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PhD in Public Health

Cycle XXXIV

Curriculum in Biostatistics and Epidemiology

TOWARDS UNIVERSAL HEALTH COVERAGE AND HEALTH SYSTEM EQUITY

ESTIMATING HEALTH OUTCOMES AND HEALTHCARE COVERAGE

IN UNDOCUMENTED MIGRANTS

KEY ISSUES IN MATERNAL & PERINATAL HEALTH AND THE COVID-19 PANDEMIC

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Abstract

Migrant populations experience poor health, and their outcomes tend to be poorer in comparison with the general population. Vulnerability and inequality are further exacerbated in undocumented migrants, as the most invisible to healthcare systems. This a public health challenge requiring tailored action towards universal health coverage and health system equity.

Objectives: To estimate health needs among undocumented migrants in the areas of maternal & perinatal health and COVID-19; and to test a combination of methodologies for systematic monitoring and evaluation.

Methods: This research is based on three retrospective cohort and cross-sectional studies using a combination of diverse and complementary data sources to reflect the complex nature of health outcomes and healthcare access in undocumented migrants, including: national/regional health management information systems, third sector healthcare provider health information systems, and surveys at selected healthcare facilities.

Cohort: Undocumented migrants having accessed: (i) maternity healthcare through National/Regional Health Services in Lombardy Region (Italy) from 2016 to 2020; (ii) healthcare through a third sector healthcare provider in Milan (Italy) from February 24th to May 24th, 2020; (iii) healthcare through participating healthcare providers in Switzerland (Geneva Region), USA (Baltimore City), Italy (Lombardy Region), and France (Paris Region) from February to May 2021.

Results: (i) The study on maternal and perinatal health included 1595 undocumented migrant women and their neonates. 57.37% women had ≥4 antenatal visits, 68.21% had the first one within 12 weeks of gestation, 63.45% had at least two ultrasound tests including one within 12 weeks of gestation, and 6.21% had complete laboratory tests. Total cesarean sections were 26.89%. Emergency resuscitation for birth asphyxia was conducted in 2.63% births, and 49.03% neonates initiated breastfeeding within 2 hours from birth. 80.56% pregnancies were physiological though severe haemorrhage (>1000ml) occurred in 2.26% women. Intra-uterine growth restriction affected 4.76% foetuses, 9.28% neonates were pre-term, 17.24% small for gestational age, 7.2% had a low weight at birth (<2.5Kg), 1.44% poor Apgar score, and 3.07% presented malformations. (ii) The study on COVID-19 illness included 272 undocumented migrants. Risk factors were frequent and included hypertension, immune depression, and prior close contact with COVID-19 cases. Presenting symptoms were worse, compared with patients with other respiratory conditions. (iii) The study on COVID-19 vaccination demand included 812 undocumented migrants. Overall, 14.1% of participants

reported prior COVID-19 infection, 29.5% risk factors, and 26.2% fear of developing severe COVID-19 infection. Self-perceived accessibility of COVID-19 vaccination was high (86.4%), yet demand was low (41.1%) correlating with age, co-morbidity, and views on vaccination which were better for vaccination in general (77.3%) than vaccination against COVID-19 (56.5%). Participants mainly searched for information about vaccination in the traditional and social media.

Conclusions: Health outcomes and healthcare access were poor in undocumented migrants. Socio-economic and health outcomes showed vulnerability and inequality in comparison to the general population. Known risk factors including fragile socio-economic conditions along with legal and linguistic barriers to healthcare need to be addressed through tailored interventions including outreach health promotion, healthcare provider training, cultural mediation, translation, and functional language learning. Furthermore, a systematic monitoring and evaluation system is needed to routinely collect, integrate, and analyze data on key indicators from both National/Regional Health Services and third sector healthcare providers in combination with ad hoc surveys for specific data outside routine information systems.

Chapter 1: Introduction

Background and rationale

Mixed migration is a complex demographic dynamic involving cross-border movements of heterogeneous population cohorts including refugees, asylum seekers, victims of human trafficking, and migrants seeking better lives and opportunities outside their country of origin [1].

Globally, migrant population is currently estimated at approximately 314.4 million people, including 33.8 million refugees and asylum seekers (10.8%) and 208.6 million migrants (89.2%) [2]. These figures do not include undocumented migrants, whose estimates are mostly unavailable except for selected countries, as by definition outside registration systems.

In Italy, migrant population is currently estimated at 6.6 million people, equivalent to 2.1% of global migrant population and 11.1% of national population, including 255 thousand refugees and asylum seekers (3.8%) and 6.4 million migrants (96.2%), plus approximately 519 thousand undocumented migrants [3]–[5].

Table 1: Mixed migration estimates

Migrant population cohorts	Global		Italy	
	Size (N)	Share (%)	Size (n)	Share (%)
Total mixed migration	314.405.900	100	6.641.663	100
Refugees and asylum seekers	33.807.795	10.8	254.665	3.8
Migrants	280.598.105	89.2	6.38.998	96.2
Undocumented migrants	n/a	n/a	500.000	7.8

Sources: [2][5]

From a public health perspective, health needs and healthcare coverage may differ significantly in respective migrant population cohorts both within and across countries and over time, due to variations in terms of epidemiology, health system, and socioeconomics. However, despite population cohort heterogeneity and temporal-spatial variations, migrant populations experience poor health, and their outcomes tend to be poorer in comparison with the general population. Vulnerability and inequality are further exacerbated in undocumented migrants, as the most invisible to healthcare systems. As a result, mixed migration including undocumented migration, is a public health challenge requiring tailored action towards universal health coverage and health system equity, as per the Sustainable Development Goals [6].

A wealth of literature consistently highlights an underlying combination of increased health needs due to higher exposure and susceptibility to disease and risk factors, along with decreased healthcare coverage due to legal and socio-economic barriers including lack of/limited access to National Health Services, language, and poverty [7]–[12].

Albeit fragmented, the current body of literature indicates major causes of morbidity and mortality involving several public health areas, as outlined in the following overview.

Maternal and neonatal health: lower number and poorer timeliness of antenatal consultations and diagnostics; higher prevalence of abortion, obstetric and neonatal complications, emergency caesarean section delivery; higher rates of stillbirths and neonatal mortality [11]–[18].

Communicable diseases: outbreaks of Measles and other vaccine-preventable diseases; higher incidence of viral infections including Hepatitis B and C, sexually transmitted infections including HIV/AIDS and cervical cancer due to Human Papilloma Virus, Tuberculosis, tropical infections including Chagas and Malaria; helminthiases; lower vaccination coverage for Hepatitis B, Measles, Mumps, Rubella, Poliomyelitis, Tetanus; higher prevalence of chronic hepatitis and risk of complications and mortality due to Hepatitis B [12], [19]–[25]. Furthermore, the COVID-19 pandemic has exacerbated pre-existing health needs and barriers to healthcare, thus resulting in additional morbidity and mortality in undocumented migrants [26]–[31].

Non-communicable disease: higher risk and associated mortality due to cardiovascular disease including hypertension, coronary heart disease, cerebrovascular disease and heart failure, and associated mortality; higher prevalence and diabetes; initially lower incidence of cancer in the early stages of migration, converging over time with host population prevalence; poorer screening rates and prognosis [32]–[41].

Nutrition: higher prevalence of malnutrition including micronutrient deficiencies, overweight and obesity [42]–[44].

Mental health: higher exposure to risk factors including stress and violence; higher prevalence of post-traumatic stress disorders and depression; higher incidence of psychotic disorders [45]–[47].

However, evidence about health outcomes and healthcare access among undocumented migrants is limited as mostly based upon *ad hoc* surveys at selected health facilities, while there is a lack of systematic monitoring and evaluation. On one hand, national/sub-national health management information systems do not currently disaggregate data by migrant status, thus limiting the

identification of this specific population cohort. On the other hand, national/sub-national health management information systems do not currently integrate data from third sector healthcare facilities, as an important service provider for undocumented migrants. As a result, specific vulnerabilities and inequalities affecting undocumented migrants tend to remain invisible to health systems, limiting their capacity to address them and hence limiting universal health coverage and health system equity [11], [48]–[51].

Purpose and objectives

The purpose of this research is to contribute to expanding current evidence, knowledge and understanding about undocumented migrants. The specific objectives are to:

1. Estimate health outcomes and healthcare access among undocumented migrants, in absolute terms and in comparison with the general population, particularly on key issues in maternal & perinatal health and the COVID-19 pandemic.
2. Identify opportunities to strengthen monitoring and evaluation of health among undocumented migrants, with disaggregated data indicators from health management information systems integrating third sector healthcare providers for routine data plus multi-centric *ad hoc* surveys for specific data.

Methods

This work is based on three retrospective studies (cohort and cross-sectional) using a combination of diverse and complementary data sources to reflect the complex nature of health outcomes and healthcare access among undocumented migrants. These included national/regional health management information systems, third sector health care provider health information systems, and surveys at selected third sector healthcare provider facilities.

1. The national/regional health management information system in Lombardy Region (Italy) provided data for maternal and perinatal health. The system is based on routine data collection on standardized certificate forms for delivery/childbirth assistance[1] and the associated database on digital platform. Each record contains a unique personal identification code, allowing to trace patient health information through record linkage across multiple databases in the national/regional health management information system, thus providing the full picture of

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1 "Certficato di assistenza al parto" (CeDAP).

healthcare through the National/Regional Health Services. These provide access to healthcare through a registration code, subject to legal residence status. For undocumented migrants, who by definition do not have residence status, they have introduced a parallel system based on temporary registration code[2], granting access to essential and emergency care including maternity. The temporary registration code is issued upon request, valid for six months, and renewable. We used this code to extract data for undocumented migrants.

2. The health information system of a third sector healthcare facility providing healthcare to undocumented migrants in Milan (Italy) provided data for COVID-19 illness. The system is based on routine data collection on patient record forms and the associated database on digital platform. Each record contains a unique personal identification code, allowing to trace patient health information within the healthcare provider system.

3. A multi-centric *ad hoc* survey conducted in four healthcare facilities providing medical care to undocumented migrants in Geneva (Switzerland), Baltimore (USA), Milan (Italy), and Paris (France) generated data for COVID-19 vaccination demand. The survey was conducted through an informal network of research institutes and healthcare providers. An anonymous, structured, and pre-tested questionnaire in 10 languages was developed based on UNICEF and WHO guidance toolkit for COVID-19 vaccination demand [52], [53] and a European Centre for Diseases Control (ECDC) document exploring vaccine hesitancy hesitancy [54]. The survey questionnaire was administered to individual patients upon informed consent at participating healthcare facilities.

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2 "Straniero Temporaneamente Presente" (STP).

Chapter 2: Maternal and perinatal health in undocumented migrants: estimating health outcomes and healthcare access through health management information systems

Abstract

Objectives: To estimate maternal and perinatal health needs among undocumented migrants and test a methodology for systematic monitoring and evaluation.

Methods: This retrospective cohort study analyzed maternity records from a sub-national Health Management Information System. Disaggregated data by undocumented migrant status was extracted based on temporary registration code, issued to undocumented migrants by the National Health Services for access to essential and emergency care including maternity.

Cohort: All undocumented pregnant women and their neonates having accessed maternity care through the National Health Services in Lombardy Region (Italy) based on temporary registration code from 2016 to 2020.

Results: 1595 undocumented migrant women and their neonates were included in the cohort. Demographic and socio-economic characteristics: maternal birthplace was Europe (non-EU) (35.1%), Africa (25.9%), the Americas (15.3%), Oceania (13.29), Asia (8.9%), and Italy (1.57%) (i.e. a women born in Italy but accessing the NHS through temporary registration code); 7.27% women were employed, 45.2% married, and 55.4% had no/low schooling compared to, respectively, 80.1%, 59% and 15.8% for the general population.

Obstetric history: Most undocumented women (17.99%) delivered at age between 26-34 years, 30.16% were unipara, 6.77% had a previous abortion, and previous 14.48% cesarean section. Antenatal care: 57.37% undocumented women had ≥4 antenatal visits, 68.21% had the first one within 12 weeks of gestation, 63.45% had at least two ultrasound tests including one within 12 weeks of gestation, and 6.21% had complete laboratory tests, compared to, respectively, 94.28%, 97.09%, 96.57%, and 74.15% for the general population. Other important diagnostics were very infrequent: ultrasound scan >22 weeks for morphology (4.08%), amniocentesis (1.07%), fetoscopy (1.59%), and Rh factor (4.08%).

Intra-partum care: 43.5% deliveries occurred in a public hospital with neonatal intensive care unit, assisted by a gynecologist (80.5%), obstetrician (78.2%), neonatologist (64%), and anesthesiologist (31.2%); 68.59% deliveries were normal, 04.51% instrumental (forceps/vacuum extraction), and 10.28% emergency cesarean section. Total cesarean sections were 26.89%. Emergency resuscitation

for birth asphyxia was conducted in 2.63% births. Only 49.03% neonates initiated breastfeeding within 2 hours from birth delivery.

Maternal and perinatal outcomes: 80.56% pregnancies were physiological. Severe haemorrhage (>1000ml) occurred in 2.26% women. Intra-uterine growth retardation affected 4.76% foetuses, 9.28% neonates were pre-term, 17.24% small for gestational age, 7.2% had a low weight at birth (<2.5Kg), 1.44% poor Apgar score, and 3.07% presented malformations

Conclusions: Maternal and perinatal health outcomes were poor in undocumented migrants, especially from Africa. Both socio-economic and health outcomes showed vulnerability and inequality in comparison to documented migrants and the general population. Inadequate antenatal care reflected poorly on maternal and perinatal health outcomes. Known risk factors including fragile socio-economic conditions along with legal and linguistic barriers to healthcare need to be addressed through tailored interventions including outreach health promotion focusing on safe motherhood and neonatal care, healthcare provider training, cultural mediation, translation, and functional language learning. Furthermore, a systematic monitoring and evaluation system needs to routinely collect, integrate, and analyze data on key indicators including: maternal migrant status, birthplace, length of stay in country, language fluency, age, hospitalization rate due to obstetric causes, antenatal care (including number of antenatal care visits, timing of first antenatal care visit, number and timing of ultrasound scans, complete laboratory tests), neonatal pre-term rate, low birth weight rate, and low Apgar score.

Introduction

Background and rationale

Undocumented migrants experience poor maternal and perinatal health, as well as inequalities in comparison to the general population. A wealth of literature consistently highlights an underlying combination of increased health needs due to higher exposure and susceptibility to disease and risk factors, along with decreased healthcare coverage due to legal and socio-economic barriers including lack of/limited access to National Health Services, language, and poverty [7]–[14].

The current body of evidence points out to multiple vulnerabilities and inequalities, including: lower number and poorer timeliness of antenatal consultations and diagnostics; higher rates of abortion, obstetric and neonatal complications, emergency caesarean section delivery, stillbirths, neonatal mortality, need for resuscitation, congenital anomalies, pre-term birth, low birth weight, and poor Apgar score [11], [12], [15]–[18], [55]–[59]. Furthermore, additional vulnerabilities and inequalities are identified for infectious disease as an underlying cause of maternal and perinatal morbidity and mortality, including: higher incidence of sexually transmitted infections including HIV/AIDS, as well as Tuberculosis and Malaria; lower immunization coverage rates for vaccine-preventable diseases including Hepatitis B, Measles, Mumps, Rubella, Poliomyelitis, and Tetanus [12], [19]–[25].

However, evidence about maternal and perinatal health among undocumented migrants is currently limited as mostly based upon *ad hoc* surveys at selected health facilities, while there is a lack of systematic monitoring and evaluation through national/sub-national health management information systems. On one hand, national/sub-national health management information systems do not currently disaggregate data by migrant status, thus limiting the identification of specific migrant population cohorts. On the other hand, national/sub-national health management information systems do not currently integrate data from third sector healthcare facilities, as an important service provider for undocumented migrants. As a result, specific vulnerabilities and inequalities affecting undocumented migrants tend to remain invisible to health systems, limiting their capacity to address them and hence limiting universal health coverage and health system equity [11], [48]–[51], [60].

Objectives

The primary objective of this study was to estimate maternal and perinatal health needs among undocumented migrants in Lombardy, as the Region with the single-largest overall and migrant populations as well as volume of deliveries/childbirths in Italy [5], [61]–[63]. The secondary objective was to test a methodology for systematic monitoring and evaluation of maternal and perinatal health among undocumented migrants, with disaggregated data by migrant status and harmonized indicators from national/sub-national health management information systems and third sector healthcare providers.

Methods

This retrospective cohort study analysed maternity records from the regional health management information system in Lombardy Region (Italy). The National/Regional Health Services adopt a health system model based on universal health coverage for promotion, prevention, diagnosis, and therapy services through public or private accredited health facilities. Both types of facilities are funded by the National/Regional Health Services and patients can opt for either of them at equal (subsidized) cost. Access is provided through a registration code, subject to legal residence status. For undocumented migrants, the National/Regional Health Services have introduced a parallel system based on temporary registration code[3], granting access to essential and emergency care including maternity. The temporary registration code is issued upon request, valid six months, and renewable.

Data source

Data was extracted from the regional health management information system in Lombardy, as routinely collected based on standardized certificate forms for delivery/childbirth assistance[4] through the associated database on digital platform. This captures selected variables and indicators for both mother and neonate including: demographic and socio-economic characteristics, delivery/childbirth facility, obstetric history, antenatal care and intrapartum care, overall diagnostics, medical procedures, and drugs prescription/administration, and delivery/childbirth outcomes including disease diagnosis based on the International Classification of Disease (ICD9 version) and fatalities.

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3 "Straniero Temporaneamente Presente" (STP).

4 "Certficato di assistenza al parto" (CeDAP).

Each record contains a unique personal identification code, allowing to trace patient health information through record linkage across multiple databases in the national/regional health management information system. Patient privacy is ensured through conversion of personal identification codes into anonymous codes and deletion of conversion tables to prevent trace-back procedures. Records were accessed on digital platform based on security credentials granted by the regional health authority.

Cohort

The cohort included all undocumented pregnant women and their neonates having accessed maternity care through the National/Regional Health Services in public or private accredited facilities in Lombardy Region (Italy) from 2016 through 2020 as recorded in the regional health management information system. The cohort was identified based on access to the National/Regional Health Services through temporary registration code, as a proxy for undocumented migrant status. All undocumented pregnant women and their neonates meeting the criteria were included in the study without any selection, sampling, or exclusion.

Two additional cohorts i.e., documented migrant and non-migrant women and their neonates with low-risk and non-complicated pregnancy[5], who had been registered in the National/Regional Health Services for >2years, and accessed maternity care through public or private accredited facilities in Lombardy Region (Italy) from 2015 through 2017 were identified based on citizenship, residence, and National/Regional Health Services standard registration and included with regard to some variables and indicators[64].

Table 2: Cohort stratification, by migrant status

Migrant status	Criteria
Undocumented migrant	Women without Italian citizenship and residence, but with NHS temporary registration
Documented migrant	Women without Italian citizenship, but with Italian residence and NHS standard registration
Non-migrant	Women with Italian citizenship, residence, and NHS standard registration

Statistical analysis

Descriptive analysis were applied to calculate absolute and percentage frequencies thus estimating the distribution of variables and indicators of interest for: demographic and socio-economic

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5 Defined as lack of fetal death and stillbirth, congenital malformation, fetal growth restriction, pregnancy complication, malignancy, radiotherapy, prescription of selected drugs, assisted reproductive technology, multiple pregnancy, gestational age <37 weeks or >42 weeks in previous/current pregnancy.

characteristics, delivery/childbirth facility, obstetric history, antenatal care and intrapartum care, diagnostics medical procedures, drugs prescription/administration, and delivery/childbirth outcomes focusing on severe maternal morbidity and neonatal outcomes. All variables and indicators were consistently analysed by maternal birthplace of undocumented migrants to identify potential associations. Additionally, some variables and indicators of interest were compared across population cohorts (undocumented migrants, documented migrants, non-migrants) to identify potential inequalities, and p-values for the chi-square or Fisher's exact test were reported based on 2-sided tests with $p < 0.05$ considered to be statistically significant.

Missing data was frequent and affected several variables and indicators of interest. However, no statistical procedure was applied to generate appropriate values for missing data, as this would have concerned a substantial proportion of data. This is reflected in study limitations.

A benchmark approach was used for accurate analysis of adherence to recommendations for laboratory tests in pregnancy, as a composite service package. Hence degrees of adherence were defined and analysed, both independently and combined.

Table 3: Laboratory tests in pregnancy, adherence benchmarks

Component	Definition	Scoring	
1. Tests recommended in each trimester	Full blood count and differential leucocyte count plus microscopy; full urine test	1	All tests recommended in each trimester are done
		0	All tests recommended in each semester are not done
2. Tests recommended in first trimester	Blood glucose, Rubella Virus antibodies, Toxoplasmosis antibodies	1	All tests recommended in first trimester are done
		0	All tests recommended in first semester are not done
3. Test recommended in first trimester	Hepatitis B Virus antigens and antibodies	1	Test recommended in first trimester is done
		0	Test recommended in first semester is not done

Overall results were presented in anonymous format, either aggregated or disaggregated by region of maternal birthplace, and interpreted based on state-of-the-art literature and evidence for maternal and perinatal health among undocumented migrants, including statistics and guidelines by the Italian Ministry of Health and the World Health Organization.

Limitations

This study explored maternal and perinatal health among undocumented migrants in Lombardy Region (Italy). To our knowledge, it was the first study generating region-wide evidence disaggregated by undocumented migrant status through routine health data flows. Hence, it made

available new information and approaches to possibly expand health coverage and improve health system equity. However, this study presents a number of limitations.

First, the total number of available records was relatively small (N=1595), hence the study was not powered to estimate the frequency of relatively rare events such as severe maternal and perinatal morbidity nor maternal and perinatal mortality. As a result, these key indicators could not be calculated. However, if systematic monitoring and evaluation improves over time, the availability of records may increase and allow to calculate these indicators too.

Second, available records were flawed with frequent missing data affecting several variables and indicators (for instance age and parity), due to either systematic or random lack of data collection, thus resulting in a significant share of incomplete records. As a result, several variables and indicators of interest could not be calculated. Nonetheless, this limitation is informative of current data challenges regarding undocumented migrants, in terms of completeness and quality.

Third, comparison across population cohorts by migrant status was only partially possible, i.e. for indicators of demographics, socioeconomics and antenatal care (not for intrapartum/perinatal care and outcomes) for the overlap period (2015-2017) and with a significant caveat around exclusion criteria for medium/high-risk pregnancies in non-migrant and documented migrants. Furthermore, potential associations among variables and indicators of interest across respective population cohorts by migration status could were calculated. However, comparison was done based on available routine statistics to identify trends of potential disproportionate vulnerabilities and/or inequalities in healthcare coverage.

Fourth, data was not analysed by year but only across the reference period. As a result, potential variations over time could not be identified, thus limiting result interpretation. This is particularly relevant for the year 2020 due to the COVID-19 pandemic, which is known to have impacted on morbidity and mortality patterns as well as maternity services for everyone including undocumented migrants. As a result, the effect of the COVID-19 pandemic on maternal and perinatal health needs among undocumented migrants is not analysed.

Fifth, maternal birthplace was based on classification by the National Institute of Statistics, whose macro-area classification may mask important differentials in terms of socioeconomics and health. In particular, the Africa region is not disaggregated in Sub-Saharan Africa and North Africa, and the Middle East is combined with Asia. Hence, data analysis and results interpretation were not

insufficiently granular to understand potential determinants of maternal and perinatal health, along with potential drivers and barriers of healthcare demand and access.

Despite these limitations, the study design may be helpful as a pilot. First, to estimate area-wide needs for maternal and perinatal health among undocumented migrants, thus facilitating their visibility and trigger response by health authorities. Second, to test a methodology for systematic monitoring and evaluation, with disaggregated data and harmonized indicators from both National Health Services and third sector healthcare providers. Going forward, this may contribute towards strengthening universal health coverage and health system equity.

Results

Demographic and socio-economic characteristics

The study included 1595 (1.25%) undocumented migrants, 28498 (22.25) documented migrants, and 97780 (76.5%) non-migrants. Maternal birthplace (country) was analysed based on classification by the National Institute of Statistics. For undocumented migrants, Europe (non-EU) was the largest group (35.1%), followed by Africa (25.9%), the Americas (15.3%), Oceania[6] (13.29), Asia (8.9%), and Italy (1.5%). The latter case of undocumented migrants born in Italy but accessing the National/Regional Health Services through temporary registration code (1.57%) may indicate a person born in Italy by foreign parents without residence.

Table 4: Demographic characteristics (N=128073)

	Undocumented migrants 1595 (1.25%)	Documented migrants 28498 (22.25%)	Non-migrant 97780 (76.5%)
Citizenship			
Italian	n/a	n/a	97780 (100)
Non-Italian	1575 (100)	28498 (100)	n/a
Maternal birthplace			
Italy	25 (1.57)	0 (0.0)	n/a
Europe (non-EU)	559 (35.05)	9449 (77.47)	n/a
Africa	413 (25.89)	7959 (6.29)	n/a
America	244 (15.30	3215 (2.54)	n/a
Asia	142 (8.90)	6197 (4.9)	n/a
Oceania	212 (13.29)	1678 (1.33)	n/a

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[6] The Region Oceania also includes the data for those (few) maternal birthplaces that were reported in records but could not be allocated to any Region based on current classification.

Only 7.27% undocumented were employed, compared to 65.3% documented migrants reflecting legal entitlement to employment as well as regularization over time, and 80.79% non-migrants. Employment rate was lowest among undocumented migrants from Africa (4.36%) and Europe (non-EU) (4.83%).

45.2% undocumented migrants were married, compared to 74.62% documented migrants reflecting family reunions and possibly integration over time, and 58.96% non-migrants. Marriage rate was lowest among undocumented migrants from the Americas (21.72%) and Oceania (24.08%).

55.4% undocumented migrants had no or low schooling, compared to 41.85% documented migrants reflecting their relatively lower deprivation, and 15.76% non-migrants. Lack of schooling was highest among undocumented migrants from Africa (64.16%) and Europe (non-EU) (58.32%). Only 12.04% undocumented migrants had high/higher education, compared to 17.46% documented migrants, and 39.56% non-migrants. High/highest education was least frequent among undocumented migrants from Africa (7.99%) and most frequent among undocumented migrants from Asia (30.99%).

Overall, socioeconomic indicators showed a mixed picture with 20% employment rate, 32% marriage rate, and 56% no/low schooling, as compared to the average for undocumented migrants, respectively (7.27%), (45.2%), and (55.36%).

Table 5: Socioeconomic characteristics (N=128073)

	Undocumented migrants							Documented migrants	Non-migrants	Chi-square p-value
	All 1595 (1.25%)	Europe (non-EU) 559 (35.05%)	Africa 413 (25.89%)	Americas 244 (15.3%)	Oceania 212 (13.29%)	Asia 142 (8.9%)	Italy 75 (0.05%)	28498 (22.25%)	97780 (76.5%)	
Employment										
Employed	116 (7.27)	27 (4.83)	18 (4.36)	25 (10.25)	24 (11.32)	17 (11.97)	5 (20.00)	18636 (65.39)	79160 (80.79)	
Not emploedr	1476 (92.54)	531 (94.99)	394 (95.40)	219 (89.75)	187 (88.21)	125 (88.03)	20 (80.00)	17746 (62.27)	18740 (19.13)	<0.0001
Missing	*3 (0.19)*	*1 (0.18)*	*1 (0.24)*	*0*	*1 (0.47)*	*0*	*0*	*106 (0.37)*	*80 (0.08)*	
Marital status										
Married	721 (45.20)	288 (51.52)	237 (57.38)	53 (21.72)	51 (24.08)	84 (59.15)	8 (32,00)	21264 (74.62)	57771 (58.96)	
Other	852 (53.42)	284 (47.23)	166 (40.19)	189 (77,46)	161 (75.94)	56 (39.44)	16 (64.00)	7216 (25.32)	40185 (41.01)	<0.0001
Missing	*22 (1.38)*	*7 (1.25)*	*10 (2.42)*	*2 (0.82)*	*0*	*2 (1.41)*	*1 (4.00)*	*11 (0.06)*	*24 (0.02)*	
Education level										
No/low	883 (55.36)	326 (58.32)	265 (64.16)	109 (44.67)	112 (52.83)	57 (40,14)	14 (56.00)	11926 (41.85)	15438 (15.76)	<0.0001
Intermediate	519 (32.54)	164 (29.34)	114 (27.60)	111 (45.49)	79 (37.26)	41 (28.87)	10 (40.00)	11575 (40.62)	43737 (44.64)	
High/higher	192 (12.04)	69 (12.34)	33 (7.99)	24 (9.84)	21 (9.91)	44 (30.99)	1 (4.00)	4975 (17.46)	38764 (39.56)	
Missing	*1 (0.06)*	*0*	*1 (0.24)*	*0*	*0*	*0*	*0*	*18 (0.06)*	*41 (0.04)*	

Obstetric history

Maternal age at delivery was mostly not recorded for undocumented migrants from all regions (62.32%). However, based on available records, most deliveries (17.99%) occurred in the 26-34 years of age cohort, compared to documented migrants (54.81%) and non-migrants (55.08%). Deliveries ≤ 25 years and ≥ 35 years (typically associated with higher risk maternal and perinatal risk) were 14.17% and 5.2%, and highest among undocumented migrants born in Italy but without residence (36%) and Asia (10.56%). The ≤ 25 years cohort was not further disaggregated to capture adolescent pregnancy as a major risk factor. On the other hand, records for documented migrants and non-migrants were fully available: most deliveries occurred in the 26-34 years of age cohort (57.69%; 55.08%) while deliveries ≤ 25 years and ≥ 35 years were, respectively 18.05% and 24.25%, and 7.71% and 37.21%. Furthermore, routine statistics provide adolescent pregnancy rates at, respectively, 0.01% and 0% in the 12-14 years of age class from Europe/non-EU and 0.9% and 0.91% in the in the 15-19 years of age class, highest from the Americas and Europe/non-EU (1.75%; 1.46%) [63].

Parity was also largely not recorded for undocumented migrants (43.89%). However, based on available records, most of them (30.16%) were unipara while 8.46% were nullipara and 17.4% multipara. Women from Oceania were most frequently unipara (35.85%) and those from Europe (non-EU) were most frequently multipara (34%). Among multipara, most had 2 deliveries (57. 471%, mostly from Asia) while 23.3% and 7.53% had 3 and 4 deliveries (mostly from the Americas and Oceania), and 11.5% were grandipara (i ≥ 5 deliveries, mostly women born in Italy but without residence. Records for documented migrants and non-migrants also had large proportions of missing data, respectively 22.42% and 36.77%. However, based on available records, most of them were multipara (67.84%; 48.32%) versus nullipara (9.74%; 14.91%).

Abortion was reported without disaggregation between spontaneous abortion versus induced abortion, nor by age class. However, based on available data, 6.77% undocumented migrants reportedly had an abortion. It was most frequent among women born in Italy but without residence (12%) and from Africa (9.44%). On the other hand, routine statistics for documented migrants and non-migrants, are available with disaggregation by type of abortion and show that spontaneous abortion is estimated at 0.27% without significant variation between documented migrants and non-migrants, while induced abortion is estimated at 20.2% among documented migrants (mostly

between 25-34 years of age) and in 13.5% of non-migrants (mostly after 35 years of age) [61], [63], [65].

Previous caesarean section delivery was reported without disaggregation between scheduled versus emergency procedure, nor by age class. However, based on available data, 14.48% undocumented migrants had a previous caesarean section delivery. It was most frequent among women born in Italy but without residence (20%) and those from Asia (19.7%). Routine statistics for documented migrants and non-migrants show that caesarean section delivery is conducted in 24,4% documented migrants and 23,4% non-migrants. Furthermore, statistics are available with disaggregation by age class and show that is highest in the 30-39 years of age cohort for both documented migrants (63.4%) and non-migrants (56.1%)[63].

Consanguinity between mother and father was reported with disaggregation of degree, yet missing data affected 5.45% of records. Overall, 89.10% of undocumented migrants reportedly presented no degree of consanguinity. The highest prevalence was observed in women from Africa, who also had a high rate of missing records (7.99%), though this was highest among women born in Italy but without residence (12%).

Table 6: Obstetric history (N=128073)

	Undocumented migrants							Documented migrants	Non-migrants	Chi-square p-value
	All	Europe (non-EU)	Africa	Americas	Oceania	Asia	Italy			
	1595 (1.25%)	559 (35.05%)	413 (25.89%)	244 (15.3%)	212 (13.29%)	142 (8.90%)	75 (0.05%)	28498 (22.25%)	97780 (76.50%)	
Maternal age at delivery										
≤ 25	226 (14.17)	89 (15.92)	46 (11.14)	36 (14.75)	37 (17.45)	9 (6.34)	9 (36.00)	5145 (18.05)	7752 (7.71)	
26-34	287 (17.99)	81 (14.49)	67 (16.22)	59 (24.18)	49 (23.11)	27 (19.01)	4 (16.00)	16441 (57.69)	53971 (55.08)	<0.0001
≥ 35	88 (5.52)	18 (3.22)	22 (5.33)	24 (9.84)	8 (3.77)	15 (10.56)	1 (4.00)	6912 (24.25)	36457 (37.21)	
Missing	*994 (62.32)*	*371 (66.37)*	*278 (67.31)*	*125 (51.23)*	*118 (55.66)*	*91 (64.08)*	*11 (44.00)*	*0 (0.0)*	*0 (0.0)*	
Parity										
Nulliparous	135 (8.46)	36 (6.44)	55 (13.32)	20 (8,20)	10 (4,72)	12 (8,45)	2 (8,00)	2476 (8.69)	14606 (14.94)	
Unipara	481 (30.16)	159 (28.44)	117 (28.33)	81 (33.20)	76 (35.85)	42 (29.58)	6 (24.00)			<0.0001
Multiparous	279 (17.49)	92 (16.46)	92 (22.28)	55 (22.54)	39 (18,40)	26 (18.31)	5 (20,00)	20177 (70.80)	47347 (48.42)	
Missing	*700 (43.89)*	*272 (48,66)*	*179 (43,34)*	*88 (36,07)*	*87 (41,04)*	*62 (43,66)*	*12 (48,00)*	*5845 (20.51)*	*36027 (36.77)*	

Table 7: Obstetric history (N=1595)

	Undocumented migrants						
	All	Europe (non-EU)	Africa	Americas	Oceania	Asia	Italy
	1595 (1.25%)	559 (35.05%)	413 (25.89%)	244 (15.30%)	212 (13.29%)	142 (8.90%)	75 (0.05%)
Previous abortion							
Spontaneous / induced	108 (6.77)	26 (4.65)	39 (9.44)	16 (6.56)	12 (5.66)	12 (8.45)	3 (12)
Previous cesarean delivery							
Scheduled / emergency	231 (14.48)	49 (8.77)	64 (15.5)	54 (22.13)	31 (14.62)	28 (19.70)	5 (20)
Consanguineity							
4th degree	13 (0.82)	4 (0.72)	6 (1.45)	0 (0.0)	1 (0.47)	2 (1.41)	0 (0.00)
5th degree	2 (0.13)	0 (0.0)	2 (0.48)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
6th degree	7 (0.44)	1 (0.18)	4 (0.97)	0 (0.0)	2 (0.94)	0 (0.0)	0 (0.0)
None	1486(93.17)	520 (93.02)	368 (89.10)	240 (98.36)	204 (96.23)	133 (93.66)	21 (84)
Missing	*87 (5.45)*	*34 (6.08)*	*33 (7.99)*	*4 (1.64)*	*5 (2.36)*	*7 (4.93)*	*4 (16.00)*

Antenatal care

Adequate antenatal care was analysed based on content and timing of key components: at least four antenatal visits including one within 12 weeks of gestation; at least two ultrasound tests including one within 12 weeks of gestation; complete laboratory tests[7]; and other selected diagnostic tests in pregnancy.

Only 57.37% undocumented migrants had at least four antenatal visits. Women from the Americas and Africa reportedly had, respectively, the highest (67.62%) and lowest (45.76%) rates. Differences with other migration cohorts were major as 91.94% undocumented migrants and 94.28% non-migrants had at least four antenatal visits.

Only 68.21% undocumented migrants had their first antenatal visit within 12 weeks of gestation. Women from the Americas and Oceania had the highest (37.41%) and lowest (01.65%) rates. Differences with other migration cohorts were major as 88.66% undocumented migrants and 97.09% non-migrants had their first antenatal visit within 12 weeks of gestation.

Only 63.45% undocumented migrants had at least two ultrasound tests including one within 12 weeks of gestation. Women from the Americas and Oceania had the highest (36.85%) and lowest (01.80%) rates. Differences with other migration cohorts were major as 87.57% undocumented migrants and 96.57% non-migrants had their first antenatal visit within 12 weeks of gestation.

As low as 06.21% undocumented migrants had complete laboratory tests. Women from Europe (non-EU) and women born in Italy but without residence reportedly had, respectively, the highest (31.31%) and lowest (01.01%) rates. Women who had no laboratory tests at all were 49.84%, while 43.95% had at least partial laboratory tests. Differences with other migration cohorts were stark as 62.71% undocumented migrants and 74.15% non-migrants had complete laboratory tests.

A very small fraction of undocumented migrants underwent other important diagnostic tests in pregnancy such as ultrasound scan >22 weeks for morphology (4.08%), amniocentesis (1.07%), fetoscopy (1.59%), and Rh factor (4.08%). Regional variations were mixed, but such low rates overall are not likely to yield meaningful analysis. However, for ultrasound scan >22 weeks, women from Africa and Oceania had, respectively, the highest (4.84%) and lowest (0.94%) coverage. For amniocentesis, women from the Americas had the highest coverage (2.87%) while women born in

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[7] Include full blood count and microscopy, full urine test, glucose test, antibodies for Rubella Virus, Toxoplasmosis, and Hepatitis B Virus.

Italy but without residence had no coverage (0.00%). For fetoscopy, women from Africa had the highest (2.05%) coverage while women from Asia and those born in Italy but without residence had no coverage at all (0.00). For Rh factor, women from Europe (non-EU) and Oceania had the highest (5.72%) and lowest (0.94%) coverage.

Table 8: Antenatal care (N=1595)

	Undocumented migrants							Documented migrants	Non-migrants	Chi-square p-value
	All 1595 (1.25%)	Europe (non-EU) 559 (35.05%)	Africa 413 (25.89%)	Americas 244 (15.3%)	Oceania 212 (13.29%)	Asia 142 (8.90%)	Italy 75 (0.05%)	28498 (22.25%)	97780 (76.50%)	
Number of antenatal care visits										
≥4 ANC visits	580 (42.63)	248 (44.36)	224 (54.24)	79 (32.38)	73 (34.43)	47 (33.10)	9 (36.00)	2297 (8.06)	5286 (5.39)	<0.0001
≥4 ANC visits	915 (57.37)	311 (55.64)	189 (45.76)	165 (67.62)	139 (65.57)	95 (66.90)	16 (64.00)	26201 (91.94)	92694 (94.28)	
Timing of first antenatal care visit										
≥12 weeks	507 (31.79)	190 (37.48)	34 (06.71)	152 (29.98)	7 (01.39)	57 (11.24)	67 (13.21)	3232 (11.34)	2850 (5.3)	<0.0001
≤12 weeks	1088 (68.21)	223 (20.59)	108 (09.93)	407 (37.41)	18 (01.65)	155 (14.24)	177 (16.27)	25266 (88.66)	95130 (97.09)	
Number and timing of ultrasound scans										
≥2 ultrasounds incl. one ≤12 weeks	1012 (63.45)	195 (19.27)	105 (10.38)	373 (36.85)	17 (01.80)	149 (14.72)	173 (17.09)	24957 (87.57)	94621 (96.57)	<0.0001
Laboratory tests										
Full adherence	99 (06.21)	31 (31.31)	17 (17.17)	24 (24.24)	13 (13.13)	13 (13.13)	1 (1.01)	17871 (62.71)	72651 (74.15)	
Partial adherence	701 (43.95)	232 (41.50)	166 (40.19)	121 (49.59)	91 (42.92)	80 (56.34)	11 (44.00)	9205 (32.30)	23261 (23.74)	<0.0001
No adherence	795 (49.84)	296 (52.95)	230 (55.69)	99 (40.57)	108 (50.94)	49 (34.51)	13 (52.00)	1422 (4.99)	2068 (2.11)	

Table 9 Laboratory tests in pregnancy, adherence to benchmarks (N=1595)

Tests recommended in each trimester	Tests recommended in first trimester	Test recommended in first trimester	Frequency	Cumulative frequency
0	0	0	795 (49.84)	795 (49.84)
0	0	1	605 (37.93)	1400 (87.77)
0	1	0	34 (2.13)	1434 (89.91)
0	1	1	15 (0.94)	1449 (90.85)
1	0	0	1 (0.06)	1450 (90.91)
1	0	1	2 (0.13)	1452 (91.03)
1	1	0	44 (2.76)	1496 (93.79)
1	1	1	99 (6.21)	1595 (100)

Table 10: Other diagnostic tests (N=1595)

	Undocumented migrants						
	All 1595 (1.25%)	Europe (non-EU) 559 (35.05%)	Africa 413 (25.89%)	Americas 244 (15.30%)	Oceania 212 (13.29%)	Asia 142 (8.90%)	Italy 75 (0.05%)
Ultrasound >22 weeks	65 (4.08)	32 (5.72)	20 (4.84)	4 (1.64)	2 (0.94)	6 (4.23)	1 (4.00)
Amniocententesis	17 (1.07)	6 (1.07)	1 (0.24)	7 (2.87)	2 (0.94)	1 (0.70)	0 (0.00
Fetoscopy	10 (1.59)	2 (0.94)	1 (0.24)	5 (2.05)	2	0 (0.00	0 (0.00
Rh factor	65 (4,08)	32 (5.72)	20 (4.84)	4 (1.64)	2 (0.94)	6 (4.23)	1 (4.00)

Intrapartum and perinatal care

Deliveries were analysed by type of healthcare service provider, whether public or private accredited. Most undocumented migrants delivered in public facilities (89.85%) versus private accredited facilities (10.15%). Delivery volumes varied across facilities, ranging from 0.13% in a public hospital in a medium-size town to 11.85% at the University Hospital in the regional chief lieu. Additionally, 2 other facilities accounted for a relatively high volume of deliveries (5.39%; 7.4%), both were public hospitals.

Deliveries were analysed by level of healthcare facility, whether including a neonatal intensive care unit. 43.51% deliveries occurred in a facility with neonatal intensive care unit. Women from Europe (non-EU) accounted for most deliveries in a facility with neonatal intensive care (39.18%), compared to women born in Italy but without residence (1.33%).

Figure 1: Delivery, public vs. private accredited provider
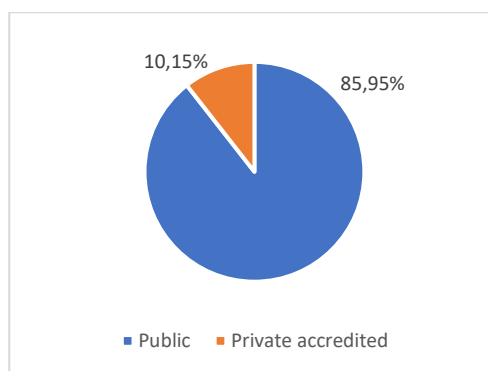
Figure 2: Delivery, facilities with neonatal intensive care unit
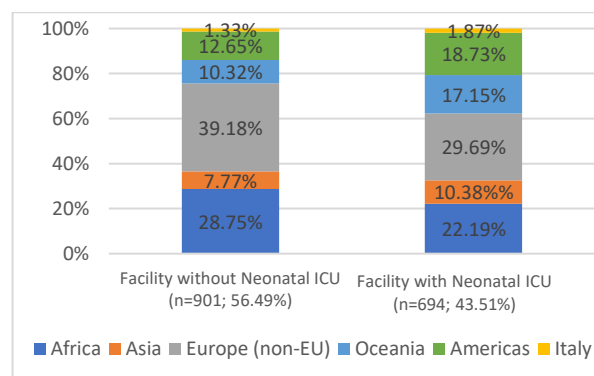
Table 11: Deliveries in facilities with neonatal intensive care units (N=1595)

|	Undocumented migrants						
	All 1595 (1.25%)	Europe (non-EU) 559 (35.05%)	Africa 413 (25.89%)	Americas 244 (15.30%)	Oceania 212 (13.29%)	Asia 142 (8.90%)	Italy 75 (0.05%)
Without neonatal ICU	901 (56.49)	353 (29.18)	259 (28.75)	114 (12.65)	93 (10.32)	70 (7.77)	12 (1.33)
With neonatal ICU	694 (43.51)	206 (29.68)	154 (22.19)	130 (18.73)	119 (17.15)	72 (10.38)	13 (1.87)

Skilled birth assistance was mostly provided by multidisciplinary teams with specialist cadres: gynaecologist (80.50%), obstetrician (77.62%), neonatologist (64.01%), anaesthesiologist (64.01%). The high prevalence of deliveries/childbirth assisted by a neonatologist is suggestive of higher needs compared to the general population, as this cadre is not typically deployed unless in case of need. Variations across maternal birthplace were not marked. However, deliveries of women from Africa were most frequently attended by all cadres, possibly due to higher need. On the other hand,

deliveries by women born in Italy but without residency were less frequently assisted by all cadres but more frequently assisted by an obstetrician. Furthermore, deliveries by women from the Americas were more frequently assisted by an anaesthesiologist, possibly consistent with their higher prevalence of epidural injection.

Companion presence was frequent (62.19%), mostly the baby's father (48.15%), especially for women from Oceania (57.08%). However, 34.98% women delivered alone, especially women from Africa (49.88%).

Normal delivery was predominant (68.59%). Instrumental delivery (forceps/vacuum extraction) were infrequent (04.51%). Caesarean section delivery was 26.89% of all deliveries in undocumented migrants: emergency (10.28%), scheduled (13.86%), elective (2.76%). Cesarean section delivery was most frequent in women from Africa, both overall (30.96%) and emergency (14.53%). For documented migrants and non-migrants, routine statistics show that caesarean section delivery is conducted in 24,4% documented migrants and 23,4% non-migrants. (56.1%)[63]. Episiotomy was conducted in 16.74% deliveries/childbirths, more frequently in women from Africa (21.07%).

Emergency neonatal care with resuscitation for birth asphyxia was conducted in 2.63% births. Despite the small number of records available, this appears to be relatively small as neonatal resuscitation is typically needed in approximately 10% of neonates [66]. In particular, no resuscitation was recorded for neonates of women born in Italy but without residence, while resuscitation was more frequent in neonates of women born in Africa (04.12%).

Pain relief was administered in 10.41% deliveries, without large variations across region of maternal birthplace. Epidural anaesthesia was administered in 13.98% deliveries, was more frequent in women from the Americas (18.03), while was *nihil* in women from Oceania. Oxytocic drugs were administered in 21.25% induced deliveries.

Early breastfeeding initiation and bonding was limited, as only 49.03% neonates initiated breastfeeding with rooming-in within 2 hours from birth delivery. This essential neonatal care intervention was least frequent in mother and baby dyads from Africa (36.32%) while relatively more frequent in those from the Americas and Oceania.

Table 12: Intra-partum and perinatal care (N=1595)

	Undocumented migrants						Italy
	All 1595 (1.25%)	Europe (non-EU) 559 (35.05%)	Africa 413 (25.89%)	Americas 244 (15.30%)	Oceania 212 (13.29%)	Asia 142 (8.90%)	75 (0.05%)
Skilled Birth Assistance							
Gynaecologist	1284 (80.50)	450 (80.50)	355 (85.96)	186 (76.23)	158 (74.53)	116 (81.69)	19 (76.00)
Obstetrician	1238 (77.62)	428 (76.57)	328 (79.42)	194 (79.51)	162 (76.42)	114 (80.28)	22 (88.00)
Neonatologist	1021(64.01)	337 (60.29)	287 (69.9)	157 (64.34)	129 (60.85)	97 (68.31)	(14 56.00)
Anaesthesiologist	498 (31.22)	120 (21.47)	158 (38.26)	102 (41.80)	55 (25.94)	55 (38.73)	8 (32.00)
Companion							
Father	768 (48.15)	293 (52.42)	146 (35.35)	121 (49.59)	121 (57.08)	75 (52.82)	12 (48.00)
Other relative	175 (10.97)	87 (15.56)	29 (07.02)	28 (11.48)	20 (09.43)	9 (06.34)	2 (08.00)
Non-relative	49 (03.07)	17 (03.04)	25 (06.05)	1 (0.41)	0 (0.00)	5 (03.52)	1 (04.00)
Nobody	558 (34.98)	153 (27.37)	206 (49.88)	76 (31.15)	63 (29.72)	51 (35.92)	9 (36.00)
Missing	*45 (02.82)*	*9 (01.61)*	*7 (01.69)*	*18 (7.38)*	*8 (3.77)*	*2 (01.41)*	*1 (04.00)*
Type of delivery							
Normal	1094 (68.59)	433 (77.46)	252 (61.02)	151 (61.89)	153 (72.17)	86 (60.56)	19 (76.00)
Instrumental (forceps/vacuum)	72 (04.51)	29 (05.19)	22 (05.33)	6 (02.46)	9 (04.25)	6 (04.23)	0 (0.00)
Cesarean	449 (26.89)	97 (21.60)	139 (30.96)	87 (19.38)	43 (09.58)	50 (11.14)	6 (01.34)
Emergency	164 (10.28)	35 (06.26)	60 (14.53)	34 (13.93)	9 (04.25)	17 (11.97)	2 (08.00)
Scheduled	221 (13.86)	52 (09.03)	64 (15.50)	47 (19.26)	26 (12.26)	28 (19.72)	4 (16.00)
Elective	44 (02.76)	10 (01.79)	15 (03.63)	6 (02.46)	8 (03.77)	5 (03.52)	0 (0.00)
Episiotomy	267 (16.74)	94 (16.82)	87 (21.07)	27 (11.07)	30 (14.15)	87 (21.07)	4 (16.00)
Missing	*123 (07.71)*	*36 (06.44)*	*40 (09.69)*	*24 (09.84)*	*12 (05.66)*	*8 (05.63)*	*3 (12.00)*
Neonatal resuscitation	42 (2.63)	13 (2.33)	17 (4.12)	5 (02.05)	3 (01.42)	4 (2.82)	0 (0.00)
Pharmaceuticals							
Pain relief	166 (10.41)	54 (09.66)	47 (11.38)	31 (12.70)	18 (08.49)	13 (09.15)	3 (10.00)
Epidural anesthetic	223 (13.98)	70 (12.52)	54 (13.08)	44 (18.03)	29 (13.68)	0 (00.00)	3 (12.00)
Oxytocics, induction	339 (21.25)	89 (15.92)	41 (28.87)	54 (22.13)	58 (27.36)	41 (28.87)	4 (16.00)
Perinatal care							
Breastifeeding & bonding <2 h	782 (49.03)	296 (52.95)?	150 (36.32)	138 (56.56)	119 (56.13)	69 (48.59)	10 (40.00)
Missing	*53 (03.32)*	*18 (03.22)*	*14 (03.39)*	*9 (03.69)*	*7 (03.30)*	*4 (02.82)*	*1 (04.00)*

Maternal and perinatal outcomes

Physiological pregnancies were 80.56% versus pathological pregnancies 16.64%, more frequent in women from Africa (22.28%). Available statistics for documented migrants and non-migrants indicate a higher caseload of pathological pregnancies (35.49%)[8]. Single deliveries were virtually universal (99.06%) versus multiple deliveries (0.72%). Foetal presentation was mostly vertex (95.42%) versus abnormal (04.58%).

Most undocumented migrant women had moderate post-partum haemorrhage (500-1000ml) (93.42%) and 2.26% had severe post-partum haemorrhage (>1000ml), compared 3.00% in[64] documented migrants and non-migrants. Perineal tears of 3rd and 4th degree in occurred 0.82% deliveries/childbirths and were nihil in women from the Americas and Oceania as well as women born in Italy but without residence. However, 12.83% records were missing. Documented migrants and non-migrants present 0.4% perineal tears of 3rd and 4th degree[64].

Intrauterine growth restriction affected 4.76% foetuses and was higher in neonates of women born in Italy but without residence (8%). Pre-term deliveries occurred in 9.28% cases, including: extremely pre-term (<28 weeks) (8%) and very pre-term (28-32 weeks) (0.5%). Only 8.09% deliveries were recorded as at term (32-37 weeks) versus late term (90.72%). 17.24% neonates were small for gestational age, especially in mothers born in Italy but without residence (28%). 7.15% neonates had a low weight at birth (<2.5Kg), especially those whose mother was from Oceania (10.38%) versus 1.4% neonates of documented migrants and non-migrants. Based on Apgar score at 5 minutes, 98.56% neonates were good, while 0.56% and 0.88% were severely or moderately depressed, versus overall 0.3% poor Apgar score at 5 minutes in neonates borne to documented migrants and non-migrants[64].

Severe birth asphyxia occurred in 2.63% neonates, who required advanced emergency resuscitation. Resuscitation was more frequent in neonates of women born in Africa (4.12%), while no resuscitation was recorded for neonates of women born in Italy but without residence. However, only a small number of records was available, hence it is challenging to interpret results. Malformations were diagnosed in 03.07% neonates, in line with national estimates. Malformation occurred in 03.07% neonates.

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[8] Lombardy Regional Health Information System, delivery/childbirth assistance records, 2015-2017

Table 13: Maternal and perinatal outcomes (N=1595)

	Undocumented migrants						Italy
	All 1595 (1.25%)	Europe (non-EU) 559 (35.05%)	Africa 413 (25.89%)	Americas 244 (15.30%)	Oceania 212 (13.29%)	Asia 142 (8.90%)	75 (0.05%)
Type of pregnancy							
Physiological	1285 (80.56)	466 (83.36)	321 (77.72)	194 (79.51)	172 (81.13)	108 (76.06)	20 (80.00)
Pathological	310 (19.44)	93 (16.64)	92 (22.28)	50 (20.49)	40 (18.87)	34 (23.94)	5 (20.00)
Type of delivery							
Single	1580 (99.06)	555 (99.28)	409 (99.03)	241 (98.77)	208 (98.11)	142 (100)	25 (100)
Multiple	15 (00.04)	4 (0.72)	4 (0.97)	3 (1.23)	4 (1.89)	0 (0.00)	0 (0.00)
Intra-uterine foetal growth restriction	76 (04.76)	20 (03.58)	21 (05.08)	10 (04.10)	14 (06.60)	9 (06.34)	2 (08.00)
Pre-term delivery	148 (09.28)	47 (08.41)	44 (10.65)	22 (09.02)	24 (11.32)	9 (06.34)	2 (8.00)
Gestational age at delivery (weeks)							
Extremely preterm (<28 w)	8	1 (01.18)	5 (1.21)	0 (0.00)	2 (0.94)	0 (0.00)	0 (0.00)
Very pre-term (28-32 w)	11 (0.50)	2 (0.36)	4 (0.97)	2 (0.82)	1 (0.47)	2 (1.41)	0 (0.00)
Complete term (32-37 w)	129 (08.09)	44 (7.87)	35 (8.47)	20 (8.20)	21 (9.91)	7 (4.93)	2 (8.00)
Late term (≥37 w)	1447 (90.72)	5112 (91.59)	369 (89.35)	222 (90.98)	188 (88.68)	133 (93.66)	23 (92.00)
Small for gestational age	275 (17.24)	88 (15.74)	62 (15.01)	34 (13.93)	53 (25.00)	31 (21.83)	7 (28.00)
Foetal presentation							
Normal	1522 (95.42)	534 (95.53)	392 (94.92)	230 (94.26)	206 (97.17)	137 (96.48)	23 (92.00)
Abnormal	73 (04.58)	25 (04.47)	21 (05.08)	14 (05.64)	6 (02.83)	5 (03.62)	2 (08.00)
Apgar score at 5minutes							
7–10	1572 (98.56)	554 (98.5)	402 (97.34)	242 (99.18)	208 (98.11)	140 (98.59)	24 (0.96)
4–6	14 (0.88)	1 (0.066)	70 (0.17)	2 (0.82)	3 (1.42)	2 0(1.41)	1 (0.4)
0–3	9 (0.56)	4 (0.25)	4 (0.97)	0 (0.00)	1 (0.48)	0 (0.00)	0 (0.00)
Low birth weight (<2.5Kg)	114 (7.15)	31 (5.55)	35 (8.47)	15 (6.15)	22 (10.38)	10 (7.04)	1 (4.00)
Malformation	49 (03.07)	13 (02.33)	15 (03.63)	10 (04.10)	6 (02.83)	4 (02.82)	1 (04.00)
Maternal illness							
Hemorrage							
Moderate (500-1000ml)	1490 (93.42)	132 (08.86)	370 (24.83)	231 (15.50)	204 (13.69)	132 (08.59)	23 (01.44)
Severe (>1000ml)	36 (02.26)	6 (16.67)	15 (41.67)	5 (13.89)	3 (08.33)	6 (16.67)	0 (0.00)
Missing	*69 (04.33)*	*2 (08.00)*	*28 (06.78)*	*7 (02.87)*	*5 (02.36)*	*4 (02.82)*	*2 (08.00)*
Perineal tears							
3rd/4th degree	13 (0.82)	6 (01.06)	4 (0.48)	0 (0.00)	0 (0.00)	3 (0.06)	0 (0.00)
Missing	*53 (12.83)*	*45 (08.05)*	*14 (03.39)*	*9 (03.69)*	*7 (03.30)*	*4 (02.82)*	*1 (04.00)*
Neonatal illness							
Birth asphyxia	42 (2.63)	13 (2.33)	17 (4.12)	5 (02.05)	3 (01.42)	4 (2.82)	0 (0.00)

Discussion

Demographic, socio-economic and health indicators consistently showed disproportionate vulnerability and inequality in undocumented migrants, in comparison to documented migrants and the general population. in particular, undocumented migrants from the Africa region frequently presented the poorest indicators.

Table 14: Indicators, by migrant status

Indicator	Undocumented migrant	Documented migrant	Non-migrant
Maternal age at delivery, 26-34 years	17.99%	54.81%	55.08%
	(62.32% missing data)		
≥ 4 antenatal care visits	57.37%	91.94%	94.28%
First antenatal care visit in first trimester	68.21%	88.66%	97.09%
≥2 ultrasounds incl. 1 in first trimester	63.45%	87.57%	96.57%
Complete laboratory tests	06.21%	62.71%	74.15%
Pre-term birth rate	09.28%		6.7%
Low birth weight rate	7.15%	1.4%	2.8%
Low Apgar Score	1.44	0.3%	1.4%

Demographics and socioeconomics

Undocumented migrants accounted for only 1.25% of the study cohort as compared to, respectively, 76.5% non-migrants (general population) and 22.25% documented migrants - notwithstanding lack of exclusion criteria (all pregnancies/childbirths including medium/high risk versus only low risk, and any length of N/RHS registration versus only >2 years) and longer reference period (2016-2020 versus 2015-2017). This may be consistent with their actual relatively small cohort size, but also suggestive of incomplete records in the regional health management information system hence need for improved record keeping and data quality.

The distribution of maternal birthplace including all regions in virtually similar proportions represented a mosaic of linguistic and socio-cultural backgrounds, indicating the importance of diversified language interpretation and cultural mediation as part of healthcare provision. This need was further highlighted by the large proportion of undocumented migrants with no or low schooling, as associated with poorer ability to access health information. No/low schooling may also be considered as a proxy for limited language fluency, for which data was not available, thus reinforcing the importance of language interpretation and access to functional language learning. Low employment rate pointed out to poverty including low purchasing power and willingness to

pay for healthcare due to financial and opportunity costs, which may drive undocumented migrants away from accessing healthcare, even in a subsidized health system like Italy.

<u>Obstetric history</u>

Data on maternal age and parity was mostly unavailable for undocumented migrants (62.32%; 43.89%) and age classes were not sufficiently disaggregated to trace adolescent pregnancy as a major risk factor. These data gaps affected results interpretation. On the other hand, these data were systematically available for both documented migrants and non-migrants, hence indicating an important issue for adequate health monitoring and evaluation. Missing data affected records consistently across regions of birth, though less for the Americas (51.23% and 36.07%) suggesting better communication between Spanish-speaker patients and Italian-speaker health personnel, hence further confirming the importance of language interpretation.

Data on abortion for undocumented migrants was not disaggregated by spontaneous abortion (a physiological event mostly associated with age and illness) versus induced abortion (a medical procedure mostly associated with unintended pregnancy), nor by age class. Lack of data disaggregation affected results interpretation. However, even considering both types of abortions combined, their prevalence was low (6.77%) compared to documented migrants and non-migrants which was relatively negligeable for spontaneous abortions (0.27%) but noteworthy for induced abortions (20.2% and 13.5%). As a result, comparatively low prevalence of abortion in undocumented migrants may raise concerns about lack of data recording and/or lack of access to a health facility in case of abortion, including risk of unsafe abortion.

<u>Antenatal care</u>

Antenatal care was clearly inadequate among undocumented migrants. Indicators were consistently poor: below 70% coverage for adequate number and timing of antenatal care visits and ultrasound tests, and only 6% coverage for complete laboratory tests. Women from the Americas had consistently the highest rates across indicators. Women from Oceania and women born in Italy but without residence had the poorest indicators.

Furthermore, indicators were staggeringly poor when compared by migrant status. In particular, non-migrants had virtually optimal coverage for adequate number and timing of antenatal care

visits and ultrasound tests, and 75% coverage for complete laboratory tests. Finally, other important diagnostic tests such as ultrasound scan >22 weeks for morphology, amniocentesis, fetoscopy, and Rh factor were extremely infrequent. This needs to be further assessed as part of drivers and barriers for antenatal care overall.

Intrapartum and perinatal care

Deliveries were analysed by type of healthcare provider and level of facility, whether including a neonatal intensive care unit. 43.51% deliveries occurred in a public facility with neonatal intensive care unit. The public sector accounts for virtually all provision of maternity care among undocumented migrants. In particular, most maternity care is currently concentrated in a few public hospitals including the Teaching Hospital in the regional chief lieu. This has implications for intervention targeting: on one hand, by focusing on those facilities with currently the higher volumes of deliveries, to capitalize on their experience and to achieve higher impact.

Furthermore, drivers and barriers of healthcare access through private accredited facilities need to be better understood as they appear to be currently under-utilized, though financial cost should not be an issue due to public subsidization that allows patient to access healthcare through either public or private healthcare providers at equivalent cost at point-of-access. Caesarean section delivery (all types combined) was somewhat higher (26.89%) in undocumented migrants compared to documented migrants and non-migrants who had virtually the same rate (24.4%; 23.4), possibly reflecting overall higher risks across several indicators.

Maternal and perinatal outcomes

Outcomes were poor across several dimensions including severe haemorrhage intrauterine fetal growth retardation, pre-term birth, small size for gestational age, low birth weight, and Apgar score. Despite a performing health system with robust clinical capacity, these poor outcomes underscored the key importance of preventive and promotion healthcare, especially antenatal care, which appeared clearly sub-optimal.

Systematic monitoring and evaluation

This study estimated needs for maternal and perinatal health among undocumented migrants using routine data from the national/regional health management information system, by tracing

temporary access codes as a proxy for undocumented migrant status, which is not a collected variable per se but can be deducted. This approach may be adopted for systematic monitoring and evaluation with a set of key indicators that may be adopted for systematic use by both National Health Services and third sector healthcare providers. The following suggested list draws on learning from this and previous studies [12], [49], [59], [60], [67], [68].

1. Demographics and socioeconomics: maternal undocumented migrant status, birthplace, length of stay in country, language fluency, and maternal age (disaggregated by age class) as important determinants of clinical characteristics as well as healthcare demand and access.

2. Health outcomes: maternal hospitalization rate due to obstetric causes, antenatal care (including number of antenatal care visits, timing of first antenatal care visit, number and timing of ultrasound scans, complete laboratory tests), neonatal pre-term rate, low birth weight rate, and low Apgar score as associated with higher morbidity and mortality as well as barriers to healthcare. Furthermore, obstetric causes represent the single-most important cause of hospitalization among documented migrant women of childbearing. Their prevalence is currently unavailable for undocumented migrants but may be assumed to similarly important or more, based on this and previous studies.

Going forward, the current monitoring and evaluation system, coordinated by the National Institute for Health Migration and Poverty and operational in 9 of total 21 Regions and Autonomous Provinces in Italy[9], may be further expanded and provide systematic information on both documented and undocumented migrants.

The table gives an overview of current inclusion of suggested key indicators in national/regional health management information.

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[9] Piemonte, Trento, Bolzano, Emilia-Romagna, Toscana, Umbria, Lazio, Basilicata, Sicilia.

Table 15: Key indicators of maternal and perinatal health among undocumented migrants

Indicator	Included in HMIS
1. Demographics and socioeconomics	
1.1 Maternal migrant status*	✓
1.2 Maternal birthplace	✓
1.3 Maternal length of stay in country	X
1.4 Maternal language fluency	X
1.5 Maternal age	✓
2. Health	
2.1 Maternal hospitalization rate due to obstetric causes	✓
2.2 Antenatal care	✓
2.2 a. Number of antenatal care visits	✓
2.2 b. Timing of first antenatal care visit	✓
2.2.c. Number and timing of ultrasound scans	✓
2.2.d. Complete laboratory tests	✓
2.3 Pre-term birth rate	✓
2.4 Low birth weight rate	✓
2.5 Low Apgar Score	✓

* Through National/Regional Health Services temporary access code.

Conclusions

Maternal and perinatal health outcomes were poor in undocumented migrants, especially from Africa. Both socio-economic and health outcomes showed vulnerability and inequality in comparison to documented migrants and the general population. Inadequate antenatal care reflected poorly on several perinatal health outcomes.

Known risk factors including fragile socio-economic conditions along with legal and linguistic barriers to healthcare need to be addressed through tailored interventions including outreach health promotion focusing on safe motherhood and neonatal care, healthcare provider training, language translation cultural mediation, and functional language learning.

Furthermore, a systematic monitoring and evaluation system needs to routinely collect, integrate, and analyze data from National/Regional Health Services and third sector healthcare providers to estimate key indicators including: maternal migrant status (currently doable through temporary registration code to National/Regional Health Services), birthplace, length of stay in country, language fluency, age, hospitalization rate due to obstetric causes, antenatal care (including number of antenatal care visits, timing of first antenatal care visit, number and timing of ultrasound scans, complete laboratory tests), neonatal pre-term rate, low birth weight rate, and low Apgar score.

Chapter 3: Undocumented migrants during the COVID-19 pandemic: socio-economic determinants, clinical features and pharmacological treatment

Abstract

Objectives: Population groups such as undocumented migrants have been almost completely forgotten during the COVID-19 pandemic, though they have been living in all European countries for decades and new arrivals have continued throughout the pandemic. The aim of this study was to investigate their health conditions during the current pandemic.

Methods: We analyzed the records of 272 patients with respiratory issues attending the outpatient clinic of a large charity in Milan, Italy: amongst them, 18 had COVID-19 confirmed by rhino-pharyngeal swab and 1 deceased.

Results: They appeared to have several risk factors for COVID-19 and chronic conditions suspected to predispose to the disease and/or to worsen severity and outcomes: hypertension, immune depression and previous close contact with COVID-19 patients were the most important ones. Presenting symptoms were worse in patients with COVID-19 than in those with other respiratory issues.

Conclusions: These results are discussed in light of the necessity to provide better healthcare to undocumented migrants.

Introduction

As of 30th July 2020, total 17,109,335 cases and 668,801 deaths due to COVID-19 have been reported in 188 countries, with 3.9% Case-Fatality Rate [69]. The global epidemic curve illustrates rapid onset and widespread transmission, with incidence still increasing. The pandemic is not yet over, it remains ongoing and dynamic with transmission currently flaring up in countries that have been less impacted so far (e.g. South America), resurging in countries that have decreased impact (e.g. China), and increasing in countries that have removed lockdown measures (e.g. Europe). Vaccine development, production, distribution, and administration will take time to materialize and provide population-wide protection. A structured and coordinated approach is needed to address the current and possibly increasing global crisis [70].

Throughout the pandemic, many researchers have worked untiringly on the clinical and epidemiological aspects of the novel disease. The current evidence base shows that it disproportionately affects males, smokers, the elderly and patients with multiple underlying co-morbidities including chronic conditions such as hypertension [71]–[73].

Both speed and magnitude of the COVID-19 pandemic have put National Health Systems under unprecedented pressure and compelled them to prioritize life-saving interventions for critically ill COVID-19 patients versus regular services (non-related to COVID-19). Notwithstanding, the pandemic has resulted in high morbidity and mortality due to COVID-19 (primary impact) and hijacked regular health service delivery with risk of health status deterioration due to causes other than COVID-19 (secondary impact).

Disproportionate impact on the elderly in long-term hospices has been documented [74] and migrant populations have been identified as a high-risk population group due to underlying vulnerability to respiratory infectious diseases such as COVID-19, as a result of overcrowded dwelling conditions, inadequate water and sanitation facilities, under-nutrition, and elevated physical and psychological stress with multiple underlying co-morbidities i.e. a well-established risk factor for increased mortality due to COVID-19 [75]–[77].

These risk factors are associated with pre-existing limited access to healthcare due to legal, administrative, linguistic, social, and cultural barriers which are further exacerbated by the

COVID-19 pandemic. Communication campaigns aimed at disseminating key messages on containment measures (i.e. mobility and activity limitations, social and physical distancing, hygiene and decontamination) are mostly in national languages hence not comprehensible for those speaking other languages and designed according to social and cultural norms that may differ for migrants. Furthermore, containment measures are challenging to implement for migrants living in overcrowded conditions, with inadequate water and sanitation facilities, without sufficient and stable employment and income sources [78], [79]. Finally, such dwelling conditions are conducive to increased risk of infection transmission: institutional settings such as reception centers entail sharing rooms and communal spaces among guests and staff, as well as restrictions to individual mobility and activity [80]; informal settlements have inadequate water and sanitation infrastructure/facilities, are overcrowded, and health facilities within proximity tend to have limited capacity [79]; transit areas are by default unsanitary and populations on the move are the most exposed to health risks with the lowest access to services.

Overall, access to healthcare was already limited among migrants before COVID-19 pandemic and thereupon further decreased due to fear of contagion in health facilities, triage protocols requiring to contact family General Physicians, and limited direct access to health facilities including Emergency Departments, hence additional barriers for undocumented migrants without a family General Physician [76].

The COVID-19 pandemic has exposed the negative effects of insufficient and inadequate coverage of primary health care among migrants. Yet, health is a fundamental right that ought to be equitably accessed by every person [81]–[84]. In spite of this, very little has been done to solve this problem, with the exception of some spontaneous initiatives by not-for-profit organizations (NPOs) already involved in health care for the poor. We think that studying the patients followed by one of these organizations could give an insight into the social and health conditions of undocumented migrants during the COVID-19 pandemic.

Methods
This retrospective cross-sectional study analyzed health records from a third sector non-profit organization providing healthcare to undocumented migrants. The data reflects the situation during the very early days of the COVID-19 pandemic in one of the most hardly hit locations.

Data source

We analyzed the records of 272 patients presenting with respiratory issues from February 24th to May 24th 2020 at Opera San Francesco (OSF), the largest NPO providing healthcare to the poor in Milan, Italy. The vast majority of patients are undocumented migrants living in Milan and neighboring areas in Lombardy Region. On February 18th, the first case of locally transmitted COVID-19 due to SARS-CoV-2 was diagnosed in Italy. Containment measures were instituted and escalated over the following days and weeks, until reaching full-fledged lock-down status nation-wide and globally, due to pandemic declaration by the World Health Organization on March 11th. Among these measures, a double-track pathway was designed to access health facility premises, with one track designated for possible COVID-19 patients (i.e. individuals with respiratory symptoms, fever, and/or close contacts of confirmed cases) and one track designated for presumed non COVID-19 patients. OSF acted in the same way and since February 24th divided the outpatient clinics into two separate groups: one group for possible SARS-CoV-2 cases and one group for all other patients.

Cohort

The patients included in this study represent the entire population seen in the clinic for possible COVID-19 cases over a period of three months i.e., since its opening February 24th until May 24th. For all patients, we obtained the following data, in addition to age, gender and country of birth: socio-economic conditions (employment and legal registration status); risk factors including unhealthy lifestyles, especially smoking [70], impaired immunologic conditions, and close contact with confirmed COVID-19 cases; pre-existing chronic conditions (e.g. hypertension, cardiac disease, diabetes and obesity) suspected to be associated with greater risk of susceptibility to SARS-COV-2 infection, and/or more severe COVID-19 morbidity, and/or higher risk of mortality due to COVID-19 [72], [79], [80]; pharmacologic treatment prescribed upon consultation; diagnostic test (rhino-pharyngeal swab) results; outcome.

Since the study was retrospective, an authorization protocol number by the local ethics committee was not required. All data were completely and permanently anonymized. All procedures were in accordance with the ethical standards of the institutional and national

research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Statistical analysis

Descriptive statistics were used to summarize patient characteristics. Continuous variables were reported as mean and standard deviations, while percentages were used for categorical variables. Continuous variables were compared between groups by using the t-test for independent samples. Differences on categorical variables between groups were tested by the Chi-square test for independence. Variables with more than 10 missing values were excluded from the analysis of the association with COVID-19. Statistical analysis was performed with Analyse-it for Microsoft Excel Ver. 5.65/2020 (Analyse-it Software Ltd., Leeds, UK).

Limitations

We are aware that our work has limitations. First, the study is health facility-based rather than population-based. Therefore, the study provides information only about those migrants who presented at the health facility, while it does not provide a true picture of the actual magnitude, characteristics, and patterns of SARS-CoV-2 transmission and COVID-19 morbidity and mortality among migrants (selection bias). This is particularly important because as much as 80% COVID-19 cases may be non-severe (i.e. mild, pauci-symptomatic, asymptomatic), hence may not present at a health facility to seek care therefore ending up missed-out by epidemiological surveillance and health care systems. Second, the study captures a small-size population (total 272 patients) seeking and accessing health care at a single health facility (OSF clinic in Milan, Italy). Therefore, observations are too few to allow for meaningful stratification and statistical analysis, and results are not representative and cannot be generalized to the overall migrant population, who tends to be highly heterogeneous. Third, the study site (OSF clinic in Milan, Italy) mostly provides healthcare to undocumented migrants, i.e. a further specific migrant population, who may have behaved differently during lockdown, compared to the general population and to the documented migrant population, respectively. As a matter of fact, undocumented migrants may have refrained from seeking healthcare for fear to be spotted and expelled from Italy. This

could have reduced the population size of our study sample and of COVID-19 positive patients. Lastly, we could not obtain 16 (47%) test results of rhino-pharyngeal swabs over total 34 patients suspected to have COVID-19, due to various reasons.

Results

During the study period, 272 patients attended OSF, including 144 (52.9%) males and 128 (47.1%) females. As shown in table 16, our study cohort's mean age was 42.6 (± 13.6) and 41.2 (±13.0) years in males and females, respectively (p=0.39). Overall, 43 patients had migrated from Africa, 37 from Asia, 155 from Latin America and 37 from Eastern Europe (data not shown).

Risk factors

Unhealthy lifestyles, particularly smoking, were significantly more frequent among males (p<0.0001), while the contrary was true for obesity (p=0.03) and arterial hypertension (p=0.03). The prevalence of type 2 diabetes (p=0.34) and cardiac diseases (p=0.95) did not differ significantly between males and females. In general, it appeared that risk factors for COVID-19 were highly represented in this population.

Table 16: Differences in risk factors and chronic conditions, by gender

	M (N = 144)	F N = 128	P
Age (years, mean ± SD)	42.6 ± 13.6	41.2 ± 13	.39
Risky beahaviours (%)	43.8	14.1	<.0001
Smoking (%)	30.6	11.3	<.0001
Obesity (%)	50.6	67.0	.03
Hypertension (%)	27.0	39.8	.026
Diabetes (%)	24.8	30.1	.34
Cardiac diseases (%)	14.8	14.5	.95

Symptoms and treatment

Presenting symptoms are shown in figure 3. Respiratory symptoms and fever were the most common complaints that induced patients to seek medical assistance. The mean peripheral arterial oxygen saturation was 97.6 ± 1.9 % (range: 85% - 100%). They were prescribed mainly

symptom relievers such as paracetamol (61 patients; 22.4%) and antihistamines (27 patients; 9.9%); 56 patients (20.6%) received oral antibiotics.

Figure 3: Presenting symptoms, percentage patients
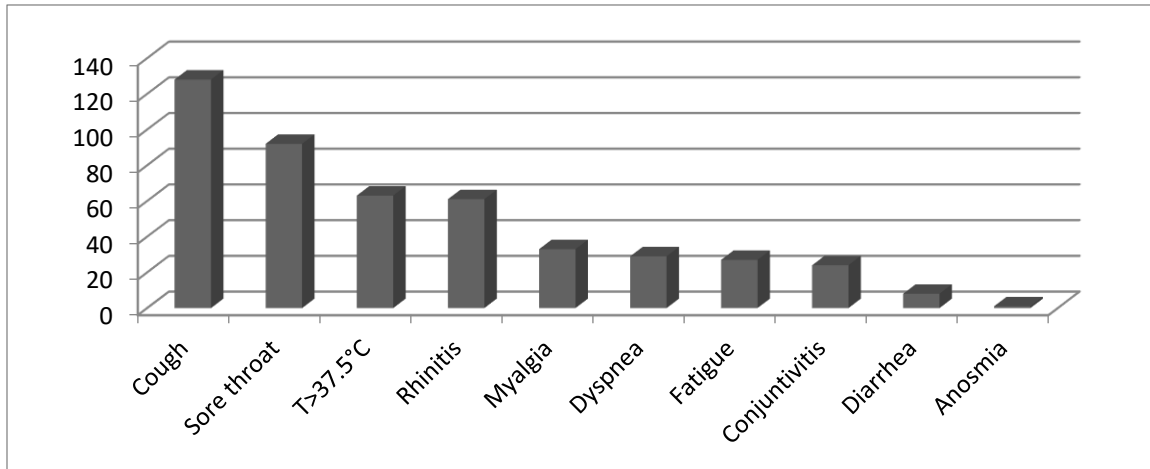
Morbidity and mortality outcomes

Eighteen patients (6,6%) had a positive swab for SARS-CoV-2 genome. One patient (with AIDS co-morbidity) died. In addition, we suspected 16 more patients (5.8%) to have the disease, based on presence of one or more criteria as per case definition. Unfortunately, we could not obtain the results of their rhino-pharyngeal swab. Positive patients included 11 males (61.1%) and 7 females (38.9%), with a mean age of 44.4 ± 15 years. Twelve were Latin-Americans, 3 Africans, 2 East Europeans and 1 Asian. Five patients were homeless (2 sleeping in a dormitory). The mean number of persons sharing accommodation with the patients was 2.1 ± 1.8.

The number of patients with confirmed COVID-19 was small, as compared to the rest of the population, we found that an association existed with some predisposing factors. However, we found that an association existed with some predisposing factors. As shown in table 17, among chronic co-morbidities, the association with hypertension was significant. In a simple logistic regression model, hypertension was a significant predictor of COVID-19 (OR 1.66; 95% CI 1.02-2.69; P = 0.04). Four of the 10 hypertensive COVID-19 patients were on either Angiotensin Converting Enzyme Inhibitors (ACE-I) or Angiotensin Receptor Blockers (ARB). For COVID-19 negative patients, the number was not consistently 254 because of missing values.

Among risk factors, previous close contact with COVID-19 cases appeared to be the most important; immune depression was also significant.

Presenting symptoms more frequently associated with COVID-19 were: dyspnea (p<0.0001), fatigue (p<0.0001), temperature over 37.5°C (p<0.0001), rhinitis (p=0.03), and cough (p=0.02). Peripheral oxygen saturation was significantly lower in patients with COVID-19: 95.6%±3.4% vs. 97.7%±1.8% (p=0.0005).

Table 17: Predisposing factors in 18 patients with confirmed COVID-19

	Covid +		Covid-		p-value
	Y	N	Y	N	
Hypertension	10	8	77	169	.035
Obesity	8	1	93	68	.064
Diabetes	6	12	12	180	.55
Smoking	4	14	53	201	.89
Contacts with positives	8	0*	31	125**	<.0001
Persons living with the patient	2.1 $\pm$ 1.8		3.1 $\pm$ 2		.058
Immunodepression	2	16	6	247	.034

Discussion

In the present study, we describe the characteristics of a population of undocumented migrants seeking medical assistance for respiratory problems during the COVID-19 pandemic.

Despite study limitations, some points are worth discussing. First, this population, though relatively young, had a significant burden of risk factors and chronic conditions that are associated with worse prognosis due to COVID-19 [71], [73], [83], [84]. Chronic conditions were unevenly distributed between men and women, i.e. an observation that we have already made earlier [85]. Among these conditions, hypertension seemed to be more frequent in COVID-19 patients, as reported by others too [73]. Of course, in consideration of the small number of COVID-19 patients with hypertension in our study, we cannot draw comments on treatment with ACEI and ARB. However, though their potential role has widely been debated [86], it has now been demonstrated that there is no evidence that they affect the risk of COVID-19 (19). The small number of positive patients could also be the reason why we did not find an association with other conditions such as smoking, which can increase both infection risk and disease severity

[87], [88]. For obesity, whose role is still unclear [84], we have no information from our study. This variable, which contained more than 10 missing values, was not analyzed.

The high number of Latin Americans among COVID-19 patients almost surely reflected the high percentage of this ethnicity in the population of the study, which may be over-represented (hence an additional selection bias and study limitation).

Interestingly, the COVID-19 patients in our study had worse-presenting symptoms than patients with other causes of respiratory disease. Therefore, severe symptoms, the presence of chronic conditions as hypertension and risk factors such as immune depression and previous close contacts with COVID-19 positives can help to discriminate the patients in whom a diagnostic test (rhino-pharyngeal swab) is more needed on priority basis. This is not a superfluous observation since currently NPOs must rely on hospital Emergency Departments and overall access to diagnostic tests remains limited.

More in general, our study demonstrates and confirms that undocumented migrants are a high-risk population for COVID-19, perhaps even more than other population segments, due to underlying socio-economic vulnerability, health risks and barriers to accessing healthcare.

Though receiving less media attention, migrant and refugee flows have remained ongoing throughout the COVID-19 pandemic and have increased after lockdown measures were lifted. For instance, arrivals in Europe were more than 28,000 from January 1st to June 15th 2020 [89]. Nonetheless, there is a lack of specific and systematic provisions for migrant populations in context of COVID-19 and cases are managed through *ad hoc* solutions, mostly through spontaneous initiatives by local NPOs or quarantine ships in case of sea arrivals, thus resulting in limited effectiveness of COVID-19 containment and unnecessary burden of disease. In June 2020, the European Center for Disease Control issued specific guidance for migrants in context of COVID-19 [80], yet these have not been translated into national and local provisions so far.

Based on these observations, migrants and refugees risk to fall in between the cracks of COVID-19 emergency preparedness and response. As the pandemic remains ongoing and further spread is possible, there is a persisting risk of cases going untimely detected and treated thus contributing disproportionately to morbidity and mortality. Therefore, specific and systematic

provisions are needed to adequately extend coverage of epidemiological surveillance and healthcare systems and services in this population. There are three reasons for this. The first is humanitarian (it is not ethic to exclude individuals and/or groups from health care, which is a fundamental human right). The second concerns Public Health, to increase effectiveness of infection prevention and control measures. The third has clinical relevance, since it is possible that COVID-19 causes important permanent pulmonary damage [90]. Acting differently could put us all at risk of "bad policy at high cost" [91].

Conclusions

To our knowledge, this is the first study describing health conditions among undocumented migrants during the COVID-19 pandemic. Migrants are at higher risk of morbidity and mortality, and represent an increasing share of total population in several countries, yet they have limited access to National Health Services. Knowing their conditions during an epidemic is fundamental both to assist them and to prevent the spread of the disease. Specific provisions for migrants need to be embedded systematically within overall emergency preparedness and response measures against COVID-19, to ensure adequate provisions for infection prevention and control, case finding and contact tracing, isolation and quarantine, and case management.

Chapter 4: COVID-19 vaccine hesitancy among undocumented migrants during the early phase of the vaccination campaign: a multi-centric cross-sectional study

Abstract

Study objectives: The marginalization of undocumented migrants raises concerns about equitable access to COVID-19 vaccination. This study aims to describe migrants' hesitancy about the COVID-19 vaccination during the early phase of the vaccination campaign.

Methods: This multi-centric cross-sectional survey was conducted in health facilities providing care to undocumented migrants in the United States, Switzerland, Italy, and France in February-May 2021. Participants Eligibility criteria included age >16, being of foreign origin and living without valid residency permit in the country of recruitment. A convenience sample of minimum 100 patients per study site was targeted. Primary and secondary outcome measures: Data was collected using an anonymous structured questionnaire. The main outcomes were perceived access to the local COVID-19 vaccination program and demand for vaccination.

Results: Altogether, 812 undocumented migrants participated (54.3% Geneva, 17.5% Baltimore, 15.5% Milano and 12.7% Paris). Most (60.9%) were women. The median age was 40 years (range 17-76). Participants originated from the Americas (55.9%), Africa (12.7%), Western Pacific (11.2%) Eastern Mediterranean (7.9%), Europe (7.6%) and South-East Asia (4.7%). Overall, 14.1% and 26.2% of participants, respectively, reported prior COVID-19 infection and fear of developing severe COVID-19 infection. Risk factors for severe infection were frequently reported (29.5%). Self-perceived accessibility of COVID-19 vaccination was high (86.4%), yet demand was low (41.1%) correlating with age, co-morbidity, and views on vaccination which were better for vaccination in general (77.3%) than vaccination against COVID-19 (56.5%) Participants mainly searched for information about vaccination in the traditional and social media.

Conclusions: We found a mismatch between perceived accessibility and demand for the COVID-19 vaccination. Public health interventions using different communication modes should build on

trust about vaccination in general to tackle undocumented migrants' hesitancy for COVID-19 vaccination with a specific attention to men, younger migrants and those at low clinical risk for severe infection.

Strengths and limitations: The study included undocumented migrants, a hard-to-reach population, in four countries. Efforts were made to overcome language, trust and literacy barriers to participation. The number of participants differed in every study sites

Introduction

It is estimated that between 3.9 and 4.8 million undocumented migrants live in Europe and 10.5 million in the United States (US)[92]–[94]. Economic opportunities, integration policies, and the rights and benefits afforded to undocumented migrants vary by host country. However, challenges including language barriers, fear of deportation, poverty, housing precariousness, and limited access to healthcare and workplace protections, are common experiences for most undocumented migrants.

Although undocumented migrants represent less than 1% of Europe's and 3.2% of the US total population, emerging evidence points to the devastating impact of COVID-19 in this group. In high-income countries, migrants have high risk of COVID-19 infection, morbidity, and mortality[26].Although COVID-19 outcomes by specific immigration status are rarely available, surrogate markers (e.g. language, country of origin, housing status, health insurance eligibility, and demographics) suggest that undocumented migrants are at particularly high risk[26], [95]–[103]. Community and health facility-based studies in Europe and the US showed exceptionally high SARS-CoV-2 positivity rates among foreign-born or limited English proficiency patients [97], [98], [104], [105] . In the US, COVID-19 case rates were highest in counties with large immigrant communities, and the correlation was stronger in areas with more Central Americans, a group with high poverty levels and irregular migrant status [92], [102], [106]In addition, there is evidence of poor outcomes due to delayed presentation to care among undocumented migrants [26], [96], [100], [107], [108].Mortality data by migrant status is limited, but what is available shows that compared to native-born citizens, migrants to Europe and the US, particularly those from low and middle-income countries, have higher excess all-cause and COVID-19 mortality [109]–[113].

Undocumented migrants play an essential role in the global economy but rely heavily on informal and low-wage labor with limited occupational protections. Mitigation strategies to reduce the social, economic and health impact of the COVID-19 pandemic frequently exclude undocumented migrants. Without a social safety net, many continued to work at the peak of the pandemic in high-risk essential jobs, such as logistics, manufacturing, domestic and care

activities, construction, and the food processing industry[101], [114], [115]. Several European countries provided food assistance to migrants during lockdown, and a few further extended benefits. For example, Ireland implemented a system to pay unemployment benefits to undocumented migrants who lost their jobs, and Portugal granted temporary citizenship rights to migrants[116].The suspension of exclusionary immigrant policies, however, was not uniform and there were many unmet needs and many vulnerable undocumented migrants fell into extreme poverty [117]. A survey conducted in Switzerland in April 2020 showed that almost one in six migrants had experienced hunger during the first lockdown [116]].

Furthermore, long-standing anti-immigrant policies and mistrust of governmental institutions have not been eased during the pandemic, and pre-existing legal, socio-economic, and linguistic barriers to social and health services have exacerbated the impact of COVID-19 among undocumented migrants. [28,29] Although countries deployed health services for COVID-19 without eligibility restrictions based on migration status, no specific measure has been implemented to facilitate access for undocumented migrants who already tended to underutilize social and health services even before the pandemic.[30,31] As a result, pre-existing barriers to accessing health and social services are exacerbated by the pandemic and likely lead to delaying life-saving care for many [96], [100], [101], [116]].

The rapid development of effective COVID-19 vaccines was an unprecedented scientific achievement, but equitable vaccine distribution is a major challenge worldwide. Undocumented migrants and other socially disadvantaged populations have faced significant hurdles to get vaccinated, including digital, transportation, and health system navigation barriers. The European Centre for Disease Prevention and Control (ECDC) and the Council of Europe have called for tailored vaccination programs for undocumented migrants that are free from immigration control enforcement activities[118]], but only a few national immunization plans explicitly include provisions for undocumented migrants, or address potential barriers, such as langauge proficiency or identification requirements [119], [120]].

In addition, the willingness and hesitancy of individuals, including undocumented migrants, to get immunized depends on a variety of factors, such as self-perceived risks and severity of illness; confidence in the safety and effectiveness of the vaccine; trust in medical, govermental, or pharmaceutical institutions; behavioral and social processes (e.g. awareness, information, education, social norms, networks, and media). The objective of this multi-centric study conducted in the early phase of COVID-19 immunization programs was to explore undocumented migrants' hesitancy about COVID-19 vaccine.

Methods

This multi-centric cross-sectional survey was conducted from mid-February to late May 2021 in four facilities providing medical care to undocumented migrants in Switzerland, the United States, Italy, and France during the early phase of the vaccination campaign (February to May 2021).

The John Hopkins University (IRB00252774), Geneva Canton (CCER 2021-0246), and the University of Milan-Bicocca (138AQ-38183) ethical boards provided clearance for this survey. In France, the INSERM review board (IRB00003888) considered this study to be exempted of ethical clearance given the nature of the survey. The study was registered with the Office of the data protection (DPO) of Sorbonne Paris Nord University. All participants gave oral informed consent to participate.

Setting

The four study sites are part of an informal network of health institutions providing care to undocumented migrants which started to share experiences and good practices during the early phase of the COVID-19 pandemic.

Geneva, Switzerland: Geneva (population 500,000) hosts an estimated 10,000 to 15,000 undocumented migrants, predominantly women from Latin America, the Philippines and South-Eastern Europe who are active in the domestic and care industry [121]]. While potentially eligible

to purchasing the mandatory health insurance to access to medical care, less than 10% are actually insured because of financial and administrative barriers.

The Geneva University Hospital acts as the main port of entry into the healthcare system for undocumented migrants and other underserved groups of population, providing the full range of preventive, curative and rehabilitation health services [122]]. While the Swiss Federal Government has decided upon the universal access to COVID-19 vaccination to all residents irrespective of their legal status in early 2021, the policy implementation has been delayed at Canton level and Geneva was the first Canton to officially integrate undocumented migrants into the vaccination program in May 2021 [123]].

At the beginning of the study, the COVID-19 incidence and mortality in Canton Geneva were at their lowest since October 2020. There was then a mild resurgence of new cases not associated with increased mortality that peaked in April before coming back to its baseline in May. The vaccination campaign started on December 28, 2020. Two vaccines were available, BNT162b2 mRNA (Pfizer/BioNTech) and mRNA-1273 (Moderna). In the first two months, vaccination was limited to high risk groups and it became available to all adults in early March 2021. By the end of the study, 37% of the population had received at least one dose. No additional public restrictions were imposed during the study period.

Milan, Italy: According to available estimates, there are currently 517,000 undocumented migrants in Italy[5]. Disaggregated estimates at city level including for Milan are not readily available. However, Milan is the economic center and the most populous region in Italy, hence likely to host a large population of undocumented migrants. In principle, the National Health Service system is based on a universalistic model providing healthcare free of charge at the point-of-use against payment of standard flat fees with waivers based on socio-economic criteria and is decentralized at regional level for both policy and service delivery aspects. Access to the NHS requires a valid health card, which is issued based on residency status. As a result, undocumented migrants do not have access to the NHS.

To address this fundamental legal and administrative barrier, the NHS provides a temporary access code, which allows access to emergency care and essential services including maternity and vaccination services. In practice, undocumented migrants face barriers even to obtain a temporary access code and rely on charities for accessing healthcare. Among them, ''Opera San Francesco per i Poveri'' is a faith-based charity operating a large size health clinic in Milan providing free-of-charge outpatient healthcare including consultations, diagnostics, and therapy for socially disadvantaged population groups including undocumented migrants.

For COVID-19 vaccination, the NHS procures and distributes vaccines and consumables, while the regional health system administers them through a client-initiated online booking system requiring a valid health card. As of 25th June 2021, the Lombardy Region, with Milan as the chief lieu, granted eligibility for online booking to undocumented migrants with a temporary access code. Charities have mobilized to provide individual support to facilitate administrative, linguistic and practicality challenges. At study inception, COVID-19 incidence and mortality were persistently elevated in Italy.

The Lombardy Region, with Milan as its chief-lieu, continued to account for the highest toll in-country. Restrictions including lockdown continued to be implemented in a modular way according to local epidemiology. The national immunization campaign kicked off officially just before the end of 2020, targeting the health workforce and the elderly in hospices; however, it struggled to pick up pace until summer 2021 and only 1.2% of total target population was fully immunized at study inception. Initially, the campaign used BNT162b2 mRNA, then mRNA-1273, ChAdOx1 nCoV-19 AZD1222 (Astra-Zeneca), and finally added JNJ-78436735 (Johnson & Johnson) vaccines, the latter having been prioritized for hard-to-reach population groups including undocumented migrants.

Baltimore, USA: Baltimore City is an emergent destination for migrants from Latin America[124]. An estimated 20,000 foreign-born Latin Americans live in the city and approximately 13,500 (67%) are not citizens. Migrants from Mexico and Central America have higher non-citizen status

(> 80%), low educational attainment (50% with less than high school education), and high rates (70%) of limited English proficiency[125].

In the US, the COVID-19 vaccine is freely available to all, regardless of immigration or insurance status, and the Department of Homeland Security has explicitly stated that immigration enforcement activities will not be conducted at vaccination site[126]. In the early stages of the COVID-19 immunization program, the state of Maryland implemented a phased distribution plan and the vaccine was not available to the general population until April 27, after data collection for this study was completed. The Access Program, Johns Hopkins Medicine in Baltimore, Maryland (TAP) acts as the main port of entry into the Johns Hopkins Health System. Patients are enrolled in TAP if they are low income (<200% federal poverty line) and are ineligible to enroll in Medicaid or subsidized health insurance because of their irregular immigration status.

In Baltimore City, cases of COVID-19 in February of 2021 were the lowest since October 2020, but by March 2021, a fourth wave of COVID-19 emerged which peaked on April 10, 2021. COVID-19 vaccine administration began on December 14, 2020 in a phased approach which sequentially prioritized first responders, the elderly and those with underlying health conditions. The vaccine became available to the general population on April 27, 2021. Three COVID-19 vaccines authorized in the US for Emergency Use or FDA-approved were available for vaccination programs: BNT162b2 mRNA, mRNA-1273 and JNJ-78436735.

Paris, France: Avicenne University hospital is located in the Department of Seine Saint Denis in the North-East of Paris. The Department is historically a place where migrants use to be provided social lodging after the Second World War (mainly Sub-Saharan Africa and North-African communities). It is estimated that more than 30% of the population is constituted of immigrants, with recently an additional wave of migrants from South Asia. Moreover, the majority of undocumented migrants in metropolitan France (around 400.000) tend to be concentrated in this Department. Undocumented migrants in France have access to health via State Medical Aid, an insurance coverage for individuals with no right to National Health Insurance. Those without any coverage may access health care via specific units created for uninsured persons (PASS,

Permanence d'accès aux soins), located in hospitals principally. Avicenne University Hospital receives uninsured persons via this unit on a daily basis.

In France, all eligible persons are entitled to Covid19 vaccination, as per government declaration. In Paris region, incidence of COVID-19 mid-February 2021 was already high at 237/100,000 inhabitants, and quickly increased further. A third lockdown was ordered on March 18, when incidence was at 426/100,000. The incidence peaked at the end of April, at 682/100,000, and slowly decreased. The survey hence took place about one month before the lockdown when virus circulation was already quite high, with a regional curfew in place since mid-January. The rate of study site enrollment was further affected by the lockdown and the increased police controls. COVID-19 vaccine national campaign began on December 27, 2020 in a phased approach which first prioritized the elderly, and those with underlying health conditions. The vaccine became available to the general population on January 18, 2021, while its uptake was very slow during the first weeks. The four COVID-19 vaccines authorized in France for were BNT162b2 mRNA, mRNA-1273, ChAdOx1 nCoV-19 AZD1222 and JNJ-78436735.Participants

Eligibility criteria were age equal or above 16 and living as a foreigner without valid residency permit (undocumented) in the country of recruitment. Participants were recruited upon spontaneous presentation (walk-in) to one of the participating health facilities.

We used several strategies to reduce the risk of recruitment and measurement bias by addressing the main barriers limiting undocumented migrants' participations in health programs such as fear of personal data misuse and socio-cultural factors. All consecutive patients consulting at the four health facilities were informed about the study orally and with written material in different languages. We explained that the questionnaire (annex 1) was anonymous, and that no identifying information was collected considering the frequent fear of undocumented migrants to disclose personal information. The questionnaire was translated in French, Spanish, Italian, Portuguese, Arabic, English, Tagalog, Albanian, Ukrainian, and Russian to match with the main languages spoken by migrants visiting the participating health facilities. Participants were

proposed the support of research assistants competent in various languages to fill the questionnaire to overcome potential difficulties in reading and understanding the questions.

Cohort

In absence of pre-existing hypothesis regarding the distribution of responses to the two main outcomes, considering the difference in the number of monthly visits in each site and the uncertainties about migrants' willingness to engage into the study in the different sites, we pragmatically set a minimal sample size of 100 participants per study site to be reached within the pre-defined study period.

Patient and Public Involvement This study was informed by patients expressing interest and concerns to healthcare workers about COVID-19 vaccine accessibility and safety in the four study sites.

Data source and variables

We designed a 15-item questionnaire (Supplementary material) based on UNICEF and WHO guidance toolkit for COVID-19 vaccination demand [52], [53] and a European Centre for Diseases Control (ECDC) document exploring vaccine hesitancy [54]. Our main outcome of interest was COVID-19 vaccine hesitancy explored through two main perspectives, perception about vaccination accessibility and the drivers and barriers for demands. Accessibility was investigated using the question: "Do you believe that migrants in your [legal] situation will have access to the COVID-19 vaccination?" with "yes", "no", and "I don't know" as possible responses; we dichotomized ''yes'' and ''I don't know" versus 'no'' in order to determine the proportion of participants perceiving that the vaccination would not be inaccessible. We further investigated the type of barrier in those responding "no". Demand was investigated using the question: "If the vaccine was offered to you, would you like to get immunized against COVID-19?". Responses to the latter question included "yes no doubt", "probably yes", "probably no", "no", "I don't know yet". In the analysis, we dichotomized ''yes no doubt'' versus all other response to determine the proportion of vaccine-hesitant respondents, based on the definition of vaccine hesitance as the reluctance or refusal to vaccinate despite the availability of vaccines along a continuum with a

broad spectrum of attitudes and intentions from active demand to passive acceptance, vaccine hesitancy, and refusal of all vaccines[44].

We explored enabling and barriers factors for vaccine accessibility and demand such as demographic characteristics, self-reported clinical risk factors for severe SARS-CoV-2 infection, previous infection with SARS-CoV-2 (self and/or household), self-perceived health risks with COVID-19, views about vaccination in general and COVID-19 vaccination in terms of safety and efficacy (both dichotomized as positive versus negative), desirable place of vaccination, and finally the main sources of information about COVID-19 vaccine (traditional media, social media, and community networks). The questionnaire was pretested in 10 participants before being implemented in all study sites.

Statistical analysis

Categorical data are presented as proportions with percentages and non-normally distributed continuous variable as median with interquartile range (IQR). We compared the distribution of variables in the four study sites using the Kruskal-Wallis test for non-normally distributed variables and the chi-square test or the Fisher's exact test, as appropriate. The significance level was set at 0.05.

We performed both univariate and multivariate logistic regression analysis to identify factors associated with the two main outcomes. Odds ratios were estimated through multivariate logistic regression models, which were mutually adjusted with all covariates in the models.

Missing values, which ranged from 0.2% to 3.6% of the total study size, were imputed by using a multiple (n=100) imputation approach. Briefly, multiple imputation is a bayesian method that allows to take into account incomplete cases (i.e. observations with any missing data) with a two-step approach. First, this method creates multiple imputed datasets, in which missing values are replaced by imputed values. These are sampled from their predictive distribution based on the observed data. The imputation procedure fully accounts for the uncertainty in predicting the missing values by conferring appropriate variability into the multiple imputed values. Second, standard statistical methods are used to fit the model of interest to each of the imputed datasets.

Estimates associated to each of the imputed datasets differ because of the variation introduced in the imputation of the missing values (stage 1), and they are, then, average together to give overall estimated associations. Valid inferences are obtained because they are based on the average of the distribution of the missing data given the observed data, and results were reported as odds ratios (OR) along with their 95% confidence intervals (CI). All analysis were performed using SAS 9.4 (Cary, NC, USA).

Results

Participants' characteristics

a total of 812 individuals completed the survey, 441 (54.3%) in Geneva, 142 (17.5%) in Baltimore, 126 (15.5%) in Milan, and 103 (12.7%) in Paris. The median age was 40.1 years (range 17-76) with a predominance of female respondents (60.9%), but gender distribution varied by city and, notably, 69.9% of participants in Paris were male (Table 1). They mainly originated from the Americas (55.9%), Africa (12.7%) and the Western Pacific regions (11.2%). Participants born in the Americas accounted for all the respondents in Baltimore, over half in Geneva and Milan, but only 1.9% in Paris, which had the largest representation of African migrants.

Table 18: Sociodemographic characteristics of the participants (n=812).

	Total N = 812, n (%) or median (IQR)	Geneva N = 441, n (%) or median (IQR)	Baltimore N = 142, n (%) or median (IQR)	Milan N = 126, n (%) or median (IQR)	Paris N = 103, n (%) or median (IQR)	p-value
Female gender	492 (60.9)	279 (63.4)	98 (70.0)	84 (67.2)	31 (30.1)	< 0.001
Missing values	4	1	2	1	0	
Age	39 (16)	39 (17)	40 (13)	41 (20)	35 (16)	0.001
Missing values	2	1	0		1	
Region of origin						0.001
Africa	103 (12.7)	52 (11.8)	0 (0)	8 (6.4)	43 (41.8)	
Americas	454 (55.9)	227 (51.5)	142 (100)	83 (65.9)	2 (1.9)	
Eastern Mediterranean	64 (7.9)	28 (6.4)	0 (0)	7 (5.6)	29 (28.2)	
Europe	62 (7.6)	39 (8.8)	0 (0)	21 (16.7)	2 (1.9)	
Asia	38 (4.7)	7 (1.6)	0 (0)	6 (4.8)	25 (24.3)	
Western Pacific	91 (11.2)	88 (20.0)	0 (0)	1 (0.8)	2 (1.9)	
Missing values	0	0	0	0	0	

Accessibility and demand for vaccination and risk factors for severe infection

The vast majority (86.4%) of participants perceived that the COVID-19 vaccination would be accessible to undocumented migrants, but a lower proportion (41.2%) reported they would get vaccinated against COVID-19 (Table 2). Approximately one third (29.5%) of participants reported at least one chronic co-morbidity that could predispose to severe COVID-19 infection, 14.1% reported prior COVID-19 infection, and 26.2% worried about developing severe COVID-19 (Table 2). In all cities, perceptions about vaccination in general were more favorable than about COVID-19 vaccination overall, more than three quarters (77.3%) of respondents had positive views on vaccination in general, compared to (56.5%) about COVID-19 vaccination. Traditional media was the most common source of information about COVID-19 vaccination, followed by social media. Community networks were a common source of information among participants in Paris (72.8%), but less so among participants in other cities.

Table 19: Undocumented migrants' perceived accessibility to and demand for COVID-19 vaccine with related enabling and barrier factors

	Total N = 812, n (%)	Geneva N = 441, n (%)	Baltimore N = 142, n (%)	Milan N = 126, n (%)	Paris N = 103, n (%)	p-value
Access to COVID-19 vaccination	697 (86.4)	377 (86.1)	116 (82.3)	110 (88.0)	94 (91.3)	0.219
Missing values	5	3	1	1	0	
Demand for COVID-19 vaccination	327 (41.2)	168 (39.0)	79 (59.0)	65 (52.0)	15 (14.6)	< 0.001
Missing values	19	10	8	1	0	
COVID-19 exposure						
COVID-19 infection (self)	114 (14.1)	62 (14.1)	32 (22.5)	11 (8.7)	9 (8.8)	0.003
Missing	3	2	0	0	1	
COVID-19 infection (household)	129 (16.1)	74 (17.0)	35 (25.2)	17 (13.5)	3 (2.9)	< 0.001
Missing values	9	6	3	0	0	
Clinical risk factors for severe COVID-19 infection						
Cardiovascular disease	109 (13.7)	46 (10.8)	14 (10.1)	34 (27.0)	15 (14.6)	< 0.001
Diabetes	85 (10.7)	21 (4.9)	27 (19.4)	13 (10.3)	24 (23.3)	< 0.001
Weight excess	79 (9.9)	29 (6.8)	22 (15.8)	16 (12.7)	12 (11.7)	0.010
Chronic lung disease	40 (5.0)	24 (5.6)	1 (0.7)	11 (8.7)	4 (3.9)	0.022
Chronic kidney disease	29 (3.7)	15 (3.5)	8 (5.8)	5 (4.0)	1 (1.0)	0.272
≥ 1 co-morbidity	234 (29.5)	96 (22.5)	52 (37.4)	57 (45.2)	29 (28.2)	< 0.001
Missing values	18	15	3	0	0	
Views on COVID-19 risks and vaccination						
High self-perceived risk of severe COVID-19 infection	208 (26.2)	95 (22.0)	35 (25.7)	42 (33.9)	36 (35.0)	0.008
Missing values	18	10	6	2	0	
Positive views on vaccination in general	605 (77.3)	300 (70.6)	126 (94.0)	98 (79.0)	81 (81.0)	< 0.001
Missing values	29	16	8	2	3	
Positive views on COVID-19 vaccination	445 (56.5)	218 (51.1)	104 (77.6)	79 (63.7)	44 (42.7)	< 0.001
Missing values	24	14	8	2	0	
Sources of information about COVID-19 vaccines						
Traditional media (TV, radio, web)	626 (79.3)	329 (76.9)	109 (82.0)	104 (83.2)	84 (81.6)	0.309
Social media	361 (45.8)	189 (44.2)	36 (27.1)	56 (44.8)	80 (77.7)	< 0.001
Community networks	214 (27.1)	99 (23.1)	6 (4.5)	34 (27.2)	75 (72.8)	< 0.001
Other	33 (4.2)	25 (5.8)	0 (0)	7 (5.6)	1 (1.0)	0.007
Missing values	23	13	9	1	0	

Barriers to and preferred place for vaccination

Although perceptions about accessibility did not vary by city, demand ranged widely and was lowest (14.6%) among participants living in Paris. Respondents who did not believe that COVID-19 vaccination would be available to undocumented migrants reported lack of health insurance or card as the main barrier to access. Overall, most participants who intended to get vaccinated preferred to do so at a hospital (73.5%) (Tables 3 and 4).

Table 20: Perceived barriers to accessing to COVID-19 vaccination in participants mentioning vaccination being not accessible

	Total N = 110, n (%)	Geneva N = 61, n (%)	Baltimore N = 25, n (%)	Milan N = 15, n (%)	Paris N = 9, n (%)
Lack of insurance/health card (National Health System)	57 (51.8)	32 (52.5)	14 (56.0)	9 (60.0)	2 (22.2)
High cost	25 (22.7)	17 (27.9)	2 (8.0)	3 (20.0)	3 (33.3)
Lack of eligibility to enroll in vaccination program	18 (16.4)	8 (13.1)	1 (4.0)	5 (33.3)	4 (44.4)
Not knowing where to go	27 (24.5)	13 (21.3)	9 (36.0)	3 (20.0)	2 (22.2)
Other reasons	13 (11.8)	6 (9.8)	0 (0)	5 (33.3)	2 (22.2)
Missing values	0	0	0	0	0

Table 21: Preferred place for COVID-19 vaccination

	Total N = 327, n (%)	Geneva N = 168, n (%)	Baltimore N = 79, n (%)	Milan N = 65, n (%)	Paris N = 15, n (%)
Hospital	236 (73.5)	144 (87.8)	40 (50.6)	39 (60.9)	13 (92.9)
Public health/community clinic	65 (20.2)	31 (18.9)	17 (21.5)	16 (25.0)	1 (7.1)
Private physician	20 (6.2)	4 (2.4)	3 (3.8)	11 (17.2)	2 (14.3)
Pharmacy	37 (11.5)	17 (10.4)	6 (7.6)	9 (14.1)	5 (35.7)
Charity	65 (20.2)	22 (13.4)	16 (20.3)	19 (29.7)	8 (57.1)
Other	10 (3.19)	4 (2.4)	2 (2.5)	4 (6.3)	0 (0)
Missing values	6	4	0	1	1

Factors associated with perceived accessibility of COVID-19 vaccination

In univariate and multivariate analysis, female gender was the only factor positively associated with self-perceived accessibility to COVID-19 vaccination overall while participants originating from the Americas or recruited in Baltimore tended to be more confident about accessibility (Table 5).

Table 22: Factors associated with perceived accessibility of COVID-19 vaccination in regression analysis

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p-value	OR (95% CI)	p- value
Study site Geneva	Reference		Reference	
Baltimore	0.75 (0.45-1.25)	0.276	0.56 (0.30-1.03)	0.063
Milan	1.20 (0.65-2.19)	0.562	1.07 (0.56-2.06)	0.838
Paris	1.70 (0.81-3.54)	0.160	2.24 (0.86-5.83)	0.100
Gender female	1.57 (1.04-2.35)	0.030	1.62 (1.03-2.56)	0.038
Age (per additional year)	1.01 (0.99-1.03)	0.272	1.01 (0.99-1.03)	0.511
Region of origin Europe	Reference		Reference	
Africa	1.82 (0.78-4.23)	0.165	1.64 (0.66-4.05)	0.286
Americas	1.77 (0.90-3.46)	0.095	1.97 (0.93-4.16)	0.075
Eastern Mediterranean	2.56 (0.91-7.25)	0.225	2.13 (0.71-6.36)	0.175
South-East Asia	1.12 (0.40-3.13)	0.827	0.84 (0.25-2.79)	0.773
Western Pacific	1.72 (0.72-4.06)	0.220	1.39 (0.55-3.48)	0.484
≥1 clinical risk factors	1.24 (0.79-1.97)	0.352	1.18 (0.70-2.00)	0.533
High self-perceived risk of severe COVID-19	0.89 (0.55-1.42)	0.615	0.90 (0.54-1.49)	0.681
COVID-19 infection (self)	1.06 (0.60-1.88)	0.841	1.01 (0.52-1.99)	0.968
COVID-19 infection (household)	0.88 (0.51-1.50)	0.637	0.90 (0.47-1.70)	0.737
Positive views on vaccination in general	1.39 (0.88-2.20)	0.158	1.33 (0.74-2.39)	0.336
Positive views on COVID-19 vaccination	1.14 (0.76-1.72)	0.518	1.18 (0.71-1.98)	0.519
Information through traditional media (TV, radio, web)	1.19 (0.73-1.93)	0.494	1.20 (0.69-2.11)	0.515
Information through social media	1.29 (0.85-1.94)	0.234	1.21 (0.75-1.96)	0.427
Information through community network	1.22 (0.76-1.97)	0.409	1.00 (0.58-1.74)	0.998
Information through other source	2.39 (0.57-10.11)	0.236	3.13 (0.70-14.08)	0.137

When the analysis was conducted at study site level (Annex 2), the strength of association with covariates associated with perceived availability were different in each location . For instance, Latin American origin in Geneva and information through social media or community network in Paris showed statistically significant associations.

Factors associated with demand for COVID-19 vaccination

Overall, demand for vaccination was associated with a variety of factors (Table 6). Before adjustment, living in the US and Italy, female gender, older age, comorbidity, perception of being at risk of severe COVID-19, positive views on vaccination including COVID-19 and mentioning traditional media as the main source of information were all associated with more chance to demand the vaccination.

On the other hand, living in France and using social media and community networks as the preferred sources of information were negatively associated with demand. After adjustment, increasing age, the presence of co-morbidities, and positive views about vaccination in general and COVID-19 in particular were all significantly associated with increased demand for vaccination, while living in France and relying on community network to get informed were associated with lower demand. Of note, the preference for social media lost its significant negative association with demand after adjustment. Although not statistically significant, there was a trend toward more demand among African migrants.

In Geneva and Baltimore, positive views about vaccines were strongly associated with demand (Appendix). In Paris and Milano, the main predictors were the sources of information. Both social media in Milano and community networks in Paris were negatively associated with demand.

Table 23: Factors associated with demand for COVID-19 vaccination in regression analysis

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p-value	aOR (95% CI)	p-value
Study site Geneva	Reference		Reference	
Baltimore	2.24 (1.51-3.33)	<0.001	0.97 (0.56-1.68)	0.920
Milan	1.70 (1.14-2.54)	0.009	1.18 (0.66-2.09)	0.578
Paris	0.26 (0.15-0.47)	<0.001	0.15 (0.06-0.38)	<0.001
Gender female	1.43 (1.07-1.92)	0.016	1.23 (0.80-1.88)	0.344
Age (per additional year)	1.04 (1.02-1.05)	<0.001	1.02 (1.00-1.04)	0.019
Region of origin Europe	Reference		Reference	
Africa	0.75 (0.38-1.46)	0.396	2.73 (0.93-8.02)	0.069
Americas	1.62 (0.94-2.80)	0.085	0.85 (0.36-1.96)	0.695
Eastern Mediterranean	0.93 (0.45-1.93)	0.852	1.93 (0.63-5.86)	0.247
South-East Asia	0.38 (0.15-1.01)	0.052	0.45 (0.12-1.65)	0.231
Western Pacific	0.90 (0.46-1.78)	0.769	0.69 (0.26-1.87)	0.467
≥ 1 co-morbidity	1.91 (1.40-2.61)	<0.001	1.77 (1.10-2.84)	0.018
High self-perceived risk of severe COVID-19	1.46 (1.06-2.01)	0.019	1.26 (0.81-1.96)	0.315
COVID-19 infection (self)	1.37 (0.92-2.05)	0.124	1.23 (0.66-2.27)	0.514
COVID-19 infection (household)	1.23 (0.84-1.79)	0.292	0.84 (0.48-1.49)	0.557
Positive views on vaccination (general)	32.5 (14.2-74.4)	<0.001	12.9 (5.17-32.22)	<0.001
Positive views on vaccination (COVID-19)	16.70 (11.2-24.8)	<0.001	9.70 (6.08-15.47)	< 0.001
Information through traditional media (TV, radio, web)	2.25 (1.53-3.29)	<0.001	1.28 (0.75-2.18)	0.360
Information through social media	0.47 (0.35-0.62)	<0.001	0.84 (0.55-1.28)	0.410
Information through community network	0.47 (0.33-0.65)	<0.001	0.61 (0.38-1.00)	0.049
Information through other source	0.30 (0.12-0.73)	0.008	0.44 (0.13-1.43)	0.170
Self-perceived accessibility to COVID-19 Vaccination	1.19 (0.78-1.81)	0.421	1.08 (0.61-1.92)	0.799

Discussion

This study shows that during the early phase of the COVID-19 immunization program in four cities in Europe and the US, most undocumented migrants believed the COVID-19 vaccine would be available to them, but fewer intended to get vaccinated. During this period, participants listed traditional media as the most common source of information, followed by social media and community networks. Although perceptions about vaccination in general were positive, they were much lower for COVID-19 vaccination. We found that factors associated with perceived availability of and demand for COVID-19 vaccination diverged across study sites, reflecting differences in samples, local health policies and cultural preferences. This highlights the importance of collecting data at local level in order to tailor responses.

These findings provide insights about the factors underlying vaccine hesitancy among undocumented migrants during the initial phase of the vaccination program and can help strengthen it as currently ongoing as well as inform the early response for future initiatives. Traditional media appears to play an important role at the early stage and positive views about general immunization programs should be leveraged through community engagement and messaging in various languages to address issues of particular concern to undocumented migrants, such as safety of the COVID-19 vaccines, confidentiality, and implications on immigration status.

The high confidence in COVID-19 vaccination access among undocumented migrants is telling given their frequent exclusion from many public health benefits. This is reassuring given the legitimate concern that access to vaccination would be limited for this population. Early in the vaccination roll-out, qualitative research among primarily female migrant farmworkers in the US and migrants with precarious immigration status in the UK showed that misinformation and lack of awareness about entitlements, including access to COVID-19 vaccines, could present substantial barriers to immunization programs[127], [128].

In our study, women were more likely to endorse access than men. This could be related to increased familiarity with the vaccination programs and overall health system through the use of

reproductive health services and as traditional caregivers for children[129].Participants thinking vaccine would not be available to them mentioned the lack of registration within the healthcare system as the predominant reason, more than financial, eligibility or practical issues. This may reflect how migrants in precarious legal situation internalize structural barriers restricting their agency to satisfy their essential needs [130]. Of interest, most participants reported hospitals as their preferred place for vaccination. This may reflect concern about vaccine safety requiring specialized care and surveillance and the perception that public hospitals are more accessible and secure regarding the management of personal data than private clinics.

Previous studies have indeed shown how migrants used camouflage to avoid detection by immigration authorities and the importance of safe places [131]. The gap between accessibility and demand is concerning. One possible explanation might pertain to the timing of the survey. Indeed, in all study locations, the COVID-19 incidence and death toll had sharply dropped by the beginning of the study which may have lessen the feeling of urgency for vaccination. Additionally, at the same time in all four countries, there were widespread public debates about the mRNA-based vaccines short and long-term safety that may have fueled hesitancy. Indeed, this may contribute to explain the discrepancy between reported confidence in vaccines in general as compared to COVID-19 vaccines in particular. In future studies, longer period of observation may help identify fluctuation on the perception of the risks and therefore of hesitancy associated with epidemiological fluctuations and the adoption by the population of scientific and lay information about new vaccine technologies.

In our study, there was regional variability, with the lowest demand among participants from Paris. Information from community networks tended also to be associated with low demand for vaccination and was more common in Paris, highlighting the need for targeted approaches for different communities. In Paris, the level of literacy (though not measured) may have been lower, given that most respondents could not fill in the questionnaire themselves but had to be helped. This would impact on the potential source of information: information through community networks is more easily accessible in case of language barriers. Also, the second most common source of information was social media, in which content is uncontrolled, opening the debate on

how to use social media to harness vaccine hesitancy. Higher demand for vaccination among older people and those with co-morbidities is consistent with global trends and may reflect the risk-benefit calculus for people at higher risk of hospitalization and death from COVID-19.

In all four sites, only one quarter to a third of participants reported concern about the risk of a severe infection. These low proportions may be related to the overall young age of participant and likely to the comparable proportion of those reporting suffering multiple chronic infections. Interestingly, high self-perceived risk of COVID-19 or prior COVID-19 infection were not associated with demand for vaccination, perhaps because this includes mild cases of the disease.

Intention to get vaccinated against COVID-19 has evolved over time. The successful implementation of large-scale immunizations programs has encouraged many previously hesitant individuals to get vaccinated, but misinformation and fake news continue to fuel mistrust and slow progress in terms of immunization coverage in many settings. In our study, only two in five individuals reported they would get vaccinated if the COVID-19 vaccine was offered to them. Although comparison with other groups is difficult due to heterogeneity of methods and timing, hesitancy appears to be higher in our sample compared to the general adult population in the countries studied.

For example, in a survey conducted in Italy in December 2020, 82% of adults reported willingness to get vaccinated compared to 52% of our study participants from Milan [132]. Similarly, in a survey conducted in France in June 2020, 71.8% of participants reported they would accept vaccination compared to only 14.6% of our Paris participants [133]. An international cross-sectional survey conducted between September 2020 and January 2021, however, showed lower intention to get vaccinated among participants from France (49.2%) [134]. Of note, all these surveys were conducted online, with likely bias towards higher educational and socioeconomic status. Specific data on undocumented migrants is very limited, but in a survey conducted in the US in late April 2021, 68% of respondents classified as potentially undocumented reported that they had either been vaccinated or planned to get vaccinated [135].

This study has several limitations. Participant recruitment was nonrandom and occurred in health facilities serving undocumented migrants, thereby involving a non-representative sample population of neither the health facilities' clients nor undocumented migrants at large, and therefore limiting the generalizability of our findings. Specifically, recruitment in healthcare setting may have biased the perception about vaccine accessibility by selecting people with better ability to navigate the healthcare system. Studies conducted in the community would bring important complementary information to our findings. Moreover, differences in sampling strategies and participants sociodemographic characteristics imply limitations in comparability among locations. Furthermore, the questionnaire was translated in 8 languages and translators were not systematically available during questionnaire administration, hence it is possible that participants speaking a different language had a limited understanding about the questionnaire, thus introducing an information bias and limiting response accuracy. Confidence about access to the COVID-19 vaccine and desire to be vaccinated may differ for undocumented migrants who have not interacted with the health system in their country of residence. Nonetheless, approximately half of respondents in our sample identified lack of health insurance/health card as a major barrier to COVID-19 vaccination. Although concerns about immigration have been shown to dampen healthcare utilization for COVID-19 services among undocumented migrants[136], we did not specifically ask whether worries about immigration repercussions impacted demand. In our study, public hospitals or clinics were identified as preferred sites for vaccination among those intending to get vaccinated, but we did not collect information about trust in public institutions among vaccine hesitant participants. Finally, for efficiency purpose, we build the questionnaire using a stringent selection of items previously shown to influence vaccine hesitancy but we cannot claim to cover all areas underlying participants' assessment of the risk-benefit balance for COVID-19 vaccination.

Conclusions

Our study showed a substantial gap between undocumented migrants' perceptions about access to COVID-19 vaccines and demand for vaccination. The World Health Organization, UNICEF, the UN High Commissioner for Refugees, the European Centre for Disease Prevention and Control

(ECDC) and the Council of Europe have issued recommendations urging access to COVID-19 vaccination to all vulnerable populations, including low-income countries, undocumented migrants, and refugees[119]. Our results show that building trust and confidence in COVID-19 vaccination is as important as promoting access to tackle hesitancy in this group. Information and promotion of vaccination should particularly focus on men, younger migrants and those with low clinical risks highlighting both individual and collective benefits and reassuring about vaccines safety.

Given the marginalization and criminalization of undocumented migrants, this may not be simple and requires tailored local solutions. [127]Our data suggests that during the first phase of a new vaccination program as for COVID-19, traditional media is an important source of information and communities need to be engaged to leverage existing confidence in general vaccination programs to reduce hesitancy. Social media play an important role on how migrants balance risks and benefits and could represent an avenue for disseminating objective information and ressources. Community engagement is also important to adequately inform and guide community networks, which can be influential but may undermine vaccination efforts unless equipped with official and verified information. Innovative strategies to foster trust in the equitable access to vaccine for everyone and to ensure a high uptake in all groups though multi-pronged tailored intervention may help better controlling the ongoing COVID-19 pandemic. Future research should include the monitoring of hesitancy in this group over longer periods in order to adapt communication strategies and the impact of health promotion interventions using different channels of communication such as social media and community interventions.

Annex 1: Participant questionnaire

<u>Questionnaire on intent to be immunized against Covid-19 amongst undocumented migrants</u>

In order to properly meet your health needs, we would like to hear your opinion on the COVID-19 vaccination. This information is anonymous and confidential.

Please tick the correct answer (s) ☒

1. Gender

    a. ☐ Female

    b. ☐ male

2. Age

3. Country of birth

4. Have you suffered from a COVID-19 infection (one choice)

    a. ☐ No

    b. ☐ Yes probably but I haven't been tested

    c. ☐ Yes and I have been tested

5. If yes, when (month/year)?

6. Has somebody living at the same place as you (family or friend) suffered from a COVID-19 infection (one choice)

    a. ☐ No

    b. ☐ Yes probably but she/he hasn't been tested

    c. ☐ Yes and she/he has been tested

7. Do you have any of the following medical conditions that could put you at risk for severe COVID-19 infection (multiple choices)

a. ☐ High blood pressure (hypertension) or a cardiac (heart) condition

b. ☐ Diabetes

c. ☐ Excessive weight

d. ☐ Chronic disease of the lungs

e. ☐ Chronic disease of the kidneys

f. ☐ No

g. ☐ I don't know

8. What do you think is the risk to your health related to COVID-19 (multiple choices)

a. ☐ I think the risk is too low to worry

b. ☐ I follow the recommendations about protection, this is sufficient to be protected

c. ☐ I don't think I am at risk of a severe infection

d. ☐ I already got COVID-19 so there is no more risk

e. ☐ I prefer being infected to develop my own immunity

f. ☐ I am worried about developing a severe form of COVID-19

g. ☐ I don't know

9. Do you believe that migrants/persons in your situation will have access to the COVID-19 vaccines here in Italy/Switzerland/France/The USA (one choice)

a. ☐ Yes

b. ☐ No

c. ☐ I don't know

10. If no, for what reasons (multiple choices)

a. ☐ Lack of health insurance/health card

b. ☐ High cost

    c.   ☐ Lack of right to enroll into immunization programs

    d.   ☐ Don't know where to go

    e.   ☐ Other reason

11. If the vaccine is offered to you, would you like to get immunized against COVID-19 (one choice)

    a.   ☐ Yes, no doubt

    b.   ☐ Probably yes

    c.   ☐ Probably no

    d.   ☐ No

    e.   ☐ I haven't decided yet

12. If yes, where could you receive the vaccine (multiple choices)

    a.   ☐ Hospital

    b.   ☐ Private doctor

    c.   ☐ Pharmacy

    d.   ☐ Community organization, charity

    e.   ☐ Public health clinic

    f.   ☐ Other

13. What is your point of view about vaccines in general (multiple choices)

    a.   ☐ I trust vaccines

    b.   ☐ I believe it will protect me

    c.   ☐ I am against vaccines in general

    d.   ☐ I prefer alternative remedies

    e.   ☐ I believe I can resist to infections without vaccines

    f.   ☐ If I have to suffer an infection, vaccine won't help for that

14. What is your point of view about the COVID-19 vaccines (multiple choices)

    a. ☐ I trust the COVID-19 vaccine

    b. ☐ I believe it will protect me

    c. ☐ I don't trust in vaccines using genetic material

    d. ☐ I am afraid of negative effects

    e. ☐ I think it won't protect me long enough

    f. ☐ I don't want to receive two doses

    g. ☐ I already had COVID-19 so I don't think I need it

15. How do you access to information about COVID-19 vaccines (multiple choices)

    a. ☐ TV, radio, newspapers in Italy/Switzerland/France/The USA

    b. ☐ TV, radio, newspapers from my country of origin

    c. ☐ Websites of the hospital/health authority in Italy/Switzerland/France/The USA

    d. ☐ Website of the government in Italy/Switzerland/France/The USA

    e. ☐ Social media (Facebook, YouTube, Instagram, WhatsApp, etc.)

    f. ☐ Friends and relatives

    g. ☐ Other

Thank you very much for your participation

Annex 2: Regression analysis, by study site

Self-perceived accessibility to vaccination

Regression analysis stratified by study site for factors associated with self-perceived accessibility to COVID-19 immunization programs. The univariate and multivariate analysis were repeated by applying a procedure of multiple imputation for missing values (100 imputations).

Geneva (N=441)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	1.36 (0.78-2.35)	0.278	1.20 (0.64-2.27)	0.571
Age (increase by 1 year)	1.01 (0.99-1.04)	0.286	1.01 (0.99-1.04)	0.413
≥1 co-morbidity	1.34 (0.67-2.68)	0.413	1.07 (0.49-2.34)	0.862
High self-perceived risk of COVID-19	0.78 (0.39-1.56)	0.479	1.00 (0.47-2.12)	0.993
COVID-19 infection (self)	1.41 (0.69-2.89)	0.345	0.58 (0.25-1.33)	0.198
COVID-19 infection (household)	1.12 (0.53-2.36)	0.769	1.09 (0.45-2.63)	0.849
Positive views on Immunization (general)	1.66 (0.94-2.94)	0.081	1.68 (0.75-3.78)	0.209
Positive views on Immunization (COVID-19)	1.16 (0.67-2.00)	0.601	0.86 (0.41-1.82)	0.693
Information through traditional media (TV, radio, web)	1.58 (0.86-2.90)	0.137	1.94 (0.95-3.95)	0.069
Information through social media	1.13 (0.65-1.99)	0.664	1.35 (0.70-2.61)	0.377
Information through community network	0.93 (0.49-1.78)	0.837	0.87 (0.43-1.74)	0.689
Information through other source	3.53 (0.47-26.73)	0.222	5.04 (0.62-41.27)	0.132
Region of origin (WHO)				
Europe	Ref.		Ref.	
Africa	1.84 (0.67-5.00)	0.235	1.86 (0.65-5.36)	0.249
Americas	3.17 (1.41-7.15)	0.005	2.68 (1.13-6.35)	0.025
Eastern Mediterranean	3.27 (0.82-13.09)	0.093	2.78 (0.67-11.65)	0.161
Asia	2.09 (0.22-19.86)	0.523	2.61 (0.25-26.82)	0.420
Western Pacific	2.46 (0.97-6.20)	0.057	1.78 (0.65-4.87)	0.260

Baltimore (N=142)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	2.29 (0.93-5.66)	0.072	1.70 (0.60-4.80)	0.317
Age (increase by 1 year)	0.97 (0.93-1.02)	0.239	0.96 (0.91-1.01)	0.105
≥1 co-morbidity	1.37 (0.54-3.43)	0.507	1.96 (0.65-5.84)	0.230
High self-perceived risk of COVID-19	0.70 (0.24-2.03)	0.513	2.69 (0.67-10.75)	0.161
COVID-19 infection (self)	0.63 (0.20-2.00)	0.434	3.31 (0.59-18.61)	0.174
COVID-19 infection (household)	0.87 (0.33-2.32)	0.786	0.72 (0.17-2.96)	0.648
Positive views on Immunization (general)	1.50 (0.28-7.90)	0.635	1.28 (0.20-8.11)	0.794
Positive views on Immunization (COVID-19)	1.46 (0.54-3.90)	0.452	2.12 (0.67-6.65)	0.199
Information through traditional media (TV, radio, web)	0.56 (0.15-2.05)	0.380	0.62 (0.09-4.45)	0.638
Information through social media	2.18 (0.69-6.87)	0.182	2.42 (0.49-11.99)	0.278
Information through community network	0.20 (0.04-1.04)	0.056	0.09 (0.01-0.76)	0.027
Information through other source	-		-	
Region of origin (WHO) Europe Africa Americas Eastern Mediterranean Asia Western Pacific	-		-	

Milan (N=126)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	3.65 (1.20 -11.08)	0.023	2.30 (0.38-13.89)	0.317
Age (increase by 1 year)	1.03 (0.99-1.07)	0.191	0.99 (0.94-1.05)	0.759
≥1 co-morbidity	0.93 (0.31-2.74)	0.893	1.34 (0.25-7.27)	0.734
High self-perceived risk of COVID-19	1.86 (0.62-5.55)	0.266	0.41 (0.09-1.86)	0.247
COVID-19 infection (self)	0.72 (0.09-6.04)	0.761	1.06 (0.06-18.00)	0.965
COVID-19 infection (household)	0.58 (0.15-2.32)	0.441	0.40 (0.05-3.08)	0.376
Positive views on Immunization (general)	0.53 (0.11-2.50)	0.421	1.42 (0.13-15.93)	0.774
Positive views on Immunization (COVID-19)	1.24 (0.40-3.67)	0.730	2.14 (0.37-12.58)	0.398
Information through traditional media (TV, radio, web)	1.28 (0.33-5.00)	0.722	-	-
Information through social media	0.67 (0.23-1.98)	0.468	0.38 (0.08-1.94)	0.246
Information through community network	1.03 (0.30-3.47)	0.967	2.43 (0.36-16.58)	0.365
Information through other source	0.80 (0.09-7.18)	0.845	0.10 (0.00-2.12)	0.138
Region of origin (WHO)				
Europe	Ref.		Ref.	
Africa	-	-	-	-
Americas	0.46 (0.38-0.58)	<0.001	0.53 (0.05-5.92)	0.603
Eastern Mediterranean	0.30 (0.22-0.40)	<0.001	1.27 (0.03-50.44)	0.897
Asia	0.01 (0.01-0.01)	<0.001	-	-
Western Pacific	-	-	-	-

Paris (N=103)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	1.56 (0.31 -7.98)	0.592	2.93 (0.18-47.09)	0.449
Age (increase by 1 year)	1.03 (0.96-1.11)	0.375	1.09 (0.97-1.24)	0.156
≥1 co-morbidity	1.41 (0.28-7.22)	0.680	0.40 (0.03-6.26)	0.517
High self-perceived risk of COVID-19	0.92 (0.22-3.94)	0.915	0.31 (0.03-3.24)	0.329
COVID-19 infection (self)	-	-	-	-
COVID-19 infection (household)	-	-	-	-
Positive views on Immunization (general)	2.40 (0.54-10.62)	0.248	15.52 (0.76-316.86)	0.075
Positive views on Immunization (COVID-19)	1.55 (0.37-6.56)	0.554	1.41 (0.11-17.50)	0.788
Information through traditional media (TV, radio, web)	0.53 (0.06-4.49)	0.559	0.15 (0.00-5.14)	0.293
Information through social media	0.99 (0.19-5.14)	0.994	51.34 (1.02-2576.27)	0.049
Information through community network	3.86 (0.96-15.59)	0.058	10.37 (1.25-86.27)	0.030
Information through other source	-	-	-	-
Region of origin (WHO)				
Europe	Ref.		Ref.	
Africa	-	-	4.06 (0.06-11.31)	0.513
Americas	1.00 (0.02-50.40)	1.000	0.03 (0.00-11.31)	0.251
Eastern Mediterranean	13.5 (0.60-305.29)	0.102	15.73 (0.26-936.44)	0.186
Asia	24 (0.79-732.38)	0.068	94.05 (0.54-16348.27)	0.084
Western Pacific	-	-	-	-

Demand for COVID-19 vaccination

Regression analysis stratified by study site for factors associated with demand for COVID-19 immunization programs. The univariate and multivariate analysis were repeated by applying a procedure of multiple imputation for missing values (100 imputations).

Geneva (N=441)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	1.08 (0.72-1.62)	0.709	1.23 (0.69-2.18)	0.484
Age (increase by 1 year)	1.03 (1.01-1.05)	0.001	1.02 (1.00-1.05)	0.068
≥1 co-morbidity	1.56 (0.98-2.49)	0.060	1.69 (0.84-3.37)	0.138
High self-perceived risk of COVID-19	1.41 (0.89-2.25)	0.143	1.22 (0.66-2.25)	0.516
COVID-19 infection (self)	1.06 (0.61-1.84)	0.826	0.81 (0.37-1.79)	0.610
COVID-19 infection (household)	1.12 (0.67-1.86)	0.673	1.13 (0.55-2.35)	0.736
Positive views on Immunization (general)	29.26 (11.63-73.60)	<0.001	10.82 (3.81-30.72)	<0.001
Positive views on Immunization (COVID-19)	16.11 (9.60-27.02)	<0.001	8.64 (4.69-15.90)	<0.001
Information through traditional media (TV, radio, web)	1.49 (0.92-2.39)	0.103	0.91 (0.46-1.79)	0.786
Information through social media	0.66 (0.45-0.98)	0.041	0.84 (0.48-1.48)	0.553
Information through community network	0.96 (0.60-1.52)	0.857	0.92 (0.50-1.69)	0.783
Information through other source	0.37 (0.14-1.01)	0.052	0.56 (0.15-2.09)	0.388
Region of origin (WHO)				
Europe	Ref.		Ref.	
Africa	0.98 (0.41-2.35)	0.964	2.16 (0.61-7.71)	0.235
Americas	1.22 (0.60-2.47)	0.586	0.79 (0.29-2.14)	0.641
Eastern Mediterranean	1.74 (0.64-4.69)	0.278	2.09 (0.53-8.33)	0.294
Asia	-	-	0.59 (0.09-3.78)	0.580
Western Pacific	1.01 (0.46-2.22)	0.987	0.61 (0.20-1.86)	0.385
Self-perceived accessibility to COVID-19 Immunization	1.29 (0.72-2.30)	0.392	1.20 (0.55-2.65)	0.647

Baltimore (N=142)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	1.23 (0.59-2.60)	0.582	1.75 (0.59-5.20)	0.311
Age (increase by 1 year)	1.07 (1.02-1.11)	0.002	1.03 (0.97-1.09)	0.282
≥1 co-morbidity	2.56 (1.24-5.67)	0.012	2.10 (0.73-6.08)	0.169
High self-perceived risk of COVID-19	0.65 (0.28-1.49)	0.308	1.30 (0.38-4.50)	0.676
COVID-19 infection (self)	0.67 (0.28-1.58)	0.360	2.57 (0.53-12.57)	0.244
COVID-19 infection (household)	0.70 (0.32-1.51)	0.364	0.37 (0.09-1.50)	0.163
Positive views on Immunization (general)	-	-	-	-
Positive views on Immunization (COVID-19)	15.63 (5.02-48.63)	<0.001	17.17 (4.74-62.16)	<0.001
Information through traditional media (TV, radio, web)	4.82 (1.82-12.75)	0.002	7.12 (0.83-61.16)	0.074
Information through social media	0.49 (0.22-1.06)	0.069	2.40 (0.34-16.98)	0.381
Information through community network	0.13 (0.01-1.13)	0.064	0.09 (0.00-1.71)	0.108
Information through other source	-		-	-

Region of origin (WHO)
    Europe
    Africa
    Americas
    Eastern Mediterranean
    Asia
    Western Pacific
	-	-	-	-

Self-perceived accessibility to COVID-19 Immunization	1.43 (0.60-3.43)	0.419	1.20 (0.55-2.65)	0.647

Milan (N=126)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	0.93 (0.44-1.96)	0.842	1.03 (0.17-6.35)	0.978
Age (increase by 1 year)	1.02 (1.00-1.05)	0.100	1.02 (0.97-1.07)	0.509
≥1 co-morbidity	1.30 (0.64-2.63)	0.469	1.51 (0.36-6.39)	0.574
High self-perceived risk of COVID-19	0.73 (0.34-1.55)	0.410	3.09 (0.68-14.01)	0.144
COVID-19 infection (self)	0.38 (0.10-1.50)	0.167	1.44 (0.11-19.19)	0.782
COVID-19 infection (household)	1.36 (0.48-3.84)	0.559	1.37 (0.17-10.75)	0.764
Positive views on Immunization (general)	-	-	-	-
Positive views on Immunization (COVID-19)	48.21 (13.36-174.0)	<0.001	-	-
Information through traditional media (TV, radio, web)	4.42 (1.51-12.97)	0.007	0.08 (0.00-2.22)	0.136
Information through social media	0.44 (0.22-0.91)	0.027	0.11 (0.02-0.48)	0.004
Information through community network	0.76 (0.34-1.66)	0.487	1.83 (0.37-9.12)	0.463
Information through other source	0.14 (0.02-1.19)	0.072	0.35 (0.01-14.84)	0.583
Region of origin (WHO)				
Europe	Ref.		Ref.	
Africa	4.00 (3.34-4.80)	<0.001	-	-
Americas	1.64 (1.49-1.81)	<0.001	0.57 (0.08-4.27)	0.584
Eastern Mediterranean	1.78 (1.50-2.11)	<0.001	3.02 (0.12-76.35)	0.503
Asia	0.27 (0.21-0.34)	<0.001	0.02 (0.00-4.19)	0.148
Western Pacific	-	-	-	-
Self-perceived accessibility to COVID-19 Immunization	1.29 (0.72-2.30)	0.392	1.02 (0.97-1.07)	0.509

Paris (N=103)

	Univariate analysis		Multivariate analysis	
	OR (CI 95%)	p-value	OR (CI 95%)	p-value
Gender: female	2.33 (2.09-2.61)	<0.001	2.43 (0.31-19.09)	0.397
Age (increase by 1 year)	1.06 (1.05-1.06)	<0.001	1.08 (0.99-1.18)	0.095
≥1 co-morbidity	3.65 (3.26-4.08)	<0.001	1.63 (0.12-21.77)	0.712
High self-perceived risk of COVID-19	0.30 (0.26-0.33)	<0.001	3.21 (0.36-28.34)	0.294
COVID-19 infection (self)	1.40 (1.13-1.74)	0.002	9.40 (0.36-245.25)	0.178
COVID-19 infection (household)	-	-	-	-
Positive views on Immunization (general)	3.65 (0.45-29.65)	0.225	1.33 (0.04-47.30)	0.876
Positive views on Immunization (COVID-19)	3.18 (2.83-3.57)	<0.001	2.70 (0.34-21.30)	0.346
Information through traditional media (TV, radio, web)	-	-	-	-
Information through social media	0.51 (0.46-0.58)	<0.001	1.91 (0.20-18.04)	0.574
Information through community network	0.18 (0.16-0.21)	<0.001	0.09 (0.01-0.61)	0.014
Information through other source	-	-	-	-
Region of origin (WHO) Europe Africa Americas Eastern Mediterranean Asia Western Pacific	-	-	-	-
Self-perceived accessibility to COVID-19 Immunization	0.16 (0.14-0.19)	< 0.001	0.05 (0.00-0.58)	0.017

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