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Regional variation of patient behaviour and reasons for consultation in the general practice of Northern Germany: protocol for an observational study

Ingmar Schäfer, Heike Hansen, Nadine Pohontsch, Laura Bole, Hans-Otto Wagner, Miriam Führ, Dagmar Lühmann, Martin Scherer

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Department of Primary Medical Care, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

Correspondence to
Dr Ingmar Schäfer;
in.schaefer@uke.de

ABSTRACT

Introduction: Inappropriate supply and an increasing demand on the healthcare system have been of concern for health policy in Germany for at least 15 years. In the primary care setting, this especially relates to an undersupply of general practitioners (GPs) in the countryside. In addition, there seem to be other regional differences, for example, a difference in accessing primary and secondary care between rural and urban areas. Despite these findings, regional differences in health services have not been studied extensively in Germany. Therefore, this study aims to explore regional variations of patient populations and reasons for accessing primary medical care.

Methods and analysis: We will conduct a cross-sectional observational study based on standardised interviews with 240 GPs and ~1200 patients. Data collection started on 10 June 2015 and will probably be completed by 31 October 2016. We will include all districts and cities within 100 km from Hamburg and assign them according to the type of regions: rural, urban and environs. All eligible GPs will be invited to participate. Each practice will recruit up to 15 patients, aged 18 years or older. Questionnaires are based on a preliminary qualitative study and were pretested. Data will be analysed with descriptive statistics and regression modelling strategies adjusted for confounders and the GP-induced cluster structure.

Ethics and dissemination: Our study was approved by the Ethics Committee of the Medical Association of Hamburg and is conducted in accordance with the Declaration of Helsinki. Study participants give written informed consent before data collection and data is pseudonymised. Survey data and person identifiers are stored separately in locked cabinets and have restricted availability. The results of our study will be presented at conferences and published in peer-reviewed journals.

Trial registration number: NCT02558322; Pre-results.

Strengths and limitations of this study

- Before the study was designed, patients and general practitioners (GPs) have been explored in a large qualitative preliminary study regarding the reasons for consultation and patient types.
- Data are collected from GPs and patients, so that both perspectives are included.
- We cover reasons for consultation such as social or financial problems that are not represented in ICD-based diagnoses and we monitor the complete spectrum of services including services paid in a lump sum or paid privately by the patients.
- The data are only representative for Northern Germany.
- There may be a selection bias in study participants (eg, if elderly patients are more likely to participate in our interviews than younger patients), which will be examined in a non-responder analysis.

BACKGROUND

An inappropriate supply of services and an increasing demand for healthcare have been of concern for the healthcare policy in Germany for at least 15 years. German social legislation binds healthcare providers and users of the German healthcare system to supply needs-based healthcare and to avoid overuse, underuse and misuse. However, in 2001, the Advisory Council for the Concerted Action in Health Care published an expertise, which pointed out a number of issues especially with the organisation and the quality of care provided to patients with chronic illnesses. For example, the care of patients with back pain was characterised by a concurrent overuse of imaging procedures and invasive therapies—and by an underuse of secondary and tertiary preventative measures. At the same time, a 'glaring lack of reliable data on health care, both in the scientific professional societies and in the public bodies and corporations with responsibilities in the health care system', was shown.[1]

With regard to primary care, the current discussion expresses concerns that especially

rural areas are increasingly faced with an undersupply of general practitioners (GPs). This, in turn, is expected to result in a lack of care especially for the elderly and chronically ill patients living in the countryside.[2–4] However there also seem to be other differences in the supply and access to services between rural and urban areas. For example, Voigt *et al*[5] found that in metropolitan areas such as Hamburg the number of house calls is lower when compared with the countryside. This may be explained either by the practices being closer to the patients or by the lower average age of the inhabitants of large cities.[6] Patients living in rural areas seem to expect a greater spectrum of services offered by their GP,[7] possibly because of problems regarding the unavailability of specialists such as paediatricians, gynaecologists, ophthalmologists, neurologists or orthopaedic surgeons in the countryside.[8] Probably, there are also differences regarding the reasons for consultation between rural and urban districts, for example, it seems that service providers in larger cities face a greater number of psychiatric (co)morbidities compared with the countryside,[9] and the frequency of consultations in both, primary and secondary care, might also differ between regions.[10]

Until now, the differences between rural and urban regions in the German primary healthcare have not been studied extensively. Many studies are based on qualitative data, have small sample sizes or include either only urban or only rural areas and, therefore, lack the option of regional comparisons. Other studies analysed insurance claims data, which contain little information on sociodemographic data or other patient-related factors. Furthermore, there are considerable doubts concerning the validity of claims data, especially regarding the coded diagnoses.[11–12] Therefore, this study aims to explore the variation in patient behaviour and to describe regional differences regarding the reason for consultations in general practice by collecting quantitative data directly from GPs and their patients in rural and urban areas. Primary outcome measures are (1) the variety of reasons for consultation and practices in GP services, (2) the number of contacts per patient with GPs and specialists and (3) the tendency to have direct contacts with specialists without consulting the GP first. Furthermore, the study will include descriptive information about the personal and professional background of the GP, the patient population from the GPs' perspective, characteristics and service spectrum of the practice, sociodemographic data, medical history, psychosocial burden and health behaviour of the patient, access to the GP and other healthcare providers, reasons for consultation of the GP and services used in the GP practice.

METHODS AND ANALYSIS

Preliminary qualitative study

The main study started in May 2015 and will probably be completed in October 2016 (see section 'Main study' below). Before designing this study, we conducted focus groups with patients and GPs from 17 districts and cities in Northern Germany in order to explore the patient types, reasons for consultation and accessed services in GP practices. The sample was stratified by region type (ie, urban, rural, environs) and—in case of patient focus groups—by the age group (ie, the age group '18–49 years old' and the age group '50 years and older', respectively). For GP and patient recruitment we contacted all eligible GPs in the respective regions by letter and invited them to participate in our study. Patients were recruited by the participating GPs. In total, 9 focus groups with 65 GPs and 18 focus groups with 145 patients were conducted between the 14th of May and the 4th of December 2014. Each focus group was based on an interview guide and led by at least two scientists. They lasted ~120 min and were digitally recorded. Recordings were transcribed verbatim and analysed using the qualitative content analysis according to Mayring.[13] Three scientists (NP, HH and IS) read and coded the transcripts independently and the research team discussed the categories afterwards. During the coding process, inductive categories were added as they arose from the material. The final set of categories was determined by consensus.

We extracted frequent reasons for consultation and services utilised by patients from the qualitative data. The categories were discussed in an expert panel of five GPs and two scientists in the field of public health/social science. On the basis of these results, the expert panel developed a short form of the German version of the International Classification of Primary Care (ICPC)[14 15] with 38 different services (eg, vaccinations, patient education or referrals) and 100 consultation reasons (eg, disorders of the upper gastrointestinal tract) in 17 subject areas (eg, digestive system). This instrument will be used in patient and GP interviews.

Furthermore, we derived 27 patient types from the focus groups, which were included as items into the GP questionnaire. They comprised the following:

- Regular patients of the practice (as opposed to patients who consulted the GP only once or only if their regular GP practice is closed)
- Privately insured patients (ie, patients who are insured outside of Germany's statutory health insurance (SHI) system)
- Patients with a chronic illness
- Patients with multimorbidity (ie, at least 2 chronic diseases)
- Patients with substance abuse disorders
- Patients with psychiatric disorders (eg, depression, burnout, anxiety, borderline disorder)
- Patients with dementia
- Patients with somatoform disorders
- Patients with migration background and culturally different disease concepts
- Patients with migration background and communication problems

- Patients with social problems due to poverty/low income
- Patients with other social problems (eg, marital problems, loneliness, workplace bullying)
- Educationally disadvantaged patients with low health literacy
- Struggling single parents
- Minors accompanied by their parents
- Minors who come to consultations on their own
- Senior citizens living on their own without caregivers
- Patients who are caregivers
- Patients regularly needing home visits
- Patients living in a nursing home
- Demanding patients (eg, patients requesting prolonged sick certificates, inappropriate medication or physiotherapy)
- Patients, who come with self-diagnoses via media (eg, internet, magazines, television)
- Patients with poor therapy adherence (eg, regarding medication, lifestyle changes)
- Frequent attenders (ie, at least one consultation per week)
- Patients who regularly make excessive demands on the GP's time
- Patients who proactively consult different GPs because of the same problem
- Patients who proactively consult additional specialists because of the same problem.

Main study

The main study is designed as a cross-sectional observational study based on standardised interviews with 240 GPs, which will be conducted face-to-face or—on the GP's request—by telephone. Additionally, we will conduct standardised telephone interviews with up to 15 patients from each GPs' patient population. GP recruitment has started on 1 May 2015. Subsequently, patient recruitment and data collection started on 10 June 2015. We expect that 1200 patients can be included in the study and that 14 GPs and 70 patients can be interviewed per month. Therefore, we anticipate that the data collection will be completed by 31 October 2016.

GP population and region types

The study is located in Northern Germany. We include all districts and cities ('Landkreise' and 'Kreisfreie Städte') that have at least 20% of their area within a maximum linear distance of 100 km from our study centre in Hamburg. The distance between Hamburg and the other regions was assessed using a map from the German Federal Agency for Cartography and Geodesy.[16] We assigned all districts and cities to three region types: 'urban area', 'environs' (ie, regions with a higher degree of agglomeration than rural areas, but lower than urban municipalities) and 'rural area' according to a map from the German Federal Institute for Research on Building, Urban Affairs and Spatial Development[17] (cf. table 1). In each region type 80 GPs will be recruited. In the major cities, Hamburg and Bremen, the sample size will be further stratified by administrative city districts. In Bremerhaven, Kiel and Lübeck a maximum of two GPs will be recruited per city district. In rural districts, the planned sample size will be stratified by cities with a population of more than 20 000 and the remaining rural area. The prospected sample size in each stratified unit corresponds to its population size in relation to the total population in the respective region type[18–22] (cf. tables 2–4). If the prospected sample size of GPs cannot be reached in some of the districts, we will accept a deviation between the districts within one region type of up to 25%.

Table 1 Assignment of region types

Region types included in the study	Region types of the Federal Institute for Research on Building, Urban Affairs and Spatial Development
Urban area	Urban municipality
Environs	Urbanised district
	Rural district with signs of agglomeration
Rural area	Rural district

Recruitment of GPs

GPs will be selected from the database of the regional Associations of SHI Physicians in the federal states of Bremen, Hamburg, Mecklenburg-Vorpommern, Niedersachsen and Schleswig-Holstein. They will only be included if they participate in the SHI system. All eligible GPs working in each district will be contacted by mail and invited to participate in the study. If more GPs

Table 2 Prospected sample size by districts: urban areas

District	Population	GP sample	Patients contacted
Bremen			
Bremen Mitte	17 637	1	15
Bremen Nord	95 989	3	45
Bremen Ost	221 424	6	90
Bremen Süd	124 120	3	45
Bremen West	89 377	3	45
Bremerhaven	108 844	3	45
Hamburg			
Hamburg Altona	254 354	7	105
Hamburg Bergedorf	120 761	3	45
Hamburg Eimsbüttel	249 239	7	105
Hamburg Harburg	150 209	4	60
Hamburg Mitte	279 206	8	120
Hamburg Nord	283 397	8	120
Hamburg Wandsbek	409 176	11	165
Kiel	241 533	7	105
Lübeck	212 958	6	90

GP, general practitioner.

Table 3 Prospected sample size by districts: environs

District	Population	GP sample	Patients contacted
Harburg	242 871	8	120
Herzogtum lauenburg	189 043	6	90
Neumünster	77 058	2	30
Nordwestmecklenburg	155 265	5	75
Osterholz	110 882	4	60
Ostholstein	197 835	6	90
Pinneberg	301 223	9	135
Plön	126 643	4	60
Rendsburg-Eckernförde	268 075	8	120
Segeberg	263 202	8	120
Schwerin	91 583	3	45
Stade	196 516	6	90
Stormarn	234 674	7	105
Verden	132 459	4	60

GP, general practitioner.

Table 4 Prospected sample size by districts: rural areas

District	Population	GP sample	Patients contacted
Celle			
Celle city	68 508	4	60
Celle rural area	107 044	6	90
Cuxhaven			
Cuxhaven city	48 325	3	45
Geestland	30 411	2	30
Cuxhaven rural area	117 871	6	90
Dithmarschen			
Heide	21 105	1	15
Dithmarschen rural area	111 560	6	90
Heidekreis			
Soltau	21 120	1	15
Walsrode	23 353	1	15
Heidekreis rural area	91 778	5	75
Ludwigslust-Parchim	211 965	11	165
Lüchow-Dannenberg	48 670	3	45
Lüneburg			
Lüneburg city	71 668	4	60
Lüneburg rural area	105 059	6	90
Rotenburg (Wümme)			
Rotenburg (Wümme) city	20 944	1	15
Rotenburg (Wümme) rural area	140 364	8	120
Steinburg			
Itzehoe	31 035	2	30
Steinburg rural area	98 982	5	75
Uelzen			
Uelzen city	33 269	2	30
Uelzen rural area	59 087	3	45

GP, general practitioner.

than needed in a region are willing to participate, GPs of this region will be randomly selected. GPs will be excluded if they do not participate in primary care or if they do not have computer software which is able to create a list of all patients who visited the GP in the past 3 months.

Recruitment of patients

Participating GPs will retrieve a list of all patients aged 18 years or older who have consulted the practice within the past 3 months and who have been patients of that practice for at least 3 years (ie, patients who have consulted the practice at least once before 36 or more months). Patients will be excluded from this list (1) if they have no capacity to consent (eg, because of dementia), (2) if their German language skills are insufficient to conduct the interview or (3) if they cannot participate in interviews (eg, because of deafness or major depression). Out of all eligible patients from this list, 15 patients will be selected at random by the study team (using random number tables) and invited to participate in the study by a letter from their GP. If they are interested in participating, the patients will consult their GP and receive written and oral information about the study. The information covers the aims and procedures of the study, the selection of participants, data collection, processing and storage as well as the possibilities for opting out. Study participants are required to sign an informed consent form to participate in the study. From our experience with similar studies we assume a response rate of 33%. This means that, on average, we expect to include five patients per practice, which would result in a total patient population of 1200. For each practice, the recourse and the number of excluded patients per exclusion criterion will be documented.

Measuring instruments

For both, GP interviews and patient interviews a standardised questionnaire has been developed. The questionnaires are based on the results of the qualitative preliminary study described above and were pretested in two GP practices and in eight patient interviews, respectively. GP interviews will be conducted to assess the personal and professional background of the GP, the characteristics and service spectrum of the practice, how often patients consult the GP practice, and the reasons for consultation and patient types in the practice. The GP questionnaire therefore comprises the following:

- Age, gender, specialty, working time and professional experience of the GP;
- Location, personnel, technical equipment and type of practice (eg, single practice or group practice);
- The service spectrum of the practice (eg, whether the GP conducts sonography or ECG);
- The number of patients treated each quarter (ie, a 3-month period);
- The frequency of the reasons for consultation and the services which patients receive (assessed with the short form of the ICPC developed from the qualitative study described above);

- The frequency of the patient types in the practice from the GPs' perspective (derived from the qualitative study described above).

The patient interviews will be conducted to assess the sociodemographic data, medical history and health behaviour of the patient, access to the GP and other healthcare providers, reasons for consultation of the GP and which services are used in the GP practice. The patient questionnaire includes information on the following:

- Age, gender, education, income, marital status, living conditions, occupational situation, migration status and health insurance of the patient;
- Care level of the patient;
- Health status of the patient, based on a self-developed list of the 42 most prevalent chronic diseases[23] and a depression screening via Patient Health Questionnaire, 9 items version (PHQ-9);[24]
- Health-related quality of life via EuroQoL five dimensions questionnaire (EQ-5D);[25]
- Perceived social support via Fragebogen zur Sozialen Unterstützung; social support questionnaire (F-SOZU) K-14;[26]
- Signs of alcohol misuse via Alcohol Use Disorders Identification Test - Consumption (AUDIT-C);[27]
- Smoking status;
- Utilisation of specialists, general hospitals and rehabilitation hospitals;
- A self-developed instrument to assess the gatekeeping function of the GP;
- Journey time and means of travel to the GP, waiting time for appointments and in the waiting room, duration of consultations, duration of relationship with GP, family members also treated by the GP, satisfaction with practice and treatment by the GP, and use of privately paid services;
- Reasons for consultation and accessed services in GP practice (assessed with the short form of the ICPC described above).

To limit a possible recall bias we will monitor the reasons for consultation and service utilisation of patients in the comparatively narrow time frame of the past 3 months only.

Sample size

Owing to the investigation of multiple outcomes and the observational character of the study, there is no issue of statistical power to be considered. However, a sample of 240 GPs and 1200 patients should allow a valid multivariate data analysis in the heterogeneous general practice population. With regard to the high work load of GPs and possible subsequent problems of GP recruitment, we will take a number of precautions to ensure that we will be able to include the full number of GPs into our study. First, all GPs will receive an adequate expense allowance for interviews and patient recruitment, covering their loss of earnings during study participation. Second, as described above, we will first contact GPs by mail. If GPs do not respond to our letter, we will give two reminders, one by fax and one by telephone call. Third, if all GPs have been contacted three times and we were not able to obtain our prospected sample size of 240 GPs, we will enlarge the study region until the sample size can be reached. The newly included regions will then be equally stratified into districts as described above.

Statistical analysis

Descriptive statistics will be used to explore the characteristics of the GP practices, the GPs and their patient population in the different regions. In addition, the regional variation of patient types from GP interviews and reasons for consultation identified in GP and patient interviews will be presented. The primary outcome measures will be compared in five statistical models. The region types are used as independent variables and will be coded as dummy variables and compare (1) urban and rural regions and (2) urban regions and environs. Dependent variables are (1) the number of categories from the ICPC short form, which are presented to the GP at least once per month; (2) the number of services, which are delivered in the GP practice at least once per month; (3) the number of contacts per patient with GPs; (4) the number of contacts per patient with specialists and (5) the tendency to have direct contacts with specialists without consulting the GP first. Our hypotheses are that (1) GPs from rural areas and environs have a larger variety of reasons for consultation and a larger service spectrum; (2) that patients from rural areas and environs have fewer contacts with GPs and specialists and (3) that patients from rural areas and environs more often show a tendency to visit the GP first before contacts with specialists.

All analyses will be conducted in naïve models without adjustment for confounding and in multivariate models. The multivariate models of analyses (1) and (2) will be adjusted for age, gender and specialty of the GP as well as the type of practice (eg, single or group practice) and the number of treated patients per quarter. The multivariate models of analyses (3), (4) and (5) will be adjusted for age, gender, education, income, occupational situation, migrant status and the morbidity of the patient. For the analyses of data from patient interviews, mixed models will be applied allowing to take the GP-induced cluster structure into account.[28] We will conduct different regression modelling strategies including linear models in the analyses (1) through (4) and logistic models in the analyses (5).[29]

There will also be a number of descriptive analyses, including a comparison of GP and practice characteristics, reasons for consultation and services in the practice, patient types from the GPs' perspective as well as the patients' sociodemographic data, morbidity, health behaviour and healthcare utilisation. Additionally, for each region, the GP and patient data will be compared regarding the identified reasons for consultation, which are measured with the same instrument. We will use two

operationalisations of the rural area in our statistical comparisons: in the first operationalisation the whole district, including cities with a population of more than 20 000 people, will be included. In the second operationalisation we will exclude these cities from the rural area. A possible selection bias in our patient population regarding age and gender will be investigated via a non-responder analysis.

Public registration

On 21 September 2015, the study was registered in a public trial archive (ClinicalTrials.gov study identifier NCT02558322).

DISSEMINATION

The study was approved by the Ethics Committee of the Medical Association of Hamburg. This approval included the preliminary study and the main study. The project is being conducted in accordance with the Declaration of Helsinki. Study participants have to give written informed consent before data collection. All data will be collected on paper and pseudonymised during data collection. Survey data and person identifiers will be stored separately in locked cabinets at the Department of Primary Medical Care at the University Medical Center Hamburg-Eppendorf for 10 years after the end of the study. Person identifiers will be only available to the principal investigator. Survey data will be entered using an optical mark reader and the resulting data set will only be available to the statistician.

Data collection and analysis will be completed 2 years after the start of the main study. We will describe the primary medical care in urban areas, rural areas and environs of Northern Germany and present information on the differences between the regions regarding patient populations and reasons for consultations. The regional variation in German primary care probably has a large variety of reasons,[30] but, at least in part, it might depend on the fact that working in general practices in rural areas is today not very attractive to medical students.[31] For example, the workload of GPs in rural regions might be higher[32] and privacy after the working hours might be more limited.[7] However, other studies also found positive aspects in the working conditions of country doctors, for example, greater flexibility in working hours, the recreational value of the environment[33 34] or a close personal physician–patient relationship.[35]

The results of our study will be presented at scientific conferences in Germany and other countries and published in international and national peer-reviewed journals. All papers will be written in accordance with the 2007 STROBE Statement for cross-sectional observational studies. Our results might help healthcare policymakers and other stakeholders decide how to respond to regional problems in supplying and accessing primary care services, for example, the expected GP shortage in rural areas. Possible strategies include the promotion of primary care in the education of medical students, GP-support by other medical professions or adjusting reimbursement schemes and demand planning by the regional Associations of SHI Physicians in Germany.[2 36–38]

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The study was approved by the Ethics Committee of the Medical Association of Hamburg on 12 August 2013 (approval number PV4535).

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