

BMJ Open How social inequalities impact the course of treatment and care for patients with type 2 diabetes mellitus: study protocol for a qualitative cross-sectional study from the patient's perspective

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ABSTRACT

Introduction: Studies from various scientific disciplines have demonstrated that socioeconomic inequalities in type 2 diabetes mellitus negatively affect groups with a low socioeconomic status. Furthermore, socioeconomic inequalities also exist in terms of access to, and utilisation and perceived quality of, diabetological care. The aim of this qualitative study, which focuses on the patient's perspective, is to provide insights into the ways socioeconomic inequalities impact the course of treatment and care of patients with type 2 diabetes mellitus. The study aims to develop an understanding of how socioeconomic inequalities in care arise.

Methods and analysis: A cross-sectional qualitative study will be conducted using a sample of about 20 patients with type 2 diabetes mellitus aged 18 and older. Patients will be recruited successively from the University Hospital in Halle/Saale, Germany, a general practitioner's office, and in a specialised diabetological practice. The patients will be interviewed personally once, using semistructured qualitative interviews. All interviews will be recorded, transcribed, and analysed based on Grounded Theory.

Ethics and dissemination: All interviewees will receive comprehensive written information about the study and sign a declaration of consent prior to the interview. The study will comply rigorously with data protection legislation. The research team has obtained the approval of the Ethical Review Committee at the MLU Halle-Wittenberg, Germany. The results of the study will be published in high-quality, peer-reviewed international journals, presented at several congresses and used for developing follow-up research projects.

Trial registration number: This study has been registered with the German Clinical Trials Register and assigned DRKS00007847.

INTRODUCTION

Socioeconomic inequality in type 2 diabetes mellitus morbidity and mortality

In Germany, as in all modern societies, type 2 diabetes mellitus has a far-reaching impact

Strengths and limitations of this study

- This cross-sectional qualitative study will explore the impact and role of socioeconomic inequalities from the patient's perspective throughout different stages of treatment and care provision for type 2 diabetes mellitus, a field of study that has previously not been examined comprehensively.
- The study will identify key points in the course of providing healthcare at which the experiences of patients from different socioeconomic backgrounds start to diverge. Thereby, the research will contribute to a more profound understanding and a better explanation of socioeconomic inequalities in healthcare.
- The study's results will help to supplement existing theoretical models of factors that contribute to inequalities in health and healthcare.
- Thanks to the close cooperation of the Department of Internal Medicine II at the University Hospital Halle-Wittenberg and various medical practices, the selection of patients and accessing information from them can proceed without major problems. Since patients may feel inhibited about voicing critical remarks regarding their treatment, information about the study will be provided by a study nurse and a project associate of the Institute of Medical Sociology (IMS) instead of the physician in charge.

on healthcare policies. This is not only due to its high incidence, which amounts to 7–8% of the general population, but also due to an increased mortality rate related mainly to cardiovascular diseases and diabetes-related secondary diseases. Countless medical, sociological and epidemiological studies have successfully demonstrated that socioeconomic inequalities in type 2 diabetes mellitus negatively affect groups with a low socioeconomic status.^{1 2} A Finnish study of patients with type 2 diabetes mellitus showed that the relative risk (RR) of an untimely

death for unemployed male patients (RR=2.58) is more than twice as high as it is among employed patients. The RR amounted to 1.61 for male patients from the two lowest income groups (compared to the two highest). For female patients, the RR of an untimely death is 1.55 for the two lowest income groups (compared to the two highest income-groups). Regarding education, female patients with the lowest level of education have a RR of an untimely death of 1.5 (compared to female patients with the highest level of education).¹ A study conducted in Germany found that the two groups with the lowest level of education were more likely to fall ill with diabetes (OR=1.46) than those with a medium or high level of education, and that the group with the lowest level of income likewise had a higher diabetes morbidity (OR=1.53) compared to the high income group.³

Socioeconomic inequality in access to and utilisation and perceived quality of diabetes care

Although there are relatively clear diagnostic criteria and well-established treatment guidelines, international studies have shown that inequalities exist in relation to access and utilisation, as well as in quality of diabetes care to the disadvantage of patients with low socioeconomic status.⁴⁻⁶ Thus, socially disadvantaged patients not only suffer from a greater health burden, but also from less favourable conditions regarding access and care, regardless of the health system concerned.

In Germany, patients with type 2 diabetes mellitus can participate in a diabetes training programme (called "Diabetesschulung") conducted by a therapeutic team or by a clinic. In this programme, patients with diabetes learn the skills necessary to implement their therapy in everyday life. The training is usually paid for by patients' health insurance, and is therefore available regardless of the patient's income. However, patients with low socioeconomic status participate in this programme less often than those with high socioeconomic status.⁷ Instead, they are treated by a general practitioner as opposed to a specialist.⁸ Knowledge about the impact of social inequalities on the quality of treatment for type 2 diabetes mellitus is fragmented, and research into the subject is sparse. Moreover, most of the time only one single sector of care (eg, rehabilitation) has been analysed.⁴ Studies from Germany suggest that the healthcare received by patients with type 2 diabetes mellitus with a low socioeconomic status differs from the care high socioeconomic status patients get. For example, secondary diseases such as hypertension and hypercholesterolaemia were often not treated appropriately.⁹ Moreover, socially disadvantaged patients are medically examined less often and less thoroughly,^{4 10} and tend to be more susceptible to complications.¹⁰

Required research

Most of the studies that have been conducted have used a quantitative approach, often providing only descriptive results.^{2 4 11} Additionally, even within international

research, only very few studies have looked at the impact and effect of social inequalities throughout the entire course of treatment (acute treatment, rehabilitation, treatment at one's place of residence).^{12 13} These studies neglect to answer questions such as how and when socioeconomic inequalities arise during the treatment process. Subjects and questions such as the patients' perception of diabetes care, why certain groups use health-care services less often or in different ways, and how this affects the quality of diabetes care remain unclear and unanswered. So far, no comprehensive scientific theory of the production of social inequalities in care exists. An explorative qualitative research design that complements quantitative approaches is needed to answer open questions and build a comprehensive theoretical framework.

Qualitative studies that can capture perception of care of patients with type 2 diabetes mellitus, and the range, depth and complexities of their subjective perspectives within their social and cultural context,¹⁴⁻¹⁷ have not yet been conducted in Germany. However, in order to develop a better understanding of the genesis and development of social inequalities in care, profound insights into the patient's perception and experience are needed. Putting the patient's experience at the centre of attention will help to identify when and how the experience of patients belonging to different status groups starts to diverge.

With new insights into the impact of socioeconomic inequalities on care, existing theoretical models of the production of health inequalities can be expanded or concretised. Moreover, knowledge of the causes of inequalities in care is necessary in order to develop measures aiming to improve and ensure equality in care for all patients.

On the basis of the results of this study, further quantitative research can examine any newly formed theories about the socially uneven distribution of factors influencing access to and utilisation and perceived quality of care. Through a multicentric prospective longitudinal study, which will focus explicitly on healthcare across different sectors, these theories will be tested quantitatively. At the same time, the study will examine whether inequalities in care also result in health inequalities.

METHODS AND ANALYSIS

Aims, objectives and research questions

This qualitative study will explore the impact of socioeconomic inequalities on access to and utilisation and perceived quality of healthcare provision for patients with type 2 diabetes mellitus. The study will focus on the perspectives of patients in different sectors of care and will also take into account a patient's previous experiences with the healthcare system. Hence, key points in the course of healthcare provision at which experiences of patients with different socioeconomic backgrounds start to diverge will be identified. The study will thus contribute to a more profound understanding of

socioeconomic inequalities in healthcare and greater insights into these inequalities.

This explorative study will focus on the following research questions:

- ▶ Are socioeconomic inequalities associated with access to and utilisation and perceived quality of healthcare services during the different stages of healthcare for type 2 diabetes mellitus?
- ▶ Can specific factors be identified that act as intermediaries between social inequalities and inequality within healthcare?

Methodological approach

The transcribed interview data will be analysed in accordance with the rules of Grounded Theory, as laid down by Anselm Strauss and Barney Glaser. This qualitative research paradigm aims to develop a theory based closely on or 'grounded in' the compiled data. It aims to reveal the importance of human experience for the discovery of social structures within the process of practical research.^{18 19} It is therefore suitable for capturing subjective experiences of patients with type 2 diabetes mellitus within their own social and cultural contexts and reviewing them with a view to creating an understanding of the perception of patients throughout the process of healthcare.^{17 20}

Study design

An open qualitative approach that aims at discovery instead of hypothesis testing helps to explore the range, depth and complexity of these intermediary factors in the patient's own social and cultural context. The study is therefore being conducted as a single-centre, cross-sectional qualitative study in Halle/Saale, Saxony-Anhalt, Germany, a high-risk area for type 2 diabetes mellitus morbidity.²¹

On the basis of existing theoretical models for the explanation of health inequalities,^{11 22} one can assume that education, income and professional position do not have a direct impact on access to and utilisation and perceived quality of medical care. Rather, one can presuppose that there is a mediating effect of different groups of factors associated with socioeconomic inequalities as well as with healthcare. Initial international studies imply that special significance should be assigned to the patient and his/her psychosocial characteristics (attitude, perceived vulnerability, cultural knowledge and interpretation of symbols, and experiences with the care system).^{13 23}

Sample size

Approximately 20 patients with type 2 diabetes mellitus will be included in this study and interviewed. To cover diverse experiences with access to and utilisation and perceived quality of healthcare provision during the interviews, participants will be recruited in three different sectors of care until theoretical saturation is reached. An overview from Mason *et al*²⁴ of social

research demonstrates that a large part the 560 PhD dissertations in this analysis that used qualitative interviews as their method of data collection reached saturation with 20–30 participants.

Sample selection and recruitment

To ensure that men and women from different socioeconomic groups are represented in each sector of care, a qualitative sampling plan will be used²⁵ and supplemented with theoretical sampling.^{18 26} In keeping with the principles of theoretical sampling, the cases to be examined will not be determined at the beginning of the research project, but instead will be recruited successively during the alternating process of data collection, development of theoretical categories and more data collection. Depending on the current state of category and theory development, a decision will be made as to whether a patient who receives inpatient or outpatient treatment with a high or low socioeconomic status will be interviewed.

The patients' inclusion criteria for participating in the study are

- ▶ Adult patients (18 years and over) with type 2 diabetes mellitus.

The patients' exclusion criteria for participating in the study are:

- ▶ Insufficient language skills to conduct an interview in German.
- ▶ Moribund patients.

The abort criterion is:

- ▶ The patient's withdrawal of consent before or during the interview.

This study is designed as a qualitative, cross-sectional study. Over the course of 6 months, patients with type 2 diabetes mellitus will be recruited in three different care sectors. Within the inpatient sector, patients will be recruited at the Department of Endocrinology and Diabetology at the University Hospital Halle/Saale. Within the outpatient sector, patients will be recruited in a diabetological, specialised medical practice as well as in a general medicine doctor's office. Recruiting patients within three different sectors of healthcare provision allows for a broad, diverse spectrum of persons (different length of sickness, different care stages), as recommended in Grounded Theory.¹⁸ This will ensure that specific and comprehensive statements on healthcare provision can be made later.

In terms of recruitment within the inpatient sector, a study nurse from the Department for Endocrinology and Diabetology at the University Hospital in Halle/Saale will identify patients as possible participants for the study (according to the inclusion criteria). The patients will be informed comprehensively about the study. In the case of written consent, an appointment will be made for the interview. Consequently, the physicians in charge will not be involved directly in the recruitment.

In terms of recruitment within the outpatient sector, physicians and staff of the doctor's offices who have agreed to cooperate will be visited and informed of the study. For their facilities, posters and flyers will be provided requesting support for the study through the patients. These flyers and posters contain compact information about the study as well as the project associate's contact details so interested patients can contact the project team. Where appropriate, the doctors' office staff might also approach possible participants directly and motivate them to get in touch with the project team.

Socioeconomic status

Patients will be assigned to a group with high or low socioeconomic status based on their formal education and occupational training qualification. The classification is based on German epidemiological standards for the measurement and quantification of sociodemographic characteristics in epidemiological studies. (Arbeitsgruppe 'Epidemiologische Methoden' in der DAE der GMDS und der DGSM: 1997) Information on the patient's highest level of schooling and his/her highest occupational training qualification will be reflected on an education scale ranging from 1 to 8. In addition to the level of education, we will also measure the current or last occupation. This will allow us to investigate whether there are any inconsistencies between occupation and education regarding the patient's SES.²⁷ Income will not be considered because it represents a very sensitive personal issue, which is why questions about it often remain unanswered^{28 29} and can disturb the interview.

Data collection

All interviews with patients recruited in the University Hospital will be conducted by the same researcher in a private, undisturbed room in the hospital. In the outpatient sector, the interview will be conducted either on the premises of the IMS, or in the patient's home according to the interviewee's preference. These facilities are expected to encourage the patient to express himself/herself freely regarding potential problems and positive as well as negative experiences with type 2 diabetes-mellitus treatment, without having to worry about possible consequences.

A guideline will be developed for semi-structured qualitative interviews. It will contain open questions and set topics of conversation that will be raised during the interview (without a prescribed order). On the basis of international literature,^{13 23} data on the following topics will be collected during semi-structured, guided interviews:

- ▶ Medical records and current health situation
- ▶ Diagnostic process
- ▶ Previous experiences with physicians and healthcare-sectors
- ▶ Expectations regarding treatment and medical care

- ▶ Needs regarding care, received care and perception of care
- ▶ Obstacles and barriers regarding access to and utilisation of healthcare services
- ▶ Participation in Disease Management Program for type 2 diabetes mellitus
- ▶ Perceived quality of healthcare
- ▶ Attitude towards the healthcare system
- ▶ Physician-patient communication, participatory decision-making
- ▶ Disease management and self-management, ability to take on a role, integration/quality of life
- ▶ Social support
- ▶ Patient's perspective on type 2 diabetes mellitus

Before any data are collected, the interview guide will be pilot tested with a minimum of two patients with type 2 diabetes mellitus.

To measure the patients' socioeconomic status and to gather sociodemographic data, questions about age, sex, nationality, marital status, education, professional qualifications and occupation will be recorded. These data will be gathered subsequent to the interview.

Data analysis

All interviews will be audiorecorded, transcribed and imported into MAXQDA software, which will be used to assist with the data management and analyses. The data will be analysed according to Grounded Theory. During the first phase of "open coding", short, concise and relatively abstract concepts (codes) which characterise the respective segment will be developed. In a second step, "axial coding" will look at a particular category more closely, and relationships between this category and other categories will be assessed. As a third step, "selective coding" will focus on key categories and prepare the following development of a theory. At the same time, relationships and interactions between topics will be examined. The coding scheme, which will emerge during the coding process, will already be developed stepwise simultaneously with the data collection stage. The project associate will conduct the coding, and there will be a continuous exchange between the associate and the head of the project, as well as a presentation of categories and interpretations in the qualitative research group at the IMS. Lastly, the consolidation criteria for reporting qualitative research (COREQ) will be taken into account during the research process to ensure high-quality qualitative research.³⁰

ETHICS AND DISSEMINATION

The IMS has obtained approval for the study from the Ethical Review Committee of the Medical Faculty at MLU, Halle-Wittenberg, and its recommendations for the study have been implemented. The Committee did not express any ethical concerns about the study. The study complies rigorously with data protection legislation, and will be conducted according to the principles

of the Helsinki Declaration, following standards of good scientific practice. All participants will receive an information sheet, which will inform them about the study. They will also be presented with a consent form before the interview is conducted. Participation is voluntary and may be discontinued at any point. There are no consequences for patients who decide not to participate. Consent withdrawal is possible at any time, in which case all relevant data will be deleted. To ensure data protection, each participant will receive an individual identification number for the purposes of pseudonymisation. All data will be collected under this pseudonym. As a result, no individuals or places will risk identification and all personal data will be protected. The name of the interviewee will not be mentioned during the interview to prevent the interviews and transcripts being attributed to any individual. The gathered interview data (record and transcript), personal data (declaration of consent) and the list assigning pseudonyms to individuals will be stored separately in locked locations. The declaration of consent, as well as the pseudonym assignment list, will be accessible only to members of the research team. The pseudonym assignment list will be deleted once data collection has been completed. The possibility that study participants might turn to the project team with questions regarding healthcare and problems will be considered, and appropriate offers of assistance and referrals will be prepared.

The results of the study will be published in high-quality peer-reviewed international journals, and will be presented at several congresses and research conferences. They will also be used for developing a follow-up study that will empirically investigate the theories developed within this research project.

CONCLUSION

By analysing socioeconomic aspects in the course of treatment and care for patients with type 2 diabetes mellitus type 2, this qualitative cross-sectional study will address one of the most urgent questions of clinical care. The patient's perspective on the impact of socioeconomic inequalities on access to quality treatment and care for type 2 diabetes mellitus as well as information on its causes will be addressed for the first time. Likewise, for the first time, different sectors of care will be examined and meaningful findings on socioeconomic risk groups will be provided. By exploring the intermediary factors between inequalities in socioeconomic status and inequalities in healthcare, existing theories about the production of health inequalities can be both expanded and concretised. The study's findings can be used to empirically investigate newly formed theories in a quantitative follow-up study and to develop measures to achieve equality in healthcare.

Contributors AB wrote the initial draft of this manuscript and will conduct the interviews. SLS is in charge of the study's sister project which looks at patients with coronary artery disease and their perspective on the process of

cardiac care provision. She gave advice and support to the development of this paper. AF is responsible for the design of the study, led the grant application, and wrote the initial study protocol. All authors have read and approved the final version of the manuscript.

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Competing interests None declared.

Ethics approval Ethical Review Committee of the Medical Faculty of Martin Luther University, Halle-Wittenberg.

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