documentation form

GP were instructed to complete the physician documentation form before the start of the study, which collected sociodemographic characteristics and practice characteristics (gender, age, size of municipality[2]). The questionnaire can be found in appendix 1. Questionnaire is based on the physician questionnaire of the SESAM-5 study and was revised for the SESAM-6 study by the study team with the support of the SGAM Scientific Advisory Board and based on the results of the pretest.

Patient documentation form

The patient documentation form is completed by the GP after the consultation with the respective patient. The patient documentation form records the patient's sociodemographic characteristics (gender, age group, familiarity with the patient) and the reason for the

[2] A rural municipality is defined as a municipality with a population of less than 5000, while towns with a population between 5000 and 20.000 are referred to as small towns. Between 20.000 and 100.000 inhabitants are medium-sized towns and towns with more than 100.000 inhabitants are called large towns.

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encounter, diagnosis and medical decisions made (referral to a specialist, inpatient referral, watchful waiting). The questionnaire can be found in appendix 2.

The respective questionnaires are completed digitally using the free and open source online statistical survey web app LimeSurvey (provided by Bildungsportal Sachsen GmbH). Once the patient´s data have been entered online, they are immediately available to the study team. If digital processing of the questionnaires by the GP is not possible, the questionnaires can be completed in paper form (for this case, GP have respective examples in their documents). Paper questionnaires will be sent by post to the study team at the TU Dresden at the end of the data collection week and subsequently digitised.

2.7. Data management

Data management is carried out by the TU Dresden study team. The data from the incoming patient documentation forms are exported quarterly by LimeSurvey during the 12-month data collection period and initially checked for plausibility. At the end of the data collection period, the final data set is checked for plausibility using a project-specific syntax.

Subsequent coding of the RFEs and results will be performed by the study team (2 coders independent of each other) based on the coding from SESAM-2 and SESAM-4. The RFEs are coded according to the ICPC-2 (International Classification of Primary Care) [30]. Consultation results and long-term diagnoses are coded using the ICD-10 classification [31]. This approach allows comparability with the previous SESAM studies and the possibility of excluding individual medical coding habits as a source of error.

2.8. Statistical analysis

Data will first analysed using IBM SPSS Statistics (version 29.0 or later). The frequencies and distribution of RFE, chronic diseases, diagnostic and therapeutic decisions will be analysed and presented descriptively. The distribution of the data will be tested for significance using a Shapiro-Wilk test or Anderson Darling test. Group-specific differences in mean values of metric data (such as age) will be tested for significance using a t-test for independent samples. Group-specific differences in means of ordinal scaled data (such as size of municipality) will be tested for significance with a chi²-test. Group-specific differences in means between more than 3 groups will be calculated with a one-factor analysis of variance (ANOVA). Linear regression models will be used to determine associations between two metric variables

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whereas multiple regression models will be used to explain relations between more than two variables. To explain changes compared to previous SESAM datasets a chi²-test will be used. Cofactors (such as age, gender or size of municipality) will be considered based on the existing literature and adjusted for depending of data level, data distribution and the employed test method.

Further topic-specific analyses are carried out in form of doctorates in order to promote young scientists.

2.9. Patient and Public Involvement

None

3. Ethics and dissemination

The study was approved by the Ethics Committee of the Technical University of Dresden on March 31, 2023 (SR-EK-7502023). Participation in the study is voluntary and will not be remunerated.

3.1. Data protection

The study is conducted in accordance with the Declaration of Helsinki. The legal basis for the storage and processing of the data is Art. 6 para. 1 and Art. 9 para. 2a EU GDPR. The collection, processing, storage, and analysis of the data is therefore subject to the voluntary consent of the participating GP as part of the declaration of consent prior to participation in the study.

The patient questionnaire is anonymous, as the items contained in the questionnaire do not allow the identification of individual patients. To maintain patient anonymity, identifiers such as patient code and year of birth are not collected. In addition, the anonymity of the patient information is enhanced by the large case number of at least 2800 doctor-patient contacts. As the anonymity is ensured, there is no need for patient consent.

In addition to the patient documentation form, the physician questionnaire collects structural data on GP practices (e.g. type of practice, number of employees, regional allocation, number of invoices). These data relate to the participating GP. The participating GP therefore give their consent to data processing by means of a declaration of consent and have the option of withdrawing their consent at any time. In the event of revocation, the data already collected

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will be deleted, unless the data have already been processed. In this case, the data processing carried out until the revocation remains lawful.

The responses to the anonymous patient documentation form and the responses to the personalised physician questionnaires are stored in separate data sets. To answer specific research questions, parts of the data sets are linked together. After completion of the survey, the raw data sets (and later the cleansed data sets) are stored on the computers of the Department of General Practice at the Technical University of Dresden. The computers of the Department of General Practice and the group drive of the Department of General Practice are subject to the security concept of the University of Technology Dresden and the University Hospital Dresden. The relevant data structure is secured by passwords that are only known to the respective authorised project members. The final data sets are transmitted to the cooperating institutes via zip encryption. The computers of the cooperating institutes and their drives are subject to respective security concepts and are protected by passwords that are only known to the respective authorised project staff.

The data collected is used to answer scientific questions in the field of epidemiology and health services research. As longitudinal comparisons and time series analyses are of particular interest, an unlimited storage period is planned.

3.2. Possible risks and benefits

As the study only collects patient-related data on the health status and does not involve medical interventions, there are no associated medical risks for the patients whose data are collected anonymously. Furthermore, there are no risks, impairments, burdens, or disadvantages for physicians to participate in this study. The study-related workload for the participating GP is low and amounts to about 1 hour per survey week. The results of this study will help to improve the evidence based on documentation of GP consultation hours in general practice and the work of GP. Based on the results, training and continuing education for GP can be supplemented with current data from GP practice. The results of the study will also be incorporated into medical education at universities.

3.3. Dissemination plan

The study results will be published in peer-reviewed scientific journals and, where possible, open access. It is also planned to disseminate the results at scientific and public symposia,

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congresses, and conferences. In the frames of the study, young scientists will be supported to write their dissertations as part of the study. A final report on the study will summarise the main findings.

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5. Contributions by the authors

Willy Gräfe conceptualized and wrote the manuscript as the first author.

Lukas Liebig developed the data protection concept, contributed to questionnaire development, study design and pretest evaluation, set up the online questionnaire.

Jeannine Schübel contributed to questionnaire development and study design.

Tobias Deutsch contributed to questionnaire development, study design, pretest evaluation and organized recruitment of GPs.

Markus Bleckwenn contributed to questionnaire development, study design and pretest evaluation.

Antje Bergmann contributed to questionnaire development and study design.

Thomas Frese recruited some of the GPs for the pretest in Saxony-Anhalt. Contributed to questionnaire development and study design.

Christine Brütting recruited some of the GPs for the pretest in Saxony-Anhalt, carried out the pretest and evaluated the interviews conducted. Contributed to questionnaire development and study design.

Henna Riemenschneider is the project coordinator. She contributed to questionnaire development, study design and pretest evaluation.

All authors were involved in the preparation of this manuscript and have critically reviewed it.

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8. Conflicts of interest

All authors declare that there are no conflicts of interest.

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Description of documenting physician and associated medical practice SESAM-6

Study ID _ _ _ _

Gender: Male ☐ Female ☐ diverse ☐

Age (years): _ _

Professional status:
established ☐
employed full-time ☐
employed part-time with _ _ hours per week ☐
other, namely _ ☐

Specialist title:
General medicine ☐
Internal medicine ☐
Doctor in further training ☐
Other: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ☐

Practising as a GP since: _ _ _ _ _ (year)

Type of medical practice:
Individual practice ☐
Joint practice/group practice ☐
Medical care centre (MVZ) ☐
other, namely _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ☐

Total number of medical staff incl. salaried doctors: _ _ _ _

Number of employed non-medical staff:
Total number: _ _ of which are MFA _ _ Nurses and health care assistants _ _

Other, namely: _ _ _ _ _ _ _ _ _ _ + Number (other): _ _

Size of the municipality in which your medical practice is located:

<5000 ☐ 5000-20.000 ☐ 20.001-100.000 ☐ >100.000 ☐

Has at least one of your medical assistants/nurses been trained as a VERAH® and/or NäPaH (care assistant in the GP practice/non-medical practice assistant)?
yes ☐ no ☐ aspired to ☐

Your estimated personal average number of notes per quarter: _ _ _ _

Your personal average number of home visits per week: _ _ _

What is the estimated percentage of patients over 65 years of age in the total patient population? _ _ %

How many nursing home patients per quarter do you care for? _ _ _

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Does your practice delegate the performance of home visits (HB)? *(multiple answers possible)*

no ☐ Yes, to:

- ☐ Doctors in further training
- ☐ Non-medical staff without additional qualifications
- ☐ Non-medical staff with additional qualifications (e.g. VERAH®)
- ☐ Home nursing care
- ☐ other, namely _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

How do you organise home visits in your practice? *(multiple answers possible*)

There are fixed days for HB, namely: ☐

Mo ☐ Tue ☐ Mi ☐ Do ☐ Fri ☐ Sat ☐ So ☐

There are fixed HB times: ☐

in the morning ☐ before midday ☐ midday ☐ in the afternoon ☐ in the evening ☐

according to requirement ☐

Other _ ☐

In which of the SESAM studies mentioned have you already participated?

SESAM-1 ☐ SESAM-2 ☐ SESAM-3 ☐ SESAM-4 ☐ SESAM-5 ☐ at none ☐

Are you ...

Member of SGAM	yes	☐	no	☐
Member of the General Practitioners' Association	yes	☐	no	☐
Teaching practice	yes	☐	no	☐
Research practice	yes	☐	no	☐

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Patient documentation form SESAM-6

Physician ID: ☐

Date of the utilisation: ☐ morning ☐ afternoon ☐

Gender of the patient: male ☐ female ☐ diverse ☐

Age group:
0-4 ☐ 5-9 ☐ 10-14 ☐ 15-18 ☐ 19-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐
51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 85-90 ☐ 91-95 ☐ >95 ☐

Mother tongue: german ☐ other ☐ don't know ☐

Language barrier: present ☐ partially present ☐ not present ☐

Familiarity: patient known ☐ patient new ☐

Scheduling: acute appointment ☐ scheduled appointment ☐

Contact initiation: independent ☐ care service ☐ relatives ☐
control date/routine date ☐ does not know ☐

Type of GP-patient contact: Presence ☐ Phone ☐ Video ☐

Chronically ill: yes ☐ no ☐

Already known .....

long-term diagnoses: .....

.....

.....

.....

Existing prescribed long-term medication: none ☐ 1-3 ☐ >3 ☐

Reasons for encounter: 1 ☐ 2 ☐ 3 ☐ >3 ☐

		known	new
Main reasons for the utilisation	.....	☐	☐
(Reasons for encounter):	.....	☐	☐
	.....	☐	☐

Current new "Diagnosis" .....

(Consultation results): .....

.....

Please turn

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GP diagnostics:

- none ☐
- symptom-related ☐
- wohle-body investigation ☐
- laboratory/PoCT investigation ☐
- long-term RR ☐
- Sono ☐
- ECG ☐
- Long-term ECG ☐
- Check-up ☐
- LuFu ☐
- Other: ..... ☐

Decisions:

- wait-and-see approach ☐
- referral ☐
- inpatient referral ☐
- Re-order
  - long-term ☐
  - short-term ☐
- DMP first prescribed ☐
- DMP following ☐
- Certificate of incapacity for work ☐

Other: ☐

.....

Therapy in practice:

- Surgical measures ☐
- Vaccination ☐
- psychosom. primary care ☐
- Counselling ☐

Other: .....

Regulation(s):

- medication
  - leave ☐
  - changed ☐
  - cancelled ☐
  - new - acute therapy ☐
  - new - long-term medication ☐
- Physiotherapy ☐
- Occupational therapy ☐
- Speech therapy ☐
- Podiatry ☐
- Aids ☐
- Home nursing care ☐
- Rehabilitation measures ☐
- ÜW Psychotherapy ☐
- Other: .....

Which long-term medication(s) was (were) newly prescribed today? .....

.....

Which acute medication(s) was (were) newly prescribed today? .....

.....

Duration of GP-patient contact (in min): .....

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