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Impact of legal status change on undocumented migrants' health and well-being (Parchemins study): protocol of a 4-year prospective mixed-methods study.

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Abstract

Introduction

Migrants without residency permit, known as undocumented, represent a growing proportion of the global migration stock. They tend to live in precarious conditions and to be exposed to an accumulation of adverse determinants of health. Only scarce evidence exists on the social, economic and living conditions-related factors influencing their health status and wellbeing. No study has assessed the impact of legal status regularization. The Parchemins study is the first prospective mixed-methods study aiming at measuring the impact on health and well-being of a regularization policy on undocumented migrants in Europe.

Methods and analysis

The Parchemins study will compare self-rated health and satisfaction with life in a group of undocumented migrants who receive a residency permit (intervention group) with a group of undocumented migrants who are not eligible for regularization (control group) in Geneva, Switzerland. Data collection will consist of standardized questionnaires complemented by semi-directed interviews in a sub-sample of migrants qualifying

for regularization. The baseline data will be collected just before or during the regularization and participants will subsequently be followed-up yearly for three years. The quantitative part explores variables about health (i.e. health status, occupational health, health seeking behaviors, access to care, healthcare utilization), wellbeing (measured by satisfaction with different dimensions of life), living conditions (i.e. employment, accommodation, social support) and economic situation (income, expenditures). Several confounders including sociodemographic characteristics and migration history will be collected. The qualitative part will explore longitudinally the experience of change in legal status at individual and family levels.

Ethics and dissemination

This study was approved by the Ethics Committee of Geneva Canton, Switzerland (CCER 2017-00897). All participants will provide informed consent. Results will be shared with migrant communities and NGOs supporting undocumented migrants and disseminated in scientific journals and in conferences. Fully anonymized data will be made available to researchers.

Article Summary

- The Parchemins study is the first of its kind in Europe to explore the effects of obtaining a residency permit (regularization) in undocumented migrants in Europe, an understudied and hard to reach group of population. The study is embedded into a pilot public policy program aiming at granting legal status to undocumented migrants in Geneva.

- The broad perspective including health and wellbeing outcomes, adding to the prospective and mixed-methods approaches will allow generating a comprehensive understanding of factors operating across time on health and wellbeing.

- The qualitative part will provide further insights into individual and family experiences in parting with their undocumented status and facing the new challenges that regularization entails.

- The main limitation will be the risk of attrition in the control group considering the harsh and unpredictable living context of such migrants. The study is designed to minimize such risk by selecting undocumented migrants having a relatively stable personal situation.

Keywords: undocumented migrants, irregular migration, health, wellbeing, regularization

Introduction

Undocumented or irregular migration is defined as "*movements that takes place outside the regulatory norms of the sending, transit and receiving countries*".[1] It results from overstaying after temporary residency permit expiration, asylum claim refusal or entering the country without valid migration documentation.[1 2] There were 20-30 million undocumented migrants (UM) worldwide in 2010.[3] In the United States, UM from Latin America increased from 8.4 in 2000 to 11.1 million in 2011, including 4.5 million children.[4] Europe hosted 1.9 to 3.8

million UM in 2008 and the most recent estimates point to 180'000-520'000 and 58'000-105'000 UM in Germany and Switzerland, respectively.[5-7]

A vulnerable population

The lack of legal residency permit interacts with social, political and economic factors to create multi-dimensional vulnerability among UM.[8 9] In most European countries, they face significant post-migration difficulties in the context of restrictive immigration policies and lack of labor protection [2 10]. Many are employed in low-skills and precarious 3D (dangerous, dirty and degrading) jobs and are exposed to abuse, exploitation and occupational hazards.[11-14] Access to other basic commodities and services such as housing, education and training, food and legal protection in case of harm or abuse is usually arduous and precarious.[10 15]

When compared to the resident and the regular migrants' populations, self-rated physical and mental health is consistently and significantly poorer among UM in Europe.[16 17] In a study conducted in 11 countries, 23% of women and 34% of men, including those in the youngest age groups, rated their health as poor or very poor.[12] UM present high prevalence of chronic conditions in primary care settings, notably of metabolic, cardiovascular and psychiatric origins.[16 18-22] Several infectious diseases are more prevalent than in the resident population such as tuberculosis and Chagas disease, which relates more to geographic origins than to the legal status.[23 24] No comparative data exist on the mortality rate ratio of UM compared to the general population but external (including accidents and suicides) and circulatory causes of death were 3.6 and 2.2 times more prevalent in a sample of UM than in the general Swedish population, respectively.[25]

Undocumented migrants in Europe face limited opportunities to respond to their healthcare needs with barriers to healthcare operating at different levels.[12 26-28] Legal entitlement to receive medical care within the public healthcare system varies considerably between countries. A majority of countries restricts access to emergency situations exclusively.[29 30] Non-governmental organizations (NGOs) play a subsidiary role but services provided are generally of limited extent and do not cover the full range of health needs.[12] Access to costly treatments in the absence of formal entitlement to healthcare is frequently restricted, which entails significant health consequences, notably in the context of severe chronic diseases such as HIV/AIDS infection.[31 32] At the health service level, communication barriers, the perceived lack of specific skills and practical difficulties encountered by healthcare workers contribute to restrict the extent and quality of care.[33 34] At the migrants' level, fear of denunciation, direct costs at charge and a lack of knowledge about how to navigate the health system impede adequate use of health services.[12 16 35 36] These factors negatively impacts the provision of health promoting and preventive interventions such as immunization, birth-control counseling, prenatal care and screening procedures.[37-39] UM have a higher rate of preventable hospitalizations compared to populations with full access to care and are less likely to receive preventive care.[39 40]

In Switzerland, the 26 cantons have a large autonomy and have the responsibility to supervise and manage their public healthcare system.[41] UM are legally entitled to purchase the mandatory basic health insurance

(which grants access to standard healthcare) but lack of awareness, financial and administrative barriers as well as fear of denunciation contribute to the estimated 10-20% insurance coverage. [42 43] Swiss cantons have implemented different policies to bridge this access gap. Geneva and Vaud provide health services within the public healthcare system which are complemented by other services (food, shelter) provided by NGOs.[42] Yet, previous studies showed that UM in Geneva tended to delay seeking care, notably for preventive interventions.[38]

Regularization policies

Several regularization programs have been implemented in Europe and an estimated 1.8 million undocumented migrants were granted a residency permit between 2002 and 2008.[2] Switzerland has never implemented large-scale programs but a handful of individual applications (mainly through NGOs or lawyers' services) have been successful to varying degrees depending on the canton. Residency permits have been granted mainly for humanitarian motives, in case of severe medical needs, long stay and satisfactory integration, absence of criminal record and financial autonomy.[5] In 2017, the Canton of Geneva implemented a two-year pilot regularization program (Operation Papyrus) aiming at granting one-year residency permits to undocumented migrants meeting the following criteria: a) stay of 10 years for individuals or 5 years for families with school-aged children; b) basic French proficiency; c) sufficient financial resources; d) lack of criminal record other than related to the residency permit.[44] The program integrates civil society actors (workers' unions, NGOs) that act as gatekeepers between UM and the Canton authorities, and support UM with the administrative process leading to regularization.

The impact of regularization policy on UM health, well-being, living conditions and economic situation have rarely been studied in Europe. Scarce evidence shows improved access to legal employment, social welfare and insurances with better housing and educational opportunities.[45] Negative effects included enhanced professional competition associated with the lack of recognition of pre-migration professional qualifications. In Italy, the 2007 amnesty policy was associated with a 1.2 to 2.7% point decline in low birth weight prevalence within the migrant population eligible for regularization.[46] In the USA, the Deferred Action for Children Arrival act (DACA) implemented in 2012 allowed around 800'000 undocumented young people to be temporarily regularized. Studies found a decline in psychological distress, improvements in self-esteem, wellbeing, and social support and pointed to beneficial trans-generational effects on children mental health.[47-49] No study has prospectively explored the impact of legal status change on health and wellbeing while taking into account UM living and working conditions.

Gaps in the existing literature

While the development of knowledge about refugees' heath is accelerating, research on UM health lags behind.[28 50] The number and quality of studies being limited, there are some major gaps in the current knowledge about UM health and wellbeing and their relationship to living and economic conditions in Europe.

Most studies have been conducted in healthcare settings, thus entailing a systematic selection bias restricting their generalizability, and are cross-sectional or retrospective, which hampers the ability to measure changes over time and to identify causal relationships.[12 16 17 26 35 38 51-55] Most studies in the literature are monodisciplinary, rely on a single methodology, typically measure a limited range of health indicators and usually overlook the wellbeing dimension. These limitations restrict the ability to foster a comprehensive understanding of the complexity and the dynamics of health and wellbeing evolution after regularization in a longitudinal perspective taking into account the interactions between medical, social, legal and economic factors.

A second gap pertains to the lack of in-depth understanding of the impact of legal status change (regularization) on the health and living conditions of individual migrants but also of the rest of their family.[13 16 26 35 36 38 43] In particular, there is a lack of evidence about how UM interpret the transformation of their living conditions during and after regularization and the ambivalent individual and family consequences of migration and regularization clearly need to be better understood. [56] This again calls for the collection of longitudinal data.[56 57] The underdevelopment of research on transnational UM families mirrors the limited interest from policymakers.[56]

Theoretical perspectives

To address the limitations of the available research, our research design is supported by two main theoretical perspectives allowing assessing the role of UM regularization.

(1) The perspective of wellbeing and quality of life (QoL) is typically articulated with the social determinants of health framework promoted among others by the World Health Organization. Indeed the model developed by the Commission on the social determinants of health maps the multiple factors that affect equity in both health and wellbeing.[58] Growing interest for wellbeing is evidenced by the Organization for Economic Co-operation and Development (OCDE) framework that associates objective indicators of material conditions with QoL indicators in different domains (including housing, education, income, etc.).[59 60] This framework is particularly relevant to assess the situation of newly regularized migrants, along the idea that QoL reflects the gap between individuals' actual situation and that to which they aspire.[61] We can hypothesize that UM wellbeing might be higher than that of Swiss residents with similar levels of resources. The wellbeing approach thus allows examining the complex interactions between living conditions and health outcomes, while taking into account the role of expectations in those domains.

(2) The dynamic approach of the life course will allow examining UM trajectories both retrospectively and prospectively. Considering how much stress and uncertainty the absence of legal documents generates, regularization represents a major transition or a turning point. At the same time, the acquisition of a legal status can bring mixed consequences, including both positive (elimination of the deportation risk, better housing) and negative (new financial constraints like taxes, competition on the labor market) influences. The life course perspective will be used to assess how regularization modifies the balance between vulnerability and resources.[62] We particularly hypothesis that the acquisition of a legal status may impact

differentially the resources of undocumented individuals and families, be they functional resources and reserves[63]: some positive influences may favor the stabilization of their social and economic resources , and ultimately improve their economic resources by giving them legal access to job opportunities in the labor market; however, some negative influences may also occur and impede the constitution of economic reserves, thus limiting their capacity to absorb the consequences of shocks and adverse events at different points of their life course.

Objectives of the study and research questions

This study aims to measure how regularization impacts the health and wellbeing of UM in Geneva. To reach this goal, five research questions have been formulated:

1. What are the living conditions of UM living in Geneva?
2. What are the health status, including the mental and somatic dimensions, and well-being of UM living in Geneva?
3. What are the health-seeking behaviors, healthcare utilization, including emergency services, and renouncement to medical care, among UM living in Geneva?
4. What is the impact of regularization on their health and well-being and its relationship with changes in living conditions?
5. How do contextual factors shape the experience of transitioning towards legality for undocumented individuals and families?

Methods and data analysis

Design

This prospective mixed-methods observational study compares a group of undocumented migrants undergoing regularization with a group of migrants not eligible for regularization. A nested qualitative longitudinal study focuses on a sub-sample of individuals undergoing regularization.

The research plan is organized to respond to the set of research questions developed on the following hypothesis: i) UM endure deleterious living and economic conditions compared to the general population which has an impact on health and wellbeing; ii) regularization of the legal status impacts on health and wellbeing; iii) differences in health and wellbeing after regularization are mediated by changes in living and economic conditions and iv) regularization may cause vulnerability in health and living conditions.

Setting

This study takes place in Canton Geneva located in French-speaking Western Switzerland. The resident population is 500’000 including 10-15’000 undocumented migrants.

Eligibility criteria

Inclusion criteria

Migrants aged ≥ 18 years, originating from countries outside the European Union or European Free Trade Association, living in Geneva without a valid residency permit (undocumented) for at least 3 years, who plan to stay in Geneva at least 3 more years, have no criminal record and are not registered as asylum seekers, are eligible to participate. They are categorized into two groups: those undergoing the regularization process or who have been regularized for less than three months (intervention group) and those who do not meet the regularization eligibility criteria or are unwilling to apply for regularization (control group).

Exclusion criteria

The inability to communicate in one of the languages spoken by investigators (French, Spanish, Portuguese, English, Albanian, and Italian) is the only exclusion criteria.

Intervention

Participants eligible for legal status regularization (intervention group) will receive a residency permit within 3-6 months after the submission of their application to the Canton authorities. This process will take place during the first year of data collection. The information about permit acceptance will be collected through participants and the NGOs. This permit is renewable annually. In the unlikely occurrence of refusal, participants will be allocated to the control group.

Outcomes

Primary outcome measure

The primary outcome is self-rated health. It will be measured by comparing intra-group differences at baseline and after 3 years. Yearly measurements will allow for observing fluctuations in such differences. This item will be measured using the SF-12 question 1, a 5-points Likert scale [64], whose large-scale use also allows for comparing the results with other groups of populations. We selected the main outcome for its prognostic value in terms of morbidity and mortality.[65 66]

Secondary outcome measure

The secondary outcome consists of self-reported satisfaction with current life as measured through the dimensions of living condition and economic situation at baseline and after three years. Each domain will be measured every year with a single question using a 10-points Likert scale ranging from 0=absolutely not satisfied to 10=absolutely satisfied. This will allow to measure key dimensions of the OCDE wellbeing framework and provide comparison with the resident population.[60]

Additional variables under investigations

The quantitative part explores four domains, i.e. personal and family characteristics, health, living conditions and employment and economic situation. Table 1 presents the main variables under study. These variables will be used as predictors for the main outcomes. We designed our questionnaire in order to provide data that

allow for comparisons with the general population living in Switzerland, by using questions from population surveys such as the Household panel study or the Swiss Health Study.[67 68] For specific domains, we use validated measurement tools selected for their validity and reliability in non-clinical setting. Screening for depression and anxiety uses the PHQ-9 and GAD-7 scales, respectively.[69 70] Occupational mental health is assessed by using the Maslach Burnout inventory test, emotional exhaustion dimension.[71] We use The Pittsburg Sleep Quality Index Sleep quality to evaluate quality of sleep.[72] We pretested our questionnaire with a sample of participants (n=5), allowing for iterative modifications.

Qualitative part

The following themes will be covered during the semi-directed interviews: marital and family dynamics, including relationships with family members not living in Switzerland; experience of the regularization process and its positive and negative implications; perspectives and aspirations for the future; for parents: educational issues and aspirations for the children's future. The interview guide has been pretested with 5 persons.

Participant timeline

Quantitative data will be collected by questionnaire at baseline and repeated annually during the following three year (4 waves in total). Questionnaires will be filled with participants in the intervention and the control groups. We restricted the follow-up to three years assuming that most changes in the domains under study will occur during the first two years, followed by a more stable situation. This restriction also aims to reduce the attrition rate. Qualitative interviews are also conducted at baseline (year 1) and then every year for three years. They are conducted at a different time from the quantitative data collection to avoid participants' fatigue.

Sample size

Considering an effect size of 0.3 for the main health outcome (self-rated health), a type 1 error of 0.05 and a power of 0.8, the total sample size is 352, rounded up to 400 to account for the possible drop-out of participants over the follow-up.

The purposive qualitative nested study sampling includes 30 participants selected from the intervention group of UM eligible for regularization. The sample size of 30 is estimated to be sufficient to reach data saturation. To ensure the diversity of the sample, participants are recruited on the respectively absence or presence of children, while ensuring the diversity of the sample regarding origins, age, gender, etc.

Recruitment

According to the local authorities, 1000-2000 UM could be eligible for the regularization policy and the total number of UM in Geneva amount to 10'0000 to 15'000. Recruitment is based on two strategies. First, UM in Geneva are informed about the study by personal contacts at migrants' organizations partnering the study and NGOs acting at gatekeepers for "Operation Papyrus", during public meetings held in the community, at

dedicated health centers attending for UM and through leaflets and a Facebook page. A direct phone line is accessible during office hours to respond to all enquiries. People interested in participating contact the investigators who present the study information and consent forms and engage in the first questionnaire passing if agreement is provided.

The second strategy is based on phone contacts with potential participants identified in partner NGOs registries of UM. During the initial call, investigators present the study and offer to organize a first meeting to provide more in-depth information. In the absence of response, potential participants are recalled up to five times.

Retention

Undocumented migrants are highly mobile and can be lost during the follow-up. In order to account for this risk, the sample size has been increased by 12.5%. All participants undergoing the first round of data collection will be contacted yearly for the subsequent waves. In order to enhance retention into the study, the following strategies are implemented: a) providing a material incentive after each questionnaire passation; b) discussing the need for and gaining acceptance for the nest contact after one year upon each encounter; c) recording a secondary phone number or email address to ensure participants are accessible. Moreover, partner NGOs inform communities of the importance of the follow-up. Contact for the following data collection will be made by phone with up to five recalls and use of email messaging in case of non-response. In order to facilitate participation and retention into the study, the field investigators can move to the preferred participant's location to pass the questionnaire.

Participants may withdraw from the study for any reason at any time. In case of withdrawal or loss to follow-up, all data will be included until the last participants' questionnaire for the analysis.

Quantitative data collection

The study questionnaire is administered face-to-face at the preferred participants' location in the community. This can be conducted in five languages. Data are recorded on a mobile tablet using Sphinx mobile® software (LeSphinx, France) and are immediately transferred on a secured server. Interviewers are trained and initially supervised by a senior staff during their first interviews.

Qualitative data collection

In the qualitative section, data are collected in semi-directed interviews with UM in the process of regularization. They are conducted in French, Spanish and English. Interviews are tape recorded and fully transcribed.

Statistical analysis

In a first step, we will compare the two groups (intervention vs. control) on all characteristics, using univariate analysis such as Fisher exact test for categorical variables and Wilcox rank sum test for continuous variables. This will allow determining the quality of the control group selection.

To study the evolution of health outcomes and living conditions over time, we will use multilevel linear models (logistic, Poisson, or Gaussian as appropriate depending on the specific outcome), including legal status (regularized vs. control) and adjusting for baseline characteristics to further account for group differences. Multilevel models account for the repeated nature of the data. To specifically focus on the different trajectories, these models will include both a random intercept and a random slope over time. Note that for rare dichotomous outcomes, we will probably need to restrict the number of covariates due to a number of events per variables below five per predictor. In that case, we will use two strategies. First, we will use propensity score adjustment, using all previously described covariates to compute the propensity score. Second, because the propensity score may not capture the importance of some confounders and lead to residual confounding, we will use a least absolute shrinkage and selection operator (LASSO) regression to determine which covariates are the most useful, before using only those covariates for adjustment.

Qualitative data analysis

Thematic analyses of the transcriptions will be conducted with Atlas.ti (www.atlasti.com), combining a set of codes defined along the interview guide and new codes inductively generated over the course of the analysis.

Ethics and dissemination

This study was approved by the Ethics Committee of Geneva Canton, Switzerland (CCER 2017-00897). All participants will provide informed consent. Results will be shared with migrant communities and NGOs supporting undocumented migrants and disseminated in scientific journals and in conferences. Fully anonymized data will be made available to researchers.

Discussion

This mixed methods study aims to measure the impact of legal status change on health and wellbeing of UM taking in account living, employment and economic conditions. It will produce the first comprehensive and longitudinal evaluation of a policy response to irregular migration in Europe. The interdisciplinary approach warrants the generation of rich data about a complex phenomenon. Considering the contemporary political and scientific interest in issues pertaining to migration worldwide, this study is at the forefront to provide original, interdisciplinary and comprehensive evidence about an ill-researched population. The results generated will influence on how such issues are framed and discussed at local, national and international levels. Data will specifically inform about unmet health needs, expectations and resources of undocumented migrants, therefore allowing for guiding clinical and public health strategies in Switzerland and similar countries. This may allow for an opportunity to mitigate inequalities in health outcomes and in access to health services. Most importantly, this study will provide a safe environment to give a voice to a silent and underserved population.

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Authors contribution

YJ conceived the study, is the co-principal investigator, drafted the protocol and wrote the manuscript.

CBJ conceived the study, is the co-principal investigator, drafted the protocol and proofread the manuscript.

GFL, AD, SC and DC contributed to the study conception and protocol and proofread the manuscript.

PB, PC, IG, and HW reviewed the protocol and proofread the manuscript.

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Table 1: variables by domain

Personal and family characteristics	Health	Living conditions	Employment and economic situation
Sociodemographical characteristics : sex; age; country of birth; nationality	Anthropomorphic measures: weight (kg); height (cm)	Housing : number of rooms; number of people sharing accommodation; quality of environment; satisfaction; type of lease contract; rent price	Professional activity : number of employers; sector of employment; number of working hours; working permit
Family composition : marital status ; number of children	Somatic health : chronic diseases; accidents; injuries; current treatment	Household composition : relation with household members	Working conditions : penibility; exposure to hazards
Children characteristics : gender ; age ; country of birth ; country of residence; current education	Mental health: anxiety ; depression ; current treatment	Discrimination : at the workplace; in public spaces; in healthcare settings	Income : individual level; household level; state subsidies
Migration history: reason for leaving country of origin; date of departure from country of origin; date of arrival in Switzerland; previous and current residency status in Switzerland; visit to country of origin; regularization procedure	Health behaviors : sleep; physical activity	Social support: satisfaction with social relationships	Financial situation : ability to cover unexpected expense; remittance to country of origin
Education : number of years at school; highest degree attained; place of education	Access to care : health insurance; deductibles; cost of premium; State-funded deductions	Integration into local life : participation to activities; French fluency	Satisfaction with financial situation
Professional qualification : professional training; employment record before migration	Utilization of the healthcare system: number of ambulatory and emergency room visits; hospitalization; affiliation with a family physician	Satisfaction with life	
	Renunciation to healthcare utilization: reasons; type of care		
	Satisfaction with health		
	Occupational health ; emotional exhaustion; professional injuries		

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Impact of legal status change on undocumented migrants' health and well-being (Parchemins): protocol of a 4-year prospective mixed-methods study.

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Abstract

Introduction

Migrants without residency permit, known as undocumented, tend to live in precarious conditions and to be exposed to an accumulation of adverse determinants of health. Only scarce evidence exists on the social, economic and living conditions-related factors influencing their health status and wellbeing. No study has assessed the impact of legal status regularization. The Parchemins study is the first prospective mixed-methods study aiming at measuring the impact on health and well-being of a regularization policy on undocumented migrants in Europe.

Methods and analysis

The Parchemins study will compare self-rated health and satisfaction with life in a group of adult undocumented migrants who qualify for applying for a residency permit (intervention group) with a group of undocumented migrants who are lack one or more eligibility criteria for regularization (control group) in

Geneva Canton, Switzerland. Asylum seekers are not included in this study. The total sample will include 400 participants. Data collection will consist of standardized questionnaires complemented by semi-directed interviews in a sub-sample (n=38) of migrants qualifying for regularization. The baseline data will be collected just before or during the regularization and participants will subsequently be followed-up yearly for three years. The quantitative part will explore variables about health (i.e. health status, occupational health, health seeking behaviors, access to care, healthcare utilization), wellbeing (measured by satisfaction with different dimensions of life), living conditions (i.e. employment, accommodation, social support) and economic situation (income, expenditures). Several confounders including sociodemographic characteristics and migration history will be collected. The qualitative part will explore longitudinally the experience of change in legal status at individual and family levels.

Ethics and dissemination

This study was approved by the Ethics Committee of Geneva, Switzerland. All participants provide informed consent. Results will be shared with undocumented migrants and disseminated in scientific journals and conferences. Fully anonymized data will be available to researchers.

Strengths and limitations of this study

- The prospective and mixed-methods approaches will allow generating a comprehensive understanding of factors operating across time on health and wellbeing.

- The qualitative part will provide further insights into individual and family experiences in parting with their undocumented status and facing the new challenges that regularization entails.

- The main limitation will be the risk of attrition in the control group considering the harsh and unpredictable living context of such migrants.

- The study is designed to minimize such risk by selecting undocumented migrants having a relatively stable personal situation.

Keywords: undocumented migrants, irregular migration, health, wellbeing, regularization

Introduction

Undocumented or irregular migration is defined as "*movements that takes place outside the regulatory norms of the sending, transit and receiving countries*".[1] It results from overstaying after temporary residency permit expiration, asylum claim refusal or entering the country without valid migration documentation.[1 2] In absence of valid methods of identification, figures provided for undocumented migrants are mainly theoretical and estimated by cross-referencing different sources. Recent valid data is generally lacking. The International Organization for Migration estimated that there were 20-30 million undocumented migrants worldwide in 2010.[3] According to the Pew Hispanic Center, the number of undocumented migrants from Latin America in the United States increased from 8.4 in 2000 to 11.1 million in 2011.[4] Europe hosted an estimated 1.9 to 3.8 million

of such migrants in 2008 and the most recent estimates point to 180'000-520'000 and 58'000-105'000 of them in Germany and Switzerland, respectively.[5-7]

A vulnerable population

The lack of legal residency permit interacts with social, political and economic factors to create multi-dimensional vulnerability among undocumented migrants.[8 9] In most European countries, they face significant post-migration difficulties in the context of restrictive immigration policies and lack of labor protection [2 10]. Many are employed in low-skills and precarious 3D (dangerous, dirty and degrading) jobs and are exposed to abuse, exploitation and occupational hazards.[11-14] Access to other basic commodities and services such as housing, education and training, food and legal protection in case of harm or abuse is usually arduous and precarious.[10 15]

When compared to the resident and the regular migrants' populations, self-rated physical and mental health is consistently and significantly poorer among undocumented migrants in Europe.[16 17] In a study conducted in 11 countries, 23% of women and 34% of men, including those in the youngest age groups, rated their health as poor or very poor.[12] Undocumented migrants present high prevalence of chronic conditions in primary care settings, notably of metabolic, cardiovascular and psychiatric origins.[16 18-22] Several infectious diseases are more prevalent than in the resident population which relates more to geographic origins than to the legal status.[23 24] No comparative data exist on the mortality rate ratio of undocumented migrants compared to the general population but external (including accidents and suicides) and circulatory causes of death were 3.6 and 2.2 times more prevalent in a sample of such migrants than in the general Swedish population, respectively.[25]

Undocumented migrants in Europe face limited opportunities to respond to their healthcare needs with barriers to healthcare operating at different levels.[12 26-28] Legal entitlement to receive medical care within the public healthcare system varies considerably between countries. A majority of countries restrict access to emergency situations exclusively.[29 30] Non-governmental organizations (NGOs) play a subsidiary role but services provided are generally of limited extent and do not cover the full range of health needs.[12] Access to costly treatments in the absence of formal entitlement to healthcare is frequently restricted, which entails significant health consequences, notably in the context of severe chronic diseases such as HIV/AIDS infection.[31 32] At the health service level, communication barriers, the perceived lack of specific skills and practical difficulties encountered by healthcare workers contribute to restrict the extent and quality of care.[33 34] At the migrants' level, fear of denunciation, direct costs at charge and a lack of knowledge about how to navigate the health system impede adequate use of health services.[12 16 35 36] These factors negatively impact the provision of health promoting and preventive interventions such as immunization, birth-control counseling, prenatal care and screening procedures.[37-39] Undocumented migrants have a higher rate of preventable hospitalizations compared to populations with full access to care and are less likely to receive preventive care.[39 40]

In Switzerland, the 26 cantons have a large autonomy and have the responsibility to supervise and manage their public healthcare system.[41] Undocumented migrants are legally entitled to purchase the mandatory basic

health insurance (which grants access to standard healthcare) but lack of awareness, financial and administrative barriers as well as fear of denunciation contribute to the estimated 10-20% insurance coverage.[42 43] Swiss cantons have implemented different policies to bridge this access gap. Geneva and Vaud provide health services within the public healthcare system which are complemented by other services (food, shelter) provided by NGOs.[42] Yet, previous studies showed that undocumented migrants in Geneva tend to delay seeking care, notably for preventive interventions.[38]

Regularization policies

Several regularization programs have been implemented in Europe and an estimated 1.8 million undocumented migrants were granted a residency permit between 2002 and 2008.[2] Switzerland has never implemented large-scale programs but a handful of individual applications (mainly through NGOs or lawyers' services) have been successful to varying degrees depending on the canton. Residency permits have been granted mainly for humanitarian motives, in case of severe medical needs, long stay and satisfactory integration, absence of criminal record and financial autonomy.[5] In 2017, the Geneva Canton implemented a two-year pilot regularization program (Operation Papyrus) aiming at granting one-year residency permits to undocumented migrants meeting the following criteria: a) stay of 10 years for individuals or 5 years for families with school-aged children; b) basic French proficiency; c) sufficient financial resources; d) lack of criminal record other than related to the residency permit.[44] The program integrates civil society actors (workers' unions, NGOs) that act as gatekeepers between undocumented migrants and the Canton authorities, and support them with the administrative process leading to regularization.

The impact of regularization policy on undocumented migrants' health, well-being, living conditions and economic situation has rarely been studied in Europe. Scarce evidence shows improved access to legal employment, social welfare and insurances with better housing and educational opportunities.[45] Negative effects included enhanced professional competition associated with the lack of recognition of pre-migration professional qualifications. In Italy, the 2007 amnesty policy was associated with a 1.2 to 2.7% point decline in low birth weight prevalence within the migrant population eligible for regularization.[46] In the USA, the Deferred Action for Children Arrival act (DACA) implemented in 2012 allowed around 800'000 undocumented young people to be temporarily regularized. Studies found a decline in psychological distress, improvements in self-esteem, wellbeing, and social support and pointed to beneficial trans-generational effects on children mental health.[47-49] No study has prospectively explored the impact of legal status change on health and wellbeing while taking into accounts undocumented migrants living and working conditions.

Gaps in the existing literature

While the development of knowledge about asylum seekers and refugees' heath is accelerating, research on undocumented migrants' health lags behind.[28 50] The number and quality of studies being limited, there are some major gaps in the current knowledge about their health and wellbeing and their relationship to living and economic conditions.

Most studies have been conducted in healthcare settings, thus entailing a systematic selection bias restricting their generalizability, and are cross-sectional or retrospective, which hampers the ability to measure changes over time and to identify causal relationships.[12 16 17 26 35 38 51-55] Most studies are monodisciplinary, rely on a single methodology, typically measure a limited range of health indicators and usually overlook the wellbeing dimension. These limitations restrict the ability to foster a comprehensive understanding of the complexity and the dynamics of health and wellbeing evolution after regularization in a longitudinal perspective taking into account the interactions between medical, social, legal and economic factors.

A second gap pertains to the lack of in-depth understanding of the impact of legal status change (regularization) on the health and living conditions of individual migrants but also of the rest of their family.[13 16 26 35 36 38 43] In particular, there is a lack of evidence about how undocumented migrants interpret the transformation of their living conditions during and after regularization and the ambivalent individual and family consequences of migration and regularization clearly need to be better understood. [56] This again calls for the collection of longitudinal data.[56 57] The underdevelopment of research on transnational undocumented migrant families mirrors the limited interest from policymakers.[56]

Theoretical perspectives

To address the limitations of the available research, our research design is supported by two main theoretical perspectives allowing assessing the role of regularization.

(1) The perspective of wellbeing and quality of life (QoL) is typically articulated with the social determinants of health framework promoted among others by the World Health Organization (WHO). Indeed the model developed by the WHO maps the multiple factors that affect equity in both health and wellbeing.[58] Growing interest for wellbeing is evidenced by the Organization for Economic Co-operation and Development (OCDE) framework that associates objective indicators of material conditions with QoL indicators in different domains (including housing, education, income, etc.).[59 60] This framework is particularly relevant to assess the situation of newly regularized migrants, along the idea that QoL reflects the gap between individuals' actual situation and that to which they aspire.[61] We can hypothesize that undocumented migrants' wellbeing might be higher than that of Swiss residents with similar levels of resources..

(2) The dynamic approach of the life course will allow examining undocumented migrants' trajectories both retrospectively and prospectively. Considering how much stress and uncertainty the absence of legal documents generates, regularization represents a major transition. At the same time, the acquisition of a legal status can bring mixed consequences, including both positive (elimination of the deportation risk, better housing) and negative (new financial constraints like taxes, competition on the labor market) influences. The life course perspective will be used to assess how regularization modifies the balance between vulnerability, resources and reserves.[62 63]

Objectives of the study and research questions

This study aims to measure how regularization impacts the health and wellbeing of undocumented migrants in Geneva Canton. To reach this goal, five research questions have been formulated:

1. What are the living conditions of undocumented migrants living in Geneva?
2. What are the health status, including the mental and somatic dimensions, and well-being of undocumented migrants living in Geneva?
3. What are the health-seeking behaviors, healthcare utilization, including emergency services, and renouncement to medical care, among undocumented migrants living in Geneva?
4. What is the impact of regularization on their health and well-being and its relationship with changes in living conditions?
5. How do contextual factors shape the experience of transitioning towards legality for undocumented individuals and families?

Methods and data analysis

Design

This prospective mixed-methods observational study compares a group of undocumented migrants undergoing regularization with a group of migrants not eligible for regularization. A nested qualitative longitudinal study focuses on a sub-sample of individuals undergoing regularization. The data collection started in 2017 and will end in 2021.

The research plan is organized to respond to the set of research questions developed on the following hypotheses: i) undocumented migrants endure deleterious living and economic conditions compared to the general population which has an impact on their health and wellbeing; ii) regularization of the legal status impacts on health and wellbeing; iii) differences in health and wellbeing after regularization are mediated by changes in living and economic conditions and iv) regularization may cause vulnerability in health and living conditions.

Setting

This study takes place in Geneva Canton located in French-speaking Western Switzerland. The resident population is 500'000 including 10-15'000 undocumented migrants.

Eligibility criteria

Inclusion criteria

Migrants aged $\geq$ 18 years, originating from countries outside the European Union or European Free Trade Association, living in Geneva without a valid residency permit (undocumented) for at least 3 years, who plan to stay in Geneva at least 3 more years, have not registered as asylum seekers, are eligible to participate. They are categorized into two groups: (1) those undergoing the regularization process or who have been regularized for

less than three months (intervention group) and (2) those who do not meet the regularization eligibility criteria or are unwilling to apply for regularization (control group).

Exclusion criteria

The inability to hold a basic conversation in one of the languages spoken by investigators (French, Spanish, Portuguese, English, Albanian, and Italian) is the only exclusion criteria.

Intervention

Participants eligible for legal status regularization (intervention group) will receive a residency permit within 3-6 months after the submission of their application to the Canton authorities. This process will take place during the first year of data collection. The information about permit acceptance will be collected through participants and the NGOs. This permit is renewable annually. Outcomes

Primary outcome measure

The primary outcome is self-rated health. It will be measured by comparing intra-group differences at baseline and after 3 years. Yearly measurements will allow for observing fluctuations in such differences. This item will be measured using the SF-12 question 1, a 5-points Likert scale [64], whose large-scale use also allows for comparing the results with other groups of population. We selected the main outcome for its prognostic value in terms of morbidity and mortality.[65 66]

Secondary outcome measure

The secondary outcome consists of self-reported satisfaction with current life as measured through the dimensions of living condition and economic situation at baseline and after three years. Each domain will be measured every year with a single question using a 10-points Likert scale ranging from 0=absolutely not satisfied to 10=absolutely satisfied. This will allow to measure key dimensions of the OCDE wellbeing framework and provide comparison with the resident population.[60]

Additional variables under investigations

The quantitative part explores four domains, i.e. (1) personal and family characteristics, (2) health, (3) living conditions and (4) employment and economic situation. Table 1 presents the variables under study, to the exception of the main outcomes. These variables will be used as predictors for the main outcomes. The questionnaire was designed to provide data that allow for comparisons with the general population living in Switzerland, by using questions from population surveys such as the Household Panel Study or the Swiss Health Survey.[67 68] For specific domains, we use validated measurement tools selected for their validity and reliability in non-clinical settings. We apply the PHQ-9 and GAD-7 scales for the screening of depression and anxiety, respectively.[69 70] Occupational mental health is assessed with the Maslach Burnout Inventory Test, specifically the emotional exhaustion dimension.[71] We use The Pittsburg Sleep Quality Index Sleep Quality to evaluate

sleep.[72] The questionnaire was pretested with a sample of participants (n=5), allowing for iterative modifications.

Table 1: variables by domain

Personal and family characteristics	Health	Living conditions	Employment and economic situation
Sociodemographical characteristics*;** : sex; age; country of birth; nationality	Anthropomorphic measures: weight (kg) *;**; height (cm) *;**	Housing : number of rooms*; number of people sharing accommodation*;**; quality of environment*; type of lease contract*;**; rent price*	Professional activity : number of employers*; sector of employment*;**; number of working hours*;**; working permit*
Family composition*;** : marital status ; number of children	Somatic health : chronic diseases*/**; accidents*;**; injuries; current treatment**	Household composition : relation with household members*;**	Working conditions : penibility**; exposure to hazards **
Children characteristics : gender ; age ; country of birth ; country of residence; current education	Mental health: anxiety ; depression** [69 70] ; current treatment	Discrimination** : at the workplace; in public spaces; in healthcare settings	Income : individual level*;**; household level*;**; state subsidies*
Migration history: reason for leaving country of origin; date of departure from country of origin; date of arrival in Switzerland; previous and current residency status in Switzerland; visit to country of origin; regularization procedure	Health behaviors : sleep [72]; physical activity*;**	Social support: satisfaction with social relationships**	Financial situation : ability to cover unexpected expense; remittance to country of origin
Education : number of years at school; highest degree attained*;**; place of education	Access to care : health insurance; deductibles**; cost of premium; State-funded deductions*	Integration into local life : participation to activities**; French fluency	
Professional qualification : professional training; employment record before migration	Utilization of the healthcare system: number of ambulatory and emergency room visits**; hospitalization*;**; affiliation with a family physician**		
	Renunciation to healthcare utilization: reasons; type of care		
	Occupational health** ; emotional exhaustion [71]; professional injuries**		

* Variables of the Swiss Household Panel; ** variables of the Swiss Health Survey

Qualitative part

The following themes will be covered during the semi-directed interviews: marital and family dynamics, including relationships with family members not living in Switzerland; experience of the regularization process

and its positive and negative implications; perspectives and aspirations for the future; for parents: educational issues and aspirations for their children's future. The interview guide has been pretested with 5 persons.

Participant timeline

Quantitative data will be collected by questionnaire at baseline and repeated annually during the following three year (4 waves in total) (Figure 1). Questionnaires will be filled face-to-face with participants in the intervention and the control groups. We restricted the follow-up to three years assuming that most changes in the domains under study will occur during the first two years, followed by a more stable situation. This restriction also aims to reduce the attrition rate. Qualitative interviews are conducted at baseline (year 1) and then every year for three years. They are conducted at a different time from the quantitative data collection to avoid participants' fatigue.

Sample size

Considering an effect size of 0.3 for the main health outcome (self-rated health), a type 1 error of 0.05 and a power of 0.8, the total sample size is 352, rounded up to 400 to account for the possible drop-out of participants over the follow-up.

The purposive qualitative nested study sampling includes 38 participants selected from the intervention group of undocumented migrants eligible for regularization. The sample size is estimated to be sufficient to reach data saturation. To ensure the diversity of the sample, participants are recruited on the respectively absence or presence of children, while ensuring the diversity of the sample regarding origins, age and gender.

Recruitment

According to the Geneva authorities, 1'000-2'000 undocumented migrants could be eligible for the regularization policy Recruitment is based on two strategies. First, undocumented migrants are informed about the study by personal contacts at NGOs acting at gatekeepers for “Operation Papyrus”, during public meetings held in the community, at dedicated health centers attending for undocumented migrants, through leaflets and a Facebook page. A direct phone line is accessible during office hours to respond to all enquiries. People interested in participating contact the investigators who present the study information and consent forms and engage in the first questionnaire passing if agreement is provided.

The second strategy is based on phone contacts with potential participants identified in partner NGOs registries of undocumented migrants. During the initial call, investigators present the study and offer to organize a first meeting to provide more in-depth information. In the absence of response, potential participants are recalled up to five times.

Retention

Undocumented migrants are highly mobile and can be lost during the follow-up. In order to account for this risk, the sample size has been increased by 12.5%. All participants undergoing the first round of data collection

will be contacted yearly for the subsequent waves. In order to enhance retention into the study, the following strategies are implemented: a) providing a material compensation (worth 10-15 euros) and information about available health and administrative services after each questionnaire passation; b) discussing the need for and gaining acceptance for the nest contact after one year upon each encounter; c) recording a secondary phone number or email address to ensure participants are accessible. Moreover, partner NGOs inform communities of the importance of the follow-up. Contact for the following data collection will be made by phone with up to five recalls and use of email messaging in case of non-response. In order to facilitate participation and retention into the study, the field investigators can move to the preferred participant's location to pass the questionnaire.

Participants may withdraw from the study for any reason at any time. In case of withdrawal or loss to follow-up, all data will be included until the last participants' questionnaire for the analysis.

Quantitative data collection

The questionnaire is administered face-to-face with participants of both groups at their preferred location in the community. It is available in the four most frequent languages (Spanish, Portuguese, French, English) spoken by undocumented migrants in Geneva. Data are recorded on a mobile tablet using Sphinx mobile® software (LeSphinx, France) and are immediately transferred on a secure server. Interviewers are trained and supervised by a senior staff during their first interviews.

Qualitative data collection

In the qualitative section, data are collected in semi-directed interviews with undocumented migrants in the process of regularization. They are conducted in French, Spanish and English. Interviews are tape recorded and fully transcribed.

Statistical analysis

In a first step, the two groups (intervention vs. control) will be compared on all characteristics, using univariate analysis such as Fisher exact test for categorical variables and Wilcox rank sum test for continuous variables. This will allow determining the quality of the control group selection.

To assess the evolution of health outcomes and living conditions over time, we will use multilevel linear models (logistic, Poisson, or Gaussian as appropriate depending on the specific outcome), including legal status (regularized vs. control) and adjusting for baseline characteristics to further account for group differences. Multilevel models account for the repeated nature of the data. To specifically focus on the different trajectories, these models will include both a random intercept and a random slope over time. Note that for rare dichotomous outcomes, we will probably need to restrict the number of covariates due to a number of events per variables below five per predictor. In that case, we will use two strategies. First, we will apply propensity score adjustment, using all previously described covariates to compute the propensity score. Second, because the propensity score may not capture the importance of some confounders and lead to

residual confounding, we will use a least absolute shrinkage and selection operator (LASSO) regression to determine which covariates are the most useful, before using only those covariates for adjustment.

Qualitative data analysis

Thematic analyses of the transcriptions will be conducted with Atlas.ti (www.atlasti.com), combining a set of codes defined along the interview guide and new codes inductively generated over the course of the analysis.

Ethics and dissemination

This study was approved by the Ethics Committee of Geneva Canton, Switzerland (CCER 2017-00897). All participants will provide informed consent. Results will be shared with migrant communities and NGOs supporting undocumented migrants and disseminated in scientific journals and in conferences. Fully anonymized data will be made available to researchers.

Patient and Public Involvement

The development of the research questions, outcome measures and investigation strategies were informed by discussions conducted with community organizations active with undocumented migrants and with undocumented migrant patients seen by the main investigator (YJ). Patients were not directly involved in the design of the study but feedbacks from participants after the questionnaire pre-testing were used to adapt its content. One of the field investigators is a former undocumented migrant. The results will be disseminated to study participants by two channels: a) regular public meetings, the first of which took place on November 6th 2018 and through partner community organizations.

Discussion

This mixed methods study aims to measure the impact of legal status change on health and wellbeing of undocumented migrants taking in account living, employment and economic conditions. It will produce the first comprehensive and longitudinal evaluation of a policy response to irregular migration in Europe. The interdisciplinary approach warrants the generation of rich data about a complex phenomenon. Considering the contemporary political and scientific interest in issues pertaining to migration worldwide, this study is at the forefront to provide original, interdisciplinary and comprehensive evidence about an ill-researched population. The results will influence how such issues are framed and discussed at local, national and international levels. Data will specifically inform about unmet health needs, expectations and resources of undocumented migrants, therefore allowing for guiding clinical and public health strategies in Switzerland and similar countries. This may allow for an opportunity to mitigate inequalities in health outcomes and in access to health services. Most importantly, this study will provide a safe environment to give a voice to a silent and underserved population.

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Authors contribution

YJ conceived the study, is the co-principal investigator, drafted the protocol and wrote the manuscript.
CBJ conceived the study, is the co-principal investigator, drafted the protocol and proofread the manuscript.
GFL, AD, SC and DC contributed to the study conception and protocol and proofread the manuscript.
PB, PC, IG, and HW reviewed the protocol and proofread the manuscript.
All authors approved the version to be published and are responsible for its accuracy.

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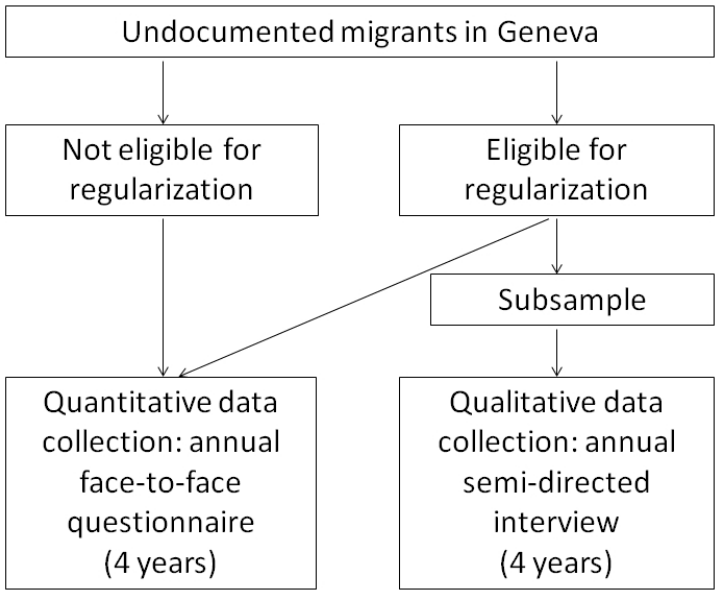
Figure caption

Figure 1: Study flow chart



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Impact of legal status change on undocumented migrants' health and well-being (Parchemins): protocol of a 4-year prospective mixed-methods study.

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Impact of legal status change on undocumented migrants' health and well-being (Parchemins): protocol of a 4-year prospective mixed-methods study.

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Abstract

Introduction

Migrants without residency permit, known as undocumented, tend to live in precarious conditions and to be exposed to an accumulation of adverse determinants of health. Only scarce evidence exists on the social, economic and living conditions-related factors influencing their health status and wellbeing. No study has assessed the impact of legal status regularization. The Parchemins study is the first prospective mixed-methods study aiming at measuring the impact on health and well-being of a regularization policy on undocumented migrants in Europe.

Methods and analysis

The Parchemins study will compare self-rated health and satisfaction with life in a group of adult undocumented migrants who qualify for applying for a residency permit (intervention group) with a group of

undocumented migrants who lack one or more eligibility criteria for regularization (control group) in Geneva Canton, Switzerland. Asylum seekers are not included in this study. The total sample will include 400 participants. Data collection will consist of standardized questionnaires complemented by semi-directed interviews in a sub-sample (n=38) of migrants qualifying for regularization. The baseline data will be collected just before or during the regularization and participants will subsequently be followed-up yearly for three years. The quantitative part will explore variables about health (i.e. health status, occupational health, health seeking behaviors, access to care, healthcare utilization), wellbeing (measured by satisfaction with different dimensions of life), living conditions (i.e. employment, accommodation, social support) and economic situation (income, expenditures). Several confounders including sociodemographic characteristics and migration history will be collected. The qualitative part will explore longitudinally the experience of change in legal status at individual and family levels.

Ethics and dissemination

This study was approved by the Ethics Committee of Geneva, Switzerland. All participants provided informed consent. Results will be shared with undocumented migrants and disseminated in scientific journals and conferences. Fully anonymized data will be available to researchers.

Strengths and limitations of this study

- The prospective and mixed-methods approaches will allow generating a comprehensive understanding of factors operating across time on health and wellbeing.

- The qualitative part will provide further insights into individual and family experiences in parting with their undocumented status and facing the new challenges that regularization entails.

- The main limitation will be the risk of attrition in the control group considering the harsh and unpredictable living context of such migrants.

- The study is designed to minimize such risk by selecting undocumented migrants having a relatively stable personal situation.

Keywords: undocumented migrants, irregular migration, health, wellbeing, regularization

Introduction

Undocumented or irregular migration is defined as "*movements that takes place outside the regulatory norms of the sending, transit and receiving countries*".[1] It results from overstaying after temporary residency permit expiration, asylum claim refusal or entering the country without valid migration documentation.[1 2] In absence of valid methods of identification, figures provided for undocumented migrants are mainly theoretical and estimated by cross-referencing different sources. Recent valid data is generally lacking. The International Organization for Migration estimated that there were 20-30 million undocumented migrants worldwide in 2010.[3] According to the Pew Hispanic Center, the number of undocumented migrants from Latin America in the

United States increased from 8.4 in 2000 to 11.1 million in 2011.[4] Europe hosted an estimated 1.9 to 3.8 million of such migrants in 2008 and the most recent estimates point to 180'000-520'000 and 58'000-105'000 of them in Germany and Switzerland, respectively.[5-7]

A vulnerable population

The lack of legal residency permit interacts with social, political and economic factors to create multi-dimensional vulnerability among undocumented migrants.[8 9] In most European countries, they face significant post-migration difficulties in the context of restrictive immigration policies and lack of labor protection [2 10]. Many are employed in low-skills and precarious 3D (dangerous, dirty and degrading) jobs and are exposed to abuse, exploitation and occupational hazards.[11-14] Access to other basic commodities and services such as housing, education and training, food and legal protection in case of harm or abuse is usually arduous and precarious.[10 15]

When compared to the resident and the regular migrants' populations, self-rated physical and mental health is consistently and significantly poorer among undocumented migrants in Europe.[16 17] In a study conducted in 11 countries, 23% of women and 34% of men, including those in the youngest age groups, rated their health as poor or very poor.[12] Undocumented migrants present high prevalence of chronic conditions in primary care settings, notably of metabolic, cardiovascular and psychiatric origins.[16 18-22] Several infectious diseases are more prevalent than in the resident population which relates more to geographic origins than to the legal status.[23 24] No comparative data exist on the mortality rate ratio of undocumented migrants compared to the general population but external (including accidents and suicides) and circulatory causes of death were 3.6 and 2.2 times more prevalent in a sample of such migrants than in the general Swedish population, respectively.[25]

Undocumented migrants in Europe face limited opportunities to respond to their healthcare needs with barriers to healthcare operating at different levels.[12 26-28] Legal entitlement to receive medical care within the public healthcare system varies considerably between countries. A majority of countries restrict access to emergency situations exclusively.[29 30] Non-governmental organizations (NGOs) play a subsidiary role but services provided are generally of limited extent and do not cover the full range of health needs.[12] Access to costly treatments in the absence of formal entitlement to healthcare is frequently restricted, which entails significant health consequences, notably in the context of severe chronic diseases such as HIV/AIDS infection.[31 32] At the health service level, communication barriers, the perceived lack of specific skills and practical difficulties encountered by healthcare workers contribute to restrict the extent and quality of care.[33 34] At the migrants' level, fear of denunciation, direct costs at charge and a lack of knowledge about how to navigate the health system impede adequate use of health services.[12 16 35 36] These factors negatively impact the provision of health promoting and preventive interventions such as immunization, birth-control counseling, prenatal care and screening procedures.[37-39] Undocumented migrants have a higher rate of preventable hospitalizations compared to populations with full access to care and are less likely to receive preventive care.[39 40]

In Switzerland, the 26 cantons have a large autonomy and have the responsibility to supervise and manage their public healthcare system.[41] Undocumented migrants are legally entitled to purchase the mandatory basic health insurance (which grants access to standard healthcare) but lack of awareness, financial and administrative barriers as well as fear of denunciation contribute to the estimated 10-20% insurance coverage.[42 43] Swiss cantons have implemented different policies to bridge this access gap. Geneva and Vaud provide health services within the public healthcare system which are complemented by other services (food, shelter) provided by NGOs.[42] Yet, previous studies showed that undocumented migrants in Geneva tend to delay seeking care, notably for preventive interventions.[38]

Regularization policies

Several regularization programs have been implemented in Europe and an estimated 1.8 million undocumented migrants were granted a residency permit between 2002 and 2008.[2] Switzerland has never implemented large-scale programs but a handful of individual applications (mainly through NGOs or lawyers' services) have been successful to varying degrees depending on the canton. Residency permits have been granted mainly for humanitarian motives, in case of severe medical needs, long stay and satisfactory integration, absence of criminal record and financial autonomy.[5] In 2017, the Geneva Canton implemented a two-year pilot regularization program (Operation Papyrus) aiming at granting one-year residency permits to undocumented migrants meeting the following criteria: a) stay of 10 years for individuals or 5 years for families with school-aged children; b) basic French proficiency; c) sufficient financial resources; d) lack of criminal record other than related to the residency permit.[44] The program integrates civil society actors (workers' unions, NGOs) that act as gatekeepers between undocumented migrants and the Canton authorities, and support them with the administrative process leading to regularization.

The impact of regularization policy on undocumented migrants' health, well-being, living conditions and economic situation has rarely been studied in Europe. Scarce evidence shows improved access to legal employment, social welfare and insurances with better housing and educational opportunities.[45] Negative effects included enhanced professional competition associated with the lack of recognition of pre-migration professional qualifications. In Italy, the 2007 amnesty policy was associated with a 1.2 to 2.7% point decline in low birth weight prevalence within the migrant population eligible for regularization.[46] In the USA, the Deferred Action for Children Arrival act (DACA) implemented in 2012 allowed around 800'000 undocumented young people to be temporarily regularized. Studies found a decline in psychological distress, improvements in self-esteem, wellbeing, and social support and pointed to beneficial trans-generational effects on children mental health.[47-49] No study has prospectively explored the impact of legal status change on health and wellbeing while taking into accounts undocumented migrants living and working conditions.

Gaps in the existing literature

While the development of knowledge about asylum seekers and refugees' heath is accelerating, research on undocumented migrants' health lags behind.[28 50] The number and quality of studies being limited, there are

some major gaps in the current knowledge about their health and wellbeing and their relationship to living and economic conditions.

Most studies have been conducted in healthcare settings, thus entailing a systematic selection bias restricting their generalizability, and are cross-sectional or retrospective, which hampers the ability to measure changes over time and to identify causal relationships.[12 16 17 26 35 38 51-55] Most studies are monodisciplinary, rely on a single methodology, typically measure a limited range of health indicators and usually overlook the wellbeing dimension. These limitations restrict the ability to foster a comprehensive understanding of the complexity and the dynamics of health and wellbeing evolution after regularization in a longitudinal perspective taking into account the interactions between medical, social, legal and economic factors.

A second gap pertains to the lack of in-depth understanding of the impact of legal status change (regularization) on the health and living conditions of individual migrants but also of the rest of their family.[13 16 26 35 36 38 43] In particular, there is a lack of evidence about how undocumented migrants interpret the transformation of their living conditions during and after regularization and the ambivalent individual and family consequences of migration and regularization clearly need to be better understood. [56] This again calls for the collection of longitudinal data.[56 57] The underdevelopment of research on transnational undocumented migrant families mirrors the limited interest from policymakers.[56]

Theoretical perspectives

To address the limitations of the available research, our research design is supported by two main theoretical perspectives allowing assessing the role of regularization.

(1) The perspective of wellbeing and quality of life (QoL) is typically articulated with the social determinants of health framework promoted among others by the World Health Organization (WHO). Indeed the model developed by the WHO maps the multiple factors that affect equity in both health and wellbeing.[58] Growing interest for wellbeing is evidenced by the Organization for Economic Co-operation and Development (OCDE) framework that associates objective indicators of material conditions with QoL indicators in different domains (including housing, education, income, etc.).[59 60] This framework is particularly relevant to assess the situation of newly regularized migrants, along the idea that QoL reflects the gap between individuals' actual situation and that to which they aspire.[61] We can hypothesize that undocumented migrants' wellbeing might be higher than that of Swiss residents with similar levels of resources.

(2) The dynamic approach of the life course will allow examining undocumented migrants' trajectories both retrospectively and prospectively. Considering how much stress and uncertainty the absence of legal documents generates, regularization represents a major transition. At the same time, the acquisition of a legal status can bring mixed consequences, including both positive (elimination of the deportation risk, better housing) and negative (new financial constraints like taxes, competition on the labor market)

influences. The life course perspective will be used to assess how regularization modifies the balance between vulnerability, resources and reserves.[62 63]

Objectives of the study and research questions

This study aims to measure how regularization impacts the health and wellbeing of undocumented migrants in Geneva Canton. To reach this goal, five research questions have been formulated:

1. What are the living conditions of undocumented migrants living in Geneva?
2. What are the health status, including the mental and somatic dimensions, and well-being of undocumented migrants living in Geneva?
3. What are the health-seeking behaviors, healthcare utilization, including emergency services, and renouncement to medical care, among undocumented migrants living in Geneva?
4. What is the impact of regularization on their health and well-being and its relationship with changes in living conditions?
5. How do contextual factors shape the experience of transitioning towards legality for undocumented individuals and families?

Methods and data analysis

Design

This prospective mixed-methods observational study compares a group of undocumented migrants undergoing regularization with a group of migrants not eligible for regularization. A nested qualitative longitudinal study focuses on a sub-sample of individuals undergoing regularization. The data collection started in 2017 and will end in 2021.

The research plan is organized to respond to the set of research questions developed on the following hypotheses: i) undocumented migrants endure deleterious living and economic conditions compared to the general population which has an impact on their health and wellbeing; ii) regularization of the legal status impacts on health and wellbeing; iii) differences in health and wellbeing after regularization are mediated by changes in living and economic conditions and iv) regularization may cause vulnerability in health and living conditions.

Setting

This study takes place in Geneva Canton located in French-speaking Western Switzerland. The resident population is 500'000 including 10-15'000 undocumented migrants.

Eligibility criteria

Inclusion criteria

Migrants aged ≥ 18 years, originating from countries outside the European Union or European Free Trade Association, living in Geneva without a valid residency permit (undocumented) for at least 3 years, who plan to stay in Geneva at least 3 more years, have not registered as asylum seekers, are eligible to participate. They are categorized into two groups: (1) those undergoing the regularization process or who have been regularized for less than three months (intervention group) and (2) those who do not meet the regularization eligibility criteria or are unwilling to apply for regularization (control group).

Exclusion criteria

The inability to hold a basic conversation in one of the languages spoken by investigators (French, Spanish, Portuguese, English, Albanian, and Italian) is the only exclusion criteria.

Intervention

Participants eligible for legal status regularization (intervention group) will receive a residency permit within 3-6 months after the submission of their application to the Canton authorities. This process will take place during the first year of data collection. The information about permit acceptance will be collected through participants and the NGOs. This permit is renewable annually. Outcomes

Primary outcome measure

The primary outcome is self-rated health. It will be measured by comparing intra-group differences at baseline and after 3 years. Yearly measurements will allow for observing fluctuations in such differences. This item will be measured using the SF-12 question 1, a 5-points Likert scale [64], whose large-scale use also allows for comparing the results with other groups of population. We selected the main outcome for its prognostic value in terms of morbidity and mortality.[65 66]

Secondary outcome measure

The secondary outcome consists of self-reported satisfaction with current life as measured through the dimensions of living condition and economic situation at baseline and after three years. Each domain will be measured every year with a single question using a 10-points Likert scale ranging from 0=absolutely not satisfied to 10=absolutely satisfied. This will allow to measure key dimensions of the OCDE wellbeing framework and provide comparison with the resident population.[60]

Additional variables under investigations

The quantitative part explores four domains, i.e. (1) personal and family characteristics, (2) health, (3) living conditions and (4) employment and economic situation. Table 1 presents the variables under study, to the exception of the main outcomes. These variables will be used as predictors for the main outcomes. The questionnaire was designed to provide data that allow for comparisons with the general population living in

Switzerland, by using questions from population surveys such as the Household Panel Study or the Swiss Health Survey.[67 68] For specific domains, we use validated measurement tools selected for their validity and reliability in non-clinical settings. We apply the PHQ-9 and GAD-7 scales for the screening of depression and anxiety, respectively.[69 70] Occupational mental health is assessed with the Maslach Burnout Inventory Test, specifically the emotional exhaustion dimension.[71] We use The Pittsburg Sleep Quality Index Sleep Quality to evaluate sleep.[72] We used validated translations of these scales when available but not all questionnaires were validated in all the languages used in this study. The questionnaire was pretested with a sample of participants (n=5), allowing for iterative modifications.

Table 1: variables by domain

Personal and family characteristics	Health	Living conditions	Employment and economic situation
Sociodemographic characteristics*;** : sex; age; country of birth; nationality	Anthropomorphic measures: weight (kg) *;**; height (cm) *;**	Housing : number of rooms*; number of people sharing accommodation*;**; quality of environment*; type of lease contract*;**; rent price*	Professional activity : number of employers*; sector of employment*;**; number of working hours*;**; working permit*
Family composition*;** : marital status ; number of children	Somatic health : chronic diseases*/**; accidents*;**; injuries; current treatment**	Household composition : relation with household members*;**	Working conditions : penibility**; exposure to hazards **
Children characteristics : gender ; age ; country of birth ; country of residence; current education	Mental health: anxiety ; depression** [69 70] ; current treatment	Discrimination** : at the workplace; in public spaces; in healthcare settings	Income : individual level*;**; household level*;**; state subsidies*
Migration history: reason for leaving country of origin; date of departure from country of origin; date of arrival in Switzerland; previous and current residency status in Switzerland; visit to country of origin; regularization procedure	Health behaviors : sleep [72]; physical activity*;**	Social support: satisfaction with social relationships**	Financial situation : ability to cover unexpected expense; remittance to country of origin
Education : number of years at school; highest degree attained*;**; place of education	Access to care : health insurance; deductibles**; cost of premium; State-funded deductions*	Integration into local life : participation to activities**; French fluency	
Professional qualification : professional training; employment record before migration	Utilization of the healthcare system: number of ambulatory and emergency room visits**; hospitalization*;**; affiliation with a family physician**		
	Renunciation to healthcare utilization: reasons; type of care		
	Occupational health** ; emotional exhaustion [71]; professional injuries**		

* Variables of the Swiss Household Panel; ** variables of the Swiss Health Survey

Qualitative part

The following themes will be covered during the semi-directed interviews: marital and family dynamics, including relationships with family members not living in Switzerland; experience of the regularization process

and its positive and negative implications; perspectives and aspirations for the future; for parents: educational issues and aspirations for their children's future. The interview guide has been pretested with 5 persons.

Participant timeline

Quantitative data will be collected by questionnaire at baseline and repeated annually during the following three year (4 waves in total) (Figure 1). Questionnaires will be filled face-to-face with participants in the intervention and the control groups. We restricted the follow-up to three years assuming that most changes in the domains under study will occur during the first two years, followed by a more stable situation. This restriction also aims to reduce the attrition rate. Qualitative interviews are conducted at baseline (year 1) and then every year for three years. They are conducted at a different time from the quantitative data collection to avoid participants' fatigue.

Sample size

Considering an effect size of 0.3 for the main health outcome (self-rated health), a type 1 error of 0.05 and a power of 0.8, the total sample size is 352, rounded up to 400 to account for the possible drop-out of participants over the follow-up.

The purposive qualitative nested study sampling includes 38 participants selected from the intervention group of undocumented migrants eligible for regularization. The sample size is estimated to be sufficient to reach data saturation. To ensure the diversity of the sample, participants are recruited on the respectively absence or presence of children, while ensuring the diversity of the sample regarding origins, age and gender.

Recruitment

According to the Geneva authorities, 1'000-2'000 undocumented migrants could be eligible for the regularization policy Recruitment is based on two strategies. First, undocumented migrants are informed about the study by personal contacts at NGOs acting at gatekeepers for “Operation Papyrus”, during public meetings held in the community, at dedicated health centers attending for undocumented migrants, through leaflets and a Facebook page. A direct phone line is accessible during office hours to respond to all enquiries. People interested in participating contact the investigators who present the study information and consent forms and engage in the first questionnaire passing if agreement is provided.

The second strategy is based on phone contacts with potential participants identified in partner NGOs registries of undocumented migrants. During the initial call, investigators present the study and offer to organize a first meeting to provide more in-depth information. In the absence of response, potential participants are recalled up to five times.

Retention

Undocumented migrants are highly mobile and can be lost during the follow-up. In order to account for this risk, the sample size has been increased by 12.5%. All participants undergoing the first round of data collection

will be contacted yearly for the subsequent waves. In order to enhance retention into the study, the following strategies are implemented: a) providing a material compensation (worth 10-15 euros) and information about available health and administrative services after each questionnaire passation; b) discussing the need for and gaining acceptance for the nest contact after one year upon each encounter; c) recording a secondary phone number or email address to ensure participants are accessible. Moreover, partner NGOs inform communities of the importance of the follow-up. Contact for the following data collection will be made by phone with up to five recalls and use of email messaging in case of non-response. In order to facilitate participation and retention into the study, the field investigators can move to the preferred participant's location to pass the questionnaire.

Participants may withdraw from the study for any reason at any time. In case of withdrawal or loss to follow-up, all data will be included until the last participants' questionnaire for the analysis.

Quantitative data collection

The questionnaire is administered face-to-face with participants of both groups at their preferred location in the community. It is available in the four most frequent languages (Spanish, Portuguese, French, English) spoken by undocumented migrants in Geneva. We acknowledge there may be a potential limitation related to the limited language skills of the subsample of participants not completely fluent in one of these four languages. Data are recorded on a mobile tablet using Sphinx mobile® software (LeSphinx, France) and are immediately transferred on a secure server. Interviewers are trained and supervised by a senior staff during their first interviews.

Qualitative data collection

In the qualitative section, data are collected in semi-directed interviews with undocumented migrants in the process of regularization. They are conducted in French, Spanish and English. Interviews are tape recorded and fully transcribed.

Statistical analysis

In a first step, the two groups (intervention vs. control) will be compared on all characteristics, using univariate analysis such as Fisher exact test for categorical variables and Wilcox rank sum test for continuous variables. This will allow determining the quality of the control group selection.

To assess the evolution of health outcomes and living conditions over time, we will use multilevel linear models (logistic, Poisson, or Gaussian as appropriate depending on the specific outcome), including legal status (regularized vs. control) and adjusting for baseline characteristics to further account for group differences. Multilevel models account for the repeated nature of the data. To specifically focus on the different trajectories, these models will include both a random intercept and a random slope over time. Note that for rare dichotomous outcomes, we will probably need to restrict the number of covariates due to a number of events per variables below five per predictor. In that case, we will use two strategies. First, we will apply

propensity score adjustment, using all previously described covariates to compute the propensity score. Second, because the propensity score may not capture the importance of some confounders and lead to residual confounding, we will use a least absolute shrinkage and selection operator (LASSO) regression to determine which covariates are the most useful, before using only those covariates for adjustment.

Qualitative data analysis

Thematic analyses of the transcriptions will be conducted with Atlas.ti (www.atlasti.com), combining a set of codes defined along the interview guide and new codes inductively generated over the course of the analysis.

Ethics and dissemination

This study was approved by the Ethics Committee of Geneva Canton, Switzerland (CCER 2017-00897). All participants will provide informed consent. Results will be shared with migrant communities and NGOs supporting undocumented migrants and disseminated in scientific journals and in conferences. Fully anonymized data will be made available to researchers.

Patient and Public Involvement

The development of the research questions, outcome measures and investigation strategies were informed by discussions conducted with community organizations active with undocumented migrants and with undocumented migrant patients seen by the main investigator (YJ). Patients were not directly involved in the design of the study but feedbacks from participants after the questionnaire pre-testing were used to adapt its content. One of the field investigators is a former undocumented migrant. The results will be disseminated to study participants by two channels: a) regular public meetings, the first of which took place on November 6th 2018 and through partner community organizations.

Discussion

This mixed methods study aims to measure the impact of legal status change on health and wellbeing of undocumented migrants taking in account living, employment and economic conditions. It will produce the first comprehensive and longitudinal evaluation of a policy response to irregular migration in Europe. The interdisciplinary approach warrants the generation of rich data about a complex phenomenon. Considering the contemporary political and scientific interest in issues pertaining to migration worldwide, this study is at the forefront to provide original, interdisciplinary and comprehensive evidence about an ill-researched population. The results will influence how such issues are framed and discussed at local, national and international levels. Data will specifically inform about unmet health needs, expectations and resources of undocumented migrants, therefore allowing for guiding clinical and public health strategies in Switzerland and similar countries. This may allow for an opportunity to mitigate inequalities in health outcomes and in access to health services. Most importantly, this study will provide a safe environment to give a voice to a silent and underserved population.

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Authors contribution

YJ conceived the study, is the co-principal investigator, drafted the protocol and wrote the manuscript.
CBJ conceived the study, is the co-principal investigator, drafted the protocol and proofread the manuscript.
GFL, AD, SC and DC contributed to the study conception and protocol and proofread the manuscript.

PB, PC, IG, and HW reviewed the protocol and proofread the manuscript.

All authors approved the version to be published and are responsible for its accuracy.

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Figure caption

Figure 1: Study flow chart

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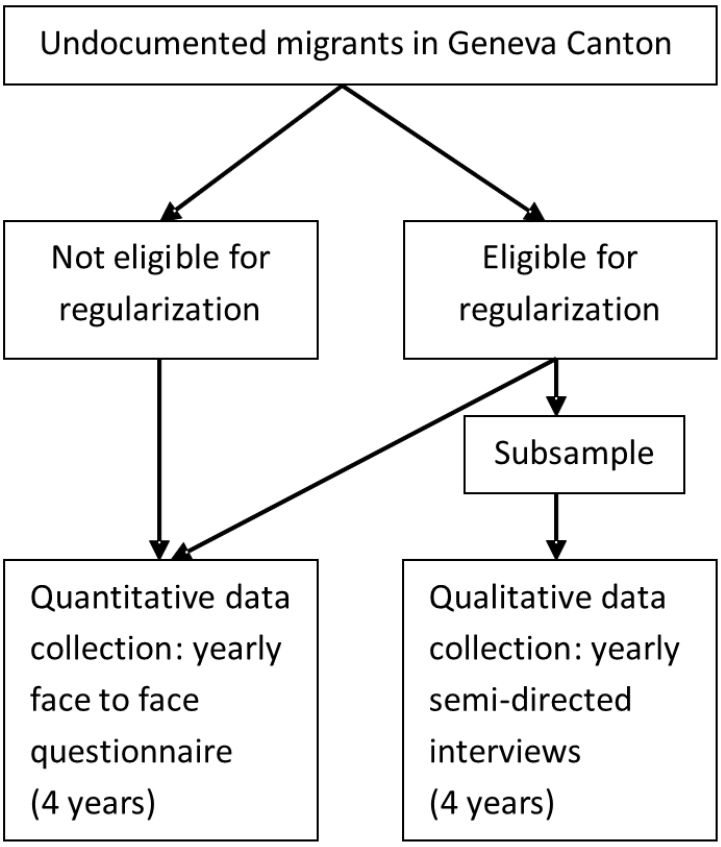

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