

BMJ Open Exploring regional healthcare utilisation and quality of care for endometriosis in rural areas in Hesse, Germany: a mixed methods study protocol

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ABSTRACT

Introduction The need of a regional healthcare monitoring in order to evaluate quality and utilisation of health services in smaller scale is internationally and in Germany well established. Little is known about variation in healthcare in rural German areas, especially for women's health. In particular, endometriosis is highly prevalent and known to be unsatisfactorily treated. Thus, this study aims to investigate utilisation and quality of care, the influence of structural determinants on quality and the patient's experiences on endometriosis healthcare in rural Hesse.

Methods and analysis We will use a mixed methods approach to ensure reliable mapping of the care situation for endometriosis patients in seven counties in Central and Eastern Hesse. First, retrospective secondary utilisation data and quality indicators will be used to describe possible regional variation in the treatment of endometriosis in the outpatient and inpatient sector. Second, we compare structural determinants of regions with quality of care. Third, we conduct qualitative, semistructured interviews with endometriosis patients on their perspective and experiences in those chosen rural regions. Data will then be analysed using descriptive statistics, small area variation analyses and multifactorial analyses of variance (ANOVAs). The interview will be interpreted using the experience-focused phenomenological approach.

Ethics and dissemination The study has been approved by the ethics committee of Philipps-University Marburg. Utilisation data and structural determinants are anonymised and partly aggregated. The interview will use tokens for pseudonymisation to prevent the collected data from being assigned to an individual person. Also, informed consent will be obtained from patients.

The results of this study will be reported to the scientific community in peer-reviewed journals and at conferences. A summary of the key findings will be provided to the interviewed patients and the *Endometriosis Association Germany*.

INTRODUCTION

Autonomy, non-maleficence, beneficence and justice are internationally accepted principles of biomedical ethics. First published in 1979 by Beauchamp and Childress, these four

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ One strength of this study is the mixed methods approach to ensure a comprehensive overview of the utilisation and quality of care for endometriosis patients in defined areas in Hesse, Germany.
- ⇒ Statistical analyses of secondary billing data and regional determinants are a valid approach to quantify utilisation and map structural differences for these areas.
- ⇒ To ensure direct patient involvement in the research process, semistructured interviews will be conducted with patients diagnosed with endometriosis.
- ⇒ Qualitative analyses of endometriosis patients' reported experiences with the healthcare system allow a detailed evaluation of strengths and weaknesses in quality of care.
- ⇒ Due to the regionally limited data collection, the findings may not be transferable to the quality of care for endometriosis in other areas of Germany or internationally.

principles are still relevant for measuring current healthcare quality.¹ For instance, the principle of justice—eg, access to quality healthcare irrespective of the person and other circumstances of life—is reflected in the political demand for equal living conditions with regard to services of general interest and stated in Article 72 (2) of the German Constitution.² In order to examine whether such equivalence exists in terms of healthcare, health monitoring of a predefined spatial and temporal population has been established in Germany since the 1980s.³

The need for regional health monitoring in order to observe the quality, utilisation and structure of healthcare even on a regional basis was first raised in 1973 by Wennberg and Gittelsohn in a study on the distribution of healthcare services in small subregions of the state of Vermont (USA).⁴ They showed a broad small area variation per region for this primarily rural state in healthcare service



utilisation, resource use and health sector expenses.⁴ Based on this study by Wennberg and Gittelsohn, the *Dartmouth Atlas of Health Care* was invented, which documents geographic variation in the distribution and use of medical resources in the USA for more than 20 years.⁵

Recent research on regional variation in medical care also exists for Europe, for example, geographic differences in the structure of care for patients with a diabetic foot in Tuscany,⁶ small area analyses for hip and knee arthroplasty rates in Switzerland⁷ or the optimal prehospital transport strategies and neurological outcomes in patients with suspected large-vessel occlusion stroke in non-urban areas in Catalonia.⁸

In Germany, the *Bertelsmann Foundation* initiated the internet portal *Fact Check Health* in 2011, which uses healthcare research to highlight deficits and regional differences in the German healthcare system.⁹ In general, the German healthcare system offers universal health insurance coverage for the population and a comprehensive benefits package with relatively low cost-sharing requirements.¹⁰ It offers free choice of provider and is financed by statutory health insurance (SHI) and private health insurance (PHI), which are mandatory for everyone registered or usually resident in Germany. Employees are paying contributions for SHI, if their income is below a certain amount, above this threshold you can optionally enrol in PHI (approximately 11% of the population).^{10,11} Both SHI and PHI are financed by contributions from their members.¹¹

The German healthcare system is characterised by a relatively strict divide into outpatient care (with general practitioners and specialists), inpatient care (hospitals) and rehabilitative care.¹² This separation leads to challenges in terms of organisation and payment of healthcare and can interfere in the coordination and continuity of patient treatment.¹⁰

Based on SHI outpatient billing data, the *Central Research Institute of Ambulatory Health Care in Germany* (*Zentralinstitut für die kassenärztliche Versorgung, Zi*) has also developed a healthcare atlas which, such as the Dartmouth atlas, focuses on analysing regional differences.¹³ Also, several current healthcare research is published for sparsely populated rural areas in Germany, such as an intervention study on patients with acute ischaemic stroke,¹⁴ the evaluation of a population-based integrated healthcare system¹⁵ and the accessibility of general practitioners and specialist physicians by car or by public transport in a rural area in Germany.¹⁶

When reviewing healthcare research in Germany, it is notable that very little regional research has been conducted focusing on women's health, especially on women with endometriosis. So far, little is known about whether endometriosis patients in Germany are cared for differently from region to region and in particular how healthcare services are delivered for sparsely populated areas. Even reliable ratios on the prevalence of endometriosis are not available due to a lack of data, according to the *Robert Koch Institute* (RKI).¹⁷ However, it is estimated

that 10%–15% of all women in reproductive age are affected and 40 000 new women develop endometriosis each year.¹⁷

The high clinical, economic and especially human relevance and disease burden of endometriosis has already been addressed in 2006.¹⁸ The Global Burden of Disease Study 2019 confirms this continuing burden and relevance. In this study, gynaecologic diseases rank ninth internationally among diseases with the most lost healthy life years (disability-adjusted life years) when women's health is considered separately.¹⁹ Therefore, the authors call for more geographically specific studies focusing on the health status of populations and for detailed reporting of the causes of the most common diseases.¹⁹

The health report of the RKI on the health situation of women in Germany (2020) also emphasises the special importance of gynaecological diseases such as endometriosis.¹⁷ Little data is available on the precise healthcare situation of endometriosis patients.¹⁷ But, it is known that patients are treated not only as outpatients but often as inpatients as well.²⁰ In 2021, endometriosis (*International Classification of Diseases, Tenth Revision* (ICD-10): N80) was listed for 81 inpatient cases per 100 000 inhabitants (age standardised) in the German hospital diagnosis statistics, for the age group 15 to less than 45 years even 91 cases per 100 000 inhabitants were recorded.²⁰

Health system contacts continue to be necessary even after surgical therapy, as recurrence rates are 50%–80%.²¹ Also, the mostly long pathway to diagnosis results in high costs and increased healthcare system utilisation until the delayed diagnosis is made.²² Up to 3 years can pass between the onset of the first symptoms and the first contact with medical professionals, and up to a further 7 years can pass since the first contact before a diagnosis is made.^{23,24} Although graduated, evidence-based recommendations are given in the German guideline *Diagnosis and Therapy of Endometriosis*,²⁵ a malfunctioning or insufficient care seems to exist due to a long diagnostic pathway.

However, it is unknown if these results can be transferred equally to all regions of Germany. In addition, it is unclear whether regions with particularly good care can be identified and whether a specific care design is responsible for this, which could possibly be transferred into other regions as best practice. Thus, empirical studies on determinants or explanations of potential variation in endometriosis healthcare are needed.

AIMS

This study aims to describe and compare the current regional care situation and possible regional differences in the treatment of endometriosis in the outpatient and inpatient sector on the basis of SHI secondary utilisation data. This is exemplified for the region of Central and Eastern Hesse, Germany, which count as rural areas. Complementary, a qualitative approach is used to assess how healthcare service utilisation is perceived from the perspective of patients with endometriosis in

these regions. A qualitative interview is intended to draw conclusions about structural and personal challenges and burdens faced by endometriosis patients in this region. Also, available resources in the healthcare system should be revealed.

METHODS AND ANALYSIS

Study design

Given this background, the mixed methods study first aims to describe and compare the current regional care situation and possible regional variations in the treatment of endometriosis in outpatient and inpatient sectors based on secondary utilisation data. As an example, this will be done for the region of Central and Eastern Hesse with the seven counties of Giessen, Marburg-Biedenkopf, Fulda, Hersfeld-Rotenburg, Vogelsberg, Lahn-Dill-Kreis and Wetteraukreis. Specifically, the region of Central and Eastern Hesse, with a population of 1.5 million, was selected here as it can be considered exemplary for rural regions in Germany and has not previously been studied in terms of the research questions. These all counties represent important clinics for the region that have a gynaecology department and treat endometriosis. In addition, a specific endometriosis centre is located in Giessen, which is why it is certainly informative to compare the care provided there with the surrounding counties. Named counties will serve as a reference for small-scale analyses and for comparison with other regions. Also, the quality of care for endometriosis in the region of Central and Eastern Hesse will be evaluated based on quality indicators (QIs) from the literature, for example, newly developed QIs based on the guideline for endometriosis.²⁵ The QIs should at least cover the quality dimensions of Donabedian (process, structural and outcome quality)²⁶ as well as those of the *Organization for Economic Cooperation and Development* (OECD) (effectiveness, patient safety and patient centredness).²⁷

Second, possible regional and structural determinants for the healthcare structure determined in the first step will be analysed in detail. Possible determinants are, for example, the structure and location of potential healthcare providers, the demographic and socioeconomic situation of the patients' regions of origin and regional inequalities in access to ambulatory care.²⁸

In a third step, primary qualitative data on the use of the healthcare system from the perspective of endometriosis patients will be collected to ensure patient centredness. Patient centredness, as one of the dimensions used to assess the quality of healthcare,^{27 29} is most commonly examined using Patient-Reported Experience Measures (PREMs), which focus on patients' experiences in a defined healthcare context.³⁰ This means that PREMs are an appropriate way to involve patients directly in the research process. Input from the patients' perspective will help to gain a better understanding of experiences, strengths and weaknesses of healthcare provision and quality of care for patients.³¹ In this study, we will collect

PREMs via semistructured interviews on healthcare system contacts and diagnosis pathway. Structural and personal challenges as well as resources of the healthcare system will also be addressed. Only patients who have received a laparoscopic confirmed diagnosis according to *ICD-10 N80 endometriosis* with all subcategories of the classification will be interviewed.

Patient and public involvement

We have decided to involve the patient itself directly in this study by conducting interviews with diagnosed endometriosis patients in the third step. The interview questions will be pilot tested with an endometriosis patient from the researcher's network and then evaluated together to decide if it is necessary to refine the interview guide. A summary of the results will be given to the interviewed patients.

The public is not involved in the research process.

Utilisation data

Data collection

First, a retrospective secondary data analysis will be performed using SHI billing data from inpatient care (*DRG statistics*) and hospital quality reports in order to reflect regional differences in the utilisation of endometriosis care. In addition, data from the *Zi* will be included in order to also include outpatient care, specifically focusing on the M2Q criterion. The M2Q criterion is met if the same ICD-10 diagnosis was made in two different quarters, indicating a chronic condition.^{32 33}

The treatment cases are defined using ICD-10 code *N80 endometriosis* and all subcategories. Also, surgical procedures related to endometriosis will be recorded. In order to evaluate frequencies and possible geographic differences in procedure frequency, inpatient therapeutic measures will be mapped using the operation and procedure code (OPS). For this purpose, operations from the OPS group *5-65 Operations on the female genital organs*, in particular the operation code *5-651.b Destruction of endometriosis lesions, 5-702.2 Excision of diseased tissue of the Douglas area* and *5-702.4 Destruction of diseased tissue of the Douglas area* is included. Utilisation of procedure data is reported for adult women aged 18 years and older. In addition, QIs for care are defined and quality is assessed using billing data to the best extent possible.

Data analysis

The guideline *Good Practice Secondary Data Analysis* is used as a guide for planning, implementing and analysing the utilisation data.³⁴ The statistical analysis will be performed with descriptive methods and a small area variation analysis, in order to be able to represent the healthcare situation at a smaller scale. For this purpose, parametric bootstrapping methods such as the *systematic component of variation* are applied, which are used in small area variation analyses of regional healthcare differences due to their robustness.³⁵ There, the number of cases per defined area is modelled hierarchically in a two-step procedure.



In the first step, it is assumed that, depending on the risk, the number of cases follows a Poisson distribution; in the second step, the heterogeneity is modelled.³⁵

Regional and structural determinants

The next study phase examines factors that can explain the spatial structure and differences in utilisation and quality, especially with regard to spatial and social determinants, and to explain them in a small-scale setting at community level (data can only be used in aggregated form) or at community association level. For this purpose, data on utilisation and quality established in the first phase will be compared with determinants of the regions, such as hospital density, accessibility of endometriosis centres, number of general practitioners and gynaecologists, unemployment rate and socioeconomic status (German Index of Socioeconomic Deprivation), using multifactorial ANOVA analyses. These data are taken from the publicly available official statistics *Indicators, Maps and Graphics on Spatial and Urban Monitoring* (INKAR) by the *Federal Institute for Research on Building, Urban Affairs and Spatial Development* on spatial and urban development and social reporting. In addition to the already mentioned data sources, sick leave reports can also provide information on determinants such as the burden of illness in the work context and sick leave due to endometriosis. A different structure of the population in terms of age and gender in the regions may influence the variation in regional care. Therefore, standardised calculations are also performed according to age groups and gender.

Interviews

In the third phase, we will use qualitative, primary data in the form of an interview. The qualitative research approach aims to specify individual experiences of patients with endometriosis in utilisation and care quality by the healthcare system in Central and Eastern Hesse. Also, the experiences with endometriosis healthcare delivery, as well as personal structural challenges and burdens in connection with the disease, is provided a space in this investigation.

Interview guide

The interviews will be performed in a semistructured format using an interview guide. Patients who have a laparoscopically confirmed diagnosis of endometriosis will be interviewed in this semistructured interview to record experiences in healthcare and individual treatment courses. The questions in the interview guide cover the patient's path to diagnosis and her contacts and experiences with the healthcare system, medical staff, health insurance companies or other relevant institutions in the healthcare system. It includes open-ended questions and focuses on the patients' perspective and way of experiencing.

Interviews will be conducted in German by one of the authors, who is trained in qualitative research methodology. The interviewer developed the guide collaboratively

with the other author and will be pilot tested internally within the research team and externally with an endometriosis patient from the researcher's network for appropriate clarity, brevity and sensitivity. The interview guide will be further refined after the pilot interview and in consultation with the other researchers until a final version is agreed on prior to participant recruitment.

Sample

Inclusion criteria are that female patients are at least 18 years old, German-speaking, have a laparoscopically confirmed diagnosis according to *ICD-10 N80 endometriosis* and have had contact with the healthcare system mainly in Central and Eastern Hesse with the seven described counties. *Mainly* is defined as: residing for at least 6 months in one of the seven counties of Giessen, Marburg-Biedenkopf, Fulda, Hersfeld-Rotenburg, Vogelsberg, Lahn-Dill-Kreis and Wetteraukreis and already having at least one contact with the healthcare system due to their disease.

The sample size cannot be determined in advance for qualitative methods since as many subjects are studied until saturation of the results is reached.³⁶ However, it is estimated that the sample will range from 5 to a maximum of 25 women when a phenomenological approach is used,³⁷ which will be used for the analysis of the interview. It will be ensured that patients from all counties are represented in the sample.

Recruitment and data collection

Patients are recruited, for example, via endometriosis centre in Giessen, via Marburg university mailing list and via flyers at clinics in Marburg, Fulda, Wetzlar and Bad Hersfeld. A suitable appointment is then arranged with interested patients by telephone or email. The qualitative interview is conducted in person and at a location chosen by the patient, for example, at the patient's home or on the premises of our institute. Furthermore, information on age and highest educational qualification of the patients, as well as date, location, length of interview and an interview token chosen by the patients is recorded for each person.

Data saturation in qualitative methods is reached when the researcher no longer collects new data from the participants, because further data collection does not provide any new characteristics or insights.³⁸

Data analysis

The interviews are recorded, then transcribed using MAXQDA software and analysed and interpreted using Creswell's simplified version³⁷ of Moustakas' modification of the Stevick-Colaizzi-Keen method,³⁹ which is one of the psychological-phenomenological analyses. This method has been used in other studies to evaluate qualitative studies, including specifically interviews with people affected by endometriosis.⁴⁰

The phenomenological approach serves as a suitable analysis tool when the meaning of lived experiences of

individuals is to be characterised.³⁷ The aim is to identify what all participants have in common when experiencing a phenomenon. Thus, the overall goal of phenomenology is to reduce individual experiences to a universal essence without including the expectations of the interviewing person in the results.³⁷ Researchers need to analyse the collected data by reducing the content to significant statements and quotes and then categorising them into themes.³⁹ Then, both the *texture* and the *structure* of the experience are identified and both combined in a final step.³⁹

After analysis and interpretation, important key statements from the interviews are paraphrased or quoted verbatim for presentation of results and publication. The Consolidated Criteria for Reporting Qualitative Research checklist⁴¹ will be used as a base for reporting and publishing the results.

ETHICS AND DISSEMINATION

Ethical and safety considerations

To minimise burdens for the patients, we use in the first and second phase retrospective data analyses, so no actions are performed on patients. Data from those phases are only accessible in anonymised or aggregated form.

Potential burdens for the patients are, if then, only seen during the interview process. During the interview, sensitive and personal stories will be collected. Therefore, patients are explicitly informed about their rights during the whole process. The interview can be cancelled at any time at the patient's request without any negative consequences. The patient can refuse to answer individual questions if they do not wish to answer them. After the interview, the patient may at any time request that her interview would not be included in the evaluation and/or request that it will be deleted. Informed consent will be obtained from patients who are willing to take part in the interview before the interview starts and individual questions will be answered by the interviewer.

In addition, it will be assured that the collected data is confidential and only accessible to authorised personal. In order to prevent the collected data from being assigned to an individual person in retrospect, pseudonymisation is used. For this purpose, an individual token is created by the patients themselves, which is used in the analysis in order to subsequently assign the interviews only to the tokens. Afterwards, no more conclusions about individual persons are possible. The token key list is stored securely together with the original completed interview guides. The completed interview guides with information on the patients as well as the individually created tokens can only be viewed by the study coordinators and are subsequently stored electronically. Also, all personal identification information will be removed from the electronic transcript.

The Philipps University Marburg is bound by the *European General Data Protection Regulation* (EU-DSGVO).

Thus, this study is bound by the EU-DSGVO during the entire data cycle from collection to disposal. The data will be treated confidentially and stored electronically only in pseudonymised form. Latest 10 years after completion of the study, all data collected for this purpose will be destroyed manually and electronically. Ethical clearance was granted from Philipps University Marburg Ethics Committee (reference number: 23-14 BO) to permit the authors to conduct the study.

Impact and dissemination

The study will present the current state of regional healthcare for endometriosis in Central and Eastern Hesse with regard to the parameters of utilisation and quality. So far, there are hardly any findings of regional health services research on patients with the disease endometriosis. Thus, little is known about whether endometriosis patients in Germany are cared for differently from region to region. This will be investigated in detail and exemplarily for the rural region of Central and Eastern Hesse.

With these findings, a benefit for the general public can be generated, as a possible malfunction in endometriosis healthcare can be uncovered. In turn, conclusions can be drawn about the state of regional endometriosis healthcare. Furthermore, depending on the results, various interventions can be developed in the future on the base of the obtained data in order to counteract underuse, misuse or overuse in endometriosis healthcare. Thus, the findings make an important contribution to uncovering the functionality and quality of healthcare in examined counties. But the results are also interesting for the German healthcare system in general, in order to be able to secure the quality of care and to be able to reasonably design the funding and resource allocation of procedures and treatment for diseases with a high disease burden, such as endometriosis. Meaning, the results of the interviews and secondary data analyses can form the base for discussions in the German healthcare system and also be of great benefit to patients, specialists and health insurers. Also, it is possible to apply the mixed methods approach used in this study in other regions of Germany, for other diseases, or even modified in other countries. Hence, this study could be the base of further research projects, implying the research process and its results create opportunities for new, follow-up research.

The results will be disseminated in form of three published articles in suitable health services research journals. Each data analysis should end in a peer-reviewed publication. Further, the results will be discussed with the *Association of Statutory Health Insurance Physicians* and *Medical Association of Hesse*. Key findings will be provided to the interviewed patients and the *Endometriosis Association Germany*.

Study status

We received ethical approval for the study in March 2023. We expect to start data analysis in April 2023, and the

enrolment for the interview in May 2023. The project will approximately be completed in 2 years.

Contributors Both authors (LB and MG) participated in conceiving this study. The concept of the study was developed by LB and supervised by MG. LB wrote the first draft, MG critically reviewed it and provided comments to revise and improve the text. The conduct of the study will be led by LB and supervised by MG. Both authors provided input into the protocol, critical feedback on the manuscript and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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