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1 **Quantifying the burden of stillbirths before 28 weeks of completed gestational age in high income**  
2 **countries: a population based study of 19 European countries.**

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29

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1 **Abstract**

2 **Background:** International comparisons of stillbirth allow assessment of variations in clinical practice  
3 to reduce mortality. Currently such comparisons only include stillbirths from 28 or more completed  
4 weeks of gestational age which underestimates the true burden of stillbirth. With increased  
5 registration of early stillbirths in high income countries we assessed the reliability of including  
6 stillbirths before 28 completed weeks.

7 **Methods:** We used national cohort data from 19 European countries participating in the Euro-  
8 PERISTAT project on live births and stillbirths from 22 completed weeks of gestation in 2004, 2010  
9 and 2015. Pooled stillbirth rates were calculated using a random-effects model and changes in rates  
10 between 2004 and 2015 were calculated using risk ratios (RR) by gestational age and country.

11 **Results:** Stillbirths at 22<sup>+0</sup>-27<sup>+6</sup> weeks of gestation accounted for 32% of all stillbirths in 2015. The  
12 pooled stillbirth rate at 24<sup>+0</sup>-27<sup>+6</sup> weeks declined from 0.97 to 0.71 per 1000 births from 2004 to  
13 2015, a reduction of 24% (RR=0.77, 95% CI 0.68 to 0.88). The pooled stillbirth rate at 22<sup>+0</sup>-23<sup>+6</sup> weeks  
14 of gestation in 2015 was 0.53 per 1000 births and had not significantly changed over time (RR 0.97,  
15 95% CI 0.80 to 1.16) although changes varied widely between countries (RRs 0.62 to 2.09). Wide  
16 variation in the percentage of all births occurring at 22<sup>+0</sup>-23<sup>+6</sup> weeks of gestation suggest  
17 international differences in the ascertainment.

18 **Conclusions:** Current definitions used for international comparisons exclude a third of stillbirths.  
19 International consistency of reporting stillbirths at 24<sup>+0</sup>-27<sup>+6</sup> weeks suggests these deaths should be  
20 included in routinely reported comparisons. This would have a major impact, acknowledging the  
21 burden of perinatal death to families, and making international assessments more informative for  
22 clinical practice and policy. Ascertainment of fetal deaths at 22<sup>+0</sup>-23<sup>+6</sup> weeks should be stabilised so  
23 that all stillbirths from 22 completed weeks of gestation onwards can be reliably compared.

24 **300 words**

## 1 Introduction

2 The 2016 Lancet stillbirth series highlighted the global impact of stillbirths on parents and families<sup>1</sup>  
3 with around 3.5 per 1000 births ending in stillbirths in high income countries<sup>2,3</sup> and a decline over the  
4 last decade for stillbirths in the third trimester<sup>2,4</sup>. However, the full extent of the burden is generally  
5 underestimated since a gestational age cut-off of 28 completed weeks for comparing the stillbirth  
6 rate has been implemented widely as recommended by WHO for international purposes  
7 ([http://www.who.int/maternal\\_child\\_adolescent/epidemiology/stillbirth/en/](http://www.who.int/maternal_child_adolescent/epidemiology/stillbirth/en/) Accessed 07/03/2017).  
8 Although WHO recommends a threshold of 22 completed weeks for ascertainment of stillbirths  
9 within countries, there are major discrepancies between countries in their registration legislation and  
10 within countries in the implementation of their legislation. These inhibit reliable international  
11 comparisons<sup>2,4,5</sup> using this limit. There are also differences in legislation about late termination of  
12 pregnancy and the extent to which late terminations are reported as stillbirths and can be  
13 distinguished from them. These have a major influence on reported stillbirth rates at early  
14 gestations, particularly at 22<sup>+0</sup> to 23<sup>+6</sup> weeks<sup>6,7</sup>. In addition international differences in the perception  
15 of viability may lead to differences in legislation about the registration of stillbirths and their  
16 ascertainment at early gestations<sup>1,8</sup>.

17 Because of the way these issues affect the comparability of stillbirth rates, there has been little  
18 international comparison of stillbirths below the gestational age threshold recommended by WHO of  
19 28 completed weeks. Over the past few decades, however, there have been consistent increases  
20 within countries in reported numbers of babies born before 28 completed weeks of gestation<sup>9</sup>, and  
21 dramatic increases in their survival rates, with most babies born alive at 25 or more completed weeks  
22 gestation surviving<sup>10</sup>. Flenady et al.<sup>2</sup> highlight that depending on the definition, between 35% and  
23 50% of stillbirths occur before 28 completed weeks of gestation. The Lancet stillbirth series  
24 suggested that stillbirth rates at earlier gestations are not showing the falls seen at 28 completed  
25 weeks of gestation and over and may possibly even be increasing<sup>2</sup>, but international comparisons to  
26 confirm this statement are lacking. By excluding these stillbirths, the burden of stillbirths in high  
27 income countries could be seriously underestimated. This could therefore fail to acknowledge the  
28 heartache suffered by many parents and their families experiencing fetal death or stillbirth<sup>11</sup>.  
29 Furthermore, by excluding these deaths, international comparisons are limited in their ability to  
30 assess the overall burden of stillbirth and the variations in clinical practice and therefore to identify  
31 best strategies for improving care.

32 Only through international studies, such as the Euro-Peristat project, that collect data on births and  
33 deaths starting at 22 completed weeks of gestation using a standardised protocol, can cross-country

1 comparisons of stillbirth rates be made. This makes the case for consistent international reporting  
2 practices for terminations of pregnancy and agreed definitions for reporting of stillbirths and live  
3 births. Here we undertake analyses of data from the Euro-Peristat project on stillbirths from 22  
4 completed weeks of gestation in 19 European countries to assess the additional burden of stillbirth at  
5 early gestational ages and to quantify changes in stillbirth rates at these early gestations over time.  
6 These analyses will also compare the consistency of the reporting of fetal deaths by gestational age  
7 to assess the evidence for moving the gestational age cut-off for the international reporting of  
8 stillbirths in the future.

9

## 10 **Methods**

### 11 *Data sources*

12 The data from this study are from the Euro-Peristat project, which developed a list of valid and  
13 reliable indicators for monitoring and evaluating perinatal health in the EU <sup>4,5,9,12</sup>. The Euro-Peristat  
14 project collected national level data from routine population-based sources on its indicators in 2004,  
15 2010 and 2015 using a common data collection instrument. Data come from medical birth registers,  
16 civil registration, child health systems and routine surveys, as described previously.<sup>4,5,9,12</sup> In 2004, 26  
17 countries participated in Euro-Peristat, rising to 29 in 2010 and 31 in 2015. The project was based on  
18 aggregated data collected routinely in each European country, following the ethics approval required  
19 locally.

20 In this study, we use aggregated data on the numbers of live births and stillbirths by gestational age  
21 for the years 2004, 2010 and 2015 for countries with data from all three periods, provided in a  
22 comparable manner for the same geographic area. We excluded countries without national data on  
23 stillbirths by gestational age in these periods (Cyprus, France and Spain), or where data available  
24 were not comparable between 2004 and 2015 (due to changes in birth and death registration in  
25 Sweden and Slovakia; due to lack of national data in 2004 in Belgium). We also excluded those  
26 countries with fewer than 10000 births per year as the proportion of stillbirths at 22<sup>+0</sup>-27<sup>+6</sup> weeks of  
27 gestation is small and consequently the numbers of these deaths are extremely small (Malta and  
28 Luxembourg). For the UK, data were provided separately for England and Wales combined, Northern  
29 Ireland and Scotland. Thus, 16 countries were included in the analyses of stillbirths at 22<sup>+0</sup> to 23<sup>+6</sup>  
30 weeks of gestation and 19 in the analyses of stillbirths at 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation. For the first  
31 period, data were for births in 2005 in England and Wales and for births in 2003 in Italy. In the latter  
32 period, data from Poland were for 2014, not 2015. Data sources are provided in Table S1.

## 1 *Definitions and analysis*

2 The stillbirth rate was defined as the number of deaths before or during birth per 1000 live and  
3 stillbirths. Stillbirth rates were calculated separately for each country, year of the study (2004, 2010  
4 and 2015) and for each gestational age subgroups (22<sup>+0</sup> to 23<sup>+6</sup> weeks; 24<sup>+0</sup> to 27<sup>+6</sup> weeks and 28<sup>+0</sup>  
5 weeks and over)<sup>12</sup>. The fetus at risk approach was used overall and by gestational age so, for  
6 example the rate at 24<sup>+0</sup>–27<sup>+6</sup> weeks was defined as the number of stillbirths from 24<sup>+0</sup> to 27<sup>+6</sup> weeks  
7 divided by the number of fetuses in utero at 24<sup>+0</sup> weeks<sup>13</sup>. Terminations of pregnancy were excluded  
8 from stillbirth rates in countries where they were included in the data source and could be  
9 differentiated from spontaneous stillbirths. In order to calculate the overall stillbirth rate in each of  
10 the time periods, pooled estimates were calculated with 95% confidence intervals (CIs) for  
11 gestational age group in 2004, 2010 and 2015. Meta-analysis techniques were used to obtain the  
12 pooled stillbirth rate. A random-effects model was fitted using the method of Der Simonian and  
13 Laird<sup>14</sup> to take account of variation between countries. The change in stillbirth rate over time was  
14 calculated using risk ratios (RR) with 95% CIs for each gestational age group in 2015 vs 2004. Again  
15 meta-analysis techniques were used to obtain a pooled RR using a random-effects model. We  
16 explored changes in ascertainment of stillbirths by calculating the RR of total births rates in 2015  
17 compared with total birth rates in 2004 by gestational age group.

18 Several sensitivity analyses were undertaken. For all analyses, the impact on stillbirth rates of  
19 including only those countries where terminations of pregnancy before 24<sup>+0</sup> weeks of gestation could  
20 be excluded from the data was explored. We also assessed the impact of excluding stillbirths with  
21 unknown gestations which were classified as being of 28 completed weeks gestation or above in the  
22 main analyses. Finally, we compared the percentage of stillbirths occurring between 22<sup>+0</sup> and 27<sup>+6</sup>  
23 week gestation in 2015 in the 8 countries excluded from our study because they did not have  
24 comparable data across the 3 periods (Cyprus, Spain, Sweden, Slovakia, Malta, Luxembourg, Belgium  
25 and France) to assess their comparability with the main results.

26 Analyses were performed with Stata, V.14.0 SE (Stata Corporation, College Station, Texas, USA).

## 27 *Role of the funding source*

28 The funders of the study had no role in study design, data collection, data analysis, data  
29 interpretation, or writing of the report. The corresponding author had full access to all the data in the  
30 study and LS and JZ had final responsibility for the decision to submit for publication.

31

1

## 2 **Results**

3 Table 1 shows the percentage of stillbirths at 22<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation in 2015. This shows that  
4 32.0% of stillbirths overall would be excluded from stillbirth statistics when reporting only deaths at  
5 28<sup>+0</sup> weeks of gestation and over. This proportion ranged from 20% in Estonia to 51% in the  
6 Netherlands. Table 1 also shows that only a few countries could not exclude terminations of  
7 pregnancy in 2004, 2010 and 2015 as, for example, the Netherlands where terminations could not be  
8 separated from spontaneous stillbirths. In most countries, inclusion of terminations of pregnancy  
9 after 24 weeks of gestation was rare. For countries reporting data on spontaneous stillbirths only,  
10 the highest rate of stillbirth at 22<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation in 2015 was 37% in Norway. This was  
11 similar to the rate in 2004 (30%) and 2010 (35%) [see Supplementary table S2 & S3]. The percentage  
12 of stillbirths at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation in 2015 varied widely between countries representing  
13 between 6% in Ireland and 36% in the Netherlands or to 23% in Hungary if excluding countries where  
14 terminations were included. Less international variation was seen for stillbirths at 24<sup>+0</sup> to 27<sup>+6</sup> weeks  
15 in 2015 where they represented between 12% in Latvia and 29% in Slovenia or 23% in Northern  
16 Ireland if excluding countries where terminations were included. In 2004 the variation was less for  
17 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation births but similar for 24<sup>+0</sup> to 27<sup>+6</sup> weeks births (see supplementary  
18 table S2 and S3).

19 The pooled estimate of the stillbirth rate at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation for the 16 countries in  
20 2015 (Figure 1a) was 0.53 per 1000 births in 2015 (95% CI 0.41 to 0.66). The relatively high I-squared  
21 value of 94% suggested variation between countries. Ireland reported a rate of 0.26 per 1000 births  
22 compared to 1.73 per 1000 births in the Netherlands, a six-fold difference. This range was reduced to  
23 0.26 to 0.69 when excluding countries where terminations were included, a three-fold difference. For  
24 births at this gestation, the stillbirth rate barely changed over time from 0.56 per 1000 births in 2010  
25 (95% CI 0.39 to 0.73) and 0.55 per 1000 births (95% CI 0.40 to 0.70) in 2004, see Figure 1a. In 2004  
26 rates ranged from 0.15 per 1000 births in Portugal to 1.37 in the Netherlands, an approximately nine-  
27 fold difference in the most extreme rates. Comparing 2015 with 2004, there was no change over time  
28 in the pooled estimate of the stillbirth rate (RR 0.97, 95% CI 0.80 to 1.16) (Figure 1a) but the changes  
29 over time ranged widely between countries, from 0.62 to 2.09. A sensitivity analysis was undertaken  
30 which included only countries where terminations of pregnancy before 24<sup>+0</sup> weeks of gestation could  
31 be excluded (see Table 1). This showed that the pooled rate did not change significantly over time  
32 (RR 0.87; 95% CI 0.72 to 1.06) and variation in the changes over time between countries reduced but  
33 was still wide ranging from 0.62 to 1.26.

1 This variation between countries at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation contrasted with the patterns for  
2 stillbirths from 24 weeks of gestation onwards. The pooled estimate of the stillbirth rate at 24<sup>+0</sup> to  
3 27<sup>+6</sup> weeks of gestation in 2015 (Figure 1b) in the 19 included countries was 0.71 per 1000 births  
4 (95% CI 0.58 to 0.84) with rates ranging from 0.43 per 1000 births in Finland to 1.77 per 1000 births  
5 in Slovenia, an approximately four-fold difference, with a relatively high I-squared value of 93%.  
6 However this range was reduced to 0.43 to 0.78 when excluding countries where terminations were  
7 included and could not be separated from spontaneous stillbirths, a two-fold difference. Over time,  
8 the pooled rate had declined substantially from 0.97 stillbirths per 1000 births in 2004 (95% CI 0.79  
9 to 1.14) and 0.81 stillbirths per 1000 births in 2010 (95% CI 0.69 to 0.93) (Figure 1b), with rates in  
10 2004 ranging between 0.54 per 1000 births in Germany and 1.62 in Slovenia, an approximately 2.5  
11 fold difference in rates. This represented a significant reduction over the decade from 2004 to 2015  
12 in the stillbirth rate of 23% (RR=0.77, 95% CI 0.68 to 0.88) (Figure 1b) with moderate variation  
13 between countries ranging from 0.42 to 1.18. A sensitivity analysis restricted to countries where  
14 terminations of pregnancy from 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation could be excluded (for countries  
15 included see Table 1) showed a similar reduction of stillbirth over time (RR=0.78, 95% CI 0.67 to  
16 0.92).

17 Over the three periods, there was wide variation in births occurring at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation  
18 as a proportion of all births (Figure 2a), ranging from a reduction of 30% in Lithuania to an increase of  
19 187% in Portugal. Overall the proportion of births at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation increased by 14%  
20 from 2004 to 2015 (RR=1.14, 95% CI 0.99 to 1.31). In contrast, there was far less variation in the  
21 change over time at 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation (Figure 2b). Overall there was a slight reduction  
22 in births at 24<sup>+0</sup> to 27<sup>+6</sup> weeks of 10% (RR=0.90, 95%CI 0.84 to 0.96) and this varied from a reduction  
23 of 43% in Northern Ireland to an increase of 9% in Germany and Italy.

24 Sensitivity analyses excluding stillbirths of unknown gestational age had minimal impact on the  
25 percentage of stillbirths occurring between 22<sup>+0</sup> to 27<sup>+6</sup> weeks gestation increasing the percentage of  
26 stillbirths from 32.0% to 32.4%. Nor was there an impact on rates and relative risks over time.  
27 Further sensitivity analyses exploring the percentage of stillbirths between 22<sup>+0</sup> to 27<sup>+6</sup> weeks  
28 gestation in 2015 for the 8 countries excluded from our study found very similar results (33.5%).

29

## 30 **Discussion**

31 We have used data from 19 European countries to explore stillbirths before 28 completed weeks of  
32 gestation, a group that is often not included in international comparisons of deaths. This has shown  
33 that around one in three stillbirths are not accounted for in standard stillbirth rates measured from



1 28 weeks of gestation<sup>1,2</sup>. Stillbirths at 24<sup>+0</sup> to 27<sup>+6</sup> weeks represent around seven per 10 000 births  
2 and are declining in a similar manner to stillbirths seen at later gestations in European and other high  
3 income countries, although our data, similar to these other reports, reveal heterogeneity in trends  
4 across countries<sup>4 12</sup>. Stillbirths occurring at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation represent around six per  
5 10 000 births. Stillbirth rates for these gestations have remained steady over time, but our  
6 hypothesis is that this is likely to be related to improvements in the reporting of deaths at these  
7 gestations as there was an increase in all births at 22<sup>+0</sup> to 23<sup>+6</sup> weeks gestation compared to a fall in  
8 births at 24<sup>+0</sup> to 27<sup>+6</sup> weeks gestation.

#### 9 Interpretation and implications for policy

10 Stillbirth rates at 24<sup>+0</sup> to 27<sup>+6</sup> weeks appear to be falling by the same proportion as stillbirth rates at  
11 28 weeks of gestation onwards<sup>12</sup>. The fall of 24% in stillbirths at 24<sup>+0</sup> to 27<sup>+6</sup> weeks is extremely  
12 similar to that seen globally for stillbirths of 28 weeks of gestation and above for a similar time period  
13 of 2000 to 2015<sup>1</sup> suggesting consistent improvements over time in the reduction of stillbirths from 24  
14 completed weeks of gestation.

15 In contrast, we found no change in the overall rate of stillbirth at 22<sup>+0</sup> to 23<sup>+6</sup> weeks between 2004,  
16 2010 and 2015. It is possible that rates of stillbirth have remained stable at this gestation but this is  
17 contrary to all other gestational age groups. In recent years the gestational age when a baby is  
18 perceived as viable has decreased with changes in the approach to early management of these  
19 babies. For example until recently, the American Academy of Pediatrics Neonatal Resuscitation  
20 Programme<sup>15</sup> recommended that resuscitation should be withheld when the gestational age is less  
21 than 23 completed weeks or a birth-weight of less than 400 grams, but this has now been amended  
22 to recommend that resuscitation should be withheld only below 22 completed weeks<sup>16</sup> and this is  
23 supported by increases in reported survival in some countries. Consequently there has been an  
24 increased tendency for resuscitation of babies born at early gestations<sup>17,18</sup> and an increase in the  
25 tendency to report babies as a neonatal death rather than stillborn<sup>18,19</sup> in some countries in Europe.  
26 At the same time, the increase in viewing these early births as potential live births may also have  
27 increased the reporting of early stillbirths.

28 Our study suggests that to ensure that the magnitude of the burden of stillbirth is better understood  
29 and to improve routine data for monitoring of the outcomes and management of extremely preterm  
30 births, WHO's threshold for international comparisons should be lowered, at least for high income  
31 countries. Mullan and Horton emphasised in the 2011 Lancet series on stillbirth that "to a mother  
32 and father, a stillbirth is no less a tragedy than the death of a newborn baby or child"<sup>20</sup> and that  
33 parents deserve "recognition of their loss and reassurance that an accurate record of it will add to

1 the global knowledge required to prevent future ones<sup>20</sup>. As part of the Lancet 2016 stillbirth series  
2 Heazell et al. emphasised the major economic and psychosocial consequences of stillbirth. To a  
3 mother or father a second trimester stillbirth is no less a tragedy than a stillbirth from 28 completed  
4 weeks onwards and these parents too deserve recognition of their loss and accurate reporting of  
5 deaths to improve care in the future.

#### 6 Strengths and limitations

7 A major strength of this work is the wide geographic coverage, the use of a standardised data  
8 collection protocol and the ability to ensure that late terminations of pregnancies at or after 22  
9 weeks wherever possible were disaggregated from the stillbirths so that they were not included in  
10 the fetal death rate. Unfortunately terminations of pregnancy could not be excluded for a few  
11 countries; these occur principally at 22<sup>+0</sup> to 23<sup>+6</sup> weeks in many countries and while increases in late  
12 terminations of pregnancy could contribute to the changes over time<sup>21</sup>, sensitivity analyses showed a  
13 similar increase over time for those countries where terminations could be excluded. While we had  
14 to exclude some countries in the Euro-PERISTAT project that didn't have comparable data for all  
15 periods, our sensitivity analyses support the generalizability of our results, as proportions of early  
16 stillbirths in these countries were very similar.

#### 17 Conclusions

18 The consistency in reporting of births over time at 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation and the similarity  
19 of reduction in the rate of stillbirth over time to births at 28 completed weeks of gestation and above  
20 suggests that stillbirths at 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation can be routinely included in rates of  
21 stillbirth for international comparisons from now on. Improvements to ascertainment of stillbirths at  
22 22 and 23 weeks of gestation within countries will allow the routine reporting of all stillbirths from 22  
23 completed weeks of gestation onwards or even earlier internationally. This would lead to better  
24 alignment of the gestational age at which stillbirths and neonatal deaths are reported as has already  
25 been done in some countries such as the US, Canada and Norway<sup>8</sup>. Such changes would enable a  
26 fuller acknowledgment of the burden of perinatal death to health services and families and allow  
27 assessment of variations in clinical practice in order to improve care.

28

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5 JZ, M Durox, M Delnord and LS had access to the full data and LS and JZ had final responsibility for  
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7  
8

### 9 **Contributors**

10 All authors contributed to the overall conception and design of the study. JZ (2004, 2010, and 2015),  
11 M Delnord (2010 and 2015) and M Durox (2015) and Ashna Hindori-Mohangoo (2004, 2010)  
12 coordinated data collection. LS wrote the first draft of this manuscript, and analysed the data. All  
13 authors contributed to the interpretation of results and drafting of the manuscript. All authors read  
14 and approved the final manuscript. LS is the guarantor.

15

### 16 **Data sharing**

17 Aggregated data from the Euro-Peristat project can be downloaded from the project's website:  
18 [www.europeristat.com](http://www.europeristat.com).

19

### 20 **Acknowledgements**

21 A full list of contributors to the European Perinatal Health Report: Health and Care of Pregnant  
22 Women and Babies in Europe in 2010 can be found online [http://www.europeristat.com/our-](http://www.europeristat.com/our-network/country-teams.html)  
23 [network/country-teams.html](http://www.europeristat.com/our-network/country-teams.html)

24

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31 LS affirms that the manuscript is an honest, accurate, and transparent account of the study being  
32 reported; that no important aspects of the study have been omitted; and that any discrepancies from  
33 the study as planned (and, if relevant, registered) have been explained.

34 The Euro-Peristat Scientific Committee comprise: Gerald Haidinger (Austria), Sophie Alexander  
35 (Belgium), Pavlos Pavlou (Cyprus), Petr Velebil (Czech Republic), Laust Mortensen (Denmark), Luule  
36 Sakkeus (Estonia), Mika Gissler (Finland), Béatrice Blondel (France), Günther Heller, Nicholas Lack  
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38 Bonham (Ireland), Marina Cuttini (Italy), Janis Misins (Latvia), Jelena Isakova (Lithuania), Yolande  
39 Wagener (Luxembourg), Miriam Gatt (Malta), Jan Nijhuis (Netherlands), Kari Klungsøyr (Norway),  
40 Katarzyna Szamotulska (Poland), Henrique Barros (Portugal), Mihai Horga (Romania), Jan Cap  
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44

1 Research in context

2 Evidence before the study

3 Over the past decade there have been several systematic reviews and scoping studies that have  
4 reviewed the literature in order to investigate the rates and risk factors for stillbirth internationally  
5 and, specifically, in high income countries<sup>2,3,22</sup>. The most recent review was published in the Lancet  
6 stillbirth series in 2016<sup>23</sup>. To update these reviews, we searched PubMed for international  
7 comparisons of stillbirth published from Jan 1 2016 to the present using the search terms  
8 “(international OR worldwide)” AND “(stillbirth\* OR fetal loss\* OR fetal death\*)” AND “(rate\*)” in  
9 titles and abstracts. We only included studies in English. Research suggested that depending on the  
10 definition, between 35% and 50% of stillbirths occur before 28 completed weeks of gestation and  
11 that stillbirth rates at earlier gestations are not showing the falls seen at 28 completed weeks of  
12 gestation and over and may possibly even be increasing but international comparisons to confirm  
13 this statement are lacking. Research also highlighted international variation in reporting of deaths at  
14 22 and 23 weeks as a stillbirth or neonatal death which could impact on reported rates of stillbirth,  
15 neonatal mortality and preterm birth.

16 Added value of this study

17 We used data from 19 countries participating in the international Euro-PERISTAT project, that  
18 collected data on births and deaths starting at 22 completed weeks of gestation in 2004, 2010 and  
19 2015. This project used a standardised protocol with consistent international reporting practices for  
20 terminations of pregnancy and agreed definitions for reporting of stillbirths and live births. We  
21 estimated 32% of stillbirths were not identified using the gestational age cut-off of 28 weeks which is  
22 recommended for international studies. The pooled stillbirth rate at 24<sup>+0</sup>-27<sup>+6</sup> weeks declined from  
23 0.97 to 0.70 per 1000 births from 2004 to 2015, a reduction of 24% (RR=0.76, 95% CI 0.67 to 0.87) in  
24 line with that reported in international studies on stillbirths over 28 weeks gestation. The pooled  
25 stillbirth rate at 22<sup>+0</sup>-23<sup>+6</sup> weeks of gestation in 2015 was 0.54 and did not significantly change over  
26 time (RR 0.97, 95% CI 0.81 to 1.16) but trends varied widely between countries (RRs 0.62 to 2.09)  
27 with evidence of differing ascertainment between countries at these earlier gestations.

28 Implications of all the available evidence

29 Current definitions used for international comparisons exclude a third of stillbirths. International  
30 consistency of reporting stillbirths at 24+0-27+6 weeks suggests that to ensure that the magnitude of  
31 the burden of stillbirth is better understood and to improve routine data for monitoring of the  
32 outcomes and management of extremely preterm births, WHO's threshold for international  
33 comparisons should be lowered, at least for high income countries. This would have a major impact,  
34 acknowledging the burden of perinatal death to families, and making international assessments more  
35 informative for clinical practice and policy. Ascertainment of fetal deaths at 22+0-23+6 weeks should  
36 be stabilised so that all stillbirths from 22 completed weeks of gestation onwards can be reliably  
37 compared. Contrary to speculation, stillbirths at 24<sup>+0</sup> to 27<sup>+6</sup> weeks are declining in a similar manner  
38 to stillbirths seen at later gestations in European and other high income countries. Stillbirths  
39 occurring at 22<sup>+0</sup> to 23<sup>+6</sup> weeks of gestation have remained steady over time, but this is likely to be  
40 related to improvements in the reporting of deaths at these gestations. Improvements to  
41 ascertainment of stillbirths at 22 and 23 weeks of gestation within countries will allow the routine  
42 reporting of all stillbirths from 22 completed weeks of gestation onwards or even earlier  
43 internationally. This would lead to better alignment of the gestational age at which stillbirths and  
44 neonatal deaths are reported.

Table 1: Total births at all gestations, number of stillbirths by gestational age, percentage of all stillbirths occurring at 22<sup>+0</sup> to 23<sup>+6</sup> weeks, 24 to 27 weeks and 22 to 27 weeks of gestation in 2015 and information on inclusion of terminations of pregnancy by country (N/A=Not available)

Country	Total births >=22 <sup>+0</sup> weeks	Number of stillbirths by gestational age				Percentage of all stillbirths			Inclusion of termination of pregnancy
		22 <sup>+0</sup> -23 <sup>+6</sup> weeks	24 <sup>+0</sup> -27 <sup>+6</sup> weeks	>=28 <sup>+0</sup> weeks	Unknown gestation	22 <sup>+0</sup> -23 <sup>+6</sup> weeks	24 <sup>+0</sup> -27 <sup>+6</sup> weeks	22 <sup>+0</sup> -27 <sup>+6</sup> weeks	
Austria	83884	32	43	202	0	11.6	15.5	27.1	Excluded
Czech Republic	111162	43	52	296	7	10.8	13.1	23.9	Excluded
Denmark	57847	24	31	115	0	14.1	18.2	32.4	Excluded
Estonia	13961	4	7	43	0	7.4	13.0	20.4	Excluded
Finland	55759	32	24	114	1	18.7	14.0	32.7	Excluded
Germany	728505	276	461	1759	63	10.8	18.0	28.8	Excluded
Hungary	92206	120	68	338	0	22.8	12.9	35.7	Excluded
Ireland	65913	17	51	222	0	5.9	17.6	23.4	Excluded
Italy	486557	338	261	1175	6	19.0	14.7	33.6	Excluded
Latvia	21826	20	13	73	0	18.9	12.3	31.1	Included 22 <sup>+0</sup> -23 <sup>+6</sup> +
Lithuania	31601	10	23	90	3	7.9	18.3	26.2	Excluded
Netherlands	169234	292	124	358	35	36.1	15.3	51.4	Included >=22 <sup>+0</sup> but rare >=24 <sup>+0</sup> +
Norway	59928	35	44	134	1	16.4	20.6	36.9	Excluded
Poland	376968	149	237	932	3	11.3	17.9	29.2	Excluded
Portugal	86048	23	45	218	0	8.0	15.7	23.8	Included 22 <sup>+0</sup> -23 <sup>+6</sup> ++
Slovenia	20397	16	36	72	0	12.9	29.0	41.9	Included >=22 <sup>+0</sup> from 2010 <sup>++</sup>
UK: England and Wales	699204	N/A	915	2232	0	N/A	27.1	N/A	Included but rare >=24 <sup>+0</sup> +
UK: Northern Ireland	24544	N/A	19	63	0	N/A	23.2	N/A	Excluded
UK: Scotland	54513	26	45	153	1	11.6	20.0	31.6	Included >=22 <sup>+0</sup> in 2004 & >=24 <sup>+0</sup> in 2010 but rare >=24 <sup>+0</sup> , excluded in 2015 <sup>++</sup>
Overall *	2516309	1457	1565	6294	120	15.4	16.6	32.0	

+ Excluded from sensitivity analysis for 22 to 23 weeks; ++ Excluded from sensitivity analysis of 22 to 23 and 24 to 27 weeks) \* Excluding England and Wales and Northern Ireland as data were not available on births and deaths at 22 to 23 weeks

Figure 1a and 1b: Rates of stillbirth per 1000 total births by country in 2004, 2010 and 2015 and risk ratio for 2015 vs. 2004 by country: 22<sup>+0</sup> to 23<sup>+6</sup> weeks and 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation.

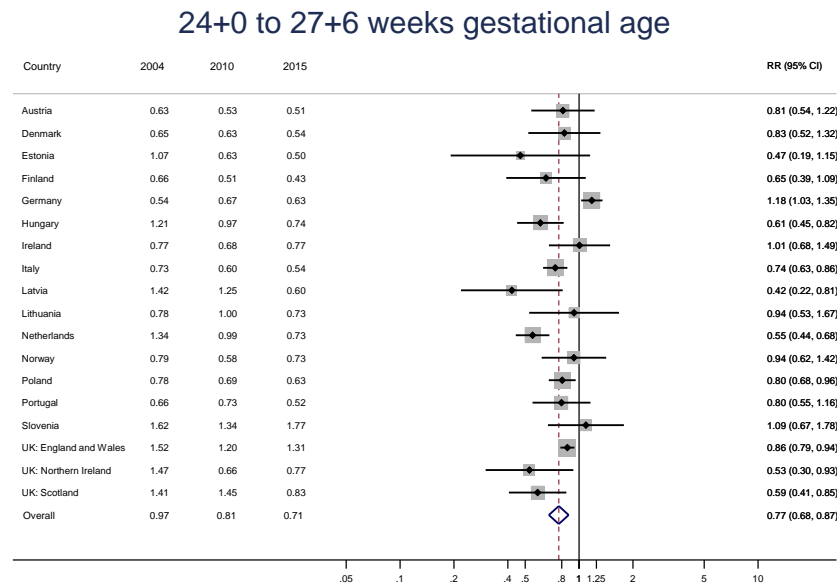
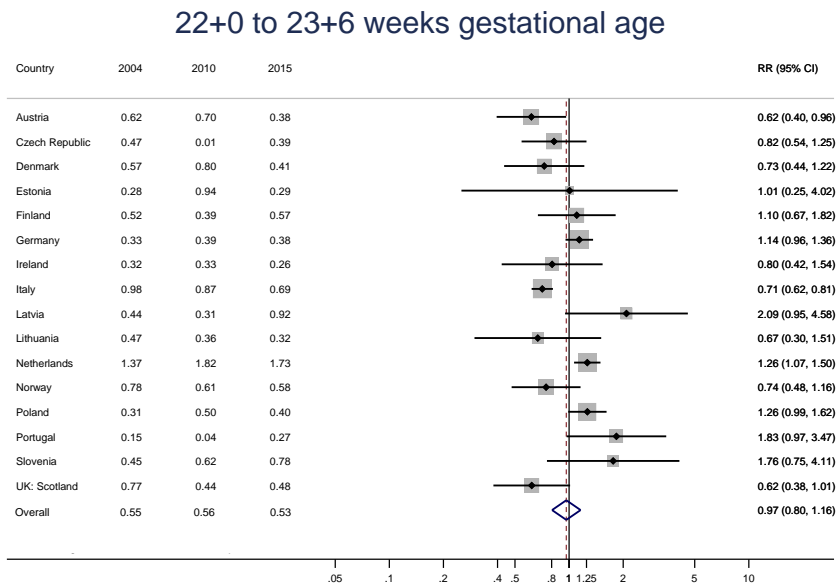
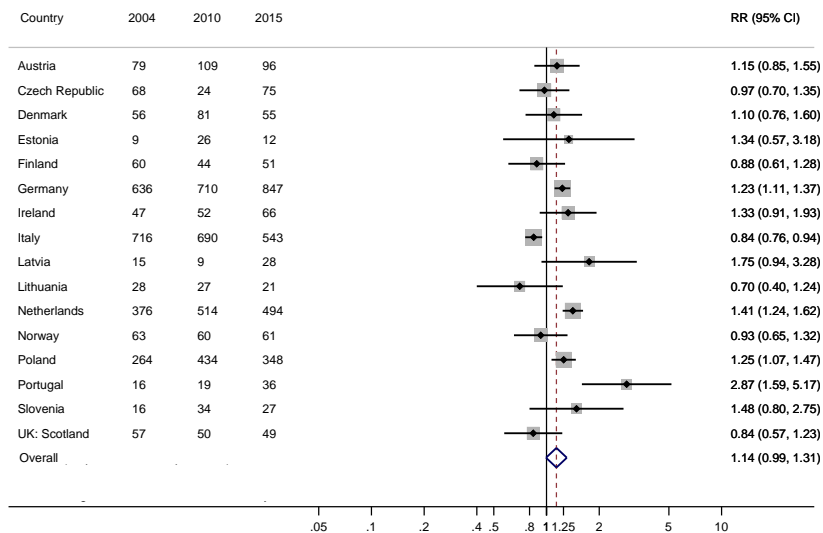
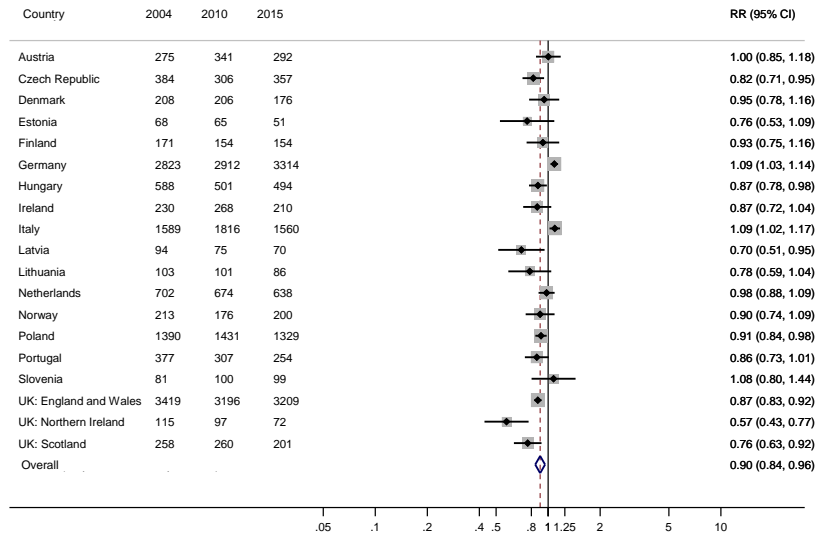


Figure 2a and 2b: Total births in 2004, 2010 and 2015 and rate ratio of gestation specific birth rate in 2015 compared to 2004 by country: 22<sup>+0</sup> to 23<sup>+6</sup> weeks and 24<sup>+0</sup> to 27<sup>+6</sup> weeks of gestation

### 22+0 to 23+6 weeks gestational age



### 24+0 to 27+6 weeks gestational age



Supplemental Table S1. Routine Euro-Peristat data sources used to report on fetal mortality in 2004, 2010 and 2015

Country	Data source, Institution		
	2004	2010	2015
<b>Austria</b>	Birth statistics, Statistics Austria	Same	Same
<b>Czech Republic</b>	Institute for Health Statistics and Information of the Czech Republic (UZIS CR)	Institute for Health Statistics and Information of the Czech Republic (UZIS CR)	CZSO Czech Statistical Office
<b>Denmark</b>	The Medical Birth Register	Same	Same
<b>Estonia</b>	Estonian Medical Birth Register, National Institute for Public Health	Same	Same
<b>Finland</b>	Medical Birth Register, National Institute for Health and Welfare	Same	Same
<b>Germany</b>	Destatis (Federal Statistical Office) and BQS Institut für Qualität & Patientensicherheit GmbH	AQUA and Destatis for TOP data	IQTIG Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (IQTIG)
<b>Hungary</b>	Hungarian Central Statistical Office	Same	Same
<b>Ireland</b>	National Perinatal Reporting System (NPRS)	Same	Same
<b>Italy 1</b>	Birth certificates CeDAP, Ministry of Health – Office of statistics	Same	Same
<b>Italy 2</b>	Survey on spontaneous abortions, National Institute of Statistics Italy ISTAT	Same	Same
<b>Italy 3</b>	Survey on induced abortions, National Institute of Statistics Italy ISTAT	Same	Same
<b>Italy 4</b>		Hospital discharge form, Regional authorities and Ministry of Health	Same as in 2010
<b>Latvia</b>	Newborn register of Latvia & Cause-of-Death register, Health Statistics and Medical Technologies State Agency	Medical Birth Register, Centre for Disease Prevention and Control	Same as in 2010
<b>Lithuania</b>	Medical Data of Births, Health Information Centre (LHIC)	Same	Same
<b>Netherlands</b>	Netherlands Perinatal Register PRN	Same	Same
<b>Norway</b>	Medical Birth Register of Norway, Norwegian Institute of Public Health	Same	Same
<b>Poland</b>	Birth and death certificates, Central Statistical Office	Same	Same
<b>Portugal</b>	Demographic statistics on births and deaths, National Institute of Statistics	Same	Same
<b>Slovenia</b>	National Perinatal Information System of Slovenia	Same	Same
<b>United Kingdom: England &amp; Wales</b>	Civil Registration of births and deaths, Office for National Statistics	Same	Same
<b>United Kingdom: Northern Ireland</b>	Confidential Enquiry into Maternal and Child health, CEMACH	Child Health System, CHS	Northern Ireland Maternity System, NIMATS
<b>United Kingdom: Scotland</b>	Scottish Stillbirth and Infant death Inquiry	Scottish Morbidity Record (SMR02)	Same as in 2010



Table S2: Total births at all gestations, number of stillbirths by gestational age, percentage of all stillbirths occurring at 22<sup>+0</sup> to 23<sup>+6</sup> weeks, 24<sup>+0</sup> to 27<sup>+6</sup> weeks and 22<sup>+0</sup> to 27<sup>+6</sup> weeks of gestational age in 2004 and information on inclusion of terminations of pregnancy by country (N/A=Not available)

Country	Total births	Number of stillbirths by gestational age				% total stillbirths by gestational age		
		22 <sup>+0</sup> -23 <sup>+6</sup> weeks	24 <sup>+0</sup> -27 <sup>+6</sup> weeks	>=28 <sup>+0</sup> weeks	Unknown gestation	22 <sup>+0</sup> -23 <sup>+6</sup> weeks	24 <sup>+0</sup> -27 <sup>+6</sup> weeks	22 <sup>+0</sup> -27 <sup>+6</sup> weeks
Austria	79243	49	50	196	0	16.6	16.9	33.6
Czech Republic	98058	46	100	241	0	11.9	25.8	37.7
Denmark	64853	37	42	239	14	11.1	12.7	23.8
Estonia	14053	4	15	44	0	6.3	23.8	30.2
Finland	57759	30	38	117	5	15.8	20.0	35.8
Germany	674436	224	362	1648	27	9.9	16.0	25.9
Hungary	95613	N/A	116	354	6	N/A	24.4	N/A
Ireland	62400	20	48	266	0	6.0	14.4	20.4
Italy	542003	531	395	2011	0	18.1	13.4	31.5
Latvia	20492	9	29	99	0	6.6	21.2	27.7
Lithuania	29633	14	23	116	0	9.2	15.0	24.2
Netherlands	182279	249	243	763	18	19.6	19.1	38.6
Norway	57370	45	45	167	0	17.5	17.5	35.0
Poland	358440	112	280	1345	6	6.4	16.1	22.5
Portugal	109778	16	72	294	40	3.8	17.1	20.9
Slovenia	17946	8	29	63	0	8.0	29.0	37.0
UK: England & Wales	649573	N/A	988	2630	68	N/A	26.8	N/A
UK: Northern Ireland	22504	25	33	84	0	17.6	23.2	40.8
UK: Scotland	53269	41	75	242	0	11.5	20.9	32.4
Overall*	2422012	1460	1879	7935	184	13.0	16.7	29.6

\*Excluding England and Wales and Hungary as data not available on births and deaths at 22<sup>+0</sup> to 23<sup>+6</sup> weeks

Table S3: Total births at all gestations, number of stillbirths by gestational age, percentage of all stillbirths occurring at 22<sup>+0</sup> to 23<sup>+6</sup> weeks, 24<sup>+0</sup> to 27<sup>+6</sup> weeks and 22<sup>+0</sup> to 27<sup>+6</sup> weeks of gestational age in 2010 and information on inclusion of terminations of pregnancy by country (N/A=Not available)

Country	Total births	Number of stillbirths by gestational age				% total stillbirths by gestational age		
		22 <sup>+0</sup> -23 <sup>+6</sup> weeks	24 <sup>+0</sup> -27 <sup>+6</sup> weeks	>=28 <sup>+0</sup> weeks	Unknown gestation	22 <sup>+0</sup> -23 <sup>+6</sup> weeks	24 <sup>+0</sup> -27 <sup>+6</sup> weeks	22 <sup>+0</sup> -27 <sup>+6</sup> weeks
Austria	78989	55	42	194	0	18.9	14.4	33.3
Czech Republic	116569	N/A	N/A	169	0	N/A	N/A	N/A
Denmark	63510	51	40	146	0	21.5	16.9	38.4
Estonia	15884	15	10	43	0	22.1	14.7	36.8
Finland	61371	24	31	120	5	13.3	17.2	30.6
Germany	637664	246	428	1429	0	11.7	20.4	32.0
Hungary	90844	130	88	304	0	24.9	16.9	41.8
Ireland	75595	25	51	275	1	7.1	14.5	21.6
Italy	547087	474	330	1276	16	22.6	15.7	38.4
Latvia	19248	6	24	79	0	5.5	22.0	27.5
Lithuania	30977	11	31	104	0	7.5	21.2	28.8
Netherlands	178838	326	177	509	9	31.9	17.3	49.3
Norway	62058	38	36	164	2	15.8	15.0	30.8
Poland	415015	209	285	1226	0	12.2	16.6	28.7
Portugal	101790	4	74	242	0	1.2	22.6	23.9
Slovenia	22416	14	30	74	0	11.9	25.4	37.3
UK: England & Wales	721925	N/A	867	2684	108	N/A	23.7	N/A
UK: Northern Ireland	25690	N/A	17	87	0	N/A	16.3	N/A
UK: Scotland	57467	25	83	208	0	7.9	26.3	34.2
Overall *	2458753	1654	2644	9333	141	16.9	17.9	34.8

\* Excluding England and Wales, Northern Ireland and Czech Republic as data not available on births and deaths at 22 to 23 weeks

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