

## AOGS ORIGINAL RESEARCH ARTICLE

# Critical evaluation of national vital statistics: the case of preterm birth trends in Portugal

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## Key words

Preterm birth, civil registration, surveillance, perinatal datasets, validity

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## Conflict of interest

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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## Abstract

**Introduction.** Using vital statistics, the Portuguese National Health Plan predicts that 14% of live births will be preterm in 2016. The prediction was based on a preterm birth rise from 5.9% in 2000 to 8.8% in 2009. However, the same source showed an actual decline from 2010 onwards. To assess the plausibility of national preterm birth trends, we aimed to compare the evolution of preterm birth and low birthweight rates between vital statistics and a hospital database. **Material and methods.** A time-trend analysis (2004–2011) of preterm birth (<37 gestational weeks) and low birthweight (<2500 g) rates was conducted using data on singleton births from the national birth certificates ( $n = 801\,783$ ) and an electronic maternity unit database ( $n = 21\,392$ ). Annual prevalence estimates, ratios of preterm birth:low birthweight and adjusted prevalence ratios were estimated to compare data sources. **Results.** Although the national prevalence of preterm birth increased from 2004 (5.4%), particularly between 2006 and 2009 (highest rate was 7.5% in 2007), and decreased after 2009 (5.7% in 2011), the prevalence at the maternity unit remained constant. Between 2006 and 2009, preterm birth was almost 1.4 times higher in the national statistics (using the national or the catchment region samples) than in the maternity unit, but no differences were found for low birthweight. **Conclusion.** Portuguese preterm birth prevalence seems biased between 2006 and 2009, suggesting that early term babies were misclassified as preterm. As civil registration systems are important to support public health decisions, monitoring strategies should be taken to assure good quality data.

**Abbreviations:** CHSJ, S. Joao Hospital Center (Centro Hospitalar S. João); INE, National Statistics Institute (Instituto Nacional de Estatística); LBW, low birthweight.

## Introduction

Preterm birth-related complications are the leading cause of neonatal mortality and contribute to child morbidity and long-term complications (1). The Global Action Report on preterm birth highlights that prevention must be accelerated (2). Time trend analyses are of particular importance to conduct and monitor public health interventions, despite difficulties in the registration of gestational age (3). Most high income countries have reliable data available (4), some of which indicate continuous

## Key message

Comparing birth certificates with an electronic clinical dataset, we found that Portuguese preterm birth rates between 2006 and 2009 were probably biased; national predictions and expected targets do not seem to be based on the best available data.

This study underlines the importance of data collection systems for later interventions. It stresses the urgent need of measures to assure good quality civil registration data, aiming to establish effective public health prevention strategies.

improvement over time (5). A recent systematic review evaluated the quality of registry of perinatal health databases. Authors found that hospital discharge databases are, in general, more accurate than birth certificate data. However, birth registers showed high accuracy when considering preterm birth or low birthweight (LBW) (6).

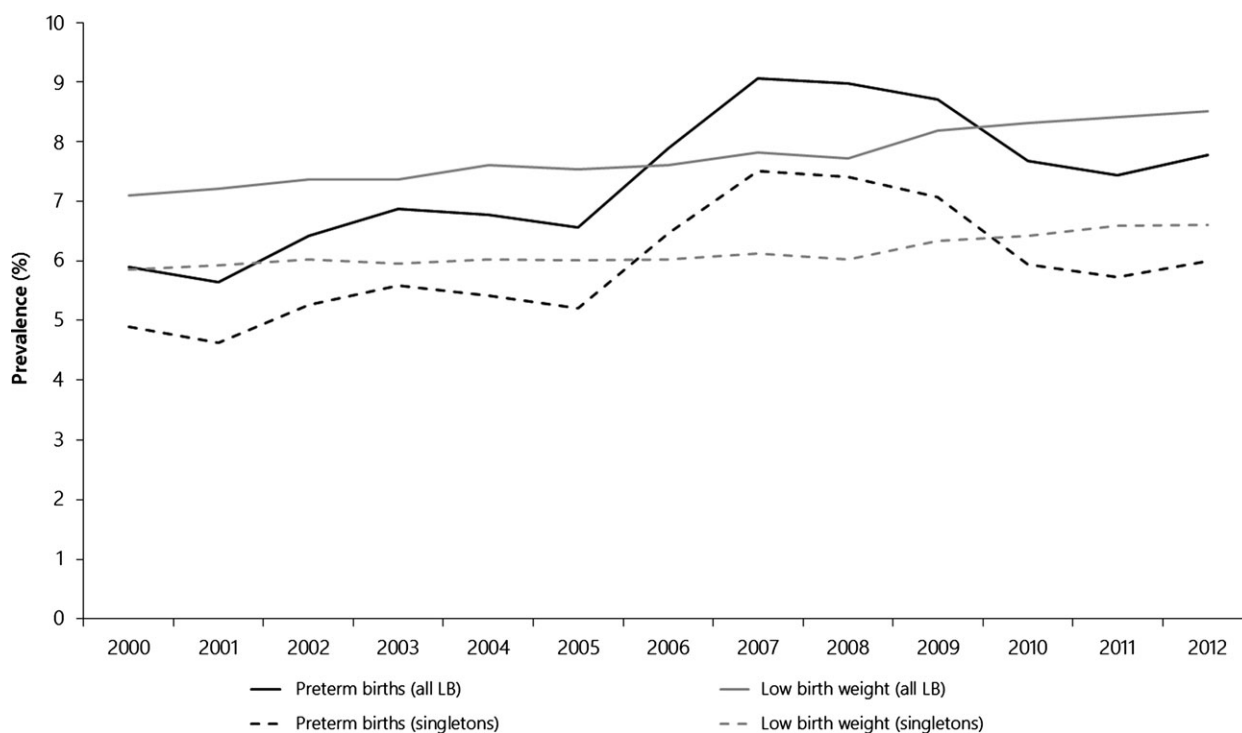
Recently, using data from vital statistics, Portugal appeared as the European country with the third highest preterm birth rate increase (7.0% in 1996, 5.9% in 2000, 6.8% in 2004 and 9.0% in 2008), in contrast to some countries that managed to maintain or reduce their estimates (7). Using the same data source, the World Health Organization evaluation of the 2004–2010 Portuguese National Health Plan pointed out that preterm birth rate was one of the five indicators (among 64) showing deteriorating performance between 2004 and 2008 (8). The recent 2012–2016 National Health Plan anticipates that 14% of all newborns in 2016 will be preterm, a prediction based on the increase observed between 2000 and 2009 (5.9–8.8%). The Plan targets a rate reduction to 11% as one of the priority strategies (9). However, in 2010 the rates of preterm birth decreased to 7.7% and remained relatively constant afterwards. LBW showed a small and linear increase after 2000 (7.1–8.3% in 2010), not following the preterm birth trend (10). Preterm birth and LBW rates among singletons were similar to the ones mentioned above (Figure 1), suggesting that increasing rates

of multiple pregnancies (10) did not explain the preterm birth peak observed between 2006 and 2009. Additionally, during that period we were unable to detect changes in maternal socio-demographic characteristics or clinical obstetric practices that would consistently explain the observed trend (10,11).

Thus, the official preterm birth rates released from 2006 to 2009 lack a plausible clinical explanation and, unless random variation occurred, they suggest that predictions and subsequent prevention strategies may have been designed in the absence of good quality data. Routine birth registries are widely used as the basis for public health plans and recommendations, reinforcing the need to assure high quality data. We hypothesized that local time trends in preterm birth and LBW would follow the national pattern even if actual rates were different, because of differentiation of care practices. Thus, aiming for a better understanding of Portuguese perinatal indicators, we compared the national preterm birth and LBW trends with the ones from a large maternity unit in the north of Portugal with a stable and quality-assured registration process.

## Material and methods

National data on live births were provided by the National Statistics Institute (INE) for 2004–2011. For this



**Figure 1.** Preterm birth and low birthweight rates between 2000 and 2012 in Portugal (from vital statistics, 2014) (10).

period, all deliveries at S. Joao Hospital Center (CHSJ), in the north of Portugal, were also obtained. National data are recorded in the civil registration process that covers virtually 100% of births. Birth certificates include maternal and paternal socio-demographics (age, education, employment, occupation and marital status), maternal obstetric history (previous pregnancies and deliveries, number of fetuses), delivery and newborn data (health care assistance, newborn gender, birthweight and duration of pregnancy). Civil registration is carried out by administrative staff; since 2007 this can be done on the spot at the maternity facilities. Information is provided by the parents, although most delivery and newborn data are registered according to data in the medical files.

Most Portuguese maternity units do not have electronic medical records, particularly not for the period considered in this study. However, in 2002, the Department of Obstetrics at CHSJ developed specific software, OBSCARE, resulting in an electronic medical database providing data from the point of registration in the antenatal clinic, through delivery until discharge. In addition to the data collected at the birth registration, this database records women's clinical history prior to conception, during pregnancy and postnatally; it also assembles pre-labor, delivery and post-natal procedures. Both datasets were provided anonymously and no record linkage was possible. National data were provided on the basis of a protocol agreement for conducting scientific research between INE and the authors' academic institutions. Researchers signed a confidentiality statement; of the authors, only S.C. accessed the dataset. The procedures were in accordance with the ethical standards of the Helsinki Declaration and national regulations (Law no. 46/2007). The study was approved by the ethics committee from the Institute of Public Health, University of Porto (CE14020, 11 July 2014).

Until 2009, duration of pregnancy was recorded in birth certificates as a categorical variable (<22, 22–27, 28–31, 32–36, 37–41 or >41 gestational weeks). Since 2010 this is registered by week, as in the maternity unit dataset. Preterm birth was defined as <37 gestational weeks, moderate-late as 32–36 gestational weeks, and very preterm birth as <32 gestational weeks. In both systems, birthweight is recorded as a continuous variable; LBW was classified as below 2500 g.

Women delivering singleton live births with complete data on birthweight and gestational age at birth were included: 801 783 women from the civil registration (99.7% of all live births) and 21 392 from the maternity unit (94.6%). For each data source the annual prevalence of LBW and preterm (including sub-categories) was estimated, as well as the annual prevalence of LBW among term and preterm newborns. The ratio between preterm

birth prevalence and LBW prevalence was determined per year. To understand differences in trends we also compared the annual proportions of older women ( $\geq 35$  years), of less educated ( $\leq$  basic schooling), unemployed and primiparas (women with no previous deliveries). Obstetric interventions are not registered in birth certificates. Thus, the national prevalence of cesarean deliveries was based on data from the annual hospital inquiries conducted by INE and the General Directorate for Health (11). Annual preterm birth and LBW prevalence ratios [PR and respective 95% confidence intervals (95% CI)] were estimated by Poisson regression, using the maternity unit as the reference class. Prevalence ratios were adjusted for maternal age, education, employment status and parity. Civil registration does not include the hospital of birth. Therefore, further analyses were performed restricting civil registration data to women resident in the Porto Metropolitan region ( $n = 101\ 858$ ), the catchment area for CHSJ.

## Results

The national prevalence of preterm birth had increased since 2004, particularly between 2006 and 2009 (7.5% was the highest value, recorded in 2007), and decreased in 2010 and 2011. However, the maternity unit data did not present the same pattern: after a decrease from 2005 to 2006 (from 6.6% to 5.2%), the prevalence remained constant up to 2010. Between 2006 and 2009, the ratio of preterm birth: LBW increased from around 0.90–1.23 in the national data (0.83–1.14 in the catchment region) but remained constant in the maternity unit. The national LBW trend was similar to the one observed using the maternity unit data (Table 1). Maternal characteristics were similar in both data sources. As observed in Table 1, the proportions of older and of less educated women were almost the same. Although the maternity unit presented a higher prevalence of primiparas and unemployed women and a lower prevalence of cesarean deliveries, the trends were similar.

In Figure 2 we present the prevalence of very and moderate-late preterm births according to the data source. Very preterm birth rates were similar. Moderate-late preterm birth was less frequent in the national data in the first and the last years; between 2006 and 2009 it was around 30–40% higher than in the maternity unit. However, in this period, the national prevalence of LBW among moderate-late preterm babies decreased: 24–40% lower than the one observed in the maternity unit.

Among very preterm births, for all the studied periods, national estimates of LBW were below 100%, varying between 82% in 2007 and 96% in 2004 (Figure 3). Prevalence estimates among women from the catchment region are available in Table S1.

**Table 1.** Maternal characteristics and pregnancy outcomes between 2004 and 2011 using national and maternity unit singleton data

	Year of birth							
	2004	2005	2006	2007	2008	2009	2010	2011
National data (birth certificates)								
<i>n</i>	105 930	106 074	102 156	99 416	100 455	96 018	98 015	93 719
Preterm birth (%)	5.4	5.2	6.5	7.5	7.4	7.0	5.9	5.7
Low birthweight (%)	6.0	6.0	6.0	6.1	6.0	6.3	6.4	6.6
Ratio preterm:LBW	0.90	0.87	1.08	1.23	1.23	1.11	0.92	0.86
≥35 years (%)	15.6	16.2	17.3	18.1	19.1	20.2	21.6	23.7
≤Basic schooling (%)	52.3	49.8	47.5	46.3	44.7	42.6	40.2	37.0
Unemployed (%)	6.9	7.8	9.9	11.6	10.9	12.8	12.8	12.6
Primiparas (%)	54.1	54.3	54.3	54.0	53.9	54.3	53.3	53.6
Cesarean deliveries (%)	33.1	34.7	35.1	35.4	36.0	36.7	36.3	35.8
Catchment region (birth certificates)								
<i>n</i>	13 061	13 177	12 685	12 829	13 387	13 404	11 943	11 373
Preterm birth (%)	5.5	5.2	6.4	7.5	7.6	6.1	6.1	5.6
Low birthweight (%)	6.6	6.5	6.1	6.6	6.7	7.1	6.7	6.8
Ratio preterm:LBW	0.83	0.80	1.05	1.14	1.13	0.86	0.91	0.82
≥35 years (%)	16.2	17.41	18.2	19.4	20.2	21.6	22.3	25.1
≤Basic schooling (%)	51.6	48.6	48.6	43.3	44.8	43.1	40.8	37.0
Unemployed (%)	6.8	8.0	11.5	13.8	13.1	15.0	16.6	17.0
Primiparas (%)	57.6	57.6	57.6	56.7	56.9	56.8	56	55.7
Cesarean deliveries (%)	43.0	45.4	42.8	44.4	44.2	45.1	43.6	44.0
Maternity unit data								
<i>n</i>	2712	2598	2426	2486	2745	2750	2918	2757
Preterm birth (%)	6.7	6.6	5.2	5.5	5.5	5.4	5.7	6.3
Low birthweight (%)	7.4	7.2	6.4	6.4	7.0	7.4	7.4	7.3
Ratio preterm:LBW	0.90	0.92	0.81	0.86	0.78	0.73	0.77	0.86
≥35 years (%)	16.1	17.4	19.7	19.7	19.7	21.3	22.2	23.5
≤Basic schooling (%)	51.6	47.2	47.7	47.2	45.4	41.8	38.9	38.8
Unemployed (%)	11.5	13.4	14.0	14.1	15.3	15.7	17.1	16.6
Primiparas (%)	56.5	56.8	56.6	58.2	59.2	59.1	59.2	56.0
Cesarean deliveries (%)	27.5	29.5	26.8	27.4	28.7	27.9	27.4	29.7

LBW, low birthweight.

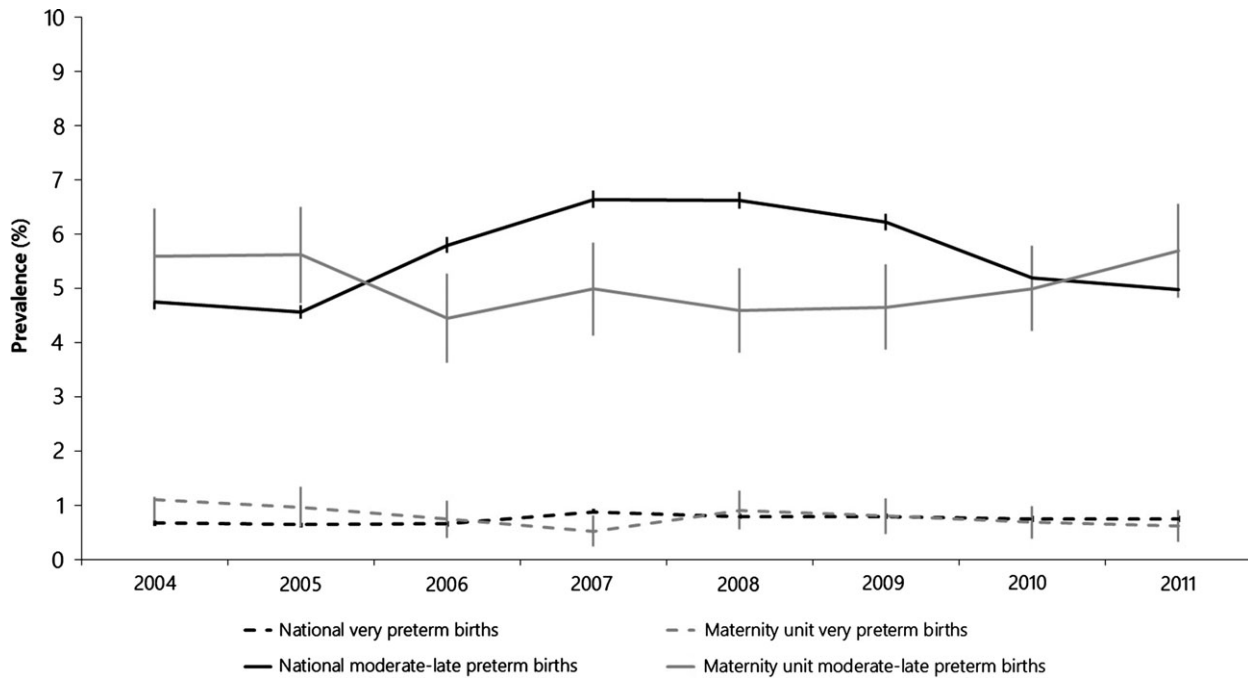
Independently of maternal characteristics, preterm birth and LBW prevalence ratios were similar for the years 2004, 2005, 2010 and 2011. Between 2006 and 2009, preterm birth was almost 1.4 times higher in the national statistics (using the national or the catchment region samples) than in the maternity unit, but no differences were found for LBW (Table 2).

## Discussion

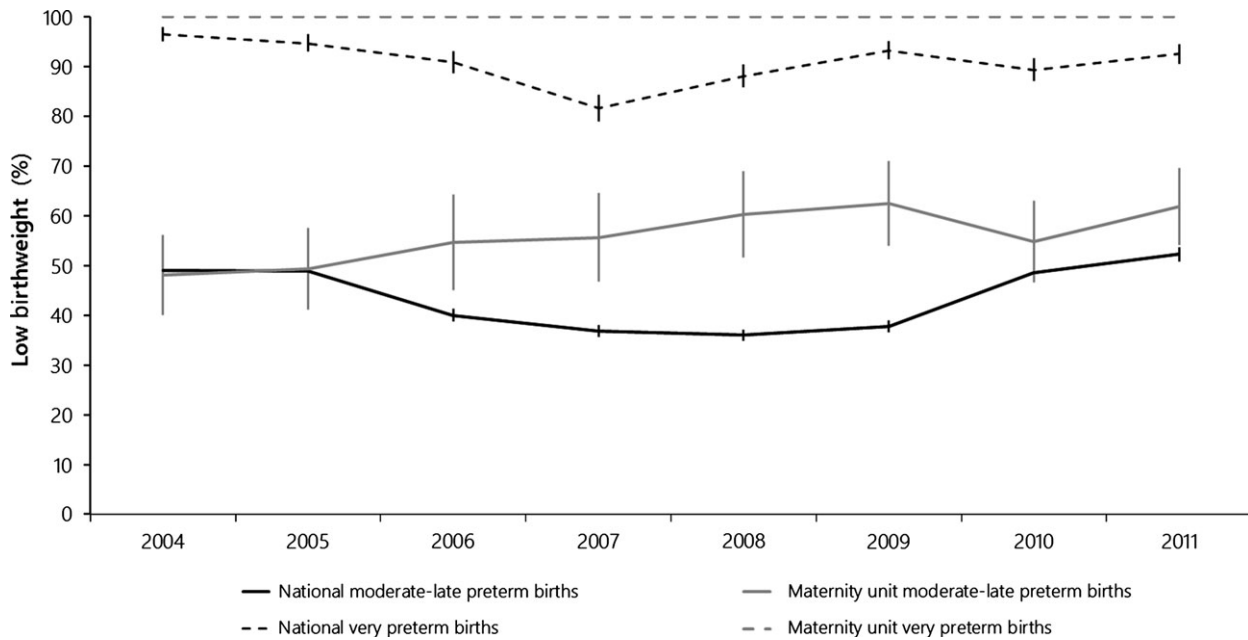
Using one large maternity unit for comparison, this study found similar national LBW trends but a different pattern for preterm birth. Differences were observed for the years 2006–2009 and were more evident for moderate-late preterm birth.

Differences in the accuracy of gestational age estimation across data sources are possible reasons for disparities in preterm birth rates (5,12,13). According to the national methodological notes for birth register, recorded gestational age should be based on the last menstrual

period. However, we could not assess which method was considered because this information has not been registered since 1994. Even so, we expect that differences in the gestational age estimation method would only partly explain our results. This is, firstly, because civil registration uses data from medical forms that are the same as available for the maternity unit dataset, and secondly, because ultrasound-based gestational age has been the recommended clinical estimation method since 2001. Thus, we believe that ultrasound-based dating was pervasive in most settings from 2004 and onwards. Nevertheless, we cannot rule out that the increase in preterm birth is related to the increase in ultrasound-based gestational age over time. However, this is not consistent with the decline in preterm birth observed in 2010 because, at that time, this method was likely to have been even more frequent. Therefore, a degree of register error may have influenced the estimates. Different types of errors (on the available forms, data register or transmission) may occur when data are collected for administrative purposes. Birth



**Figure 2.** Prevalence of very and moderate-late preterm births between 2004 and 2011 using national and maternity unit data. Vertical bars represent 95% confidence limits for the estimated prevalence.



**Figure 3.** Low birthweight prevalence among preterm newborns between 2004 and 2011 using national and maternity unit data. Vertical bars represent 95% confidence limits for the estimated prevalence. No cases of very preterm births  $\geq 2500$  g were observed in the maternity unit in any time period. No confidence intervals could be estimated.

certificates undergo periodical changes to include new variables or change the existing ones. Regarding pregnancy duration, the forms in use between 1998 and 2006 imposed a categorized gestational age, affecting precision

and the ability to check for misclassifications. In 2006–2007, electronic civil registration was implemented but methodological documents are not accessible and we do not know how gestational age was registered. Errors in

**Table 2.** Associations between adverse birth outcomes and the data source

	Prevalence ratio (95%CI) <sup>a,b</sup>			
	All live births		Live births from catchment area <sup>c</sup>	
	Preterm birth	Low birthweight	Preterm birth	Low birthweight
2004	0.85 (0.73–1.00)	0.84 (0.73–0.98)	0.86 (0.72–1.02)	0.92 (0.78–1.08)
2005	0.82 (0.70–0.97)	0.85 (0.73–1.00)	0.83 (0.69–0.99)	0.92 (0.78–1.09)
2006	1.37 (1.14–1.66)	0.97 (0.82–1.15)	1.34 (1.10–1.64)	0.98 (0.82–1.17)
2007	1.44 (1.21–1.72)	1.01 (0.86–1.19)	1.43 (1.19–1.73)	1.08 (0.90–1.28)
2008	1.40 (1.18–1.65)	0.88 (0.76–1.02)	1.42 (1.19–1.70)	0.97 (0.83–1.14)
2009	1.33 (1.12–1.58)	0.90 (0.78–1.05)	1.44 (1.20–1.72)	0.99 (0.85–1.16)
2010	1.10 (0.94–1.29)	0.92 (0.80–1.06)	1.12 (0.94–1.33)	0.94 (0.81–1.10)
2011	0.99 (0.80–1.23)	0.99 (0.81–1.20)	0.93 (0.74–1.16)	0.99 (0.80–1.22)

<sup>a</sup>Reference class: maternity unit.

<sup>b</sup>Adjusted for maternal age, education, employment status and parity.

<sup>c</sup>Birth certificate data of women living in Porto Metropolitan Region.

the design and development of the electronic forms could explain our results. We assume that gestational age was recorded as a categorical variable, but inaccuracies in the definition of each gestational age category can not be ascertained. Since 2010, gestational age has been recorded as a continuous variable, and we expect that quality of the data has improved.

Some changes in the civil registration process have also been implemented. Since 2007 an official from the civil register is located at the maternity units, allowing on-the-spot electronic civil birth registration. When data are received at INE (currently, certificates are continuously sent via the web), the consistency between birthweight and gestational age is assessed using a broad set of predefined validation rules. According to this, extreme or inconsistent values generate an error message for further analysis. However, in most cases it is not possible to confirm the provided information and the potential for correction is limited. Considering the existing rules (birthweight >5500 g, <1000 g for singleton pregnancies above 32 gestational weeks, <2000 g for pregnancies above 41 gestational weeks and >500 g for pregnancies below 22 gestational weeks; pers. commun., C. Patão), the errors observed in the current study were neglected, which underlines the need for more robust validation systems, particularly in relation to such important indicators as preterm birth or LBW.

The distinct pattern observed for LBW supports the explanation that the proposed 2006–2009 national preterm birth rate increase may be a data artifact. Higher LBW estimates were observed in the maternity unit, probably because of its differentiated level of care (CHSJ is a level III facility, one of the largest maternity units in the country). Despite this, the overall LBW trends were similar in both data sources, suggesting that the maternity unit data reflect national trends. Also, the ratio of

preterm:LBW remained constant in the maternity unit at between 0.77 and 0.92. Nationally, it was constant before 2006 and after 2009 (between 0.86 and 0.92) and the increase in 2006–2009 (varying between 1.08 and 1.23) suggests recording errors.

Finally, the national prevalence of LBW among babies born before 37 weeks decreased from 54% in 2005 to 41–45% in 2006–2009 and increased again to 54% in 2010; a pattern not observed in the maternity unit data. This may be a systematic error in 2006–2009 with regard to classification of early term babies who were not LBW but preterm. The prevalence of LBW among very preterm births should be close to 100% because of the short duration of pregnancy. However, for all the studied periods, significantly lower proportions were observed in the national data. This suggests that register errors may be present in very preterm births but are likely of a different nature from those observed in moderately preterm births.

Apart from a registry error, the observed national preterm birth trend could be accepted as true if significant changes had occurred in multiple pregnancies, in the social and clinical maternal profile, in the obstetric protocols (mainly those related to iatrogenic preterm delivery) or in the referral of cases. We only considered singleton live births, thus excluding a possible reason for the increasing rates of preterm birth (14). Maternal characteristics do not seem to explain the results. As observed in this study, women delivering at CHSJ were similar to the national pregnant population or to those from the catchment region, despite a higher prevalence of unemployment and primiparity. Even so, age, education, unemployment and parity trends were similar in both data sources. It would be useful to compare ethnicity or marital status distribution in these two samples. However, different recording criteria are used in civil registration and in the maternity unit, limiting comparability. Despite

this, we know that the proportion of foreign women delivering in Portugal has increased by around 5%/year between 2000 and 2011. Additionally, the proportion of non-married women has increased, particularly after 2008. Similar results were observed among women from the catchment region (10). Both changes would contribute to an increase in preterm birth over time (without the observed peak). It is important to analyze other behavior-related characteristics (such as smoking habits, weight gain, infection status and pregnancy complications) but no national data are available for the study periods to allow such comparisons. However, we do not expect that the mentioned characteristics would present a pattern congruent with the observed preterm birth trend.

According to what we have previously found in induction procedures among level III hospitals from the Porto Metropolitan Region (15), country variation in obstetric practices is expected. However, induction practices are more likely to vary among term babies, which will decrease any impact on the preterm prevalence. We do not have national data on induction techniques and we can only compare cesarean trends. Although national cesarean rates were higher than at CHSJ, particularly after 2005, constant differences were observed throughout time and the pattern did not change for in 2006–2009. Finally, our results could reflect lower than expected preterm birth prevalence in the maternity unit between 2006 and 2009 (and not an increase in the national data). This could be explained if more preterm pregnancies had been referred from CHSJ to other maternity units during this period. Maternal and neonatal health care services were restructured in 2006, resulting in the closure of delivery units with fewer than 1500 deliveries per year, in the increase of high-risk in-utero transfers and in the creation of more highly differentiated perinatal facilities. These changes are likely to have a greater effect on very preterm than moderate-late preterm birth estimates. Also, the effect is likely to be reflected in 2006 and onwards, and not only for the period 2006–2009.

This analysis has the limitation that it compares all Portuguese births with only one maternity unit (2.7% of all deliveries), which might be significantly different from the rest of the country. However, the parallel trend in all characteristics other than preterm birth strengthens the results and increases study validity. We also restricted the analysis to women living in the Porto Metropolitan Region and similar results were obtained. Although women might have delivered at one of the other four maternity units serving the area, similar results would have been expected, had we been able to link datasets.

These results have implications when used as a basis for public health strategies towards a reduction in preterm birth rates. They also flag up the need for caution

when comparing preterm birth rates between different countries. Portuguese routine data are used by different national and international entities that monitor perinatal health, such as the World Health Organization (16) and European health information projects (17), reinforcing that high quality data must be assured. The overall preterm birth rate seemed to be increasing but, in 2010, it did not reach the projection of the National Health Plan for 2004–2010 (7.7% vs. 4.9%). It is no longer expected to reach 14% in 2016, as forecast by the National Health Plan 2012–2016, based on official trend data published for the years 2000–2009. The Plan targeted a preterm birth rate reduction to 11%. Our results indicate that this target can now be considered overly conservative.

Our results are also relevant to re-define methods of data gathering and reporting. Although a systematic error is likely to have occurred in moderate-late preterm birth rates between 2006 and 2009, differences were also observed for very preterm births and in all time periods, reinforcing the need for data validation. Perinatal datasets, data linkage processes, and well defined and robust consistency validation rules are fundamental to establish timely estimates based on clinical data. Portuguese and other civil registration systems, which are of undoubted value to support public health decisions (6,18), need innovative monitoring strategies to guarantee high quality health indicators.

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## Supporting information

Additional Supporting Information may be found in the online version of this article:

**Table S1.** Prevalence of preterm birth and low birthweight in women from the catchment area.