

Addressing the challenge of preventable neonatal deaths of moderate and late preterm infants in a middle-income country: a population-based study

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Abstract: Moderate and late preterm newborns comprise around 85% of live births <37 weeks gestation. Data on their neonatal mortality in middle-income countries is limited. This study aims to analyze the temporal trend, causes and timing of neonatal mortality of infants with 32–36 weeks gestation without congenital anomalies from 2004–2015 in the population of São Paulo State, Brazil. A database was built by deterministic linkage of birth and death certificates. Causes of death were classified by ICD-10 codes. Among 7,317,611 live births in the period, there were 545,606 infants with 32–36 weeks gestation without congenital anomalies and 5,782 of them died from 0–27 days. Neonatal mortality rate decreased from 16.4 in 2004 to 7.6 per thousand live births in 2015 (7.47% annual decrease by Prais-Winsten model). Perinatal asphyxia, respiratory disorders and infections were responsible, respectively, for 14%, 27% and 44% of the 5,782 deaths. Median time to death was 24, 53 and 168 hours respectively for perinatal asphyxia, respiratory disorders, and infections. Although the neonatal mortality rate of infants 32–36 weeks gestation without congenital anomalies

decreased significantly over the study period, improvement in the quality of perinatal care may further decrease these preventable deaths.

Keywords: Infant newborn; Infant; premature; Neonatal mortality; Cause of death; Developing countries; Epidemiological studies

Introduction

Prematurity was, globally, the leading cause of death among children younger than 5 years in 2019. Among 5.3 million deaths (95% Uncertainty Range 4.92-5.68) of children younger than 5 years, preterm birth complications were responsible for 17.7% (95%UR 16.1-19.5) [1]. In high-income countries, the challenge is the survival without neurodevelopmental impairments of extremely preterm infants (<28 weeks gestation) [2,3], with an increasing interest in nano-preterm infants of 22-23 weeks gestation [4]. In low and middle-income countries, almost 80% of newborn deaths occur among babies who weigh less than 2500g at birth, especially those born preterm [5,6]. Deaths of moderate and late preterm infants (32-36 weeks gestation) [7,8] have a special interest because they are potentially preventable [9].

Rates of preterm birth vary worldwide from 7-14%, but in all countries, the major contributors are births of moderate and late preterm infants [8]. In 2020, in the USA, live births with 32-36 weeks gestation comprised 85% of the 364,487 live births under 37 weeks gestation [10]. Moderate and late preterm infants are both physiologically and developmentally immature and have a higher risk for morbidity compared with infants born at term [7], including difficulties in the cardiopulmonary transition at birth, respiratory disorders, hypoglycemia, jaundice, infections, delayed breastfeeding, along with adverse neurodevelopmental outcomes, and death [11-13].

In 2020, in Brazil, considered an upper middle-income country [14], among 2,730,145 live births, 308,702 were preterm and 86% of them had a gestational age of 32-36 weeks. Moderate and late preterm infants were responsible for 17% of neonatal deaths in 2020 in the country, with a neonatal mortality rate of 12.5 per thousand live births [15]. Among the 27 federative units of the country, São Paulo State, with around 47 million inhabitants, comprises 22% of the Brazilian population [16]. The state has the second-highest Human Development Index of the country (HDI: 0.806 in 2021) [17], but there are important social and economic inequalities, as commonly seen in middle-income countries [18]. The study of neonatal mortality of infants with 32-36 weeks gestation in São Paulo State, who have more than 98% chance of survival in high-income countries [19], may help to understand what are the bottlenecks that need to be overcome in order to increase equity in healthcare. According to Marmot, there are positive reasons for working with cities and regions on action to achieve health equity: locally is where people are born, grow, live, work and age. There is more understanding of the reality of people's lives and the actions necessary to change the social determinants of health [20].

In this context, the objective of this study was to analyze the temporal trend, causes and timing of neonatal mortality of infants with 32-36 weeks gestation without congenital anomalies in the state of São Paulo, Brazil, from 2004 to 2015.

Materials and Methods

This population-based study enrolled all live births with 32-36 weeks gestation without congenital anomalies in the State of São Paulo, Brazil, from 2004 to 2015. Only infants of mothers residing in the state were studied. The vital statistics database was provided by the Fundação SEADE (Foundation of the State System of Data Analysis) based on Civil Registry information. Civil registry of births and deaths covers, respectively, 99.7% and 99.8% of these events in the State of São Paulo, Brazil [21].

Two different sets of data were provided by Fundação SEADE: 1) Data on all born alive infants during the study period retrieved from Certificates of Live Births; 2) Data on all infant deaths during the study period, retrieved from Death Certificates linked to Certificates of Live Births, as previously detailed [22].

During the study period, infants were classified as alive if they survived the neonatal period or as neonatal death if occurring between 0-27 days. The gestational age of 32-36 weeks, as reported in the Live Birth and/or in the Death Certificate, was considered for inclusion. The exclusion criteria were the presence of congenital malformations reported in Live Birth and/or Death Certificates with any Q code, according to the International Classification of Diseases, 10th revision (ICD-10) [23], and/or unknown birth weight.

For the included infants, the following information was collected: year of birth, birth in the hospital setting, maternal age, marital status, maternal education, primiparity, single or multiple pregnancy, number of prenatal visits, type of delivery, sex of the newborn, birth weight, 1st and 5th minute Apgar score. For neonatal deaths, in addition to the items above, the following was collected: age of death and causes mentioned in lines A, B, C, and D of part I and part II of the Death Certificate. The causes of death were classified in four main groups according to the codes written in the Death Certificate [23]: perinatal asphyxia (codes P20, P21, P24.0), respiratory disorders [codes P22, P23, P24 (except P24.0), P25 to P28], infections (codes P35 to P39), and others.

The annual trend of the neonatal mortality rate was analyzed by Prais-Winsten model. This analysis considers the first and last rates and estimates the annual percent change (APC) with 95% confidence intervals (95% CI). APC is classified as: stationary in time, increasing or decreasing. For a non-stationary trend in time, Poisson regression analysis was modeled with year as the only independent variable.

The annual trend of neonatal mortality rate by perinatal asphyxia, respiratory disorders, infections, and other causes was also analyzed by Prais-Winsten model. The proportion of deaths by these causes during the study years was compared by chi-square for trend. Age at death was assessed for each of the four main groups of causes occurring during the 12-year study period using the Kaplan-Meier curve.

The maternal and neonatal variables were compared between newborn infants who died between 0-27 days after birth vs. those who survived for at least 27 days. Poisson multivariate regression was applied with backward analysis adjusted by year of birth to evaluate variables associated with neonatal death. Data are expressed in incidence rate ratio (IRR) and 95% CI.

Statistical analysis was done using Stata/SE 17 (StataCorp, 2021. College Station, TX: StataCorp LLC). The significance level was established at 5%. The study was approved by the Ethics Committee on Human Research of Escola Paulista de Medicina – Universidade Federal de São Paulo, and by the Board of Directors of Fundação SEADE.

Results

From 2004 to 2015, there were 7,317,611 live births in São Paulo State, Brazil. Among them, 545,606 infants with 32-36 weeks gestation without congenital anomalies were included and 5,782 died from 0-27 days (Figure 1), with a mortality rate 10.58 (95% CI 10.32 - 10.84) per thousand live births during the study period.

Figure 1

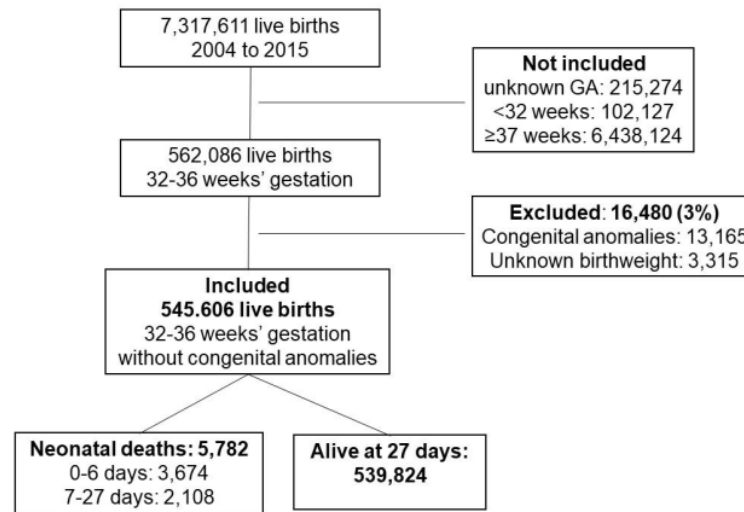


Figure 1. Flow diagram of the included infants in the study.

The mortality rate decreased from 16.4 in 2004 to 7.6 per thousand live births in 2015 (Figure 2). Prais-Winsten model showed an annual decrease of -7.47% (95%CI: -6.35 to -8.58%) in the neonatal mortality rate of infants with 32-36 weeks gestation without congenital anomalies in São Paulo State. The annual trend of neonatal mortality rate, adjusted by Poisson regression analysis with robust variance, showed 46% (95% CI 41-52%) decrease from 2004-2015 ($p < 0.001$).

Figure 2

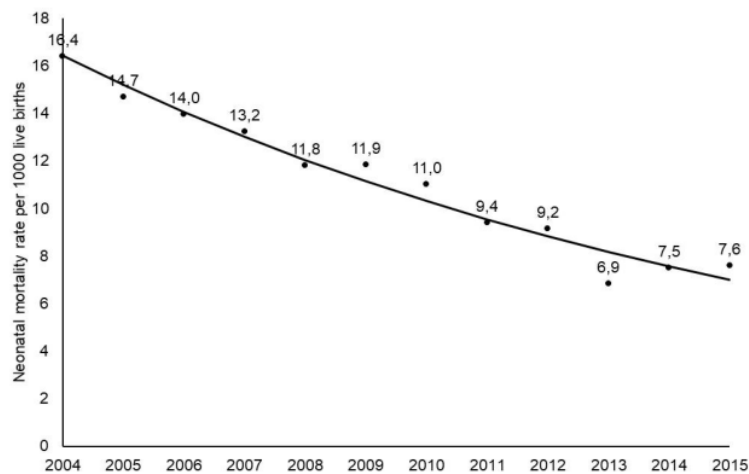


Figure 2. Annual trend of neonatal mortality rate of infants with 32-36 weeks gestation without congenital malformations adjusted by Prais-Winsten model (• observed rate; — expected rate).

The neonatal mortality rate per thousand live births during the study period decreased for all causes of death (Figure 3). The Prais-Winsten model showed an annual

percent reduction of -7.59% (95% CI -9.95 to -5.18) for deaths associated with perinatal asphyxia; -9.66% (-10.78 to -8.53) for deaths associated with respiratory disorders; -7.07% (-9.62 to -4.44) for deaths associated with infections; and -4.18% (-6.46 to -1.84) for other causes of death. During the study period, perinatal asphyxia, respiratory disorders, and infections were responsible, respectively, for 14%, 27% and 44% of the 5,782 deaths. From 2004 to 2015, the yearly proportion of deaths associated with respiratory morbidities have significantly decreased (Table 1).

Figure 3

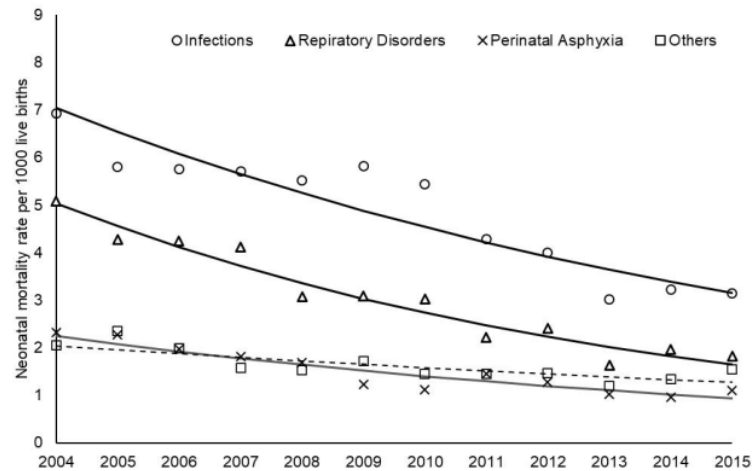


Figure 3. Annual trend of neonatal mortality rate of infants with 32-36 weeks gestation without congenital malformations adjusted by Prais-Winsten model, according to cause of death (o, Δ, □ and × observed rate; — expected rate).

Table 1. Causes of neonatal death of preterm infants with 32-36 weeks gestation without congenital malformations. São Paulo State, Brazil, 2004-2015.

Year	Total number of deaths	Perinatal Asphyxia	Respiratory disorders	Infections	Other
2004	606	14%	31%	42%	13%
2005	575	15%	29%	40%	16%
2006	490	14%	31%	41%	14%
2007	494	14%	31%	43%	12%
2008	441	14%	26%	47%	13%
2009	491	10%	26%	49%	15%
2010	471	10%	28%	49%	13%
2011	420	16%	24%	45%	15%
2012	516	14%	26%	44%	16%
2013	437	15%	24%	44%	17%
2014	427	13%	26%	43%	18%
2015	414	15%	24%	41%	20%
Total	5,782	14%	27%	44%	15%
Chi-square for trend		$p = 0.666$	$p < 0.001$	$p = 0.291$	$p < 0.001$

Information on the maternal and neonatal characteristics were available as follows: 100% for neonatal sex, birthweight, and mortality timing; 98% or more for maternal age, prenatal care, multiple/single gestation, type of delivery, hospital delivery; 78% for marital status, maternal schooling and 1st and 5th Apgar score; and 67% for parity. Comparison of maternal and neonatal characteristics according to death or survival up to 27 days after birth are shown in Table 2. Deliveries occurred in the hospital setting in 99% of infants that survived or died in the neonatal period. The multivariate analysis of variables associated with neonatal death is shown in Table 2. The following variables were independently associated with neonatal death in infants with 32-36 weeks gestation according to Poisson multivariate regression analysis adjusted by year of birth: maternal age <20 years, maternal schooling <12 years, prenatal care <7 visits; cesarean section; male sex; birthweight <2500g, and Apgar score <7 in the 1st minute.

Table 2. Variables associated with neonatal deaths of infants with 32-36 weeks gestation without congenital malformations according to Poisson multivariate regression adjusted by year. São Paulo State, Brazil, 2004-2015.

	Alive at 27 days	Death 0-27 days	Incidence Rate Ratio (95% CI)
Maternal age	n=539,808	n=5,781	
<20 years	16%	21%	1.22 (1.12-1.34)
20-34 years	68%	65%	reference
≥35 years	16%	14%	0.84 (0.75-0.93)
Unmarried	n=424,361	n=4,864	
Yes	52%	60%	1.06 (0.98-1.14)
Schooling	n=422,885	n=4,852	
≤7 years	24%	32%	1.35 (1.20-1.52)
8-11 years	55%	56%	1.22 (1.10-1.36)
≥ 12 years	21%	12%	reference
Primiparity	n=359,937	n=3,964	
Yes	49%	45%	0.80 (0.75-0.87)
Prenatal care	n=531,442	n=5,646	
Zero visits	2%	5%	2.09 (1.77-2.46)
1-3 visits	8%	13%	1.56 (1.39-1.74)
4-6 visits	30%	40%	1.40 (1.30-1.51)
≥ 7 visits	60%	42%	reference
Gestation	n=539,693	n=5,778	
Multiple	13%	12%	0.75 (0.68-0.84)
Delivery	n=539,507	n=5,779	
Cesarean section	61%	63%	1.25 (1.17-1.35)
Sex	n=539,824	n=5,782	
Male	53%	58%	1.27 (1.19-1.36)
Birthweight	n=539,824	n=5,782	
<2500g	49%	81%	3.43 (3.14-3.75)
1st and 5th minute Apgar	n=423,470	n=4,725	
0-6 and 0-6	2%	24%	20.16 (18.44-22.04)
0-6 and 7-10	11%	26%	3.07 (2.83-3.33)
7-10 and 7-10	87%	50%	reference

Median timing of mortality for all 5,782 neonatal deaths was 96 hours (95%CI 96-98) after birth. Regarding the median time of death according to cause: perinatal asphyxia 24 hours (24-24); respiratory disorders 53 hours (48-66); infections 168 hours (156-168); and other 96 hours (75-98) (Figure 4).

Figure 4

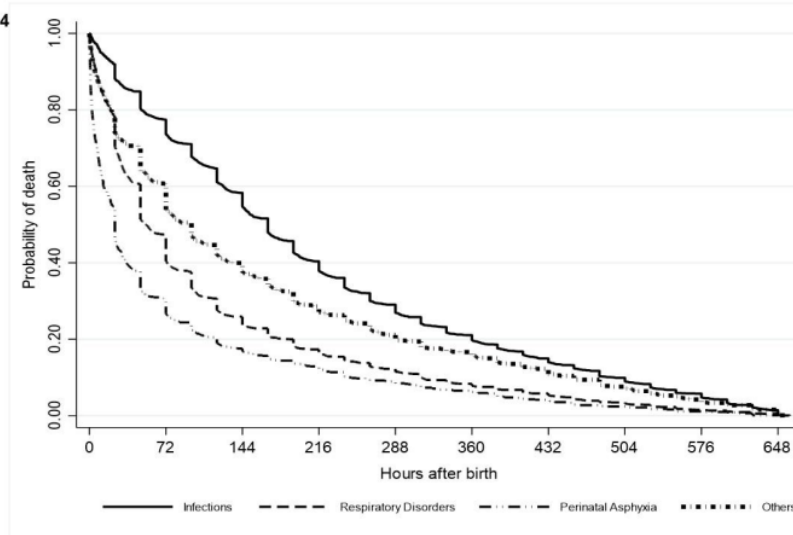


Figure 4. Kaplan-Meier estimate of hours after birth until death according to cause of death.

Discussion

This population-based study shows that the neonatal mortality rate of infants with 32–36 weeks gestation without congenital malformations decreased from 16.4 in 2004 to 7.6 per thousand live births in 2015, in São Paulo State, Brazil, with an annual reduction of 7.47%. Perinatal asphyxia, respiratory disorders, and infections were responsible, respectively, for 14%, 27% and 44% of the 5,782 deaths. The neonatal mortality rate for each one of these causes decreased from 2004 to 2015. Maternal and neonatal demographic variables were associated with the studied deaths. A persistent 0–6 Apgar score at 1 and 5 minutes after birth was associated with a 20 times higher chance of neonatal death, while the recovery at 5 minutes to a score of 7–10 was associated with a 3 times higher chance of neonatal death, compared to infants that have 7–10 Apgar scores at 1 and 5 minutes.

The neonatal mortality rate of 10.58 per thousand live births of infants with 32–36 weeks gestation without congenital malformations in the most developed state of the country is high if we compare with data from high-income countries. In the United Kingdom, the neonatal mortality rate per thousand live births with 32–36 weeks gestation decreased from 6.33 in 2007, to 5.24 in 2015 and to 4.67 in 2018 [24]. In the USA, the neonatal mortality was 8.57 per thousand live births with 32–36 weeks gestation in 2018 [25]. Both datasets considered live births with congenital malformations, different from our population-based study that focused on preventable neonatal deaths. According to Rutstein et al [26], preventable deaths are those that could have been prevented, in whole or in part, by effective health services. In Brazil, preventable deaths of children younger than 5 years have been classified as those reducible through immunoprevention measures and adequate care for women during pregnancy and delivery, adequate care for fetuses and newborns, adequate measures of diagnosis and treatment and adequate health promotion measures [27]. Deaths associated with perinatal asphyxia, respiratory disorders and infections are considered preventable and may be reduced by the combination of measures cited above. It is important to emphasize that the studied population had a mean birth-weight of 2511 ± 554 g, which points out the high survival probability. If essential care is offered promptly to these infants, it is possible that almost all of them would survive, even without intensive care interventions [28].

Despite the high neonatal mortality rate of moderate and late preterm infants without congenital anomalies, there was a significant reduction during the study period, with the

most impressive decline from 2004 to 2013, followed by a plateau from 2013 to 2015. The same reduction could be noted for the neonatal mortality rate associated with perinatal asphyxia, respiratory disorders, and infections. These findings follow the same pattern found by Saltarelli et al [27] in a populational study about preventable deaths of children younger than five years in the Southeast Region of Brazil from 2000 to 2013. According to these authors, the preventable causes of death had a reduction of 4.4% per year, with a 44% decrease in the period. Since the beginning of the 21st century, Brazil granted a special attention to maternal and neonatal care, with a sequence of public policies that lead to the strengthening of comprehensive perinatal care, from pregnancy to neonatal care, as a strategy progressively organized in the country [29]. The impact of these healthcare strategies probably contributed to the continuous reduction of neonatal deaths of moderate and late preterm infants without congenital anomalies reported in our study.

The median neonatal mortality timing was 96 hours, but it varied according to the cause of death as early as 24 hours for perinatal asphyxia and as late as 168 hours for infections. Our results are consistent with those reported in a systematic review of neonatal mortality timing of late preterm and term infants. Based on data from 46 studies with 6,760,731 live births and 47,551 neonatal deaths, the highest proportion of neonatal deaths occurred on day 1 (39.5%), followed closely by days 2-7 (36.8%), with the remainder occurring between days 8 and 28 (23.0%). Ten studies of 1,326 deaths with perinatal asphyxia and 1,562 deaths with infections show that 68% of the first ones occurred on the first day after birth and 48% of the latter occurred between days 2-7 [30]. The results of our population-based study, with 99% of in-hospital births, show that infections were responsible for 40-49% of neonatal deaths of moderate and late preterm infants without congenital malformations yearly, with a median neonatal mortality timing at the end of the first week after birth. These findings reinforce the need for investment in the quality of healthcare system. According to Dol et al [30], health care providers should be well-trained, knowledgeable, and have access to life-saving equipment and medication to provide a high quality of care across the high-risk time points during the first month after birth.

Social (lower maternal age and schooling), maternal (lower number of prenatal care visits, and cesarean section), and neonatal factors (male sex, low birthweight, and low 1st and 5th minute Apgar score) were associated with the neonatal deaths of moderate and late preterm infants without congenital malformations. These variables are extensively studied as risk factors for unfavorable neonatal outcomes [5,22,31]. It is interesting to note the contribution of the low vitality at birth to these deaths: one in every four neonatal deaths of the studied infants had a persistent Apgar score of 0-6. Adequate care for mothers at delivery and skilled teams apt to provide appropriate resuscitation procedures to the neonate immediately after birth could change these preventable deaths [32].

One of the main limitations of the study is the use of secondary data, with limited available information on clinical variables that are important in the determination of death. The dataset did not allow to evaluate more granularly deaths by each gestational age week, as it only contains the aggregate data on live births with 32-36 weeks gestation. Also, the database used in this analysis is provided by Fundação SEADE after linkage and anonymization, a process that has a manual component and is time consuming. Therefore, the most recent year available to the study was 2015. Of course, the neonatal mortality data presented here is regional, but, as cited in the introduction, there are positive reasons for working with cities and regions on action to achieve health equity: locally is where people are born, grow, live, work and age [20].

Despite these limitations, this study is one of the first to provide a populational picture of preventable neonatal deaths of moderate and late preterm infants without congenital malformations in a middle-income country. Although the neonatal mortality rate of these infants decreased significantly from 16.4 in 2004 to 7.6 per thousand live births in 2015, the rate is still high, when compared to high income countries. The causes associated with these deaths were perinatal asphyxia, respiratory disorders, and infections, which are largely preventable. Social disadvantage, quality of prenatal and delivery care and

neonatal practices were associated with these preventable deaths. The findings of this study add information to subsidize recommendations related to care of moderate and late preterm infants, that comprises the great majority of the livebirths with gestational age lower than 37 weeks.

Authors contributions: RG and MFBA participated in the concept and design of the study; analysis and interpretation of data; drafting and revising the manuscript. AS participated in concept and design of the study; statistical analysis and interpretation of data; drafting and revising the manuscript. CRVK, ASSM, DTCN, KNA, MDK, MHM, PBP, RCXB, TK, LCM, RMF, MLT and BW have participated in the concept and design of the study, interpretation of data, and revising the manuscript. All authors listed on the manuscript approved the submission of this version of the manuscript, take full responsibility for the manuscript and agree to be personally accountable for their own contributions and for ensuring that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and documented in the literature.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Universidade Federal de São Paulo – UNIFESP: protocol code 2.580.929, approved on April 4th, 2018.

Informed consent statement: Informed consent was waived given the retrospective nature of the study and use of unidentified anonymized database.

Data availability statement: The data are publicly available just in part. The datasets were provided by Fundação SEADE. Requests to access these datasets should be directed to <http://produtos.seade.gov.br/produtos/mrc/>. The database with linked information of birth and death certificates of São Paulo State, from 2004 to 2015, is available on request with the corresponding author.

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Conflicts of interest: The authors declare that they do not have any conflict of interest. The funding agency (Fapesp) had no role in the design, execution, interpretation, or writing of the study.

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