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Title Page

How socioeconomic inequalities impact pathways of care for coronary artery disease among elderly patients. Study protocol for a qualitative longitudinal study

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Abstract

Introduction

Several studies identified socioeconomic inequalities in coronary artery disease (CAD) morbidity and mortality to the disadvantage of patients with low socioeconomic status (SES). International studies showed that socioeconomic inequalities also exist in terms of access, utilization, and quality of cardiac care. The aim of this qualitative study is to provide information on the impact of socioeconomic inequalities on the pathway of care for CAD and to establish which factors lead to socioeconomic inequality of care to form and expand existing scientific theories.

Methods and analysis

A longitudinal qualitative study with 60 CAD-patients, aged 60-80, will be conducted. Patients will be recruited consecutively at the University Hospital in Halle/Saale, Germany, and followed for a period of six months. The patients are going to be interviewed two times faceto-face using semi-structured interviews. The data will be transcribed and analysed based on Grounded Theory.

Ethics and dissemination

Only participants who have been informed and signed a declaration of consent will be interviewed. The study will comply rigorously with data protection legislation. The approval of the Ethical Review Committee at the Martin-Luther University Halle-Wittenberg, Germany was obtained. The results of the study will be presented at several congresses, and will be published in high-quality peer-reviewed international journals.

Trial registration number

This study has been registered with the German Clinical Trials Register and assigned DRKS00007839.

Strengths and Limitations of the Study

- This longitudinal qualitative study will target the impact and role of socioeconomic inequalities from the patient's perspective throughout the entire process of cardiac care provision, an area that has previously received limited research attention.
- It will provide knew knowledge of key points at which the experiences of patients with different SES diverge, thus contributing to a deeper understanding and more detailed explanation of socioeconomic inequalities in healthcare.
- It will help to develop a scientific theory and establish which factors might lead to socioeconomic inequality of care.
- In consequence of the longitudinal design this study might have a high attrition rate.

Introduction

Socioeconomic inequality in coronary artery disease morbidity and mortality

Coronary artery disease (CAD) is the leading cause of death in Europe.[1] Its classic cardiovascular risk factors have been well investigated, with the most common being cigarette smoking, high cholesterol-level, arterial hypertension and obesity.[2-4] Countless medical, sociological and epidemiological studies have been able to demonstrate socioeconomic inequalities in CAD to the disadvantage of patients with low socioeconomic status (SES).[5–8] The Oslo Study showed that the predicted risk for CAD is more than double for men with low SES (13.3), compared to men with high SES (5.7), measured by education and income.[6] The British Whitehall II Cohort Study showed that men in the lowest SES category, classified by their occupational position, have an increased risk of death compared to those in the highest category. These inequalities in cardiovascular mortality are more distinct than for all-cause mortality.[9] Using cross-national data from the United States and 11 western European countries Mackenbach et al. found that cardiovascular mortality is higher among persons from a lower occupational class or with a lower level of education.[5] Similar results regarding higher morbidity and mortality for persons with lower SES were also replicated in a German cohort.[10, 11] Further studies showed that in Great Britain socioeconomic inequalities in CAD morbidity increased from 1960-1993[8] and CAD mortality increased in relative terms from 1994 to 2008, but decreased in absolute terms in the same period.[12]

Socioeconomic inequality in access, utilization and quality of cardiac care

Despite the relatively accurate diagnostic criteria and established therapeutic principles,[13] international studies showed inequalities in access and utilization, but also with respect to the quality of cardiac care, to the disadvantage of patients with low SES.[14, 15] Furthermore, socially disadvantaged patients do not only suffer from a greater health burden and poorer outcomes, but also from less favourable conditions in access and care, irrespectively of the health system concerned. In a review, Quatromoni and Jones compiled data showing that in the USA and UK the waiting times for coronary angiography (CA) and percutaneous coronary interventions (PCI)/coronary artery bypass grafts (CABG) were longer for individuals with low SES. These patients also experienced reduced rates of CA and CABG/PCI compared to patients with high SES.[15] Alter *et al.* demonstrated that more affluent or better educated patients were more likely to undergo coronary angiography, receive cardiac rehabilitation (CR), or be followed up by a cardiologist.[16] After adjustment, patients in New York State with high SES, measured by neighborhood income, were 76% more likely to undergo any revascularization procedure than were patients with low SES.[17]

Conversely, other studies could not find socioeconomic inequalities in access to care. After adjustment for clinical need, the Whitehall II study showed no association in the use of cardiac procedures or prescription of secondary prevention drugs in London, using civil service employment grade as a measure of socioeconomic position.[18] Mathur *et al.* also demonstrated that in London, no differences in prescribing rates for recommended CAD drugs between low and high SES could be found.[19]

Initial findings from various domains of healthcare showed that in Germany individuals who are socially disadvantaged and who experience a greater health burden are often among the

groups which are reached least by healthcare services and also obtain the least benefit from them.[20–22] Altenhöner studied socioeconomic inequalities in access, utilization, and quality of rehabilitation for patients with CAD in Germany; he established that CR procedures are used less frequently by patients of a lower SES.[23] Conversely, a study by Brause *et al.* found no socioeconomic difference for the appropriateness of a medical indication for coronary interventions in Germany.[24]

Factors influencing socioeconomic inequality in access, utilization, and quality of cardiac care

Only partial light has been shed upon the factors which impact upon socioeconomic inequalities in access to cardiac care: Perelman et al. found income-related inequalities in the use of high-technology treatment and diagnostic techniques that could not be attributed to differences in patients' health characteristics. Those inequalities were mainly explained by inequalities in distances to hospitals with on-site cardiac facilities.[25] Shanmugasegaram et al. found that patients with lower subjective SES reported significantly lower referral, enrolment, and participation in CR compared to patients with high subjective SES. Patients with low SES also reported significantly greater barriers to CR (e.g. distance, cost, transportation problems, and that it takes too long to get referred and into the program).[26] An increase in the overall rate of coronary revascularisation procedures in Finland resulted in a reduction in socioeconomic disparities. Nonetheless, socioeconomic inequalities continued to exist for patients with the same level of need.[27]

Research required

 In the past, the majority of studies have used a quantitative approach, often yielding merely descriptive results about the influence of SES on certain predefined factors, e.g. invasive coronary procedure, CR or drug treatment. Additionally, often only one separate care sector (e.g. acute care clinics or rehabilitation services) has been investigated.[23, 27–29] So far, only few exploratory qualitative studies have targeted the impact and role of socioeconomic inequalities throughout the entire process of cardiac care provision.[30, 31] Yet, a plethora of questions, such as, for example, how and at what point on clinical pathways socioeconomic inequalities arise, remain unanswered. So far, no scientific theory on the factors that might lead to socioeconomic inequalities in health care exists. Complementary studies with a qualitative approach are fit to answer these questions and to help in building up a theoretic framework.

The patient's perspective has rarely been taken into account by researchers. But an in-depth understanding of the patients' experiences during care, his/her values, beliefs, and disease understanding is important to expand the scientific knowledge. This will help to identify key points in the course of healthcare provision at which the experiences of patients with different socioeconomic backgrounds begin to diverge, thus contributing to a deeper understanding and more detailed explanation of socioeconomic inequalities in healthcare.

While quantitative studies can only explore the influence of SES on known factors, a qualitative study with the patient's experience at the centre of attention can also uncover previously unknown factors. A qualitative approach helps to develop a scientific theory and provide information on the impact of socioeconomic inequalities on care, as well as establishing which

factors can lead to socioeconomic inequality of care. Building on the findings, further quantitative studies can take other novel factors leading to socioeconomic inequality into account. Lastly, knowledge of the processes leading to socioeconomic differences is obligatory in order to develop and evaluate interventions aiming for equality in treatment and care for all patients.

Methods and analysis

Aims

This study will investigate socioeconomic inequality in access, utilization and quality across different stages of care in CAD, from hospitalisation in an acute care clinic to rehabilitation and subsequent outpatient treatment by a general practitioner (GP) and a cardiac specialist.

The aim of this explorative study is to answer the following research questions:

- 1. What impact do socioeconomic inequalities have on the access to, and the utilization and quality of healthcare services during the particular stages of healthcare for CAD patients?
- 2. Can specific factors and mechanisms be identified that lead to inequality of healthcare?
- 3. How do socioeconomic inequalities interact and accumulate over the course of treatment and care?

Study design

A qualitative design is used to answer these research questions. This allows for an open approach, enabling the scope, depth and complexity of the subjective perspectives of patients with CAD to be analysed in their own social and cultural context. The study is being conducted as a single-center qualitative longitudinal study in Halle/Saale, Saxony-Anhalt, Germany, a high-risk area for poverty and CAD mortality.[32, 33]

Sample selection and recruitment

Patients with CAD are recruited consecutively over a period of six months at the Department of Internal Medicine III (Cardiology and Angiology) at the University Hospital Halle/Saale, Germany, and followed up for a period of six months. The first interview will be conducted with 60 patients aged 60-80 who suffer from CAD. The patients will be interviewed once again after 6 months. In anticipation of the higher attrition rate due to the severity of the disease and the advanced age of the patients, the target number of patients attending the first interview has been set relatively high at 60. In order to cover the greatest possible variety of experiences in relation to access, utilization and quality of care in the interviews, patients with the most frequent clinical manifestations – stable angina pectoris, acute coronary syndrome and cardiac arrhythmia – will be selected and grouped. Of the twenty patients with each clinical manifestation, ten will be selected from a low and ten from a high SES group. In order to ensure that men and women from different socioeconomic groups with different clinical manifestations of CAD are represented, a qualitative sampling plan will be used. Care will be taken to ensure a gender balance, and due account of multi-morbidity and different levels of severity of disease.

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

- 60-80 years old,
- with CAD as the principal or secondary diagnosis,
- and additionally one other principal or secondary diagnosis: stable angina pectoris, acute coronary syndrome or cardiac arrhythmia.

The patients are excluded from the study if they fulfill one of the following criteria:

- insufficient language skills to conduct an interview in German language,
- other heart diseases excluding CAD,
- moribund patients.

The abort criterion is:

• withdrawal of consent by the patient before or during the interview.

Enrolment started in November 2014. Patients meeting inclusion criteria are identified by a study nurse at the Department of Internal Medicine III at the University Hospital Halle/Saale and informed about the study by means of an information sheet. If the patient is interested in participating, an appointment is arranged prior to their estimated discharge date, and a researcher of the project team explains the study to the patient. Patients are given comprehensive information and are enrolled in the study after providing written informed consent. If the patient attends the first interview, a project team member contacts the participant by post and telephone after six months to schedule a second interview. Enrolment is planned to be completed in April 2015.

Data collection

A researcher conducts the baseline interview (T1) at the acute hospital. In order to protect patient privacy and to provide a comfortable atmosphere for the conversation, the interviews are conducted in a separate, undisturbed room in the hospital, where patients cannot be interrupted or overheard by attending physicians, nursing staff or other patients. The second interview (T2) will be conducted six months after the discharge from the acute hospital. The patients are free to decide whether the second interview is conducted in their own homes or on the premises of the Institute of Medical Sociology.

The same researcher will question patients face-to-face on the two data collection dates using guided interviews. The interviews may not exceed a maximum time of 45 min, and a digital recording will be made with the interviewee's consent. Guidelines based on the methods used by Helfferich have been developed for the semi-structured qualitative interviews; these contain key questions which evoke narrations, supplemented by areas of conversation around specific topics and specific supplementary questions, as well as questions aimed at maintaining the conversational flow.[34] The interview guide T1 was pilot-tested with two patients with CAD before any data was collected, the interview guide T2 will be tested prior to the first T2 interview.

The following key questions are asked during the baseline interview:

• Please begin by telling me about the medical history of your heart disease from when it first started until this hospital stay.

- Which positive and negative experiences have you gained, concerning the care you have received?
- How would you describe the quality of your treatment?
- How do you manage your heart disease right now?

In order to collect data on SES and other socio-demographic variables, questions are asked about the patients' age, gender, nationality, marital status, level of schooling, occupational training qualifications, and profession. This data is collected verbally in a standardised way at the end of the first guided interview T1.

In the follow-up-interview T2 the following key questions will be asked:

- Please begin by telling me how the treatment of your heart disease has progressed after our last conversation.
- Which positive and negative experiences have you gained, concerning the care you have received?
- Last time we talked about your expectations for your medical care to what extend were they fulfilled?
- How does your heart disease influence your everyday life?
- What will happen next?

Socioeconomic status:

Patients are allocated to a group with high or low SES based on their level of schooling and academic qualifications. The classification is based on German epidemiological standards.[35] Information on the patient's highest level of schooling and his/her highest occupational training qualification is merged in a scale which rates education on a scale of 1 to 8. In addition to educational level we also measure the current or last occupation. This allows us to investigate whether there are any inconsistencies between occupation and education regarding the patient's SES.[36] Since most of the patients will be pensioners, and as income is not a reliable indicator of current SES, especially in the elderly, income is disregarded when determining SES. Furthermore, income presents a sensitive personal issue, and questions on this topic thus frequently remain unanswered.[37, 38]

Data analysis

After conducting the interviews, the recordings will be transcribed by a transcription agency and pseudonyms will be used to protect personal data. The data will be analysed in accordance with Glaser and Strauss's rules of Grounded Theory.[39] MAXQDA software will be used to assist with the data management and analyses. Using Grounded Theory, the codes are generated openly and inductively from the text in the first instance. Categories are then identified from the developed codes, and relationships will be made between them (axial coding). As a last step, a key category will be identified using selective coding. The other categories are related both to one another and to the key category. Memos play a very important role at each stage of coding in Grounded Theory, because they represent the hypotheses and thoughts of the researcher, which are formed during coding, comparison, and evaluation of the interviews. The memos help the researcher to bring his/her thoughts to their logically consistent conclusion. Through the method of constant comparison, a key element of Grounded Theory, the statements made during the interviews at two different times can be compared with one

another and can be related to one another. Finally, similarities and differences in the patients' situation, beliefs, and experiences of care between the two points of interviews are identified.[40] Information from low SES groups will be compared to that from high SES groups. The qualitative research group at the Institute of Medical Sociology will be involved in discussion and evaluation of the data to ensure a high quality of the results. Lastly, the consolidation criteria for reporting qualitative research (COREQ), will be taken into account during the research process to ensure high quality qualitative research.[41]

Ethics and dissemination

The Institute of Medical Sociology has obtained the approval from the Ethical Review Committee of the Medical Faculty of Martin Luther University, Halle-Wittenberg, and implemented its recommendations for the projected study. The Committee has expressed no ethical issues about the study. The study complies rigorously with data protection legislation. Before interviews are conducted, patients will be informed about the study in an information sheet and give their written informed consent. Participation is voluntary and may be withdrawn at any point during the study. A withdrawal of one's consent is possible at any time; in such cases, all data will be deleted. Each patient is assigned a unique pseudonym, and all data is compiled under this pseudonym, this will prevent any individuals or places from being identified and will ensure that all personal data is protected. The name of the patient is not to be mentioned during the interview in order to prevent the interviews and transcripts from being associated with any individual. The study data, personal data, and list assigning pseudonyms to individuals are stored securely at separate locations. Only authorised members of the research team have access to the declaration of consent and the pseudonym assignment list. Once all data has been collected, the pseudonym assignment list will be deleted. Because of the close cooperation with the Department of Internal Medicine III at the University Hospital Halle/Saale, patients might feel inhibited about criticising their hospital stay. Accordingly, the attending physician will not be involved in the recruitment for the study. In addition, the initial interview is conducted in a separate room at the clinic at the end of the hospital stay, so that the patient can express him or herself freely, without any concerns about potential consequences for their treatment. The second interview will be conducted either in the patient's home or on the facilities of the Institute of Medical Sociology.

The results of the study will be presented at several congresses and research conferences, and will be published in one PhD thesis (SLS), and in high-quality peer-reviewed international journals.

Conclusion

This study will provide further evidence from the patient's perspective on the impact of socioeconomic inequalities in care in coronary artery disease and central factors, which may lead to socioeconomic inequality of care. It will address explicitly different sectors of health care, and will provide meaningful insights about socioeconomic risk groups. With the gained knowledge of the mediating aspects between socioeconomic status and inequalities in health care, present theoretical models can be expanded and made more specific with respect to the production of health inequalities. The results of this study can be used to empirically investi-

 gate theories of how unequally distributed socioeconomic factors influence the access, utilization and quality of care and to develop interventions to reduce these inequalities.

Authors contribution:

Sara L Schröder, Astrid Fink, Nadine Schumann, Irene Moor, Alexander Plehn, Matthias Richter

SLS wrote the initial draft of this manuscript, will conduct the interviews, and analyze the data. MR is the principal investigator of the study and is responsible for the conception of the project, led the grant application and critically reviewed the manuscript. MR and AF wrote the original study protocol in collaboration with AP, NS and IM. AP gave advice on the clinical background of the study. All authors have read and approved the final version of the manuscript.

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Ethics approval

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

Competing Interests

The authors declare that they have no competing interests.

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Abstract

Introduction

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Methods and analysis

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- It will provide knew knowledge of key points at which the experiences of patients with different SES diverge, thus contributing to a deeper understanding and more detailed explanation of socioeconomic inequalities in healthcare.
- It will help to develop a scientific theory and establish which factors might lead to socioeconomic inequality of care.
- In consequence of the longitudinal design this study might have a high attrition rate.

Introduction

Socioeconomic inequality in coronary artery disease morbidity and mortality

Coronary artery disease (CAD) is the leading cause of death in Europe.[1] Its classic cardiovascular risk factors have been well investigated, with the most common being cigarette smoking, high cholesterol-level, arterial hypertension and obesity.[2-4] Countless medical, sociological and epidemiological studies have been able to demonstrate socioeconomic inequalities in CAD to the disadvantage of patients with low socioeconomic status (SES).[5–8] The Oslo Study showed that the predicted risk for CAD is more than double for men with low SES (13.3), compared to men with high SES (5.7), measured by education and income.[6] The British Whitehall II Cohort Study showed that men in the lowest SES category, classified by their occupational position, have an increased risk of death compared to those in the highest category. These inequalities in cardiovascular mortality are more distinct than for all-cause mortality.[9] Using cross-national data from the United States and 11 western European countries Mackenbach et al. found that cardiovascular mortality is higher among persons from a lower occupational class or with a lower level of education.[5] Similar results regarding higher morbidity and mortality for persons with lower SES were also replicated in a German cohort.[10, 11] Further studies showed that in Great Britain socioeconomic inequalities in CAD morbidity increased from 1960-1993[8] and CAD mortality increased in relative terms from 1994 to 2008, but decreased in absolute terms in the same period.[12]

Socioeconomic inequality in access, utilization and quality of cardiac care

Despite the relatively accurate diagnostic criteria and established therapeutic principles,[13] international studies showed inequalities in access and utilization, but also with respect to the quality of cardiac care, to the disadvantage of patients with low SES.[14, 15] Furthermore, socially disadvantaged patients do not only suffer from a greater health burden and poorer outcomes, but also from less favourable conditions in access and utilization of cardiac care, irrespectively of the health system concerned. In a review, Quatromoni and Jones compiled data showing that in the USA and UK the waiting times for coronary angiography (CA) and percutaneous coronary interventions (PCI)/coronary artery bypass grafts (CABG) were longer for individuals with low SES. These patients also experienced reduced rates of CA and CABG/PCI compared to patients with high SES.[15] Alter *et al.* demonstrated that more affluent or better educated patients were more likely to undergo coronary angiography, receive cardiac rehabilitation (CR), or be followed up by a cardiologist.[16] After adjustment, patients in New York State with high SES, measured by neighborhood income, were 76% more likely to undergo any revascularization procedure than were patients with low SES.[17]

Conversely, other studies could not find socioeconomic inequalities in access and utilization of care. After adjustment for clinical need, the Whitehall II study showed no association in the use of cardiac procedures or prescription of secondary prevention drugs in London, using civil service employment grade as a measure of socioeconomic position.[18] Mathur *et al.* also demonstrated that in London, no differences in prescribing rates for recommended CAD drugs between low and high SES could be found.[19]

Initial findings from various domains of healthcare showed that in Germany individuals who are socially disadvantaged and who experience a greater health burden are often among the

groups which are reached least by healthcare services and also obtain the least benefit from them.[20–22] Altenhöner studied socioeconomic inequalities in access, utilization, and quality of rehabilitation for patients with CAD in Germany; he established that CR procedures are used less frequently by patients of a lower SES.[23] Conversely, a study by Brause *et al.* found no socioeconomic difference for the appropriateness of a medical indication for coronary interventions in Germany.[24]

In the majority of international studies, access and utilization have not been clearly differentiated. Access to health care is predominantly a characteristic of care providers and the health system, and is influenced by geographic, financial and cultural barriers. Access is limited if offered and required health services cannot be used without these barriers. Utilization of health care is predominantly a characteristic of patients and influenced by their preferences and possibilities.[20, 25]

Factors influencing socioeconomic inequality in access, utilization, and quality of cardiac care

Only partial light has been shed upon the factors which impact upon socioeconomic inequalities in access and utilization of cardiac care: Perelman et al. found income-related inequalities in the use of high-technology treatment and diagnostic techniques that could not be attributed to differences in patients' health characteristics. Those inequalities were mainly explained by inequalities in distances to hospitals with on-site cardiac facilities.[26] Shanmugasegaram et al. found that patients with lower subjective SES reported significantly lower referral, enrolment, and participation in CR compared to patients with high subjective SES. Patients with low SES also reported significantly greater barriers to CR (e.g. distance, cost, transportation problems, and that it takes too long to get referred and into the program).[27] An increase in the overall rate of coronary revascularisation procedures in Finland resulted in a reduction in socioeconomic disparities. Nonetheless, socioeconomic inequalities continued to exist for patients with the same level of need.[28]

Research required

 In the past, the majority of studies have used a quantitative approach, often yielding merely descriptive results about the influence of SES on certain predefined factors, e.g. invasive coronary procedure, CR or drug treatment. Additionally, often only one separate care sector (e.g. acute care clinics or rehabilitation services) has been investigated.[23, 28–30] So far, only few exploratory qualitative studies have targeted the impact and role of socioeconomic inequalities throughout the entire process of cardiac care provision.[31, 32] Yet, a plethora of questions, such as, for example, how and at what point on clinical pathways socioeconomic inequalities arise, remain unanswered. So far, no comprehensive scientific theory on the factors that might lead to socioeconomic inequalities in health care exists. Existing models for the genesis of health inequalities assume that education, income and occupational status do not have any direct influence on health inequalities; the relationship between social inequality and inequalities in health care is rather mediated by factors.[33–35] Complementary studies with a qualitative approach are fit to answer these questions and to help in building up a theoretic framework.

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While quantitative studies can only explore the influence of SES on known factors, a qualitative study with the patient's experience at the centre of attention can also uncover previously unknown factors. A qualitative approach helps to develop a scientific theory and provide information on the impact of socioeconomic inequalities on care, as well as establishing which factors can lead to socioeconomic inequality of care. Building on the findings, further quantitative studies can take into account other novel factors leading to socioeconomic inequality. Lastly, knowledge of the processes leading to socioeconomic differences is obligatory in order to develop and evaluate interventions aiming for equality in treatment and care for all patients.

Due to the longitudinal study design it is possible to obtain retrospective and prospective data of the complete clinical pathway starting from the first symptoms of CAD. By consulting patients several times, detailed information from the patient's perspective can be obtained and evolving and complex processes can be explored. The benefit of qualitative longitudinal studies is that a relationship of trust is established and patients are more willing to talk about deeply personal aspects during the follow-up interviews.[36] Furthermore, qualitative longitudinal research can provide deep insights into the dynamic experience of illness, and change can be detected, for example in the context of time, when a story is retold and re-interpreted by the participant at later interviews.[37, 38]

So far, there is only limited research on socioeconomic differences in CAD-treatment in Germany. The available evidence showed socioeconomic inequalities in access and utilization, but no clear influence of SES has been identified in the conducted studies. Due to the fact that the German health care system provides comprehensive coverage for most medical and hospital services, it is not based on user fees at point of health care services. Patients have to pay very low out of pocket payments, limited to 1-2% of their annual gross income.[39] This circumstance should provide equitable access based on medical needs rather than SES. This contradiction is addressed in this study through finding factors that cause socioeconomic differences of CAD care in Germany.

Methods and analysis

Aims

This study will investigate socioeconomic inequality in access, utilization and quality across different stages of care in CAD, from hospitalisation in an acute care clinic to rehabilitation and subsequent outpatient treatment by a general practitioner (GP) and a cardiac specialist.

The aim of this explorative study is to answer the following research questions:

- 1. What impact do socioeconomic inequalities have on the access to, and the utilization and quality of healthcare services during the particular stages of healthcare for CAD patients?
- 2. Can specific factors and mechanisms be identified that lead to inequality of healthcare?
- 3. How do socioeconomic inequalities interact and accumulate over the course of treatment and care?

Study design

A qualitative design is used to answer these research questions. This allows for an open approach, enabling the scope, depth and complexity of the subjective perspectives of patients with CAD to be analysed in their own social and cultural context. The study is being conducted as a single-center qualitative longitudinal study in Halle/Saale, Saxony-Anhalt, Germany, a high-risk area for poverty and CAD mortality.[40, 41]

Sample selection and recruitment

Patients with CAD have been recruited consecutively over a period of six months at the Department of Internal Medicine III (Cardiology and Angiology) at the University Hospital Halle/Saale, Germany, and are followed up for a period of six months. The first interview has been conducted with 48 patients aged 60-80 who suffer from CAD. In order to cover the greatest possible variety and diversity of experiences in relation to access, utilization and quality of care, patients have been sampled purposively using a maximum variation sampling strategy until theoretical saturation was reached. Patients with the most frequent clinical manifestations - stable angina pectoris, acute coronary syndrome and cardiac arrhythmia - have been selected and grouped. In accordance to the maximum variation sampling strategy we aimed to recrute one third of patients with each clinical manifestation and around half of the patients from a high SES group. Additionally we aimed to recrute around 50% women and took multi-morbidity and different levels of severity of CAD into account. 19 (40%) women and 29 men have been interviewed at T1. 34 (71%) patients were multi-morbid, 27 (56%) patients had a long history of CAD and thereby long-time experiences with care, and 18 (37.5%) patients had a higher severity of CAD with three vessel disease, stenosis of the left mainstem, stents, or a bypass. The distribution of the patients to diagnosis and SES can be found in table 1.

Diagnosis: CAD in combination with	total	high SES	low SES
stable Angina Pectoris	14	6	8
acute coronary syndrome	18	7	11
cardiac arrhythmia	16	8	8
total	48	21	27

Table 1: Sample of CAD-patients interviewed at baseline (T1)

The patients' inclusion criteria for participating in the study have been:

- 60-80 years old,
- with CAD as the principal or secondary diagnosis,
- and additionally one other principal or secondary diagnosis: stable angina pectoris, acute coronary syndrome or cardiac arrhythmia.

The patients have been excluded from the study if they fulfill one of the following criteria:

- insufficient language skills to conduct an interview in German language,
- other heart diseases excluding CAD,
- moribund patients.

The abort criterion is:

• withdrawal of consent by the patient before or during the interview.

Enrolment started in November 2014. Patients meeting inclusion criteria have been identified by a study nurse at the Department of Internal Medicine III at the University Hospital Halle/Saale and have been informed about the study by means of an information sheet. If the patient was interested in participating, an appointment was arranged prior to their estimated discharge date, and a researcher of the project team explained the study to the patient. Patients have been given comprehensive information and have been enrolled in the study after providing written informed consent. If the patient attended the first interview, he/she is contacted by a project team member 6 months later by post and telephone to schedule a second interview. Enrolment was completed in April 2015.

Data collection

A researcher conducted 48 baseline interviews (T1) at the acute hospital. In order to protect patient privacy and to provide a comfortable atmosphere for the conversation, the interviews have been conducted in a separate, undisturbed room in the hospital, where patients could not be interrupted or overheard by attending physicians, nursing staff or other patients. The second interview (T2) is conducted six months after discharge from the acute hospital. The patients are free to decide whether the second interview is conducted in their own homes or on the premises of the Institute of Medical Sociology.

The same researcher questions patients face-to-face on the two data collection dates using guided interviews. The interviews may not exceed a maximum time of 45 min, and a digital recording is made with the interviewee's consent. Guidelines based on the methods used by Helfferich have been developed for the semi-structured qualitative interviews; these contain key questions which evoke narrations, supplemented by areas of conversation around specific topics and specific supplementary questions, as well as questions aimed at maintaining the conversational flow.[42] The interview guides for T1 and T2 (see online supplementary files) have been pilot-tested with two patients with CAD before any data was collected.

The following key questions have been asked during the baseline interview:

• Please begin by telling me about the medical history of your heart disease starting from the first symptoms until this hospital stay.

- Which positive and negative experiences have you made, concerning the care you have received?
- How would you describe the quality of your treatment?
- How do you manage your heart disease right now?

In order to collect data on SES and other socio-demographic variables, questions have been asked about the patients' age, gender, nationality, marital status, level of schooling, occupational training qualifications, and profession. This data have been collected verbally in a standardised way at the end of the first guided interview T1.

In the follow-up-interview T2 the following key questions are asked:

- Please begin by telling me how the treatment of your heart disease has progressed after our last conversation.
- Which positive and negative experiences have you made, concerning the treatment and care you have received?
- Last time we talked about your expectations of your medical care to what extend were they fulfilled?
- What kind of influence does your heart disease have on your everyday life?
- What will happen next?

Socioeconomic status:

 Patients are allocated to a group with high or low SES based on their level of schooling and academic qualifications. The classification is based on German epidemiological standards.[43] Information on the patient's highest level of schooling and his/her highest occupational training qualification is merged in a scale which rates education on a scale of 1 to 8. Values from 6 to 8 points are considered high SES, this includes all patients with a degree from university or technical school. Patients with less than 6 points are classified as having a low SES; this includes mainly patients with 10 or less years at school and a company-based apprenticeship. In addition to educational level we also measure the current or last occupation. This allows us to investigate whether there are any inconsistencies between occupation and education regarding the patient's SES.[44] Data on income have not been collected to determine SES. For older people and pensioner income is a problematic indicator for SES for several reasons. First, retirement is often associated with a decline in income and therefore financial assets are discussed to be a better measure than income for SES of older people. Second, income presents a sensitive personal issue, and questions on this topic thus frequently remain unanswered.[45, 46]

Data analysis

After conducting the interviews, the recordings are transcribed by a transcription agency and pseudonyms are used to protect personal data. Transcribed interviews are analysed in accordance with Glaser and Strauss's rules of Grounded Theory.[47] MAXQDA software is used to assist with the data management and analyses. Using Grounded Theory, the codes are generated openly and inductively from the text in the first instance. Categories are then identified from the developed codes, and relationships will be made between them (axial coding). As a last step, a key category is identified using selective coding. The other categories are related

 both to one another and to the key category. Memos play a very important role at each stage of coding in Grounded Theory, because they represent the hypotheses and thoughts of the researcher, which are formed during coding, comparison, and evaluation of the interviews. The memos help the researcher to bring his/her thoughts to their logically consistent conclusion. Through the method of constant comparison, a key element of Grounded Theory, the statements made during the interviews at two different times can be compared with one another and can be related to one another. Finally, similarities and differences in the patients' situations, beliefs, and experiences of care between the two points of interviews are identified.[48] Information from low SES groups are compared to that from high SES groups. The qualitative research group at the Institute of Medical Sociology is involved in discussion and evaluation of the data to ensure a high quality of the results. Lastly, the consolidation criteria for reporting qualitative research (COREQ), are taken into account during the research process to ensure high quality qualitative research.[49]

Ethics and dissemination

The Institute of Medical Sociology has obtained the approval from the Ethical Review Committee of the Medical Faculty of Martin Luther University, Halle-Wittenberg, and implemented its recommendations for the projected study. The Committee has expressed no ethical issues about the study. The study complies rigorously with data protection legislation. Before interviews had been conducted, patients have been informed about the study in an information sheet and gave their written informed consent. Participation is voluntary and may be withdrawn at any point during the study. A withdrawal of one's consent is possible at any time; in such cases, all data will be deleted. Each patient is assigned a unique pseudonym, and all data are compiled under this pseudonym, this will prevent any individuals or places from being identified and will ensure that all personal data is protected. The name of the patient is not to be mentioned during the interview in order to prevent the interviews and transcripts from being associated with any individual. The study data, personal data, and list assigning pseudonyms to individuals are stored securely at separate locations. Only authorised members of the research team have access to the declaration of consent and the pseudonym assignment list. Once all data has been collected, the pseudonym assignment list will be deleted. Because of the close cooperation with the Department of Internal Medicine III at the University Hospital Halle/Saale, patients might feel inhibited about criticising their hospital stay. Accordingly, the attending physician will not be involved in the recruitment for the study. In addition, the initial interview was conducted in a separate room at the clinic at the end of the hospital stay, so that the patient could express him/herself freely, without any concerns about potential consequences for their treatment. The second interview is conducted either in the patient's home or on the facilities of the Institute of Medical Sociology.

The results of the study will be presented at several congresses and research conferences, and will be published in one PhD thesis (SLS), and in high-quality peer-reviewed international journals.

Conclusion

This study will provide further evidence from the patient's perspective on the impact of socioeconomic inequalities in health care for CAD and on central factors, which may lead to socioeconomic inequality. It will address explicitly different sectors of health care, and will provide meaningful insights about socioeconomic risk groups. With the gained knowledge of the mediating aspects between SES and inequalities in health care, present theoretical models can be expanded and made more specific with respect to the production of health inequalities. The results of this study can be used to empirically investigate theories of how unequally distributed socioeconomic factors influence access, utilization and quality of care, and to develop interventions reducing these inequalities.

Authors contribution:

Sara L Schröder, Astrid Fink, Nadine Schumann, Irene Moor, Alexander Plehn, Matthias Richter

SLS wrote the initial draft of this manuscript, will conduct the interviews, and analyse the data. MR is the principal investigator of the study and is responsible for the conception of the project, led the grant application and critically reviewed the manuscript. MR and AF wrote the original study protocol in collaboration with AP, NS and IM. All authors have read and approved the final version of the manuscript.

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Ethics approval

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

Competing Interests

The authors declare that they have no competing interests.

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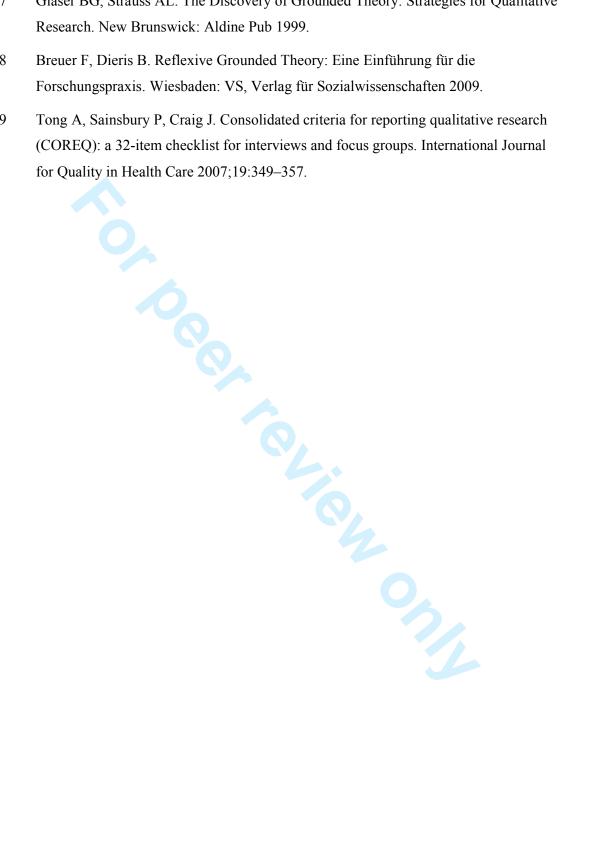
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Interview Guide T1

Key question	Concrete supplementary questions		
Please begin by telling me about the medical	- Have you ever been to a general practitioner/ cardiologist/ in ₹rehabilitation clinic before because		
history of your heart disease starting from the first	of your heart disease? စ္ခ်		
symptoms until this hospital stay.	- How was your disease diagnosed?		
	- Why are you currently in hospital?		
Which positive and negative experiences have you made, concerning the care you have received?	- Can you think of any other positive or negative experience you have made with the hospital or office-based physicians? - Was there anything you were particularly satisfied with? - Was there anything you were unsatisfied with? - Have you experienced any problems with the further processing of the treatment?		
	- How have you experienced talking with your physicians?		
	- How was a decision reached about what treatment you were to receive?		
How would you describe the quality of your treatment?	 How satisfied are you with your treatment? Do you think that everyone in Germany is able to receive good treatment? Why do you think that is? 		
How do you manage your heart disease right now?	- What will happen next? - What medical care do you expect to receive in the next months? - What hopes do you have for your health in the future? - Is there something else you would like to tell me?		
 Please tell me exactly how things went with Could you perhaps give me a few more details? What happened next? / And after that? What else comes into your mind? What do you associate with? 	on April 18, 2024 by guest. Protected by copyright		

Questions aimed at maintaining the conversational flow:

- Please tell me exactly how things went with...
- Could you perhaps give me a few more details?
- What happened next? / And after that?
- What else comes into your mind?
- What do you associate with ...?

Interview Guide T2

Key question	Concrete supplementary questions
Please begin by telling me how the treatment of your	- Which doctors have you seen meanwhile, e.g. general prace itioner (GP)/ cardiologist?
heart disease has progressed after our last	- Have you been in a rehabilitation clinic or do you attend a f eart training group?
conversation.	- What exactly has been done by each of the physicians (GP) ardiologist, hospital, rehabilitation)?
	- Which tasks of medical care have been taken care of b www. which doctor?
	- Who prescribes you heart drugs?
What positive and negative experiences have you	- Can you think of any other experiences you have had with the GP/ cardiologist/ rehabilitation clinic?
made, concerning the treatment and care you have	- Was there anything you were particularly satisfied or not setisfied with?
received?	- How does the cooperation between GP, specialists and the doctors at the hospital work?
	- Have you experienced any problems with the postoperativ management and any further treatment
	after you have been discharged from hospital?
	- Have you had to actively arrange yourself to the further treatment?
	- Have you ever changed your GP or cardiologist and what have been the particular reasons?
Last time we talked about your expectations of your	- Have your expectations changed during the course of treatment?
medical care – to what extend were they fulfilled?	jóp p
What kind of influence does your heart disease have on	- What kind of heart disease/s do you have?
your everyday life?	- How far is your everyday life constrained by your heart disease, and which tasks can't be managed by
	yourself anymore?
	- Who assists you in coning with the disease?
	- What do you personally contribute to a better health?
What will happen next?	- What hopes do you have for your future health? ,
What will happen next.	
	- Is there something else you would like to tell me? Onal flow: St. Protected by copyright.
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Questions aimed at maintaining the conversation	onal flow:
- Please tell me exactly how things went with	.÷
- Could you perhaps give me a few more details?	ro te
 What happened next? / And after that? 	cte
 What else comes into your mind? 	. Ω
- What do you associate with?	y co
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Questions aimed at maintaining the conversational flow:

- Please tell me exactly how things went with...
- Could you perhaps give me a few more details?
- What happened next? / And after that?
- What else comes into your mind?
- What do you associate with ...?