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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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3 1 **Title Page**
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7 2 **Inequalities in realized access to health care among recently arrived refugees**
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9 3 **depending on local access model: study protocol for a quasi-experimental study**
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16 27 **Word count of main text: 3774**
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19 28 **Abstract**

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23 29 Introduction: In many countries, including Germany, newly arriving refugees face specific
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26 30 entitlement restrictions and access barriers to health care. While entitlement restrictions apply
27
28 31 to all refugees that seek protection in Germany during the first months, the barriers to access
29
30
31 32 depend on the model that the states and the municipalities implement locally. Currently, two
32
33 33 different models exist: the health care voucher model (HcV) and the electronic health card model
34
35 34 (eHC). Aim of the study is to analyse the consequences of these two different access models for
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37 35 newly arrived refugees' realized access to health care.
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41 36 Methods and analysis: The random assignment of refugees to municipalities allows for a quasi-
42
43
44 37 experimental design by comparing realized access to health care among refugees in six
45
46 38 municipalities in North Rhine-Westphalia (NRW) which have implemented HcV or eHC. We
47
48 39 compare realized access to health care using ambulatory care sensitive conditions and health
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50 40 expenditure as outcome indicators and use of emergency care, preventive care,
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52 41 psychotherapeutic or psychiatric care, and use of therapeutic devices as process indicators.
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3 42 Results will be adjusted for aggregated information on age, sex, socioeconomic structure of the
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6 43 municipalities and density of general or specialized practitioners.
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9 44 Ethics and dissemination: We cooperated with local welfare offices and the statutory health
10
11 45 insurance for data collection. Thereby, we were able to avoid recruiting large numbers of refugee
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13
14 46 patients immediately at arrival for health service research – while their access and entitlement to
15
16 47 health care is limited at that time. We developed an extensive data protection concept and
17
18 48 ensured that all data collected is fully anonymized. Results will be published in peer-review
19
20
21 49 journals and summarized in reports to the funding agency.
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51 **Strengths and limitations of this study**

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

59

60 **Key Words**

1
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3 61 Refugee health, access to health care, quasi-experimental design, health policy, organization of
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6 62 health services, public health
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63 MAIN TEXT

64 INTRODUCTION

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

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

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3 83 Besides these entitlement restrictions that apply to all newly arrived refugees – with the
4
5 84 exception of unaccompanied minors – the bureaucratic procedures of how to actually access
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8 85 health care services are identified as barriers to necessary care.[9] Given that these bureaucratic
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10 86 procedures differ between municipalities and federal states, the actual access also differs.
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13 87 Basically, two different access models exist: the electronic health card model (eHC) and the health
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15 88 care voucher mode (HcV) (Fig. 1). The eHC model guarantees access similarly to the statutory
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17 89 health insurance. Refugees receive e-health cards once they are assigned to a municipality. They
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19 90 can directly access health care services presenting the card at the hospital or in a doctor's office,
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21 91 but the entitlement restrictions largely remain. The HcV model constitutes a parallel access model
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23 92 specifically for recently arrived refugees. In municipalities using the HcV model, refugees apply
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25 93 for health care vouchers at the local welfare authorities before accessing care. These health care
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27 94 vouchers are valid usually for three months.[9–11]
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33 95 After usually 15 months, all refugees receive e-health cards and are allowed to join a statutory
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35 96 health insurance. The restrictions of articles 4 and 6 no longer apply (Fig. 1). If their asylum claims
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37 97 have been approved or they take up an employment, this might even happen earlier. In some
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39 98 cases (e.g. when persons have not revealed their identities), the restrictions are extended (Article
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41 99 2 AsylbLG).

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46 100 [Fig 1]
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49 101 **Figure 1: Health care for newly arrived refugees in Germany: simplified access model and**
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51 102 **entitlement in municipalities** (own illustration)
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3 104 It is on each of the 16 federal states in Germany to decide on an access model for refugees during
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5 105 the first months after arrival. However, the state government in NRW decided to leave it to the
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7 106 municipalities to either opt for the HcV or the eHC model. NRW is the only federal state in which
8
9 107 both models are currently used in a considerable number of municipalities. Refugees in NRW are
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11 108 randomly assigned to municipalities – and thereby to the different coexisting access models –
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13 109 after they have stayed in the initial reception centers during the first weeks.
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18 110 We hypothesize that the choice of the model affects access to health care, utilization as well as
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20 111 health care expenditures. So far, there has been no quantitative empirical research actually
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22 112 comparing on a larger scale the ways in which these models impact on the actual use of health
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24 113 care, the range of services that can be accessed and the related health care expenditures.
25
26 114 However, available research results suggest that the HcV model constitutes a barrier to
27
28 115 ambulatory health care,[9] leads to higher health care expenses [12] and might explain – at least
29
30 116 partly – the increased use of emergency care among refugees in Germany and the lower
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32 117 utilization of outpatient health care services.[13]
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39 118 These research results and the current regulations on access to health care lead to the following
40
41 119 overall study hypothesis: The access model (macro level) and its implementation (meso level)
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43 120 influence the access to health care for refugees living in the municipalities (micro level). As a
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45 121 consequence, we expect to observe differences in realized access between individuals (micro
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47 122 level), resulting also in different patterns of realized access on municipality level (meso level) and
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49 123 between access models (macro level) (c.f. Fig. 2).
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54 124 [Fig. 2]
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3 **Figure 2: Graphical summary of the overall study hypothesis** (own illustration based on,[14] p.
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8 **METHODS AND ANALYSIS**

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10 11 12 **Design, setting, participants and sample size**

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14
15 130 We here define refugees as all people who recently migrated to Germany seeking legal protection
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18 131 – irrespective of their legal status and the reasons for seeking protection. Refugees are randomly
19
20 132 assigned to municipalities. Assignment of refugees takes place according to the population size
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22 133 and spatial extent of the municipalities without prior consideration of their assumed health care
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24 134 needs.[15] As municipalities have implemented different access models (eHC or HcV), a quasi-
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27 135 experimental study design can be realized
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31 136 At the end of 2016, 191,312 refugees lived in municipalities in NRW and were entitled to health
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33 137 care services according to article 4 and 6 AsylbLG. Of these, 21.6% (41,348) lived in one of the 20
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35 138 municipalities using the eHC model at that time. In 2017, of the 122,405 recently arrived refugees,
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37 139 23.3% lived in one of the meanwhile 24 municipalities using the eHC model.[16]
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41 140 We calculated the sample size based on the primary outcome (ambulatory care sensitive
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43 141 conditions, ACSC). In a similar study, incidence rate of ACSC was 38 per 1000 among refugees
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45 142 living in municipalities with eHC.[8] There was no study investigating the ACSC of refugees living
46
47 143 in municipalities with HcV. Based on results from reports and qualitative studies, we estimated
48
49 144 an incidence rate of 50 per 1000. With a predefined power of 0.8 and a significance level of 0.05
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51 145 we calculated a sample size of 4750 per group. We decided to include one larger city, one medium
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53 146 size city and one smaller city for each group in order to meet the necessary sample size. In total,
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3 147 we thus recruited six municipalities. In these municipalities, all newly arrived refugees entitled to
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6 148 health care through the local welfare offices are included in the study.
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8
9 149 As the number of municipalities with eHC is a comparatively small (22 with eHC compared to 374
10
11 150 with HcV), recruitment starts among the 22 eHC-municipalities. As the data access would depend
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14 151 on the willingness of the insurances to participate in the project, recruitment will be realized
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16 152 through the statutory health insurance companies. The municipalities should differ in population
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18 153 size and organizational structure (independent city or district-affiliated city). Subsequently, we
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21 154 apply purposive sampling to recruit municipalities using the HcV model, considering their
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23 155 population size and organizational structure. As we were able to include all refugees entitled to
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26 156 services during the study period, no further sampling was necessary.
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29 157 Data collection started in June 2018 and will last until beginning of 2019. Data has to be collected
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31 158 retrospectively, as health care providers need several months for controlling and billing.
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34 159 Ultimately, we will include data on health care use for seven subsequent quarters (2-2016 until
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36 160 4-2017) to be able to compare differences between municipalities and over time.
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39 40 161 **Variables and data sources**

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43 162 For municipalities using the HcV model, all demographic data and data on used of health care
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45 163 services has to be collected directly at the local welfare office or from the external service
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48 164 provider if the municipalities have outsourced the verification and payment of invoices. In
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50 165 municipalities which have implemented the eHC model, data has to be collected from the
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53 166 responsible statutory health insurance.[17]
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3 167 Data includes principle and secondary diagnoses (ICD-10-Codes), type of care used (primary,
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5 168 specialist, emergency or hospital care), procedures and prescriptions and date of use (quarterly).
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8 169 Quarterly data on number of refugees according to age and sex is inquired separately from the
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10 170 health insurances or the welfare offices. It is available as aggregated information only. Similarly,
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13 171 health care expenditure is available as aggregated variable only.
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16 172 *Outcomes: realized access*
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19 173 The primary outcome we are interested in is realized access to health care. The only available
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21 174 data that might serve as an indicator of access to health care are use of health care services and
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23 175 related expenditures. Given that expenditures are the direct consequence of use and thus
24
25 176 primarily determined by use, we initially focus here on the relationship between access and use.
26
27 177 In line with the “Behavioral Model of Health Service Use” developed and updated by Ronald M
28
29 178 Anderson, we consider use to be equal to realized access and thereby a suitable proxy for
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31 179 access.[18] The available claims data does not allow for analysis of more complex concepts of
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33 180 access – e.g. as the fit between the individuals’ and the systems’ characteristics.[19] Use and
34
35 181 expenditure are generalized measures that need hypothesis-based concretization. We developed
36
37 182 three sub-hypothesis on the effects of the HcV model on use and thereby also on local health care
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39 183 expenditure. Either explicitly or implicitly it is suggested that the hypothesized effects are absent
40
41 184 in municipalities using the eHC model. All three hypotheses thus refer to differences in use and
42
43 185 expenditure between refugees in municipalities using health vouchers (exposed) and refugees in
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45 186 municipalities issuing e-health cards (unexposed). For each sub-hypothesis, we operationalize
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47 187 suitable outcome measures.
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3 188 1) Emergency care
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6 189 Health care vouchers are said to complicate access to care – especially to primary or specialized
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9 190 ambulatory care.[13] The vouchers are valid only for three months, they are not always known
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11 191 by the health professionals, and they immediately show that a person has no full entitlement to
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14 192 health care. Patients might delay use or refrain from using ambulatory services to avoid applying
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16 193 for and showing the vouchers. There is no need to present the health care voucher for emergency
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18 194 care.[9,20–23] As a consequence, we assume a higher use of emergency care services. We
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20
21 195 calculate incidence rates of emergency cases (=outcome 1) and relative risks for each quarter. If
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23 196 the emergency case led to hospitalization, only the date of admission is considered. We count
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26 197 emergency cases (even if a person uses emergency services several times per quarter) and relate
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28 198 the cases to the number of persons eligible to services according to AsylbLG Article 4 and 6. We
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30
31 199 also count the number of individuals that have used emergency services at least once in the
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33 200 quarter. For individual level regression analysis, a dichotomous outcome variable will be coded
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35 201 containing the information whether or not an individual had used emergency care in the quarter.
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38 202 For ecological regression analysis, quarterly incidence of emergency cases in the six municipalities
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41 203 will serve as outcome variable.
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44 204 2) Delayed treatment
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47 205 The necessary additional effort to access care in municipalities with HcV model might also lead to
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49 206 delays in treatment. Instead of accessing primary care, patients might delay treatment until
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52 207 hospitalization is necessary. Hospitalizations that could have been avoided with adequate
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54 208 outpatient care are defined as ambulatory care sensitive hospitalizations (ACSH). Usually, ACSH
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3 209 are identified based on the related diagnoses. Accordingly, ambulatory care sensitive conditions
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6 210 (ACSC) are thus defined as “conditions for which good outpatient care can potentially prevent the
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8 211 need for hospitalization, or for which early intervention can prevent complications or more severe
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10 212 disease”[25, p.1]. ASCH are considered to be a valid indicator of access barriers to ambulatory
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13 213 care in general [25–28] and have been also identified as a useful indicator of access to primary
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15 214 ambulatory care among forced migrants.[8,29,30] Several different catalogues of ACSC have been
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18 215 developed internationally. Recently, they have been adapted and validated for the German
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20 216 context.[31] The full list of ACSC consists of 40 diagnoses groups with 22 being considered as core
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22 217 diagnosis groups. The full list compiled by Sundmacher et al. includes 258 ambulatory sensitive
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25 218 ICD-10 codes.[32] For children, we use a slightly modified list developed by Lichtl et al.[30] Based
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28 219 on this lists, we define ambulatory care sensitive cases (=outcome 2) and calculate incidence rates
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30 220 per quarter in municipalities using the HcV model and the eHC model (with N being all refugees
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32 221 entitled to services in the quarter). We compare incidence rates over time and between
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35 222 municipalities. We also calculate relative risk comparing the incidence between models. Again we
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37 223 calculate incidence rates (counting all cases even if one person has several ACSC diagnosed) and
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39
40 224 in addition the share of individuals with at least one ASCS per quarter. As described for outcome
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42 225 1, we use a dichotomous outcome variable and the quarterly incidence as outcomes for
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45 226 regression analysis. If the number of cases allows, we further differentiate between ACSC cases
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47 227 with regular referral and emergency ACSC cases where the patients have been hospitalized after
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50 228 visiting or being brought to the emergency department.

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53 229 3) Non-urgency of treatment
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3 230 The delay in treatment and the increase in emergency care use or hospitalizations might not
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6 231 materialize during the observation period (first 15 months) as assumed in hypothesis 1 and 2
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8 232 (above), but afterwards, once the entitlement restrictions cease to apply and e-health cards are
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10 233 issued for all. During the observation period, this would still result in a lower use of outpatient
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12 234 cases (primary care) among refugees living in municipalities with a health care voucher –
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15 235 especially for deferrable services such as check-ups or prevention.[13] The participation in
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17 236 medically necessary check-ups (Z- codes according to ICD-10-GM) has been used as outcome
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19 237 measure for access barriers and discrimination related to minority or migration status.[22,33,34]
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21 238 However, the use of preventive care (=outcome 3) as outcome is conditioned on the size of the
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23 239 population groups entitled to preventive services (pregnant women, children, elderly) in the
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25 240 available data and the quality of information on age and sex. If information on age and sex is not
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27 241 detailed enough, we only include the incidence of persons using outpatient care among all people
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29 242 entitled to care in the quarter – also differentiating between ambulatory and specialized care. As
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31 243 mentioned earlier, dental care will be excluded from the analysis.
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38 244 In addition to postponing preventive care (which should be refunded according to article 4
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40 245 AsylbLG in all municipalities), municipalities using the HcV model might refuse to refund services
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42 246 as part of the case-by-case review (Art. 6 AsylbLG) referring to the non-urgency of the treatment
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44 247 (*Kriterium der Aufschiebbarkeit*). The framework agreement on the e-health card abolishes any
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46 248 consideration of non-urgency of treatment. Thus, in municipalities using the e-health cards, most
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48 249 services are granted irrespective of their urgency. However, in municipalities using the HcV model
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50 250 urgency of treatment might still be considered. Psychotherapy and therapeutic devices
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52 251 (“Hilfsmittel”) have been identified as services for which the consideration of urgency might lead
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3 252 to differences in realized access.[3,35–37] We thus compare psychotherapeutic care cases
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6 253 (outcome 4) and refunded therapeutic devices (outcome 5) between access models. Cases of
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8 254 psychotherapeutic care are defined as visits to specialized doctors (psychiatrists and
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10 255 psychological psychotherapists) and not based on diagnoses. For psychotherapeutic care,
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13 256 repeated visits by the same person in the same quarter are not counted separately. For
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15 257 therapeutic devices, prescriptions for the same device for the same person in the same quarter
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17
18 258 are not counted separately. Incidence rates and relative risk are calculated for each quarter
19
20 259 comparing risks between models and over time.
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22

23 260 *Outcomes: expenditures*
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26
27 261 So far, we only referred to the ACSC as outcome indicator and several process indicators related
28
29 262 to health care use. However, data on health care expenditure is available (excluding
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31 263 administrative costs). This allows us to relate our indicators of use to the related health care
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33 264 expenditure in the municipalities. We assume the following consequences for per capita
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35 265 expenditure:
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40 266 1) Expenditures on emergency care
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43 267 In line with the hypothesis on *emergency care*, the HcV access model goes along with higher use
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45 268 of emergency care and thereby leads to higher health care expenditures for emergency care per
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47 269 capita (per quarter) in municipalities using the HcV model compared to municipalities with eHC
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49 270 model.
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53 271 2) Expenditures related to delayed treatment
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3 272 In line with the hypothesis on *delayed treatment*, the HcV access model goes along with higher
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6 273 risk for ambulatory care sensitive hospitalizations. We therefore assume higher health care
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8 274 expenditures for inpatient care per capita (per quarter) in municipalities using the HcV model
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11 275 compared to municipalities with eHC model.
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13 14 276 3) Expenditures related to the non-urgency of treatment 15

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17 277 The HcV access model is hypothesized to go along with lower use of preventive, psychiatric,
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19 278 psychotherapeutic (outpatient) care and therapeutic devices if the use of these services are
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22 279 postponed or considered as non-urgent by the municipalities. As a consequence, we assume to
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24 280 observe lower health care expenditures for outpatient care per capita (per quarter) in
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27 281 municipalities using the HcV model compared to municipalities with eHC model.
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30 282 Health care expenditure per capita and quarter in the municipalities will thus be differentiated
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32 283 according to inpatient, outpatient and emergency care and interpreted against the backdrop of
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35 284 the results from the analysis of realized access. More detailed analysis of expenditures for specific
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37 285 health services are not feasible as information on expenditures are only available on aggregated
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40 286 level.
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42 43 287 *Covariates or confounders* 44

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46 288 The major determinant of health care use we are interested in is the access model used in the
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48 289 municipalities. However, health care policies and their implementation as locally diverging access
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51 290 models are only one of many determinants of health care use. Andersen and colleagues identified
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53 291 several additional determinants of health care use with the health system being just one of them
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55
56 292 and access models being just one element of the health system.[18] Thus, a much broader
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293 approach is needed given that confounding by other determinants of use of health care services
 294 is probable. We thus adapted Andersen's general model of Health Service Use with regard to our
 295 research setting and analyze the availability of data or information for the different determinants
 296 (c.f. [18,38]).

297 **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

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299 Table 1 shows that there are important individual-level determinants of use that we are not able

300 to consider (especially socio-economic status, health beliefs, individual enabling resources, need

301 and personal health practices). Given that refugees are almost randomly assigned to the

302 municipalities, our study can be considered as a natural experiment or a quasi-experimental

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3 303 study. Under these quasi-experimental conditions, the determinants should be independent of
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6 304 the access model. As a result, confounding by these determinants of use should be minimized.
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8 305 We still control for significant differences in demographic characteristics that persist despite
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10 306 random assignment, based on the available aggregated data on sex and age. As listed in Table 1,
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12 307 information on important contextual, health system and community related determinants are
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15 308 available. This is the case for availability of doctors, overall socio-demographic, economic and
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17 309 political context are (partly) available. Adjustment for these aspects is thus possible at
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20 310 municipality level.
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23 311 **Planned statistical analysis**

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27 312 We aim to shed light on the development of health inequalities in the socially critical phase
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29 313 refugees face immediately after arrival in Germany and the importance of the local context in
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31 314 providing access to health care. However, we analyze inequalities only in the sense of (descriptive)
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33 315 differences and not in the sense of inequities which constitutes a separate interpretative step.
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37 316 Incidence rates and relative risks of all five outcomes are analyzed for seven quarters comparing
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39 317 municipalities with eHC and with HcV. Timing and pathways of care will also be explored. Analysis
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41 318 will be adjusted for aggregated information on age and sex provided by the municipalities. As part
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43 319 of the descriptive analysis we will also compare health care expenditures in the municipalities.
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47 320 Subsequently, we will perform a multivariate regression analysis. As the detailedness of the data
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49 321 is limited (few municipalities and no individual level data on age and sex), we explore different
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51 322 possible statistical analysis and compare the results. In ecological analysis, we use general linear
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54 323 regression models with quarterly incidence rates in the six municipalities as outcomes. In
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3 324 individual level analysis, we include each of the outcomes as (dependent) outcome variable, the
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5 325 access model as (independent) exposure variable and conduct repeated (7 quarters) cross-
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8 326 sectional regression analysis. In both cases, we will include the age-sex distribution, socio-
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10 327 economic and political structure of the community and density of general and specialized
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13 328 practitioners respectively as covariates in the regression models (c.f. Table 1).
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16 329 **Public and patient involvement**

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19 330 The described quantitative study is embedded in a larger mixed-methods project. As part of the
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22 331 project, we conduct qualitative semi-structured interviews (not described in detail here) with
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24 332 actors in welfare agencies, social workers, health care providers and refugees in all six
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27 333 municipalities. Interview material will be analyzed to understand how the models are actually
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29 334 implemented in the municipalities and how access is organized from the perspective of
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32 335 providers and patients. Their perspectives and needs are also considered during data collection
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34 336 and analysis. The final results will be discussed with interviewees in the six municipalities.
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37 337 **ETHICS AND DISSEMINATION**

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41 338 Research evaluating the (health) consequences of legal provisions for newly arrived refugees'
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43 339 access to health care in a methodologically and ethically sound way constitutes a challenge.
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46 340 Refugees are usually not included or not identifiable in the official health reporting
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48 341 systems.[39,40] In addition, we know from previous research that it is difficult to recruit newly
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51 342 arrived refugees on a large scale due to language differences, frequent relocations and assumed
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53 343 low response rates.[41,42] Inequalities stemming from different formal access to health care are
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56 344 thus not easily detectable. As a consequence, we need new methodological approaches to
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3 345 document possible inequalities – which might increase their visibility and ultimately contribute to
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5 346 their reduction. At the same time, it is ethically questionable to recruit large numbers of refugees
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8 347 for quantitative health service research shortly after arrival in their new country of residency –
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10 348 while their access and entitlement to health care is still restricted.

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13 349 In order to overcome these difficulties, we cooperated with local welfare offices and the statutory
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15 350 health insurance to collect data on use of health care among newly arrived refugees. We ensured
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17 351 that data collection would lead to fully anonymized (and even partly aggregated) data, so there
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19 352 was no need to seek consent from individuals and conduct interviews. This approach and the full
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21 353 study have been approved by the ethical committee and the data protection office at Bielefeld
22
23 354 University (application no. 2017-099, 10th May 2017).

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26 355 We developed a data protection concept in close cooperation with the data protection officer
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28 356 and our study data trustee. Data will be managed, analyzed and stored on encoded offline servers.
29
30 357 Ten years after the end of the study, the data trustee will delete the data. Results will be published
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32 358 in peer-reviewed journals and summarized in reports to the funding agency.
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505 **List of Abbreviations**

- 25 506 ACSC Ambulatory care sensitive conditions
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28 507 ACSH Ambulatory care sensitive hospitalizations
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33 509 AsylbLG Asylbewerberleistungsgesetz/Asylum Seeker's Benefits Act
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36 510 eHC Electronic health card model
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38 511 HcV Health care voucher model
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41 512 NRW Nordrhein-Westfalen/North Rhine-Westphalia
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3 515 **Acknowledgements**
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7 516 **Data sharing**
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10 517 Data collection is still ongoing. Details of the data sharing will be agreed upon once the data collection
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12 518 has been completed.
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15 519 **Ethics approval and consent to participate**
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18 520 The study has been positively reviewed by the Ethics Committee and the data protection officer
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21 521 of Bielefeld University.
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24 522 Application Number: 2017-099
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27 523 Date: 10th May 2017
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31 524 Consent was not obtained because the patient cannot be traced. However, there was no need
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33 525 to obtain consent, because data is fully anonymized.
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36 526 **Competing interests**
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39
40 527 The authors declare that they have no competing interests.
41
42

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47
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1
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3 533 **Authors' contributions**
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5

6 534 JW, KR und OR designed the study. JB, OS und KB made substantial contributions to its
7
8 535 conception and design. JW drafted the manuscript. KR, JB, OS, KB und OR revisited the
9
10 536 manuscript critically for important intellectual content. All authors read and approved the final
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17 538 **Acknowledgements**
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20 539 Not applicable
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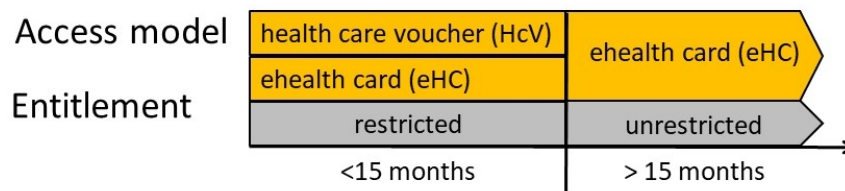


Figure 1: Health care for newly arrived refugees in Germany: simplified access model and entitlement in municipalities (own illustration)

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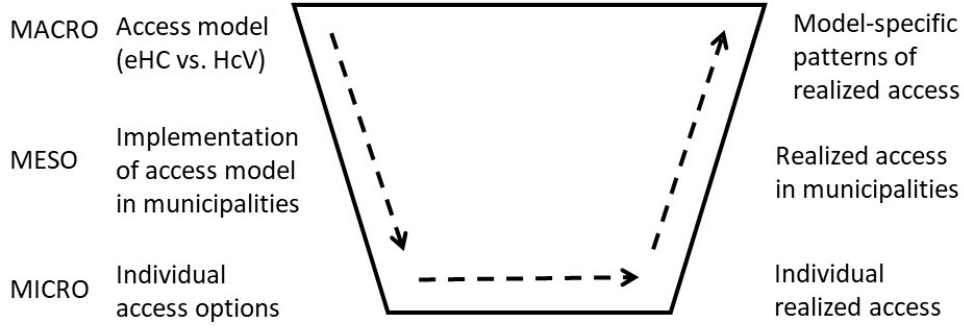


Figure 2: Graphical summary of the overall study hypothesis (own illustration based on,[14] p. 10)
254x190mm (96 x 96 DPI)

BMJ Open

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

Journal:	<i>BMJ Open</i>
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3 1 **Title Page**
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7 2 **Inequalities in realized access to health care among recently arrived refugees**
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10 3 **depending on local access model: study protocol for a quasi-experimental**
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12 4 **study**
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23 32 **Word count of main text: 4442**
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25 26 27 33 **Abstract** 28

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30
31 34 Introduction: In many countries, including Germany, newly arriving refugees face specific
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33 35 entitlement restrictions and access barriers to health care. While entitlement restrictions
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35 36 apply to all refugees that seek protection in Germany during the first months, the barriers to
36
37 37 access depend on the model that the states and the municipalities implement locally.
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39 38 Currently, two different models exist: the health care voucher model (HcV) and the electronic
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41 39 health card model (eHC). The aim of the study is to analyse the consequences of these two
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43 40 different access models on newly arrived refugees' realized access to health care.
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49 41 Methods and analysis: The random assignment of refugees to municipalities allows for a quasi-
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51 42 experimental design by comparing realized access to health care among refugees in six
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53 43 municipalities in North Rhine-Westphalia (NRW) which have implemented HcV or eHC. We
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55 44 compare realized access to health care using ambulatory care sensitive conditions and health
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57 45 expenditure as outcome indicators; and use of emergency care, preventive care,
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3 46 psychotherapeutic or psychiatric care, and of therapeutic devices, as process indicators.
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6 47 Results will be adjusted for aggregated information on age, sex, socioeconomic structure of
7
8 48 the municipalities, and density of general practitioners or specialists.
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10
11 49 Ethics and dissemination: We cooperated with local welfare offices and the statutory health
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13 50 insurance for data collection. Thereby, we were able to avoid recruiting large numbers of
14
15 51 refugee patients immediately after arrival while their access and entitlement to health care is
16
17 52 restricted. We developed an extensive data protection concept and ensured that all data
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19 53 collected is fully anonymized. Results will be published in peer-reviewed journals and
20
21 54 summarized in reports to the funding agency.
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30 56 **Strengths and limitations of this study**

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33 57 • Our study comprises a large and diverse sample of refugees during the period of
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35 58 restricted entitlements that are usually excluded from health system research and
36
37 59 official health reporting.
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41 60 • Refugees are randomly assigned to different municipalities which allows for a quasi-
42
43 61 experimental research design.
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45
46 62 • Due to selection bias we might underestimate the effect size as municipalities with
47
48 63 restrictive refugee health policies are less likely to participate.
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51 64 • Demographic information is not collected on the individual, but on the municipality
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53 65 level.
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67 **Key Words**

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3 68 Refugee health, access to health care, quasi-experimental design, health policy, organization
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6 69 of health services, public health
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For peer review only

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3 70 **MAIN TEXT**
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6
7 71 **INTRODUCTION**
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10 72 In many countries, newly arriving refugees face specific entitlement restrictions and access
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12 73 barriers to health care.[1,2] The underlying regulations have been discussed from ethical,
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14 74 human rights and legal perspectives.[3–5] While we acknowledge the importance of these
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16 75 fundamental debates, our study focuses on the actual consequences of these regulations for
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18 76 the use of health care among recently arrived refugees. We concentrate on the regulations
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20 77 that apply to refugees during their first years after arrival as we consider this time to be a
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22 78 socially critical period (as defined by Bartley et al. [6]), and as such as decisive for the
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24 79 individual's further life course and the development of social and health inequalities.
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31 80 In the first 15 months after arrival, entitlement to health care is restricted and formal access
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33 81 is not equal to that of persons covered via the statutory health insurance. Entitlement is
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35 82 restricted by article 4 and 6 of the Asylum Seekers' Benefits Act (AsylbLG). The AsylbLG covers
36
37 83 the cost of health care provision in case of acute illness and pain, pregnancy and birth, as well
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39 84 as for officially recommended vaccination and medically necessary check-ups. Other services,
40
41 85 for example diagnoses and treatment of non-acute chronic illness or (long-term)
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43 86 psychotherapy, are only granted on a case-by-case basis.[7] Among persons facing these
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45 87 restrictions, hospitalizations and emergency care use is increased while numbers of
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47 88 prescriptions and dental visits are decreased compared to persons insured via the standard
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49 89 statutory health insurance, showing that these legal regulations actually shape patterns of
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51 90 health care use.[8]
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3 91 Besides these entitlement restrictions that apply to all newly arrived refugees – with the
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5 92 exception of unaccompanied minors – the bureaucratic procedures required before health
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7 93 care services can be accessed have been identified as barriers to necessary care.[9] Given that
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10 94 these procedures differ between municipalities and federal states, the actual access also
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13 95 differs. Basically, two different access models exist: the electronic health card model (eHC)
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15 96 and the health care voucher mode (HcV) (Fig. 1). The eHC model provides access comparable
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18 97 to that of patients in the statutory health insurance. Refugees receive e-health cards once they
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20 98 are assigned to a municipality. They can directly access health care services presenting the
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23 99 card at the hospital or in a doctor's office, but the entitlement restrictions largely remain. The
24
25 100 HcV model constitutes a parallel access model specifically for refugees during the first 15
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28 101 months. In municipalities using the HcV model, refugees need to apply for health care
29
30 102 vouchers at the local welfare authorities before accessing care. These health care vouchers
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33 103 are valid usually for three months.[9–11]

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36 104 After 15 months, all refugees receive e-health cards and join a statutory health insurance. The
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38 105 restrictions of articles 4 and 6 no longer apply (Fig. 1). If their asylum claims have been
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40 106 approved or they find employment, this happens even earlier. In some cases (e.g. when
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43 107 persons have not revealed their identities), the restrictions are extended (Article 2 AsylbLG).

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46 108 [Fig 1]

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49 109 **Figure 1: Health care for newly arrived refugees in Germany: simplified access model and**
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52 110 **entitlement in municipalities** (own illustration)

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56 112 Each of the 16 federal states in Germany decides on the access model to be implemented. An
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59 113 exception is the state government in North-Rhine Westphalia (NRW), which left it to the
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3 114 municipalities to either opt for the HcV or the eHC model. NRW is the only federal state in
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6 115 which both models are concurrently in use in a considerable number of municipalities.
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8 116 Refugees in NRW are randomly assigned to municipalities – and thereby to the different access
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10 117 models – after leaving the initial reception centers. Assignment of refugees takes place
11
12
13 118 according to the population size and area size of the municipalities without prior consideration
14
15 119 of assumed health care needs of the refugees. Members of one family (parents and children)
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17
18 120 are assigned to the same municipality. Exceptional circumstances – including psycho-medical
19
20 121 needs – might later lead to reassignment (e.g. if treatment is only possible in a certain
21
22
23 122 municipality).[12]

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26 123 We hypothesize that the choice of the model affects access to health care, utilization, and
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28 124 health care expenditures. So far, this has not been studied. However, available research
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31 125 results suggest that the HcV model constitutes a barrier to ambulatory health care,[9] leads
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33 126 to higher health care expenses, [13] and might explain – at least partly – the increased use of
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36 127 emergency care among refugees, and the lower utilization of outpatient health care
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38 128 services.[14] This leads to the overall study hypothesis: The access model (macro level) and its
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41 129 implementation (meso level) influence the access to health care for refugees living in the
42
43 130 respective municipalities (micro level). As a consequence, we expect to observe different
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46 131 patterns of realized access on municipality level (meso level) and between access models
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48 132 (macro level) (c.f. Fig. 2, based on [15], p. 10).

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51 133 [Fig. 2]

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54 134 **Figure 2: Overall study hypothesis** (own illustration)

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57 58 136 **METHODS AND ANALYSIS**

137 **Design, setting, participants and sample size**

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

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

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

157 As the number of municipalities with eHC is comparatively small (22 with eHC compared to
158 374 with HcV), recruitment started among the 22 eHC-municipalities. Recruitment was
159 realized through the statutory health insurance companies. The municipalities differ in

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3 160 population size and organizational structure (independent city or district-affiliated city).
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6 161 Subsequently, we applied purposive sampling to recruit municipalities using the HcV model,
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8 162 considering their population size and organizational structure. As we were able to include all
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10 163 refugees entitled to services during the study period, no further sampling was necessary.

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14 164 Data collection started in June 2018 and will last until beginning of 2019. Data has to be
15
16 165 collected retrospectively, as health care providers need several months for controlling and
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18 166 billing. Ultimately, we will include data on health care use for seven subsequent quarters (2-
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20
21 167 2016 until 4-2017).

22 23 24 168 **Variables and data sources**

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26
27 169 For municipalities using the HcV model, refugees' demographic data and data on use of health
28
29 170 care services has to be collected directly at the local welfare office or from the external service
30
31 171 providers in case the municipalities have outsourced the verification and payment of invoices.
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33
34 172 In municipalities which have implemented the eHC model, data has to be collected from the
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36
37 173 responsible statutory health insurance.[17]

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40 174 Data includes principle and secondary diagnoses (ICD-10-Codes), type of care used (primary,
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42 175 specialist, emergency or hospital care), procedures and prescriptions and date of use
43
44 176 (quarterly). Quarterly data on number of refugees according to age and sex is provided by the
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46
47 177 health insurances or the welfare offices. It is available as aggregated information only.
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50 178 Similarly, health care expenditure is available as aggregated variable only.

51 52 53 179 *Outcomes: realized access*

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57 180 The primary outcome we are interested in is realized access to health care. The only available
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59 181 data that might serve as an indicator of access to health care are use of health care services
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3 182 and related expenditures. Given that expenditures are the direct consequence of use and thus
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6 183 primarily determined by use, we focus here on the relationship between access and use. In
7
8 184 line with the “Behavioral Model of Health Service Use” developed and updated by Ronald M
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10 185 Anderson, we consider use to be equal to realized access and thereby a suitable proxy for
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12
13 186 access.[18] The available claims data does not allow for analysis of more complex concepts of
14
15 187 access – e.g. as the fit between the individuals’ and the systems’ characteristics.[19] Use and
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18 188 expenditure are generalized measures that need hypothesis-based concretization. We
19
20 189 developed three sub-hypotheses on the effects of the HcV model on use and thereby also on
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22
23 190 local health care expenditure, assuming that the hypothesized effects are absent in
24
25 191 municipalities using the eHC model. All three hypotheses thus refer to differences in use and
26
27
28 192 expenditure between refugees in municipalities using health vouchers (exposed) and refugees
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30 193 in municipalities issuing e-health cards (unexposed). For each sub-hypothesis, we
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33 194 operationalized suitable outcome measures.

35 195 1) Emergency care

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39 196 Health care vouchers are said to complicate access to care – especially to primary or
40
41 197 specialized ambulatory care.[14] The vouchers are valid only for three months, they are not
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43
44 198 always known to the health professionals, and they immediately show that a person has no
45
46 199 full entitlement to health care. Patients might delay, or refrain from, using ambulatory services
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48
49 200 to avoid applying for and showing the vouchers. There is no need to present the health care
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51 201 voucher for emergency care.[9,20–23] As a consequence, we assume a higher use of
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53
54 202 emergency care services. We will calculate incidence rates of emergency cases (=outcome 1)
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56 203 and relative risks for each quarter. If the emergency case led to hospitalization, only the date
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59 204 of admission will be considered. We count emergency cases (even if a person uses emergency
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205 services several times per quarter) and relate the cases to the number of persons eligible to

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3 206 services according to AsylbLG Article 4 and 6. We will also count the number of individuals
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6 207 that have used emergency services at least once in the quarter. For individual level regression
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8 208 analysis, a dichotomous outcome variable will be coded containing the information whether
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10 209 or not an individual had used emergency care in the quarter. For ecological regression analysis,
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13 210 quarterly incidence of emergency cases in the six municipalities will serve as outcome variable.
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16 211 2) Delayed treatment

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19 212 The additional effort needed to access care in municipalities with HcV model might also lead
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21
22 213 to delays in treatment. Instead of accessing primary care, patients might delay treatment until
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24 214 hospitalization is necessary. Hospitalizations that could have been avoided with adequate
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26
27 215 outpatient care are defined as ambulatory care sensitive hospitalizations (ACSH). Usually,
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29 216 ACSH are identified based on the related diagnoses. Accordingly, ambulatory care sensitive
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31 217 conditions (ACSC) are thus defined as “conditions for which good outpatient care can
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34 218 potentially prevent the need for hospitalization, or for which early intervention can prevent
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36 219 complications or more severe disease”[24, p.1]. ASCH are considered to be a valid indicator of
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38
39 220 access barriers to ambulatory care in general [25–28] and have also been identified as a useful
40
41 221 indicator of access to primary ambulatory care among forced migrants.[8,29,30] Several
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43
44 222 different catalogues of ACSC have been developed internationally. Recently, they have been
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46 223 adapted and validated for the German context.[31] The full list of ACSC comprises 40 diagnosis
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49 224 groups, with 22 being considered as core diagnosis groups. The full list compiled by
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51 225 Sundmacher et al. includes 258 ambulatory sensitive ICD-10 codes.[32] For children, we use a
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54 226 slightly modified list developed by Lichtl et al.[30] Based on this lists, we define ambulatory
55
56 227 care sensitive cases (=outcome 2) and calculate incidence rates per quarter in municipalities
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58 228 using the HcV model and the eHC model (with N being all refugees entitled to services in the
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60 229 quarter). We will compare incidence rates over time and between municipalities. We will also

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3 230 calculate relative risk comparing the incidence between models. Again, we will calculate
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6 231 incidence rates (counting all cases even if one person has several ACSC diagnosed) and in
7
8 232 addition the share of individuals with at least one ASCS per quarter. As described for outcome
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10 233 1, we will use a dichotomous outcome variable and the quarterly incidence as outcomes for
11
12 234 regression analysis. If the number of cases allows, we will further differentiate between ACSC
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15 235 cases with regular referral and emergency ACSC cases where the patients have been
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18 236 hospitalized after visiting or being brought to the emergency department.

21 237 3) Non-urgency of treatment

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24 238 The delay in treatment and the increase in emergency care use or hospitalizations might not
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27 239 materialize during the observation period (first 15 months of stay in Germany) as assumed in
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29 240 hypothesis 1 and 2 (above). It may materialize only afterwards, once the entitlement
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31 241 restrictions cease to apply and e-health cards are issued for all. During the observation period,
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33
34 242 this would still result in a lower use of outpatient cases (primary care) among refugees living
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36 243 in municipalities with a health care voucher – especially for deferrable services such as check-
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39 244 ups or prevention.[14] The participation in medically necessary check-ups (Z- codes according
40
41 245 to ICD-10-GM) has been used as outcome measure for access barriers and discrimination
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43
44 246 related to minority or migration status.[22,33,34] However, the use of preventive care
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46 247 (=outcome 3) as outcome is conditioned on the size of the population groups entitled to
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49 248 preventive services (pregnant women, children, elderly) in the available data and the quality
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51 249 of information on age and sex. If information on age and sex is not detailed enough, we will
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54 250 only include the incidence of persons using outpatient care among all people entitled to care
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56 251 in the quarter – also differentiating between ambulatory and specialized care.

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3 252 In addition to postponing preventive care (which should be guaranteed according to article 4
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5 253 AsylbLG in all municipalities), municipalities using the HcV model might refuse to refund
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8 254 services as part of the case-by-case review (Art. 6 AsylbLG) referring to the non-urgency of the
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10 255 treatment (*Kriterium der Aufschiebbarkeit*). The framework agreement on the e-health card
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13 256 abolishes any consideration of non-urgency of treatment. Thus, in municipalities using the e-
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15 257 health cards, most services are granted irrespective of their urgency. However, in
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18 258 municipalities using the HcV model, urgency of treatment might still be considered.
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20 259 Psychotherapy and therapeutic devices (“Hilfsmittel”) have been identified as services for
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23 260 which the consideration of urgency might lead to differences in realized access.[3,35–37] We
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25 261 will thus compare psychotherapeutic care cases (outcome 4) and refunded therapeutic
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28 262 devices (outcome 5) between access models. Cases of psychotherapeutic care are defined as
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30 263 visits to specialized doctors (psychiatrists and psychological psychotherapists) and not based
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33 264 on diagnoses. For psychotherapeutic care, repeated visits by the same person in the same
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35 265 quarter will not be counted separately. For therapeutic devices, prescriptions for the same
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38 266 device for the same person in the same quarter will not be counted separately. Incidence rates
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40 267 and relative risk will be calculated for each quarter comparing risks between models and over
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42 268 time.

45 269 *Outcomes: expenditures*

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49 270 So far, we only referred to the ACSC as outcome indicator and several process indicators related
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51 271 to health care use. However, data on health care expenditure is available (excluding
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54 272 administrative costs). This allows us to relate our indicators of use to the related health care
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56 273 expenditure in the municipalities. We assume the following consequences for per capita
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58 274 expenditure:

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3 275 1) Expenditures on emergency care
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6 276 In line with the hypothesis on *emergency care*, the HcV access model is associated with higher
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9 277 use of emergency care and thereby leads to higher health care expenditures for emergency
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11 278 care per capita (per quarter) in municipalities using the HcV model compared to municipalities
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14 279 with eHC model.
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17 280 2) Expenditures related to delayed treatment
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20 281 In line with the hypothesis on *delayed treatment*, the HcV access model is associated with
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23 282 higher risk for ambulatory care sensitive hospitalizations. We therefore assume higher health
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25 283 care expenditures for inpatient care per capita (per quarter) in municipalities using the HcV
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27
28 284 model compared to municipalities with eHC model.
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31 285 3) Expenditures related to the non-urgency of treatment
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33

34 286 The HcV access model is hypothesized to be associated with lower use of preventive,
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36 287 psychiatric, psychotherapeutic (outpatient) care and therapeutic devices if use of these
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39 288 services is postponed or considered as non-urgent by the municipalities. As a consequence,
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41 289 we expect lower health care expenditures for outpatient care per capita (per quarter) in
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44 290 municipalities using the HcV model compared to municipalities with eHC model.
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47 291 Health care expenditure per capita and quarter in the municipalities will thus be differentiated
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49 292 according to inpatient, outpatient and emergency care and interpreted against the backdrop
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51
52 293 of the results from the analysis of realized access. More detailed analysis of expenditures for
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54 294 specific health services will not be feasible as information on expenditures are only available
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56
57 295 on aggregated level.
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60 296 *Covariates or confounders*

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

306 **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	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) [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

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

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3 312 experimental study. Under these quasi-experimental conditions, the determinants should be
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5 313 independent of the access model. As a result, confounding by these determinants of use
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8 314 should be minimal. We will still control for significant differences in demographic
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10 315 characteristics that persist despite random assignment, based on the available aggregated
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13 316 data on sex and age. In addition, information on important contextual, health system, and
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15 317 community related determinants are available, as listed in Table 1. This is the case for
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17 318 availability of doctors, overall socio-demographic, economic and political context. Adjustment
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19 319 for these aspects is thus possible at municipality level. However, we will be unable to control
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21 320 for confounding by other individual level determinants, e.g. health beliefs or needs and
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23 321 clustering by family relations or country of origin. We will acknowledge these limitations when
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25 322 discussing the results.
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31 **Planned statistical analysis**

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34 324 We aim to shed light on the development of health inequalities in the socially critical phase
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36 325 refugees face immediately after arrival in Germany and the importance of the local context in
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38 326 providing access to health care. However, we analyze inequalities only in the sense of
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40 327 (descriptive) differences and not in the sense of inequities which would constitute a separate
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42 328 interpretative step.
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47 329 Incidence rates and relative risks of all five outcomes will be analyzed for seven quarters
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49 330 comparing municipalities with eHC and with HcV. Timing and pathways of care will also be
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51 331 explored. Analysis will be adjusted for aggregated information on age and sex provided by the
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53 332 municipalities. As part of the descriptive analysis we will also compare health care
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55 333 expenditures in the municipalities. Subsequently, we will perform a multivariate regression
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57 334 analysis. As the detailedness of the data is limited (few municipalities and no individual level
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3 335 data on age and sex), we will explore different possible approaches to statistical analysis and
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5 336 compare the results. In ecological analysis, we will use general linear regression models with
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8 337 quarterly incidence rates in the six municipalities as outcomes. In individual level analysis, we
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10 338 will include each of the outcomes as (dependent) outcome variable, the access model as
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12 339 (independent) exposure variable and conduct repeated (7 quarters) cross-sectional regression
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15 340 analysis. In both cases, we will include the age-sex distribution, socio-economic and political
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17 341 structure of the community and density of general and specialized practitioners respectively
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19 342 as covariates in the regression models (c.f. Table 1). Table 2 summarizes the most important
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21 343 methodological aspects of this study.
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26 344 **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	<ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> - descriptive analysis of IR and RR for seven quarters - individual level analysis: logistic regression analysis - ecological analysis: generalized linear models

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59 346 **Public and patient involvement**
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3 347 The quantitative study described here is embedded in a larger mixed-methods project. As part
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6 348 of the project, we have conducted qualitative semi-structured interviews (not described in
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8 349 detail here) with refugees and other informants from one of the six municipalities. The
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10 350 perspectives of the interview participants informed the hypotheses and the selection of
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13 351 suitable outcomes. The final results will be made available to refugee patients through social
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15 352 workers in the six municipalities. As data was collected through local welfare offices and
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18 353 statutory health insurances and not directly from patients, there was no further patient or
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20 354 public involvement in recruitment or conduct of the study.
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23 355 **ETHICS AND DISSEMINATION**

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27 356 To avoid ethical issues, we cooperated with local welfare offices and the statutory health
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30 357 insurance to collect data on use of health care among newly arrived refugees. We ensured
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32 358 that data collection would lead to fully anonymized (and even partly aggregated) data, so
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35 359 there was no need to seek consent from individuals and conduct interviews. This approach
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37 360 and the full study have been approved by the ethical committee and the data protection office
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39 361 at Bielefeld University (application no. 2017-099, 10th May 2017).
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42 362 We developed a data protection concept in close cooperation with the data protection officer
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45 363 and our study data trustee. Data will be managed, analyzed and stored on encoded offline
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48 364 servers. Ten years after the end of the study, the data trustee will delete the data. When
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50 365 publishing our results, we will adhere to the STROBE guidelines.[43] Results will be published
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52 366 in peer-reviewed journals and summarized in reports to the funding agency.
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369 **LITERATURE**

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505 List of Abbreviations

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45 506 ACSC Ambulatory care sensitive conditions
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47 507 ACSH Ambulatory care sensitive hospitalizations
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50 508 AsylbLG Asylbewerberleistungsgesetz/Asylum Seeker's Benefits Act
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52 509 eHC Electronic health card
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55 510 HcV Health care voucher
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57 511 NRW Nordrhein-Westfalen/North Rhine-Westphalia
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3 514 **Acknowledgements**
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7 515 **Data sharing**
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9

10 516 **There are no data in this work.**
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13 517 **Ethics approval and consent to participate**
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15

16 518 The study has been positively reviewed by the Ethics Committee and the data protection
17 officer of Bielefeld University.
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20 519 Application Number: 2017-099
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23 520 Date: 10th May 2017
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26 521 Consent was not obtained because the patient cannot be traced. However, there was no
27 need to obtain consent, because data is fully anonymized.
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30 522
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33 524 **Competing interests**
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36 525 The authors declare that they have no competing interests.
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50 529
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53 531 **Authors' contributions**
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3 532 JW, KR und OR designed the study. JB, OS und KB made substantial contributions to its
4
5 533 conception and design. JW drafted the manuscript. KR, JB, OS, KB und OR revisited the
6
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8 534 manuscript critically for important intellectual content. All authors read and approved the
9
10 535 final manuscript.

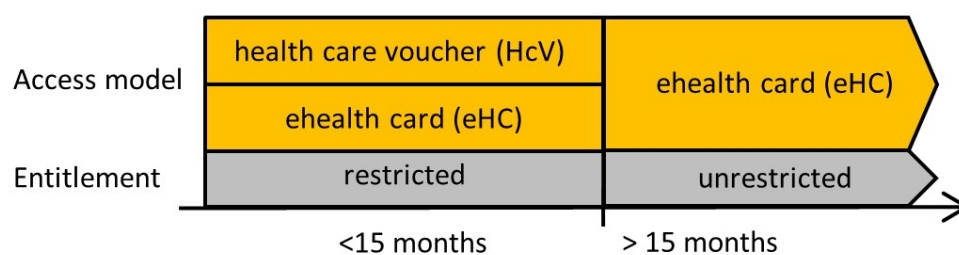
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14 536 **Acknowledgements**

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17 537 Not applicable

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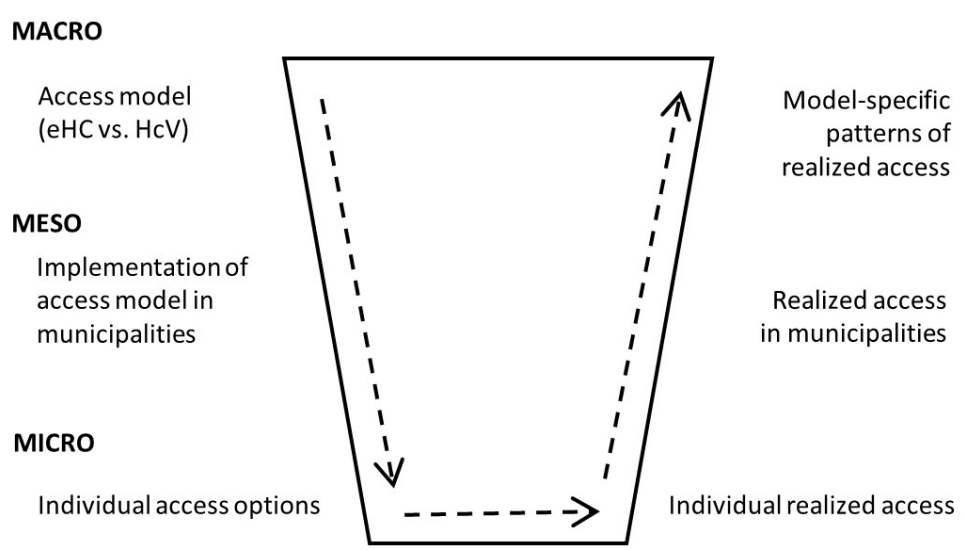
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Simplified overview of local access models and entitlements in municipalities in Germany

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Graphical summary of the overall study hypothesis

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