



## Research article

# Effect of access to antenatal care on risk of preterm birth among migrant women in Italy: A population-based cohort study

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## ABSTRACT

**Objective:** To evaluate the association between maternal migration status and preterm birth, and whether a better adherence to antenatal care during pregnancy mitigates the risk of preterm birth.

**Design:** Population-based cohort.

**Setting:** Administrative databases of the Lombardy region, Italy.

**Population:** First singleton births of women aged 15–55 years at 22–42 gestational weeks, between 2016 and 2021.

**Methods:** Assessed the risk of preterm birth (<37 weeks).

**Main outcome measures:** A multivariable logistic regression mediation model calculated the mediation effect of adherence to antenatal care in the association between maternal migrant status and preterm birth and the residual effect not mediated by it. Analyses were adjusted for the socio-demographic and pregnant characteristics of the women.

**Results:** Of 349,753 births in the cohort, Italian nationality accounted for 71 %; 28.4 % were documented migrants and 0.4 % undocumented migrants. Among them, 5.3 %, 6.4 %, and 9.3 % had a preterm birth, respectively. Using deliveries of Italian citizens as referent, migrants had a significantly increased risk of preterm birth (adjusted relative risk: 1.22, 95 % confidence interval: 1.18–1.27). Adherence to antenatal care mediated the 62 % of such risk. We have calculated that adherence to antenatal pathways set to the highest level for the whole population could lead to a 37 % reduction in preterm birth risk.

**Conclusion:** Part of the excess of preterm birth among documented and undocumented migrants in Italy can be explained by a lack of adherence to the antenatal care path despite equal access to National Health care. The adherence of all pregnant women to antenatal care would reduce the risk of preterm birth by about one-third.

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## 1. Introduction

Preterm birth (PTB), defined as birth before 37 completed weeks of gestation, is a significant global health challenge with a complex aetiology; it complicates 6%–16% of pregnancies, with the highest rates in low-income countries [1]. The incidence of PTB varies across populations, but it consistently imposes a substantial burden on healthcare systems and families due to associated morbidities and mortalities for both mothers and infants [2].

While numerous risk factors have been identified, the precise mechanisms underlying PTB remain enigmatic. It is multifactorial in its origin and related to maternal, obstetric and psychosocial features [3]. In recent years, growing attention has been directed towards the potential impact of migration on maternal and child health outcomes. Data from 2017 indicates that the World Health Organization (WHO) European Region housed approximately 90 million international migrants, representing roughly 10% of the total population [4]. Notably, women comprised over half of these migrants, with a significant portion being of childbearing age. Italy specifically reflected this trend. In 2005, a report revealed that half of all migrants residing in Italy were foreign-born women, and over 65% of this female migrant population fell within the reproductive age range [5]. A report by WHO concludes that there is a higher risk of pre- and perinatal adverse events and complications for mothers and children among migrants compared with non-migrant women [3]. Poorer outcomes in pregnancy, among which PTB, are closely related to lower utilization of antenatal care (ANC) but also to ethnicity, country of origin, age, socio-demographic and socio-economic factors [6–8]. Immigrant women often face challenges accessing the healthcare system due to language barriers, living conditions, poverty, illiteracy, economic issues, and cultural differences [9]. However, the specific relationship between migration and PTB requires further investigation.

The ANC is a cornerstone of maternal and child health, with well-established benefits in reducing PTB risk. Adherence to recommended ANC guidelines has been shown to improve pregnancy outcomes and overall maternal well-being [10]. The WHO recommends a minimum of ANC standards to reduce perinatal mortality, improve women's experience of care, and improve communication with and support for pregnant women [10]. In Italy, a national panel of experts, working under the auspices of the Italian Ministry of Health, has established and validated a framework for evaluating integrated care pathways for pregnancy. This framework incorporates a suite of performance indicators that assess the appropriateness and timeliness of obstetric consultations, ultrasound examinations, and laboratory testing [11]. A significant factor contributing to the elevated risk of PTB among Italian citizens is suboptimal adherence to ANC [11]; similar findings have been reported in Australia [12]. In Italy, as in many Western countries, immigrant women face a heightened risk of PTB compared to native-born women [13]. This disparity persists despite the universal access to a cost-free National Health Care system, including prenatal care, also afforded to immigrant women.

In Italy, as in most other Western countries, the risk of PTB is higher among migrants than among national women [13], despite the fact that immigrant women are typically provided with access to the National Health Care system, which covers the care of pregnancy without costs [14].

However, while Italy boasts a relatively low PTB rate compared to some other developed countries, there is still a significant number of cases annually. Data suggests that immigrant populations and women in socioeconomically disadvantaged situations are at higher risk of this condition. Ensuring culturally sensitive and accessible ANC services for this population is crucial in Italy, considering the high proportion of women of childbearing age among female migrants. Strengthening access to high-quality ANC services in Italy is an essential strategy for lowering PTB rates and promoting optimal health outcomes for both mothers and newborns.

To date, limited research has explored the interplay between migration, antenatal care, and PTB. Understanding these relationships is crucial for developing effective interventions to reduce PTB rates among migrant women. Therefore, our study aims to evaluate whether the risk of PTB is affected by migrants' status (documented vs undocumented), and whether adherence to the ANC standards has any mediating effect on PTB.

## 2. Methods

### 2.1. Data source and study cohort

The study cohort consisted of the first singleton births between January 1st, 2016 to December 31st, 2021 in the Lombardy Region, Italy. Lombardy, a region within Italy with approximately ten million residents (16% of the national population), ensures equitable access to healthcare services for all Italian citizens through the National Health Service (NHS). A Healthcare Utilization (HCU) database system facilitates regional management of NHS services. HCU databases capture information on services provided to NHS beneficiaries, encompassing discharge diagnoses, inpatient care from public or private hospitals, outpatient drug prescriptions, specialist visits, and diagnostic examinations. In addition, a database reporting the Certificates of Delivery Assistance is consistently collected in all Italian regions; it provides detailed information on mothers' socioeconomic traits and medical information on pregnancy, childbirth, including gestational age at delivery, and neonate. A unique personal identification code is assigned to all individuals within each region, enabling the record linkage across databases. This facilitates comprehensive tracking of the care pathway for NHS beneficiaries. To safeguard privacy, identification codes are automatically converted into anonymous equivalents, and the conversion table is subsequently deleted to prevent reverse identification. Details of HCU databases in the field of maternal health have been previously reported [15,16].

Using the Certificates of Delivery Assistance database, we have identified the first singleton births within the time frame considered in women aged 15 to 55 with gestational age between 22 and 42 weeks. We excluded pregnancies of mothers who did not have a hospital admission ICD-9 code for deliveries, who had missing socio-demographic or clinical information, and who experienced a

stillbirth (Fig. 1).

The results were reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines [17].

## 2.2. Assessment of exposure variables: italians, documented and undocumented migrant status

Births included in our cohort were classified based on their mother's citizenship (Italian vs migrant). Immigration status was classified as documented (i.e., women with regular residency permits) and undocumented (i.e., women without a residency permit but with temporary permission to receive Italian care) [18]. The geographic area of origin of pregnant women was based on the WHO classification: Africans, Americans, Eastern Mediterranean, Europe, South-East Asian, Western Pacific, and Stateless [19–24]. Italians were considered the reference group.

## 2.3. Assessment of outcome: preterm birth (PTB)

The primary outcome of interest was PTB (i.e., gestational age at delivery less than 37.0 weeks).

## 2.4. Assessment of maternal socio-demographic and clinical characteristics

Information on covariates used for confounding adjustment was obtained from the certificate of delivery assistance registry. Maternal covariates were measured at registration into prenatal care. We considered several baseline maternal characteristics that may affect PTB: socio-demographic variables as a proxy of social vulnerability and acculturation, including maternal age, employment status (i.e., any employment vs unemployment), education level [i.e., low (i.e., none or primary education), intermediate (i.e., secondary education), and high (i.e., high school or more)], and marital status, as well as obstetric characteristics (i.e., parity).

## 2.5. Assessment of potential mediator: antenatal care (ANC) path

The certificate of delivery assistance and the specialist visits and diagnostic exams registry were used to calculate adherence to ANC during pregnancy. Since the mothers' ANC was in the path between exposure of interest (i.e., mothers' nationality) and the outcome of interest (i.e., PTB), we categorized the mothers based on their adherence to the recommended ANC and considered this variable as a potential mediator (Supplementary materials Fig. S1). Promptness and appropriateness of the number and timing of ANC, including prenatal visits, ultrasound exams, and laboratory tests, were considered with respect to the length of pregnancy; in particular: (i) the appropriateness of prenatal visits (i.e., at least five visits during pregnancy and between two and four for those women with a gestational age <27 weeks); (ii) the promptness of prenatal visits (i.e., at least one of the four visits done within the 12th week of

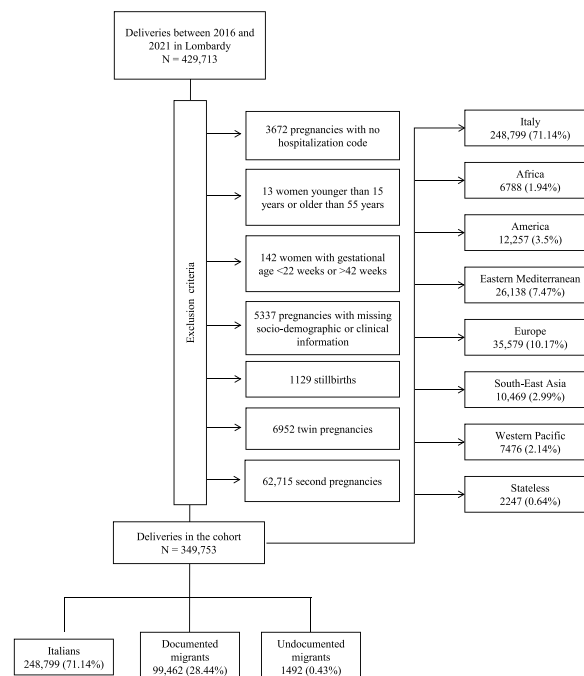


Fig. 1. Flow-chart of exclusion and inclusion criteria.

gestation); (iii) the appropriateness of ultrasound examinations (i.e., at least two examinations during pregnancy, of which at least one within the 12th week of gestation); and (iv) laboratory test appropriateness, evaluating whether appropriate tests were performed as recommended for each pregnancy trimester [11]. Women were classified as adherent if they adhered to all the four recommendations described above.

## 2.6. Statistical analyses

Baseline socio-demographic and obstetric maternal characteristics were compared between those who did and who did not experience PTB. Moreover, the absolute risk of PTB among the above characteristics was assessed and compared using the chi-squared test or trend tests, as appropriate. ANC adherence was assessed according to PTB and mothers' nationality. Chi-square or trend tests were used as appropriate.

We used log-binomial regression models to estimate the relative risk (RR) with 95 % confidence intervals (CIs) for the association between adherence to the recommended ANC and PTB. The same analysis was also performed by country of origin.

To isolate the impact of ANC level on the relationship between maternal nationality and PTB, a mediation analysis was conducted. Using complete ANC adherence as a reference, a multivariate log-binomial regression mediation model decomposed the total effect of maternal nationality on PTB into an indirect effect mediated by ANC and a residual effect not mediated by ANC adherence. Potential variables for inclusion in the analysis were identified through a directed acyclic graph representing the primary effects: the exposure (maternal nationality) on the outcome (PTB) and the mediator (ANC adherence) on the outcome [25]. Factors situated on the causal pathways between these variables were excluded [26]. Percentages of the total effect that are attributed to mediation  $\left(\left(\frac{\text{Indirect Effect}}{\text{Total Effect}}\right)100\%\right)$  and of the total effect eliminated  $\left(\left(1 - \frac{\text{Direct Effect}}{\text{Total Effect}}\right)100\%\right)$  by controlling for the mediator level (i.e., fixing the mediator to the completely adherent level of the ANC) were reported [27–30]. The latter would be interpreted as the “percentage gained” on the risk of PTB if a healthcare intervention could set every woman to be completely adherent to the ANC path.

All models were adjusted by maternal sociodemographic and clinical characteristics (i.e., age at LMP, employment level, education level, marital status, and parity)(Supplementary materials Table S1).

All statistical analyses were performed using SAS software version 9.4 (SAS Institute, Inc., Cary, NC, USA). A two-sided *P*-value of <0.05 was considered significant.

**Table 1**

Socio-demographic characteristics of the study population in relation to preterm birth (PTB). Lombardy, 2016–2021. N = 349,753.

			Prevalence of PTB	p-value <sup>a</sup>
	Term births (N = 330,030)	Preterm Births (N = 19,723)	5.6 %	
	N (%)	N (%)		
Age at LMP in yr. – mean (std)	32.2 (5.5)	32.9 (5.8)		
Age at LMP				<0.0001
15 - 19	3442 (1.01)	212 (1.07)	5.8 %	
20 - 29	97,341 (29.5)	5227 (26.5)	5.1 %	
30 - 39	200,302 (60.7)	11,753 (59.6)	5.5 %	
40 - 49	28,780 (8.7)	2499 (12.7)	8 %	
50 - 55	165 (0.05)	32 (0.16)	16.2 %	
Parity				<0.0001
Nulliparous	189,167 (57.3)	11,575 (58.7)	5.8 %	
Multiparous	140,863 (42.7)	8148 (41.3)	5.5 %	
Employment				<0.0001
Employed	219,559 (66.5)	12,322 (64.5)	5.3 %	
Others	110,471 (33.5)	7401 (37.5)	6.3 %	
Educational level				<0.0001
High	102,662 (31.1)	5235 (26.5)	4.9 %	
Intermediate	139,464 (42.3)	8428 (42.7)	5.7 %	
Low	87,904 (26.6)	6060 (30.7)	6.4 %	
Marital status				0.0824
Married	199,774 (60.5)	11,816 (59.9)	5.6 %	
Others	130,256 (39.5)	7907 (40.1)	5.7 %	
Migration status				<0.0001
Italians	235,550 (71.4)	13,249 (67.2)	5.3 %	
Documented migrants	93,126 (28.2)	6336 (32.1)	6.4 %	
Undocumented migrants	1354 (0.4)	138 (0.7)	9.3 %	

std: Standard deviation; LMP: Last Menstrual Period.

<sup>a</sup> Chi-square test or Trend test as appropriate.

### 3. Results

#### 3.1. Description of the cohort by geographic area of origin

Of 349,753 births that met the inclusion criteria, 248,799 were of Italian women (71 %), 99,462 (28 %) of documented migrants, and 1492 (0.4 %) of undocumented migrants. The geographic area of origin among documented and undocumented migrants also in relation to PTB was quite different (Supplementary materials Table S2). For both, most deliveries occurred to women from Europe (35 % and 36 %, respectively, for documented and undocumented migrants), followed by Eastern Mediterranean, Americas, South-East Asia and Africa in different measures (Supplementary materials Table S2). PTB occurred in 5.3 % of Italian women (13,249/248,799) compared with 6.4 % (6336/99,462) of documented migrant women, and 9.3 % (138/1492) of those with undocumented migrant status (Supplementary materials Tables S3 and S4). Among Italian women, 3.3 % (432/13,249) of preterm births were extremely preterm (i.e., before 28 weeks gestation), 7.9 % (1049/13,249) were very preterm (i.e., 28–32 weeks), and 88.8 % (11,768/13,249) were late preterm. Documented migrant women had a slightly higher percentage of extremely preterm births (266/6336, 4.2 %) compared to Italians with respect to undocumented migrants (5/138, 3.6 %). A similar pattern was observed for very preterm births, with documented migrants having the highest percentage (566/6336, 8.9 %) and undocumented migrants the lowest (8/138, 5.8 %). Moreover, there was a different distribution of PTB in relation to the geographic area of origin among documented and undocumented migrants (Supplementary materials Table S4): documented migrants from the Eastern Mediterranean and Western Pacific (6 %, respectively) and Europe (5.6 %), and undocumented migrants from Western Pacific (5.7 %), had a prevalence of PTB similar to Italians (5.3 %) (Supplementary materials Tables S3 and S4).

#### 3.2. Description of the cohort by preterm birth

The socio-demographic characteristics were quite different between women with preterm vs term births. PTB occurred more frequently in older women, unemployed, and with lower educational attainment. Moreover, there was an increasing trend of PTB rate with increasing maternal age (from 6 % in young women to 16 % in older ones,  $p$ -value for trend  $<0.0001$ ), unemployed condition (5 % in employed vs 6 % in unemployed women,  $p < 0.0001$ ), low education (from 5 % in high to 6 % in low education attainment,  $P < 0.0001$ ), and undocumented migrant status (from 5 % in Italian to 9 % in undocumented women,  $p < 0.0001$ ) (Table 1).

#### 3.3. Description of the cohort by ANC

Table 2 shows the distribution of adherence to the recommended indicators used to measure ANC during pregnancy by PTB and maternal nationality. Despite the quite similar distribution between preterm and term births, there were several differences between Italians, documented, and undocumented migrants. Adherence to ANC decreased with social deprivation (i.e., from Italian to documented and undocumented migrants,  $p$ -value for trend  $<0.0001$ ). The adherence to the indicators related to the promptness and appropriateness of the number and timing of prenatal visits and ultrasound exams decreased from an average of 95 % of adherence for Italians to 86 % for documented migrants and 65 % for undocumented migrants ( $p$ -value for trend  $<0.0001$ ). Similarly, the gap in adherence to the recommended laboratory tests was 65 % for Italian women, 52 % for documented migrants, and 6 % for undocumented migrants ( $p$ -value for trend  $<0.0001$ ).

#### 3.4. Association between mother's nationality, ANC adherence, and preterm birth

Overall, migrant women had an 18 % (95 % CI: 18%–19 %) lower probability of adhering to the ANC path during pregnancy

**Table 2**

Adherence with recommendations for antenatal care by preterm birth and mother's nationality. Lombardy, 2016–2021. N = 349,753.

Process Indicators	Preterm Birth			Migration status			p-value <sup>a</sup>
	Absent (N = 330,030)	Present (N = 19,723)	p-value <sup>a</sup>	Italians (N = 248,799)	Documented (N = 99,462)	Undocumented (N = 1492)	
Appropriateness of prenatal visits	290,108 (87.9)	16,407 (83.2)	<0.0001	223,883 (90)	81,742 (82.2)	890 (59.7)	<0.0001
Promptness of prenatal visits	311,492 (94.4)	18,478 (93.7)	<0.0001	241,581 (97.1)	87,368 (87.8)	1021 (68.4)	<0.0001
Appropriateness of ultrasound examinations	309,728 (93.8)	18,317 (92.9)	<0.0001	240,469 (96.7)	86,597 (87.1)	979 (65.6)	<0.0001
Laboratory test appropriateness			<0.0001				<0.0001
Not adherent	22,415 (6.8)	2956 (15)		15,122 (6.1)	9538 (9.6)	711 (47.7)	
Partially adherent	99,111 (30)	11,475 (58.2)		72,066 (28.9)	37,832 (38)	688 (46)	
Completely adherent	208,504 (63.2)	5292 (26.8)		161,611 (65)	52,092 (52.4)	93 (6.2)	

<sup>a</sup> Chi-square test or Trend test as appropriate.

compared with Italian women (data not shown). In addition, partial and low or null ANC adherence was associated with PTB (adjusted RR 3.93, 95 % CI 3.80–4.06; 3.83, 3.62–4.05, respectively) (Table 3). The association between ANC adherence and PTB risk was confirmed in all countries of origin, suggesting a consistent effect across migrant populations (Supplementary materials Fig. S2). In the mediation path analysis adjusted for the socio-demographic and obstetric maternal characteristics, migrant status remained significantly associated with PTB (aRR 1.22, 95%CI 1.18–1.27); however, the ANC adherence-mediated indirect effect was modest (aRR 1.13, 95%CI 1.12–1.13) or 62 % of the total association (Table 4). We estimated that if all women had a maximum level of complete ANC adherence, 37 % of PTB risk could have been prevented.

## 4. Discussion

### 4.1. Main findings

Migrant women had a 21 % higher risk of PTB than Italian women. This risk was largely attributed to lower rates of ANC adherence among migrants, especially undocumented migrants. Improving ANC for all women could reduce PTB rates by 37 %.

However, factors beyond ANC, such as socioeconomic disparities, cultural barriers, and limited healthcare access, likely contribute to the higher PTB risk among migrant women [31]. Our study also found significant differences in PTB rates among different migrant subgroups. Undocumented migrants experienced the lowest rates of ANC adherence, followed by documented migrants. This was evident in the number and timing of prenatal visits, ultrasound exams, and laboratory tests. These disparities highlight the need for targeted interventions to address the specific challenges faced by migrant women.

## 5. Interpretation

Our analysis further revealed heterogeneity among migrant subgroups in PTB rates. While an increasing trend was observed from Italian to documented and undocumented migrant populations, the distribution of PTB varied according to the migrant's place of birth. Notably, documented migrants from the Eastern Mediterranean, Western Pacific, and Europe exhibited PTB prevalence rates comparable to those of the native Italian population.

The literature on PTB rates among migrant women is inconclusive. A meta-analysis of 11 studies comparing migrant women to native-born women in their host countries revealed inconsistent findings, with overall PTB risk being similar or lower among migrants but exhibiting significant heterogeneity based on maternal region of origin [32]. While women born in Africa and Asia had higher PTB risks, those born in Europe and North Africa had comparable rates, and Latin American-born women experienced lower PTB risks than the majority native-born population in their host countries [33]. Conversely, another meta-analysis using the general receiving-country population as a reference group found improved birth outcomes in migrants, attributed to a "healthy migrant" effect decreasing over time [34]. In our study, none of the migrant groups had lower PTB rates than the Italian population.

Our findings are in line with other European studies: a Norwegian study has shown that women from several geographic areas, including South Asia, East Asia Pacific/Oceania and sub-Saharan Africa, had an increased risk for extreme PTB compared to Norwegian-born women [35]. The same findings were reported in a Swedish study [36]. If a "healthy immigrant" effect exists, it does not seem to apply equally to all ethnic/racial groups. An Italian study reported an increased PTB risk for African women but not for Asian women. The increased risk was not associated with delayed access to ANC, suggesting that the lower PTB rates among migrant European women (western and Eastern Europeans) and the higher PTB rates in Africans could be due to reasons other than socio-demographic factors and a lower social integration [37]. Race is a social construct, not a biological one. The pervasive effects of racism, encompassing structural, institutionalized, and interpersonal forms, as well as implicit and explicit biases, contribute to numerous health inequities, including PTB.

There is a paucity of evidence regarding the effectiveness of ANC programs in improving perinatal health in disadvantaged groups of women [38]. Liu et al., in a population study from Sweden, where access to ANC is free, obtained results similar to ours. They defined arbitrarily having less than 50 % of the expected number of visits as inadequate ANC and observed a lower antenatal usage in pregnant migrant women (16 %, 7 %, and 6 % of inadequate access, respectively, for undocumented, documented and Swedish-born

**Table 3**

Association between antenatal care (ANC) adherence and risk of preterm birth. Lombardy, 2016–2021. N = 349,753. RR= Relative risk; CI= Confidence intervals.

ANC Adherence	Adjusted RR (95 % CI)
Complete	1 (Reference)
Partial	3.93 (3.80–4.06)
Low or null	3.83 (3.62–4.05)

Adherence to ANC was classified as complete if women fully adhered to all the recommendations for ANC; partial if they followed 3 or 4 of the ANC recommendations, and low or null if they followed two or fewer of the ANC recommendations.

RR Adjusted for age, education and employment level, marital status, and parity.



**Table 4**

Association and mediators between the mother's nationality (Italians vs migrants) and preterm birth. Lombardy, 2016–2021. N = 349,753. Mediated and eliminated percentages was calculated in the presence of a significant indirect effect ( $p < 0.05$ ). aRR = adjusted Relative risk; CI= Confidence intervals.

	Total aRR (95 % CI)	Direct aRR (95 % CI)	ANC-mediated Indirect aRR (95 % CI)	% Mediated	% eliminated
Italian	1.00 (Reference)	1.00 (Reference)	1.00 (Reference)	62 %	37 %
Migrant status	1.22 (1.18–1.27)	1.08 (1.04–1.12)	1.13 (1.12–1.13)		

RR Adjusted for age, education and employment level, marital status, and parity.

Total aRR: represents the overall effect of a mother's nationality on the risk of PTB.

Direct aRR: represents the direct effect of a mother's nationality on PTB, excluding the influence of other factors, particularly ANC adherence in this context.

ANC-mediated Indirect aRR: estimates how much of the total effect observed in the total aRR can be attributed to the impact of nationality on a mother's likelihood of adhering to ANC recommendations.

The total aRR provides the overall picture, the direct aRR isolates the direct influence of nationality, and the ANC-mediated indirect aRR helps to understand how ANC adherence plays a role in explaining the observed association.

women) [39]. To note, the overall rate of immigrant pregnant women was lower in Sweden (11 %) than in our study (28 %), and no differences in rates of adherence to ANC and PTB were observed in documented migrants with respect to Swedish women. On the contrary, a higher rate of PTB was observed in undocumented migrants vs Swedish women (OR 1.4), confirming the plausible role of ANC in this outcome.

A systematic review of migrant women's pregnancy, childbirth and maternity care experiences in European countries highlighted the need for innovative maternity care models. These models should go beyond clinical care and address the unique socio-economic and psychosocial challenges of migrant women. Culturally competent healthcare providers, operating within interdisciplinary teams and providing continuous care, are essential to deliver equitable, high-quality maternity care [40]. Moreover, stereotypes and implicit bias in maternity care by healthcare providers can also affect ANC. The migrant population is very heterogeneous, including people with a valid residency status and people with a failed asylum application, an expired visa, or irregular entry. Evidence about health status and health needs is limited for undocumented migrants due to the difficulties of accurate data collection. Pregnancy offers a unique window into the quality of care received by undocumented migrants because delivery inevitably leads to a birth certification and a detailed entry into the regional HCU database. Numerous studies have documented that the status of undocumented migrants amplifies existing health risks and hinders their access to services. While documented migrants enjoy a degree of social protection, undocumented migrants face significant barriers in their interactions with the healthcare system, including individual and institutional discrimination and a lack of social protection [41].

Therefore, to reduce PTB risk in immigrant women, it is essential to explore well-designed multifaceted strategies to address the complex needs of all migrant women and to provide culturally sensitive maternity care [42,43]. Substandard ANC care may cause an increased risk of severe maternal morbidity and mortality, although the effects of different profiles of care have not been substantiated.

Our findings align with a recent review highlighting the tendency of undocumented women to underutilize available healthcare services, resulting in poorer maternal and child health outcomes [43]. Fear of deportation is the primary reason for undocumented migrants to use healthcare services only when severely ill and to access services less frequently than national guidelines recommend. However, such fear is unlikely to have played a role in our study since the migrant women's status is not reported to the Authorities by healthcare workers.

Undocumented migrants are more likely to underutilize maternal and child healthcare services due to factors such as limited knowledge and awareness about legal entitlements and the availability of services, recent arrival in the country, language barriers, social isolation, and poor housing conditions. Such causes of limited access to ANC for undocumented migrants may partially explain why PTB risk was correlated with low adherence to ANC in our study despite the fact that even undocumented migrant women were provided with the same access to the Italian National Health Care system as Italian citizens.

## 6. Strengths and limitations

A strength of our study is the large population-based sample, providing real-world evidence on the relationship between maternal nationality, ethnicity, documented status, and preterm birth. Another strength is the clear and specific migrant definitions that we used. Moreover, the effect on PTB played by adherence to a recommended ANC path validated in the local population, to our knowledge, has never been investigated before.

A limitation of our study is the lack of data on factors such as smoking, alcohol, illicit drug use, previous pregnancy outcomes, health status before pregnancy, and multiple social factors related to migration status that may contribute to both the mechanism underlying PTB and the ANC. Moreover, we could not differentiate between spontaneous and medically indicated PTB; however, it has been shown that both share common risk factors, such as infection, chronic vascular disease, and social deprivation [44]. Finally, the exclusion of mothers who experienced a stillbirth or those with missing information for socio-demographic and/or clinical characteristics could mainly affect less healthy women. However, missing data were infrequent (at most 0.36 % from employment status). Nevertheless, outcome prevalence did not vary between complete and non-complete cases, supporting the hypothesis of missing at random (Supplementary materials Table S5). However, we performed one imputation (i.e. as a rule of thumb, the number of imputed datasets should be at least equal to the percentage of incomplete cases [45]) using the fully conditional specification model for

arbitrary missing patterns that assume the existence of a joint distribution for all variables [46,47]; the main results were completely confirmed (data not shown).

## 7. Conclusions and research implications

Our study reveals a strong association between migrant status and PTB, with undocumented migrants experiencing the highest risk. Inadequate ANC significantly contributes to this disparity. While improving access to and utilization of ANC is crucial, addressing broader social and economic factors affecting migrant women is equally important. Targeted interventions, such as cultural competency training for healthcare providers, language support, and social services integration, are essential to reduce PTB rates among migrant populations.

### Disclosure statement

Giovanni Corrao received research support from the European Community (EC), the Italian Agency of Drug (AIFA), and the Italian Ministry for University and Research (MIUR). He took part to a variety of projects that were funded by pharmaceutical companies (i.e., Novartis, GSK, Roche, AMGEN and BMS). He also received honoraria as member of Advisory Board from Roche.

### Ethics approval and consent to participate

According to the rules from the Italian Medicines Agency (available at: [http://www.agenziafarmaco.gov.it/sites/default/files/det\\_20marzo2008.pdf](http://www.agenziafarmaco.gov.it/sites/default/files/det_20marzo2008.pdf)) retrospective studies without direct contact with patients do not need a written consent to process personal data when they are used for research aims.

### Consent for publication

I confirm that I had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Availability of data and materials

The data that support the findings of this study are available from Lombardy Region, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the Lombardy Region upon reasonable request.

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### CRedit authorship contribution statement

**Anna Cantarutti:** Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Methodology, Investigation, Funding acquisition, Conceptualization. **Francesca Arienti:** Writing – original draft, Visualization, Validation, Investigation. **Riccardo Boroacchini:** Writing – original draft, Formal analysis, Data curation. **Eleonora Genovese:** Writing – original draft, Validation, Investigation. **Sara Ornaghi:** Writing – review & editing. **Giovanni Corrao:** Writing – original draft, Visualization, Validation, Methodology, Investigation, Conceptualization. **Alessandro Ghidini:** Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Conceptualization. **Anna Locatelli:** Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Conceptualization.

### Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Giovanni Corrao received research support from the European Community (EC), the Italian Agency of Drug (AIFA), and the Italian Ministry for University and Research (MIUR). He took part to a variety of projects that were funded by pharmaceutical companies (i.e., Novartis, GSK, Roche, AMGEN and BMS). He also received honoraria as member of Advisory Board from Roche. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2024.e36958>.

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