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Title Page

Inequalities in realized access to health care among recently arrived refugees depending on local access model: study protocol for a quasi-experimental study

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Abstract

Introduction: In many countries, including Germany, newly arriving refugees face specific entitlement restrictions and access barriers to health care. While entitlement restrictions apply to all refugees that seek protection in Germany during the first months, the barriers to access depend on the model that the states and the municipalities implement locally. Currently, two different models exist: the health care voucher model (HcV) and the electronic health card model (eHC). Aim of the study is to analyse the consequences of these two different access models for newly arrived refugees' realized access to health care.

Methods and analysis: The random assignment of refugees to municipalities allows for a quasi-experimental design by comparing realized access to health care among refugees in six municipalities in North Rhine-Westphalia (NRW) which have implemented HcV or eHC. We compare realized access to health care using ambulatory care sensitive conditions and health expenditure as outcome indicators and use of emergency care, preventive care, psychotherapeutic or psychiatric care, and use of therapeutic devices as process indicators.

Results will be adjusted for aggregated information on age, sex, socioeconomic structure of the municipalities and density of general or specialized practitioners.

Ethics and dissemination: We cooperated with local welfare offices and the statutory health insurance for data collection. Thereby, we were able to avoid recruiting large numbers of refugee patients immediately at arrival for health service research – while their access and entitlement to health care is limited at that time. We developed an extensive data protection concept and ensured that all data collected is fully anonymized. Results will be published in peer-review journals and summarized in reports to the funding agency.

Strengths and limitations of this study

- Our study comprises a large and diverse sample of newly arrived refugees that are usually excluded from health system research and official health reporting.
- Refugees are randomly assigned to different municipalities which allows us to realize a quasi-experimental research design.
- Selection bias might lead to underestimated effects as municipalities with very restrictive refugee health policies are less likely to participate.
- Demographic information is not collected on the individual, but on the aggregated level.

Key Words

Refugee health, access to health care, quasi-experimental design, health policy, organization of health services, public health

MAIN TEXT

INTRODUCTION

In many countries, newly arriving refugees face specific entitlement restrictions and access barriers to health care.[1,2] These regulations have been discussed from ethical, human rights and legal perspective.[3–5] While we acknowledge the importance of these fundamental debates, our study focuses on the actual consequences of these regulations for the use of health care among recently arrived refugees. We concentrate on the regulations that apply to refugees during their first years after arrival as we consider this time to be a socially critical period, (as defined by Bartley et al. [6]), and as such as decisive for the further course of individual's life and the development of social or health inequalities.

During the first 15 months after arrival, the level of entitlement to health care is restricted and the formal access to health care is not equal to that of persons covered via the statutory health insurance. Entitlement is restricted by article 4 and 6 of the Asylum Seekers Benefits Act (AsylbLG). The AsybLG covers the costs of health care services in the case of acute illness and pain, pregnancy and birth as well as for officially recommended vaccination and medically necessary check-ups. Other services, for example diagnoses and treatment of non-acute chronic illness or (long-term) psychotherapy, are only granted on a case-by-case basis.[7] Among persons facing these restrictions, hospitalizations and emergency care use is increased while prescriptions and dental visits are decreased compared to persons regularly insured via the statutory health insurance, showing that these legal regulations actually shape patterns of health care use.[8]

Besides these entitlement restrictions that apply to all newly arrived refugees – with the exception of unaccompanied minors – the bureaucratic procedures of how to actually access health care services are identified as barriers to necessary care.[9] Given that these bureaucratic procedures differ between municipalities and federal states, the actual access also differs. Basically, two different access models exist: the electronic health card model (eHC) and the health care voucher mode (HcV) (Fig. 1). The eHC model guarantees access similarly to the statutory health insurance. Refugees receive e-health cards once they are assigned to a municipality. They can directly access health care services presenting the card at the hospital or in a doctor's office, but the entitlement restrictions largely remain. The HcV model constitutes a parallel access model specifically for recently arrived refugees. In municipalities using the HcV model, refugees apply for health care vouchers at the local welfare authorities before accessing care. These health care vouchers are valid usually for three months.[9–11]

After usually 15 months, all refugees receive e-health cards and are allowed to join a statutory health insurance. The restrictions of articles 4 and 6 no longer apply (Fig. 1). If their asylum claims have been approved or they take up an employment, this might even happen earlier. In some cases (e.g. when persons have not revealed their identities), the restrictions are extended (Article 2 AsylbLG).

[Fig 1]

Figure 1: Health care for newly arrived refugees in Germany: simplified access model and entitlement in municipalities (own illustration)

It is on each of the 16 federal states in Germany to decide on an access model for refugees during the first months after arrival. However, the state government in NRW decided to leave it to the municipalities to either opt for the HcV or the eHC model. NRW is the only federal state in which both models are currently used in a considerable number of municipalities. Refugees in NRW are randomly assigned to municipalities – and thereby to the different coexisting access models – after they have stayed in the initial reception centers during the first weeks.

We hypothesize that the choice of the model affects access to health care, utilization as well as health care expenditures. So far, there has been no quantitative empirical research actually comparing on a larger scale the ways in which these models impact on the actual use of health care, the range of services that can be accessed and the related health care expenditures. However, available research results suggest that the HcV model constitutes a barrier to ambulatory health care,[9] leads to higher health care expenses [12] and might explain – at least partly – the increased use of emergency care among refugees in Germany and the lower utilization of outpatient health care services.[13]

These research results and the current regulations on access to health care lead to the following overall study hypothesis: The access model (macro level) and its implementation (meso level) influence the access to health care for refugees living in the municipalities (micro level). As a consequence, we expect to observe differences in realized access between individuals (micro level), resulting also in different patterns of realized access on municipality level (meso level) and between access models (macro level) (c.f. Fig. 2).

[Fig. 2]

Figure 2: Graphical summary of the overall study hypothesis (own illustration based on,[14] p. 10)

METHODS AND ANALYSIS

Design, setting, participants and sample size

We here define refugees as all people who recently migrated to Germany seeking legal protection – irrespective of their legal status and the reasons for seeking protection. Refugees are randomly assigned to municipalities. Assignment of refugees takes place according to the population size and spatial extent of the municipalities without prior consideration of their assumed health care needs.[15] As municipalities have implemented different access models (eHC or HcV), a quasi-experimental study design can be realized

At the end of 2016, 191,312 refugees lived in municipalities in NRW and were entitled to health care services according to article 4 and 6 AsylbLG. Of these, 21.6% (41,348) lived in one of the 20 municipalities using the eHC model at that time. In 2017, of the 122,405 recently arrived refugees, 23.3% lived in one of the meanwhile 24 municipalities using the eHC model.[16]

We calculated the sample size based on the primary outcome (ambulatory care sensitive conditions, ACSC). In a similar study, incidence rate of ACSC was 38 per 1000 among refugees living in municipalities with eHC.[8] There was no study investigating the ACSC of refugees living in municipalities with HcV. Based on results from reports and qualitative studies, we estimated an incidence rate of 50 per 1000. With a predefined power of 0.8 and a significance level of 0.05 we calculated a sample size of 4750 per group. We decided to include one larger city, one medium size city and one smaller city for each group in order to meet the necessary sample size. In total,

we thus recruited six municipalities. In these municipalities, all newly arrived refugees entitled to health care through the local welfare offices are included in the study.

As the number of municipalities with eHC is a comparatively small (22 with eHC compared to 374 with HcV), recruitment starts among the 22 eHC-municipalities. As the data access would depend on the willingness of the insurances to participate in the project, recruitment will be realized through the statutory health insurance companies. The municipalities should differ in population size and organizational structure (independent city or district-affiliated city). Subsequently, we apply purposive sampling to recruit municipalities using the HcV model, considering their population size and organizational structure. As we were able to include all refugees entitled to services during the study period, no further sampling was necessary.

Data collection started in June 2018 and will last until beginning of 2019. Data has to be collected retrospectively, as health care providers need several months for controlling and billing. Ultimately, we will include data on health care use for seven subsequent quarters (2-2016 until 4-2017) to be able to compare differences between municipalities and over time.

Variables and data sources

For municipalities using the HcV model, all demographic data and data on used of health care services has to be collected directly at the local welfare office or from the external service provider if the municipalities have outsourced the verification and payment of invoices. In municipalities which have implemented the eHC model, data has to be collected from the responsible statutory health insurance.[17]

Data includes principle and secondary diagnoses (ICD-10-Codes), type of care used (primary, specialist, emergency or hospital care), procedures and prescriptions and date of use (quarterly). Quarterly data on number of refugees according to age and sex is inquired separately from the health insurances or the welfare offices. It is available as aggregated information only. Similarly, health care expenditure is available as aggregated variable only.

Outcomes: realized access

The primary outcome we are interested in is realized access to health care. The only available data that might serve as an indicator of access to health care are use of health care services and related expenditures. Given that expenditures are the direct consequence of use and thus primarily determined by use, we initially focus here on the relationship between access and use. In line with the "Behavioral Model of Health Service Use" developed and updated by Ronald M Anderson, we consider use to be equal to realized access and thereby a suitable proxy for access.[18] The available claims data does not allow for analysis of more complex concepts of access – e.g. as the fit between the individuals' and the systems' characteristics.[19] Use and expenditure are generalized measures that need hypothesis-based concretization. We developed three sub-hypothesis on the effects of the HcV model on use and thereby also on local health care expenditure. Either explicitly or implicitly it is suggested that the hypothesized effects are absent in municipalities using the eHC model. All three hypotheses thus refer to differences in use and expenditure between refugees in municipalities using health vouchers (exposed) and refugees in municipalities issuing e-health cards (unexposed). For each sub-hypothesis, we operationalize suitable outcome measures.

1) Emergency care

Health care vouchers are said to complicate access to care – especially to primary or specialized ambulatory care.[13] The vouchers are valid only for three months, they are not always known by the health professionals, and they immediately show that a person has no full entitlement to health care. Patients might delay use or refrain from using ambulatory services to avoid applying for and showing the vouchers. There is no need to present the health care voucher for emergency care.[9,20–23] As a consequence, we assume a higher use of emergency care services. We calculate incidence rates of emergency cases (=outcome 1) and relative risks for each quarter. If the emergency case led to hospitalization, only the date of admission is considered. We count emergency cases (even if a person uses emergency services several times per quarter) and relate the cases to the number of persons eligible to services according to AsylbLG Article 4 and 6. We also count the number of individuals that have used emergency services at least once in the quarter. For individual level regression analysis, a dichotomous outcome variable will be coded containing the information whether or not an individual had used emergency care in the quarter. For ecological regression analysis, quarterly incidence of emergency cases in the six municipalities will serve as outcome variable.

2) Delayed treatment

The necessary additional effort to access care in municipalities with HcV model might also lead to delays in treatment. Instead of accessing primary care, patients might delay treatment until hospitalization is necessary. Hospitalizations that could have been avoided with adequate outpatient care are defined as ambulatory care sensitive hospitalizations (ACSH). Usually, ACSH

are identified based on the related diagnoses. Accordingly, ambulatory care sensitive conditions (ACSC) are thus defined as "conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease"[25, p.1]. ASCH are considered to be a valid indicator of access barriers to ambulatory care in general [25–28] and have been also identified as a useful indicator of access to primary ambulatory care among forced migrants.[8,29,30] Several different catalogues of ACSC have been developed internationally. Recently, they have been adapted and validated for the German context.[31] The full list of ACSC consists of 40 diagnoses groups with 22 being considered as core diagnosis groups. The full list compiled by Sundmacher et al. includes 258 ambulatory sensitive ICD-10 codes.[32] For children, we use a slightly modified list developed by Lichtl et al.[30] Based on this lists, we define ambulatory care sensitive cases (=outcome 2) and calculate incidence rates per quarter in municipalities using the HcV model and the eHC model (with N being all refugees entitled to services in the quarter). We compare incidence rates over time and between municipalities. We also calculate relative risk comparing the incidence between models. Again we calculate incidence rates (counting all cases even if one person has several ACSC diagnosed) and in addition the share of individuals with at least one ASCS per quarter. As described for outcome 1, we use a dichotomous outcome variable and the quarterly incidence as outcomes for regression analysis. If the number of cases allows, we further differentiate between ACSC cases with regular referral and emergency ACSC cases where the patients have been hospitalized after visiting or being brought to the emergency department.

3) Non-urgency of treatment

The delay in treatment and the increase in emergency care use or hospitalizations might not materialize during the observation period (first 15 months) as assumed in hypothesis 1 and 2 (above), but afterwards, once the entitlement restrictions cease to apply and e-health cards are issued for all. During the observation period, this would still result in a lower use of outpatient cases (primary care) among refugees living in municipalities with a health care voucher – especially for deferrable services such as check-ups or prevention.[13] The participation in medically necessary check-ups (Z- codes according to ICD-10-GM) has been used as outcome measure for access barriers and discrimination related to minority or migration status.[22,33,34] However, the use of preventive care (=outcome 3) as outcome is conditioned on the size of the population groups entitled to preventive services (pregnant women, children, elderly) in the available data and the quality of information on age and sex. If information on age and sex is not detailed enough, we only include the incidence of persons using outpatient care among all people entitled to care in the quarter – also differentiating between ambulatory and specialized care. As mentioned earlier, dental care will be excluded from the analysis.

In addition to postponing preventive care (which should be refunded according to article 4 AsylbLG in all municipalities), municipalities using the HcV model might refuse to refund services as part of the case-by-case review (Art. 6 AsylbLG) referring to the non-urgency of the treatment (*Kriterium der Aufschiebbarkeit*). The framework agreement on the e-health card abolishes any consideration of non-urgency of treatment. Thus, in municipalities using the e-health cards, most services are granted irrespective of their urgency. However, in municipalities using the HcV model urgency of treatment might still be considered. Psychotherapy and therapeutic devices ("Hilfsmittel") have been identified as services for which the consideration of urgency might lead

to differences in realized access.[3,35–37] We thus compare psychotherapeutic care cases (outcome 4) and refunded therapeutic devices (outcome 5) between access models. Cases of psychotherapeutic care are defined as visits to specialized doctors (psychiatrists and psychological psychotherapists) and not based on diagnoses. For psychotherapeutic care, repeated visits by the same person in the same quarter are not counted separately. For therapeutic devices, prescriptions for the same device for the same person in the same quarter are not counted separately. Incidence rates and relative risk are calculated for each quarter comparing risks between models and over time.

Outcomes: expenditures

So far, we only referred to the ACSC as outcome indicator and several process indictors related to health care use. However, data on health care expenditure is available (excluding administrative costs). This allows us to relate our indicators of use to the related health care expenditure in the municipalities. We assume the following consequences for per capita expenditure:

1) Expenditures on emergency care

In line with the hypothesis on *emergency care*, the HcV access model goes along with higher use of emergency care and thereby leads to higher health care expenditures for emergency care per capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC model.

2) Expenditures related to delayed treatment

In line with the hypothesis on *delayed treatment*, the HcV access model goes along with higher risk for ambulatory care sensitive hospitalizations. We therefore assume higher health care expenditures for inpatient care per capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC model.

3) Expenditures related to the non-urgency of treatment

The HcV access model is hypothesized to go along with lower use of preventive, psychiatric, psychotherapeutic (outpatient) care and therapeutic devices if the use of these services are postponed or considered as non-urgent by the municipalities. As a consequence, we assume to observe lower health care expenditures for outpatient care per capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC model.

Health care expenditure per capita and quarter in the municipalities will thus be differentiated according to inpatient, outpatient and emergency care and interpreted against the backdrop of the results from the analysis of realized access. More detailed analysis of expenditures for specific health services are not feasible as information on expenditures are only available on aggregated level.

Covariates or confounders

The major determinant of health care use we are interested in is the access model used in the municipalities. However, health care policies and their implementation as locally diverging access models are only one of many determinants of health care use. Andersen and colleagues identified several additional determinants of health care use with the health system being just one of them and access models being just one element of the health system.[18] Thus, a much broader

approach is needed given that confounding by other determinants of use of health care services is probable. We thus adapted Andersen's general model of Health Service Use with regard to our research setting and analyze the availability of data or information for the different determinants (c.f. [18,38]).

Table 1: Determinants of health care utilization according to Andersen (1995)

	Explanation and concretization (adapted from [18])	Availability of information
Predisposing characteristics		
Demographics	Age, sex	Aggregated data available for all municipalities; individual level data only available from municipalities with eHC
Social structure	Socio-economic status, origin/nationality	Not available
Health beliefs	Attitudes, values, and knowledge about health or health services	Not available
Enabling resources		
Individual /family	Financial means, health insurances	Not available; entitlements to benefits according to AsylbLG are need-based and thus these regulations apply only to people whose financial means are generally limited and who do not have a valid health insurance in Germany (Art. 7 AsylbLG)
Community	Availability of health personnel and facilities, travel and waiting time	Limited availability: density of general practitioners and specialized doctors [43,44]
Social relationships	Social support	Not available
Need		
Perceived need	Subjective health	Not available
Evaluated need	Professional judgments about health care needs (e.g. diagnoses)	Only available for those who actually used health care and even among those who used health care limited to the condition for which health care was used; the number of severe cases with annual individual health care costs of

		more than 35.000 € are known for municipalities due to state refunding policies [15]
Health care system		
Policy	Macro characteristics of the health system not further specified by Andersen and colleagues	With exception of the access model and its implementation, this should be the same for all municipalities in NRW
Resources		
Organization		
External environment		
Physical	Natural and build environment	Availability very limited: information on types of accommodation in municipalities (central or decentralized) [16]
Political	Political context (global, national, state, local)	No difference between municipalities for global, national and state level; local level: information on population size, organizational structure (e.g. independent city, county-affiliated) [45] and results from local elections as well as the political party of the ruling major [46]
Economic	Economic structure	No difference between municipalities for global, national and state level; local level: data available for municipalities in Germany (unemployment rate, average household purchasing power, age-structure) [45]
Health practices		
Personal health practices	Diet, exercise, self-care (not related to seeking care)	Not available

Table 1 shows that there are important individual-level determinants of use that we are not able to consider (especially socio-economic status, health beliefs, individual enabling resources, need and personal health practices). Given that refugees are almost randomly assigned to the municipalities, our study can be considered as a natural experiment or a quasi-experimental

study. Under these quasi-experimental conditions, the determinants should be independent of the access model. As a result, confounding by these determinants of use should be minimized. We still control for significant differences in demographic characteristics that persist despite random assignment, based on the available aggregated data on sex and age. As listed in Table 1, information on important contextual, health system and community related determinants are available. This is the case for availability of doctors, overall socio-demographic, economic and political context are (partly) available. Adjustment for these aspects is thus possible at municipality level.

Planned statistical analysis

We aim to shed light on the development of health inequalities in the socially critical phase refugees face immediately after arrival in Germany and the importance of the local context in providing access to health care. However, we analyze inequalities only in the sense of (descriptive) differences and not in the sense of inequities which constitutes a separate interpretative step.

Incidence rates and relative risks of all five outcomes are analyzed for seven quarters comparing municipalities with eHC and with HcV. Timing and pathways of care will also be explored. Analysis will be adjusted for aggregated information on age and sex provided by the municipalities. As part of the descriptive analysis we will also compare health care expenditures in the municipalities. Subsequently, we will perform a multivariate regression analysis. As the detailedness of the data is limited (few municipalities and no individual level data on age and sex), we explore different possible statistical analysis and compare the results. In ecological analysis, we use general linear regression models with quarterly incidence rates in the six municipalities as outcomes. In

individual level analysis, we include each of the outcomes as (dependent) outcome variable, the access model as (independent) exposure variable and conduct repeated (7 quarters) cross-sectional regression analysis. In both cases, we will include the age-sex distribution, socio-economic and political structure of the community and density of general and specialized practitioners respectively as covariates in the regression models (c.f. Table 1).

Public and patient involvement

The described quantitative study is embedded in a larger mixed-methods project. As part of the project, we conduct qualitative semi-structured interviews (not described in detail here) with actors in welfare agencies, social workers, health care providers and refugees in all six municipalities. Interview material will be analyzed to understand how the models are actually implemented in the municipalities and how access is organized from the perspective of providers and patients. Their perspectives and needs are also considered during data collection and analysis. The final results will be discussed with interviewees in the six municipalities.

ETHICS AND DISSEMINATION

Research evaluating the (health) consequences of legal provisions for newly arrived refugees' access to health care in a methodologically and ethically sound way constitutes a challenge. Refugees are usually not included or not identifiable in the official health reporting systems.[39,40] In addition, we know from previous research that it is difficult to recruit newly arrived refugees on a large scale due to language differences, frequent relocations and assumed low response rates.[41,42] Inequalities stemming from different formal access to health care are thus not easily detectable. As a consequence, we need new methodological approaches to

document possible inequalities – which might increase their visibility and ultimately contribute to their reduction. At the same time, it is ethically questionable to recruit large numbers of refugees for quantitative health service research shortly after arrival in their new country of residency – while their access and entitlement to health care is still restricted.

In order to overcome these difficulties, we cooperated with local welfare offices and the statutory health insurance to collect data on use of health care among newly arrived refugees. We ensured that data collection would lead to fully anonymized (and even partly aggregated) data, so there was no need to seek consent from individuals and conduct interviews. This approach and the full study have been approved by the ethical committee and the data protection office at Bielefeld University (application no. 2017-099, 10th May 2017).

We developed a data protection concept in close cooperation with the data protection officer and our study data trustee. Data will be managed, analyzed and stored on encoded offline servers. Ten years after the end of the study, the data trustee will delete the data. Results will be published in peer-reviewed journals and summarized in reports to the funding agency.

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List of Abbreviations

ACSC	Ambulatory care sensitive conditions
ACSH	Ambulatory care sensitive hospitalizations
AsylbLG	Asylbewerberleistungsgesetz/Asylum Seeker's Benefits Act
eHC	Electronic health card model
HcV	Health care voucher model
NRW	Nordrhein-Westfalen/North Rhine-Westphalia

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Data sharing

Data collection is still ongoing. Details of the data sharing will be agreed upon once the data collection has been completed.

Ethics approval and consent to participate

The study has been positively reviewed by the Ethics Committee and the data protection officer of Bielefeld University.

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Consent was not obtained because the patient cannot be traced. However, there was no need to obtain consent, because data is fully anonymized.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JW, KR und OR designed the study. JB, OS und KB made substantial contributions to its conception and design. JW drafted the manuscript. KR, JB, OS, KB und OR revisited the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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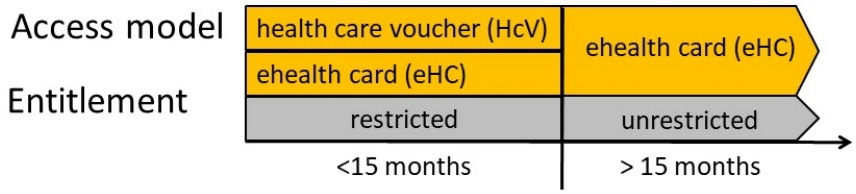

Figure 1: Health care for newly arrived refugees in Germany: simplified access model and entitlement in municipalities (own illustration)

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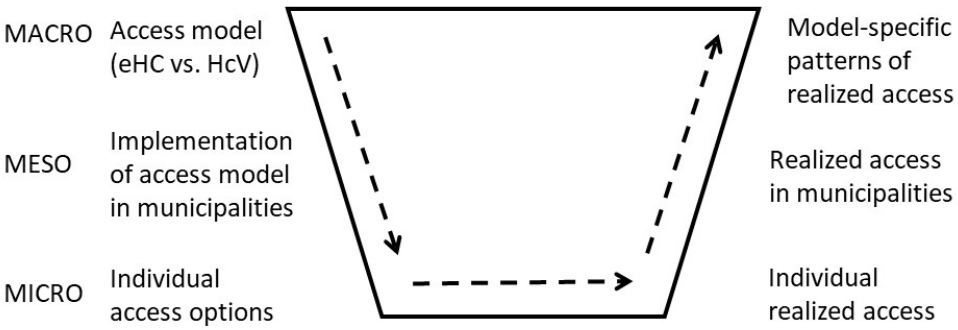

Figure 2: Graphical summary of the overall study hypothesis (own illustration based on,[14] p. 10)

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Inequalities in realized access to health care among recently arrived refugees depending on local access model: study protocol for a quasi-experimental study

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Title Page

Inequalities in realized access to health care among recently arrived refugees depending on local access model: study protocol for a quasi-experimental study

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Abstract

Introduction: In many countries, including Germany, newly arriving refugees face specific entitlement restrictions and access barriers to health care. While entitlement restrictions apply to all refugees that seek protection in Germany during the first months, the barriers to access depend on the model that the states and the municipalities implement locally. Currently, two different models exist: the health care voucher model (HcV) and the electronic health card model (eHC). The aim of the study is to analyse the consequences of these two different access models on newly arrived refugees' realized access to health care.

Methods and analysis: The random assignment of refugees to municipalities allows for a quasi-experimental design by comparing realized access to health care among refugees in six municipalities in North Rhine-Westphalia (NRW) which have implemented HcV or eHC. We compare realized access to health care using ambulatory care sensitive conditions and health expenditure as outcome indicators; and use of emergency care, preventive care,

psychotherapeutic or psychiatric care, and of therapeutic devices, as process indicators. Results will be adjusted for aggregated information on age, sex, socioeconomic structure of the municipalities, and density of general practitioners or specialists.

Ethics and dissemination: We cooperated with local welfare offices and the statutory health insurance for data collection. Thereby, we were able to avoid recruiting large numbers of refugee patients immediately after arrival while their access and entitlement to health care is restricted. We developed an extensive data protection concept and ensured that all data collected is fully anonymized. Results will be published in peer-reviewed journals and summarized in reports to the funding agency.

Strengths and limitations of this study

- Our study comprises a large and diverse sample of refugees during the period of restricted entitlements that are usually excluded from health system research and official health reporting.
- Refugees are randomly assigned to different municipalities which allows for a quasi-experimental research design.
- Due to selection bias we might underestimate the effect size as municipalities with restrictive refugee health policies are less likely to participate.
- Demographic information is not collected on the individual, but on the municipality level.

Key Words

Refugee health, access to health care, quasi-experimental design, health policy, organization of health services, public health

MAIN TEXT

INTRODUCTION

In many countries, newly arriving refugees face specific entitlement restrictions and access barriers to health care.[1,2] The underlying regulations have been discussed from ethical, human rights and legal perspectives.[3–5] While we acknowledge the importance of these fundamental debates, our study focuses on the actual consequences of these regulations for the use of health care among recently arrived refugees. We concentrate on the regulations that apply to refugees during their first years after arrival as we consider this time to be a socially critical period (as defined by Bartley et al. [6]), and as such as decisive for the individual's further life course and the development of social and health inequalities.

In the first 15 months after arrival, entitlement to health care is restricted and formal access is not equal to that of persons covered via the statutory health insurance. Entitlement is restricted by article 4 and 6 of the Asylum Seekers' Benefits Act (AsylbLG). The AsybLG covers the cost of health care provision in case of acute illness and pain, pregnancy and birth, as well as for officially recommended vaccination and medically necessary check-ups. Other services, for example diagnoses and treatment of non-acute chronic illness or (long-term) psychotherapy, are only granted on a case-by-case basis.[7] Among persons facing these restrictions, hospitalizations and emergency care use is increased while numbers of prescriptions and dental visits are decreased compared to persons insured via the standard statutory health insurance, showing that these legal regulations actually shape patterns of health care use.[8]

Besides these entitlement restrictions that apply to all newly arrived refugees – with the exception of unaccompanied minors – the bureaucratic procedures required before health care services can be accessed have been identified as barriers to necessary care.[9] Given that these procedures differ between municipalities and federal states, the actual access also differs. Basically, two different access models exist: the electronic health card model (eHC) and the health care voucher mode (HcV) (Fig. 1). The eHC model provides access comparable to that of patients in the statutory health insurance. Refugees receive e-health cards once they are assigned to a municipality. They can directly access health care services presenting the card at the hospital or in a doctor's office, but the entitlement restrictions largely remain. The HcV model constitutes a parallel access model specifically for refugees during the first 15 months. In municipalities using the HcV model, refugees need to apply for health care vouchers at the local welfare authorities before accessing care. These health care vouchers are valid usually for three months.[9–11]

After 15 months, all refugees receive e-health cards and join a statutory health insurance. The restrictions of articles 4 and 6 no longer apply (Fig. 1). If their asylum claims have been approved or they find employment, this happens even earlier. In some cases (e.g. when persons have not revealed their identities), the restrictions are extended (Article 2 AsylbLG).

[Fig 1]

Figure 1: Health care for newly arrived refugees in Germany: simplified access model and entitlement in municipalities (own illustration)

Each of the 16 federal states in Germany decides on the access model to be implemented. An exception is the state government in North-Rhine Westphalia (NRW), which left it to the

municipalities to either opt for the HcV or the eHC model. NRW is the only federal state in which both models are concurrently in use in a considerable number of municipalities. Refugees in NRW are randomly assigned to municipalities – and thereby to the different access models – after leaving the initial reception centers. Assignment of refugees takes place according to the population size and area size of the municipalities without prior consideration of assumed health care needs of the refugees. Members of one family (parents and children) are assigned to the same municipality. Exceptional circumstances – including psycho-medical needs – might later lead to reassignment (e.g. if treatment is only possible in a certain municipality).[12]

We hypothesize that the choice of the model affects access to health care, utilization, and health care expenditures. So far, this has not been studied. However, available research results suggest that the HcV model constitutes a barrier to ambulatory health care,[9] leads to higher health care expenses, [13] and might explain – at least partly – the increased use of emergency care among refugees, and the lower utilization of outpatient health care services.[14] This leads to the overall study hypothesis: The access model (macro level) and its implementation (meso level) influence the access to health care for refugees living in the respective municipalities (micro level). As a consequence, we expect to observe different patterns of realized access on municipality level (meso level) and between access models (macro level) (c.f. Fig. 2, based on [15], p. 10).

[Fig. 2]

Figure 2: Overall study hypothesis (own illustration)

METHODS AND ANALYSIS

Design, setting, participants and sample size

We here define refugees as all persons who recently migrated to Germany seeking legal protection – irrespective of their legal status and the reasons for seeking protection. Refugees are randomly assigned to municipalities. As municipalities have implemented different access models (eHC or HcV), a quasi-experimental study design can be realized.

At the end of 2016, 191,312 refugees lived in municipalities in NRW and were entitled to health care services according to articles 4 and 6 AsylbLG. Of these, 21.6% (41,348) lived in one of the 20 municipalities using the eHC model at that time. In 2017, of the 122,405 recently arrived refugees, 23.3% lived in one of the meanwhile 24 municipalities using the eHC model.[16]

We calculated the sample size based on the primary outcome (ambulatory care sensitive conditions, ACSC). In a similar study, incidence rate of ACSC was 38 per 1000 among refugees living in municipalities with eHC.[8] We found no study investigating the ACSC of refugees living in municipalities with HcV. Based on results from reports and qualitative studies, we estimated an incidence rate of 50 per 1000. With a predefined power of 0.8 and a significance level of 0.05 we calculated a sample size of 4750 per group. We decided to include one larger city, one medium size city and one smaller city for each group in order to meet the necessary sample size and reflect possible differences between settings. In total, we thus recruited six municipalities. In these municipalities, all newly arrived refugees entitled to health care through the local welfare offices are going to be included in the study.

As the number of municipalities with eHC is comparatively small (22 with eHC compared to 374 with HcV), recruitment started among the 22 eHC-municipalities. Recruitment was realized through the statutory health insurance companies. The municipalities differ in

population size and organizational structure (independent city or district-affiliated city). Subsequently, we applied purposive sampling to recruit municipalities using the HcV model, considering their population size and organizational structure. As we were able to include all refugees entitled to services during the study period, no further sampling was necessary.

Data collection started in June 2018 and will last until beginning of 2019. Data has to be collected retrospectively, as health care providers need several months for controlling and billing. Ultimately, we will include data on health care use for seven subsequent quarters (2-2016 until 4-2017).

Variables and data sources

For municipalities using the HcV model, refugees' demographic data and data on use of health care services has to be collected directly at the local welfare office or from the external service providers in case the municipalities have outsourced the verification and payment of invoices. In municipalities which have implemented the eHC model, data has to be collected from the responsible statutory health insurance.[17]

Data includes principle and secondary diagnoses (ICD-10-Codes), type of care used (primary, specialist, emergency or hospital care), procedures and prescriptions and date of use (quarterly). Quarterly data on number of refugees according to age and sex is provided by the health insurances or the welfare offices. It is available as aggregated information only. Similarly, health care expenditure is available as aggregated variable only.

Outcomes: realized access

The primary outcome we are interested in is realized access to health care. The only available data that might serve as an indicator of access to health care are use of health care services

and related expenditures. Given that expenditures are the direct consequence of use and thus primarily determined by use, we focus here on the relationship between access and use. In line with the "Behavioral Model of Health Service Use" developed and updated by Ronald M Anderson, we consider use to be equal to realized access and thereby a suitable proxy for access.[18] The available claims data does not allow for analysis of more complex concepts of access – e.g. as the fit between the individuals' and the systems' characteristics.[19] Use and expenditure are generalized measures that need hypothesis-based concretization. We developed three sub-hypotheses on the effects of the HcV model on use and thereby also on local health care expenditure, assuming that the hypothesized effects are absent in municipalities using the eHC model. All three hypotheses thus refer to differences in use and expenditure between refugees in municipalities using health vouchers (exposed) and refugees in municipalities issuing e-health cards (unexposed). For each sub-hypothesis, we operationalized suitable outcome measures.

1) Emergency care

Health care vouchers are said to complicate access to care – especially to primary or specialized ambulatory care.[14] The vouchers are valid only for three months, they are not always known to the health professionals, and they immediately show that a person has no full entitlement to health care. Patients might delay, or refrain from, using ambulatory services to avoid applying for and showing the vouchers. There is no need to present the health care voucher for emergency care.[9,20–23] As a consequence, we assume a higher use of emergency care services. We will calculate incidence rates of emergency cases (=outcome 1) and relative risks for each quarter. If the emergency case led to hospitalization, only the date of admission will be considered. We count emergency cases (even if a person uses emergency services several times per quarter) and relate the cases to the number of persons eligible to

services according to AsylbLG Article 4 and 6. We will also count the number of individuals that have used emergency services at least once in the quarter. For individual level regression analysis, a dichotomous outcome variable will be coded containing the information whether or not an individual had used emergency care in the quarter. For ecological regression analysis, quarterly incidence of emergency cases in the six municipalities will serve as outcome variable.

2) Delayed treatment

The additional effort needed to access care in municipalities with HcV model might also lead to delays in treatment. Instead of accessing primary care, patients might delay treatment until hospitalization is necessary. Hospitalizations that could have been avoided with adequate outpatient care are defined as ambulatory care sensitive hospitalizations (ACSH). Usually, ACSH are identified based on the related diagnoses. Accordingly, ambulatory care sensitive conditions (ACSC) are thus defined as "conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease"[24, p.1]. ASCH are considered to be a valid indicator of access barriers to ambulatory care in general [25–28] and have also been identified as a useful indicator of access to primary ambulatory care among forced migrants.[8,29,30] Several different catalogues of ACSC have been developed internationally. Recently, they have been adapted and validated for the German context.[31] The full list of ACSC comprises 40 diagnosis groups, with 22 being considered as core diagnosis groups. The full list compiled by Sundmacher et al. includes 258 ambulatory sensitive ICD-10 codes.[32] For children, we use a slightly modified list developed by Lichtl et al.[30] Based on this lists, we define ambulatory care sensitive cases (=outcome 2) and calculate incidence rates per quarter in municipalities using the HcV model and the eHC model (with N being all refugees entitled to services in the quarter). We will compare incidence rates over time and between municipalities. We will also

calculate relative risk comparing the incidence between models. Again, we will calculate incidence rates (counting all cases even if one person has several ACSC diagnosed) and in addition the share of individuals with at least one ASCS per quarter. As described for outcome 1, we will use a dichotomous outcome variable and the quarterly incidence as outcomes for regression analysis. If the number of cases allows, we will further differentiate between ACSC cases with regular referral and emergency ACSC cases where the patients have been hospitalized after visiting or being brought to the emergency department.

3) Non-urgency of treatment

The delay in treatment and the increase in emergency care use or hospitalizations might not materialize during the observation period (first 15 months of stay in Germany) as assumed in hypothesis 1 and 2 (above). It may materialize only afterwards, once the entitlement restrictions cease to apply and e-health cards are issued for all. During the observation period, this would still result in a lower use of outpatient cases (primary care) among refugees living in municipalities with a health care voucher – especially for deferrable services such as check-ups or prevention.[14] The participation in medically necessary check-ups (Z- codes according to ICD-10-GM) has been used as outcome measure for access barriers and discrimination related to minority or migration status.[22,33,34] However, the use of preventive care (=outcome 3) as outcome is conditioned on the size of the population groups entitled to preventive services (pregnant women, children, elderly) in the available data and the quality of information on age and sex. If information on age and sex is not detailed enough, we will only include the incidence of persons using outpatient care among all people entitled to care in the quarter – also differentiating between ambulatory and specialized care.

In addition to postponing preventive care (which should be guaranteed according to article 4 AsylbLG in all municipalities), municipalities using the HcV model might refuse to refund services as part of the case-by-case review (Art. 6 AsylbLG) referring to the non-urgency of the treatment (*Kriterium der Aufschiebbarkeit*). The framework agreement on the e-health card abolishes any consideration of non-urgency of treatment. Thus, in municipalities using the e-health cards, most services are granted irrespective of their urgency. However, in municipalities using the HcV model, urgency of treatment might still be considered. Psychotherapy and therapeutic devices ("Hilfsmittel") have been identified as services for which the consideration of urgency might lead to differences in realized access.[3,35–37] We will thus compare psychotherapeutic care cases (outcome 4) and refunded therapeutic devices (outcome 5) between access models. Cases of psychotherapeutic care are defined as visits to specialized doctors (psychiatrists and psychological psychotherapists) and not based on diagnoses. For psychotherapeutic care, repeated visits by the same person in the same quarter will not be counted separately. For therapeutic devices, prescriptions for the same device for the same person in the same quarter will not be counted separately. Incidence rates and relative risk will be calculated for each quarter comparing risks between models and over time.

Outcomes: expenditures

So far, we only referred to the ACSC as outcome indicator and several process indictors related to health care use. However, data on health care expenditure is available (excluding administrative costs). This allows us to relate our indicators of use to the related health care expenditure in the municipalities. We assume the following consequences for per capita expenditure:

1) Expenditures on emergency care

In line with the hypothesis on *emergency care*, the HcV access model is associated with higher use of emergency care and thereby leads to higher health care expenditures for emergency care per capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC model.

2) Expenditures related to delayed treatment

In line with the hypothesis on *delayed treatment*, the HcV access model is associated with higher risk for ambulatory care sensitive hospitalizations. We therefore assume higher health care expenditures for inpatient care per capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC model.

3) Expenditures related to the non-urgency of treatment

The HcV access model is hypothesized to be associated with lower use of preventive, psychiatric, psychotherapeutic (outpatient) care and therapeutic devices if use of these services is postponed or considered as non-urgent by the municipalities. As a consequence, we expect lower health care expenditures for outpatient care per capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC model.

Health care expenditure per capita and quarter in the municipalities will thus be differentiated according to inpatient, outpatient and emergency care and interpreted against the backdrop of the results from the analysis of realized access. More detailed analysis of expenditures for specific health services will not be feasible as information on expenditures are only available on aggregated level.

Covariates or confounders

The major determinant of health care use we are interested in is the access model used in the municipalities. However, health care policies and their implementation as locally diverging access models are only one of many determinants of health care use. Andersen and colleagues identified several additional determinants of health care use, with the health system being just one of them and access models being just one element of the health system.[18] Thus, a much broader approach is needed given that confounding by other determinants of use of health care services is probable. We thus adapted Andersen's general model of Health Service Use with regard to our research setting and analyze the availability of data or information for the different determinants (c.f. [18,38]).

Table 1: Determinants of health care utilization according to Andersen (1995)

	Explanation and concretization (adapted from [18])	Availability of information
Predisposing characteristics		
Demographics	Age, sex	Aggregated data available for all municipalities; individual level data only available from municipalities with eHC
Social structure	Socio-economic status, origin/nationality	Not available
Health beliefs	Attitudes, values, and knowledge about health or health services	Not available
Enabling resources		
Individual /family	Financial means, health insurances	Not available; entitlements to benefits according to AsylbLG are need-based and thus these regulations apply only to people whose financial means are generally limited and who do not have a valid health insurance in Germany (Art. 7 AsylbLG)
Community	Availability of health personnel and facilities, travel and waiting time	Limited availability: density of general practitioners and specialized doctors [39,40]
Social relationships	Social support	Not available
Need		
Perceived need	Subjective health	Not available

Evaluated need	Professional judgments about health care needs (e.g. diagnoses)	Only available for those who actually used health care and even among those who used health care limited to the condition for which health care was used; the number of severe cases with annual individual health care costs of more than 35.000 € are known for municipalities due to state refunding policies [12]
Health care system		
Policy **Resources** **Organization**	Macro characteristics of the health system not further specified by Andersen and colleagues	With exception of the access model and its implementation, this should be the same for all municipalities in NRW
External environment		
Physical	Natural and build environment	Availability very limited: information on types of accommodation in municipalities (central or decentralized) [16]
Political	Political context (global, national, state, local)	No difference between municipalities for global, national and state level; local level: information on population size, organizational structure (e.g. independent city, county-affiliated) [41] and results from local elections as well as the political party of the ruling major [42]
Economic	Economic structure	No difference between municipalities for global, national and state level; local level: data available for municipalities in Germany (unemployment rate, average household purchasing power, age-structure) [41]
Health practices		
Personal health practices	Diet, exercise, self-care (not related to seeking care)	Not available

Table 1 shows that there are important individual-level determinants of use that we are not able to consider (especially socio-economic status, health beliefs, individual enabling resources, need and personal health practices). Given that refugees are almost randomly assigned to the municipalities, our study can be considered as a natural experiment or a quasi-

experimental study. Under these quasi-experimental conditions, the determinants should be independent of the access model. As a result, confounding by these determinants of use should be minimal. We will still control for significant differences in demographic characteristics that persist despite random assignment, based on the available aggregated data on sex and age. In addition, information on important contextual, health system, and community related determinants are available, as listed in Table 1. This is the case for availability of doctors, overall socio-demographic, economic and political context. Adjustment for these aspects is thus possible at municipality level. However, we will be unable to control for confounding by other individual level determinants, e.g. health beliefs or needs and clustering by family relations or country of origin. We will acknowledge these limitations when discussing the results.

Planned statistical analysis

We aim to shed light on the development of health inequalities in the socially critical phase refugees face immediately after arrival in Germany and the importance of the local context in providing access to health care. However, we analyze inequalities only in the sense of (descriptive) differences and not in the sense of inequities which would constitute a separate interpretative step.

Incidence rates and relative risks of all five outcomes will be analyzed for seven quarters comparing municipalities with eHC and with HcV. Timing and pathways of care will also be explored. Analysis will be adjusted for aggregated information on age and sex provided by the municipalities. As part of the descriptive analysis we will also compare health care expenditures in the municipalities. Subsequently, we will perform a multivariate regression analysis. As the detailedness of the data is limited (few municipalities and no individual level

data on age and sex), we will explore different possible approaches to statistical analysis and compare the results. In ecological analysis, we will use general linear regression models with quarterly incidence rates in the six municipalities as outcomes. In individual level analysis, we will include each of the outcomes as (dependent) outcome variable, the access model as (independent) exposure variable and conduct repeated (7 quarters) cross-sectional regression analysis. In both cases, we will include the age-sex distribution, socio-economic and political structure of the community and density of general and specialized practitioners respectively as covariates in the regression models (c.f. Table 1). Table 2 summarizes the most important methodological aspects of this study.

Table 2: Overview and brief explanation of the methodological approach of the study

Methods overview	Explanation
Study design	Quasi-experimental
Sample	9500 newly arrived refugees (4750 per access model) in six municipalities in the federal state of NRW, Germany
Study period	2/2016 to 4/2017
Main hypothesis	The local access model (HcV vs. eHC) and its implementation influences the access to health care for newly arrived refugees, leading to differences in realized access between models.
Sub hypotheses	1) Emergency care: Using the HcV model leads to higher use of emergency care services compared to the eHC model 2) Delayed treatment: Using the HcV model leads to higher rates of ambulatory care sensitive conditions (ACSC) compared to the eHC model 3) Non-urgency of treatment: Using the HcV model leads to lower use of (deferrable) outpatient services compared to the eHC model
Outcomes	Quarterly incidence rates (IR) and relative risks (RR) of emergency cases (1), ACSC (2) and use of (deferrable) outpatient services (3)
Analyses	For each of the three outcomes we will perform: - descriptive analysis of IR and RR for seven quarters - individual level analysis: logistic regression analysis - ecological analysis: generalized linear models

Public and patient involvement

The quantitative study described here is embedded in a larger mixed-methods project. As part of the project, we have conducted qualitative semi-structured interviews (not described in detail here) with refugees and other informants from one of the six municipalities. The perspectives of the interview participants informed the hypotheses and the selection of suitable outcomes. The final results will be made available to refugee patients through social workers in the six municipalities. As data was collected through local welfare offices and statutory health insurances and not directly from patients, there was no further patient or public involvement in recruitment or conduct of the study.

ETHICS AND DISSEMINATION

To avoid ethical issues, we cooperated with local welfare offices and the statutory health insurance to collect data on use of health care among newly arrived refugees. We ensured that data collection would lead to fully anonymized (and even partly aggregated) data, so there was no need to seek consent from individuals and conduct interviews. This approach and the full study have been approved by the ethical committee and the data protection office at Bielefeld University (application no. 2017-099, 10th May 2017).

We developed a data protection concept in close cooperation with the data protection officer and our study data trustee. Data will be managed, analyzed and stored on encoded offline servers. Ten years after the end of the study, the data trustee will delete the data. When publishing our results, we will adhere to the STROBE guidelines.[43] Results will be published in peer-reviewed journals and summarized in reports to the funding agency.

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List of Abbreviations

ACSC	Ambulatory care sensitive conditions
ACSH	Ambulatory care sensitive hospitalizations
AsylbLG	Asylbewerberleistungsgesetz/Asylum Seeker's Benefits Act
eHC	Electronic health card
HcV	Health care voucher
NRW	Nordrhein-Westfalen/North Rhine-Westphalia

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Data sharing

There are no data in this work.

Ethics approval and consent to participate

The study has been positively reviewed by the Ethics Committee and the data protection officer of Bielefeld University.

Application Number: 2017-099

Date: 10th May 2017

Consent was not obtained because the patient cannot be traced. However, there was no need to obtain consent, because data is fully anonymized.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JW, KR und OR designed the study. JB, OS und KB made substantial contributions to its conception and design. JW drafted the manuscript. KR, JB, OS, KB und OR revisited the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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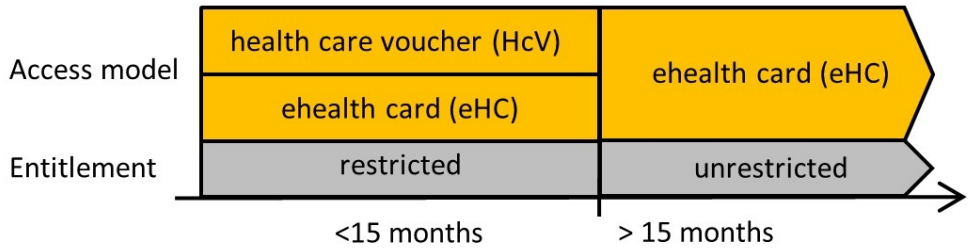
Not applicable



Simplified overview of local access models and entitlements in municipalities in Germany

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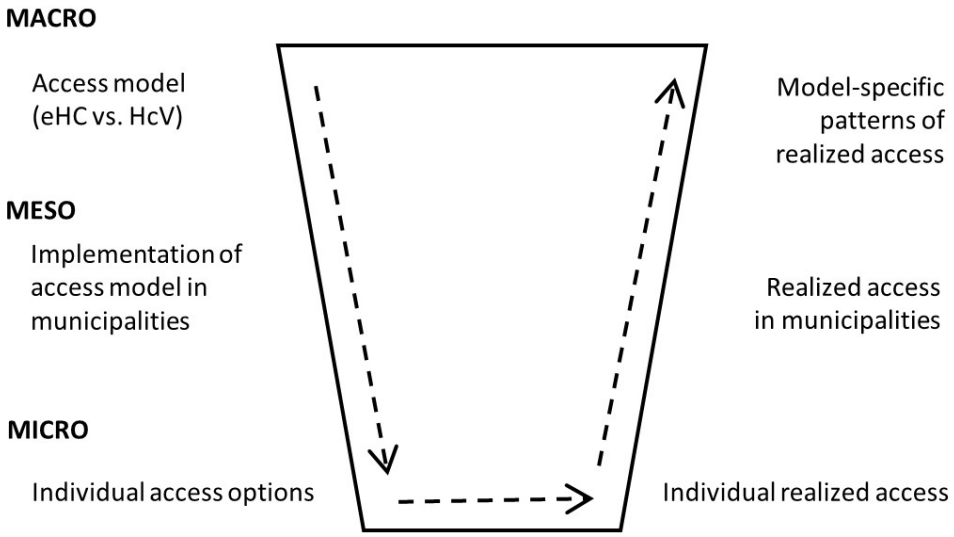

Graphical summary of the overall study hypothesis

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