Small Vulnerable Newborns 2

Small babies, big risks: global estimates of prevalence and mortality for vulnerable newborns to accelerate change and improve counting

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Small newborns are vulnerable to mortality and lifelong loss of human capital. Measures of vulnerability previously focused on liveborn low-birthweight (LBW) babies, yet LBW reduction targets are off-track. There are two pathways to LBW, preterm birth and fetal growth restriction (FGR), with the FGR pathway resulting in the baby being small for gestational age (SGA). Data on LBW babies are available from 158 (81%) of 194 WHO member states and the occupied Palestinian territory, including east Jerusalem, with 113 (58%) having national administrative data, whereas data on preterm births are available from 103 (53%) of 195 countries and areas, with only 64 (33%) providing national administrative data. National administrative data on SGA are available for only eight countries. Global estimates for 2020 suggest 13·4 million livebirths were preterm, with rates over the past decade remaining static, and 23·4 million were SGA. In this Series paper, we estimated prevalence in 2020 for three mutually exclusive types of small vulnerable newborns (SVNs; preterm non-SGA, term SGA, and preterm SGA) using individual-level data (2010–20) from 23 national datasets (~110 million livebirths) and 31 studies in 18 countries (~0·4 million livebirths). We found 11·9 million (50% credible interval [Crl] 9·1–12·2 million; 8·8%, 50% Crl 6·8–9·0%) of global livebirths were preterm non-SGA, 21·9 million (50% Crl 20·1–25·5 million; 16·3%, 14·9–18·9%) were term SGA, and 1·5 million (50% Crl 1·2–4·2 million; 1·1%, 50% Crl 0·9–3·1%) were preterm SGA. Over half (55·3%) of the 2·4 million neonatal deaths worldwide in 2020 were attributed to one of the SVN types, of which 73·4% were preterm and the remainder were term SGA. Analyses from 12 of the 23 countries with national data (0·6 million stillbirths at ≥22 weeks gestation) showed around 74% of stillbirths were preterm, including 16·0% preterm SGA and approximately one-fifth of term stillbirths were SGA. There are an estimated 1·9 million stillbirths per year associated with similar vulnerability pathways; hence integrating stillbirths to burden assessments and relevant indicators is crucial. Data can be improved by counting, weighing, and assessing the gestational age of every newborn, whether liveborn or stillborn, and classifying small newborns by the three vulnerability types. The use of these more specific types could accelerate prevention and help target care for the most vulnerable babies.

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Introduction

In 2020, there were 8·6 million stillbirths and deaths in newborns, children, and adolescents, of which more than half died during pregnancy or around the time of birth.[1,2] Notably, almost two million stillbirths occurred in the last 3 months of pregnancy[3,4] and 2·3 million liveborn babies died within their first 28 days of life (ie, neonatal deaths).[1,3] Additionally, an estimated 287 000 women died of pregnancy complications with linked underlying causes.[5]

The Every Newborn action plan set targets of 12 or fewer neonatal deaths per 1000 livebirths, adopted as sustainable development goal (SDG) 3.2, and for 12 or fewer stillbirths per 1000 total births by 2030, which was not set as an SDG.[6,7] At the halfway point for the SDGs, the countries needing the greatest acceleration to meet these targets are in sub-Saharan Africa and southern Asia, where the risk of death around the time of birth is the highest, yet data availability is lowest—also known as the inverse data law.[8] Vulnerability at birth and global inequalities in the care for these newborns is driving these high numbers of deaths for babies around the time of birth.[9,10]

For over a century, the assessment of vulnerability at birth has traditionally focused on low-birthweight (LBW) babies defined as less than 2500 g.[11] LBW is a marker for early death and long-term health, being a foundational metric underpinning life-course epidemiology and the developmental origins of health and disease theory.[12] Globally, an estimated 19·8 million babies were born with LBW in 2020.[13] There have been global targets for LBWs since 1990; however, none of these targets have been met and currently the Global Nutrition Target for LBW, set at the World Health Assembly, which aims for a 30% reduction in the prevalence of LBW babies between 2012 and 2030, is far off track.[13,14] The estimated annual rate of reduction is 0·3%, which would need to be eleven times faster to achieve the target.[13]

LBW is caused by two underlying pathways: short pregnancy gestation (ie, preterm birth before

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Key messages

Small babies, big numbers, slow progress
Preterm birth rates have not changed measurably in the past decade, and low birthweight (LBW) targets are off track. One in ten livebirths (13·4 million) were preterm (known as born too soon) and one in five (23·4 million) were small for gestational age (SGA; known as born too small) in 2020. Of 135 million livebirths in 2020, 35·3 million (26·2%) were small vulnerable newborns (SVNs), defined as any baby born preterm, or SGA or both preterm and SGA. Together, these three vulnerable newborn types account for 99·5% of the world's 20 million LBW babies. Nearly two thirds (63·0%) of the world's term SGA newborns are in southern Asia (14·8 million, 40·9% of livebirths). Preterm birth rates have less regional variation but are also highest in southern Asia (13·2%).

Big risks inform targeting for prevention and care
Mortality risk is highest for preterm birth, especially at lower gestational ages. Newborns who are born both preterm and small for gestational age (SGA) are less prevalent at 1·1% (50% credible interval [CrI] 0·9–3·1) of births worldwide in 2020, but have the highest mortality risk. SGA, including many non-LBW newborns, has an elevated mortality risk but lower risk than that of preterm births. Just over half of neonatal deaths (1·4 million) were attributable to SVN types, with most (73·4%) attributable to preterm or preterm with SGA and the reminder to term SGA. Applying these newborn types could accelerate the evaluation of mechanisms, diagnostics, and interventions.

Stillbirths are more likely to be preterm and small
For 12 middle-income and high-income countries with individual-level data, around three-quarters of stillbirths were preterm. Around a fifth of term stillbirths were SGA. Compared with term non-SGA, the median stillbirth rate ratio was 84·4 for preterm SGA, 25·8 for preterm non-SGA, and 5·9 for term SGA, showing a clear association between stillbirth and SVN types. More data are needed, especially from high-SGA contexts.

Counting every newborn
158 (81%) of 194 WHO member states and the occupied Palestinian territory, including east Jerusalem, have national LBW or survey data, yet only 103 (53%) have preterm data (64 national administrative data and 40 from research studies). Given that more than 80% of births are now in facilities, routine national data can be improved through increasing the coverage of gestational age measurement. In addition to aggregate data, countries and areas need electronic individual-level data on gestational age information, sex, and birthweight to calculate SGA. More investment will enable every baby (including stillbirths) everywhere to be classified by SVN types, thereby improving individual care, the tracking of outcomes, and accountability for progress.

37 completed weeks of gestation, also known as born too soon[15]) and fetal growth restriction (FGR) typically identified as a baby who is a small-for-gestational-age (SGA) assessment (ie, below tenth centile of birthweight for gestational age and sex, also known as born too small).[16] Clinical obstetric and neonatal risk prediction for viability rely primarily on gestational age thresholds. There are more than 20 published scoring models for risk prediction and most note that gestational age is more highly predictive than birthweight alone.[17] The dichotomous classification of LBW at 2500 g is not granular enough to understand the continuous gradients of risk for vulnerability. In addition, historical thresholds might be less relevant given medical advances, especially regarding the care of preterm neonates, with many neonates born at 23 weeks gestation surviving if neonatal intensive care is available.[11,18]

More accurately identifying types of vulnerable newborns is crucial to individual-level care and to faster progress for primary prevention, including delineating causal mechanisms and improving targeted clinical care. Defining vulnerability on the basis of LBW or preterm birth alone also omits the consideration of newborns who are term and SGA. Separate measures do not account for overlapping categories; for example, newborns could be both preterm and SGA.

Stillbirths can result from the same pathways affecting liveborn newborns, but are currently not in relevant tracking or burden assessments.[19] For instance, the denominator for both LBW and preterm rates is per 1000 livebirths.[20] Stillbirths are strongly associated with FGR and might be SGA at birth.[21] Preterm labour can result in stillbirth and, conversely, a stillbirth might result in preterm labour. If measurement and research for SVNs focuses only on livebirths, the true burden and major effects on women, families, and society are missed.[22] Omitting information on stillbirths from efforts to quantify and address the burden of SVNs can be misleading. With better obstetric monitoring of vulnerability in utero, inductions of labour and caesarean sections might be increased to prevent stillbirth, yet this might also increase preterm and SGA rates among livebirths.[23] The opposite might be seen when obstetric care is restricted; for example, during the COVID-19 pandemic lockdowns, some analyses showed reductions in LBW and preterm birth among livebirths[24] but omitted stillbirth data, which is potentially misleading given the increased stillbirth rates during lockdowns.[25]

Evidence regarding preterm births, SGA, and stillbirths are impeded by gaps in data availability and quality. However, there have been improvements in data availability and some low-income and middle-income countries have achieved remarkable shifts in the past two decades within routine national data systems, notably for measuring LBW (Ohuma EO and colleagues, unpublished). Learning from improvements in the data systems of these countries could help to accelerate the

availability and use of data regarding SVNs, which is urgently needed in the time remaining to reach SDG targets.

This paper is part of a four-paper *Lancet* Series on SVNs. We aim to provide novel, epidemiological data and estimates for all SDG regions regarding SVNs to inform faster progress for primary prevention and improved data collection and use. New analyses presented in this Series paper include: (1) preterm estimates for 2020, and trends between 2010 and 2020 with population-level aggregate data, described in detail elsewhere, are used in this paper as an input to the first worldwide SGA estimates; (2) individual-level data analyses and Bayesian modelling for the first prevalence estimates for three mutually exclusive types of SVN among liveborn neonates (preterm and non-SGA, including appropriate for gestational age [AGA] and large for gestational age [LGA]; preterm and SGA; and term and SGA, including full term and post-term); (3) neonatal mortality risk for types of liveborn SVNs worldwide and stillbirth rates and rate ratios across multiple countries; and (4) better measurement for every baby, everywhere, including stillbirths, based on descriptive analyses of data from 194 WHO member states and the occupied Palestinian territory (including east Jerusalem; herein referred to as countries and areas). We also outline implications of better data on these SVN types for guiding basic research, clinical practice, and country programmatic and policy responses.

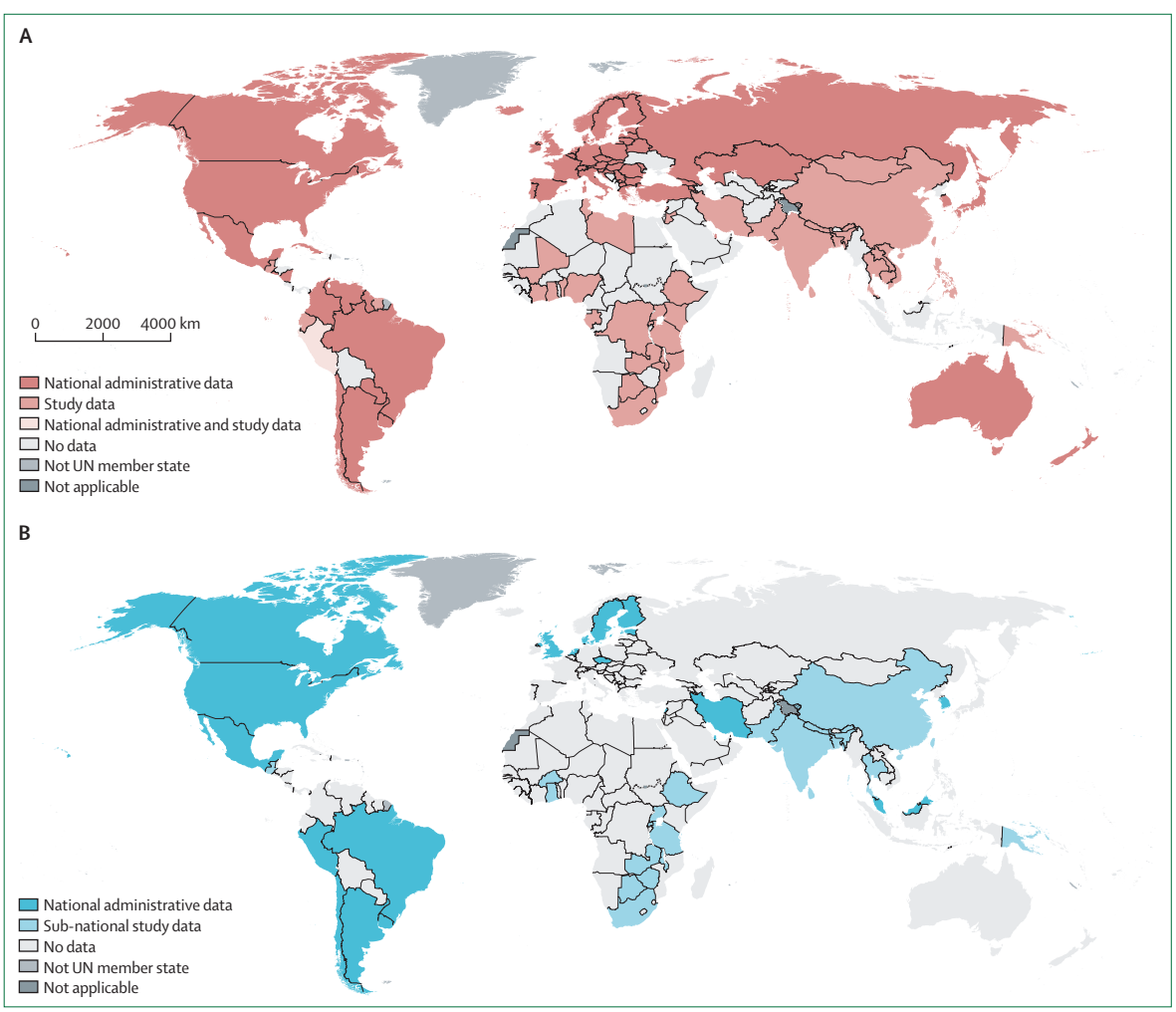
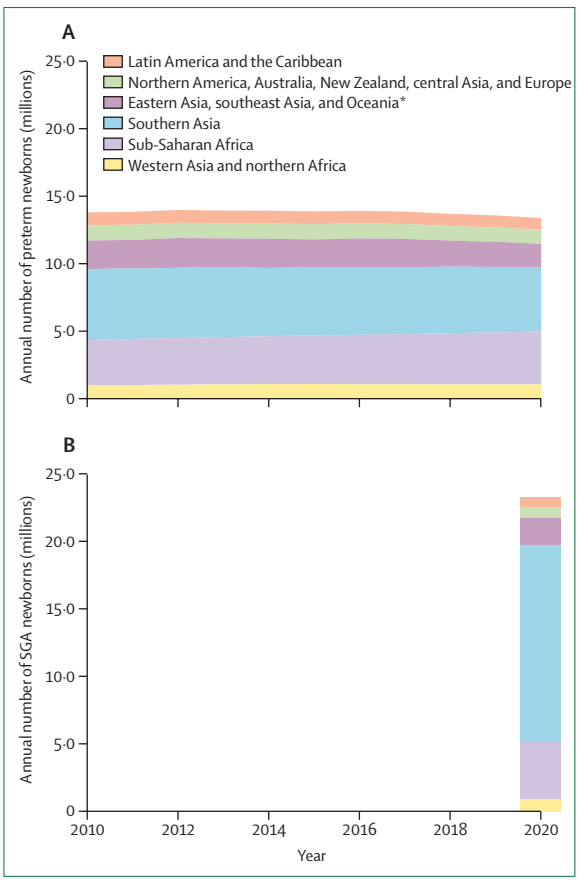


Figure 1: **Input data for vulnerable newborn types and regional and global estimates**
(A) Aggregate data available for national rates of preterm birth used in UNICEF and WHO 2020 estimates (Ohuma EO and colleagues, unpublished). For more details, see the appendix (pp 9–14). (B) Individual-level data available for estimation of SGA and SVN types. National data available from 23 countries and areas (110 million livebirths for 2010–20) and study or subnational data from 18 countries and areas (0·4 million livebirths).[40,41] In total, 41 countries and areas contributed data as Argentina, Brazil, and Mexico had both national and subnational data sets. The UK provided inputs for Scotland, Northern Ireland, England, and Wales, but was modelled as one nation. For more details, see the appendix (pp 19–20). The maps show 42 countries with permission to be named. Dotted and dashed lines on maps represent approximate border lines for which there might not be full agreement. The boundaries shown on these maps do not signify any official endorsement of borders or the legal status of any country or territory. SGA=small for gestational age. SVN=small vulnerable newborn.



See Online for appendix

Figure 2: **Preterm birth and SGA: regional and global estimated numbers**
(A) Preterm birth numbers by region for 2020, with trends from 2010–20, based on WHO/UNICEF estimates.[42] (B) SGA estimated numbers by region for 2020. No time trend data available. For more details, see the appendix (pp 5, 15–30). SGA=small for gestational age. *Excluding Australia and New Zealand.

Preterm and SGA estimates worldwide

The history of data for SVNs varies for the different measures, with LBW receiving over a century of focus, 30 years of prevention targets, and now 20 years of national time trends with two rounds of UN estimates (ie, 2020 and 2015).[14] Preterm birth rate is a newer measure, even in high-income countries, with more variability in measurement ranging from the gold standard of early-pregnancy ultrasound to more uncertain methods, such as last menstrual period, but with promising innovations in the pipeline.[26–30] There are now preterm time trends for 10 years, 2010–20, with three WHO estimation exercises for the years 2010 (for the Born Too Soon report), 2014, and 2020.[9,15,31]

In contrast, SGA has had two sets of estimates by use of two different growth standards. However, these estimates were only for some regions and there are no worldwide estimates or time trends.[32–34] To categorise size for gestational age the baby's sex, gestational age, and birthweight are needed and compared with a standard. Until the past decade, comparable multicountry estimates were impeded by the absence of an international standard for newborn size at birth according to gestational age and sex, but a standard is now available as provided in the INTERGROWTH-21st project.[35,36] These standards are becoming widely used and we applied them in our analyses given the need for international comparisons. In the past, observed differences in human growth were attributed to biological differences leading to descriptive population-specific charts. However, evidence shows similarities in the growth trajectories in healthy, optimally nourished populations across different geographical contexts worldwide, giving a scientific basis for international, prescriptive growth charts.[37–39]

Preterm birth-rate estimates are based on aggregate national data, often from facility-based routine health information systems. For WHO and UNICEF preterm estimates for 2020, 64 (33%) of 195 countries and areas had nationally representative, administrative, preterm birth-rate data that met the inclusion criteria, compared with 113 (58%) with administrative data for LBW. Input data for these preterm estimates are shown in figure 1A. National routine data gaps are most notable across southern and southeast Asia and sub-Saharan Africa. Details of data collation, quality assessment, and the Bayesian modelling approach used to generate these estimates are provided elsewhere.[42]

In 2020, there were an estimated 13·4 million preterm livebirths or babies born too soon, constituting one in every ten newborns (9·9%; 95% credible interval [CrI] 9·1–11·2; appendix p 5; Ohuma EO and colleagues, unpublished). Trend estimates for 2010–20 suggest no measurable change in preterm birth rates for most regions and no downward trend, especially in the highest burden regions (figure 2A). Preterm rates vary within most regions, with rates above the global average in some high-income countries, such as the USA at 10·0% (95% CrI 9·6–10·4). For preterm subgroups, globally, 15·0% of all preterm births are born before 32 weeks, 10·4% at 28–32 weeks (95% CI 9·5–10·6), and 4·2% before 28 weeks (95% CI 3·1–5·0).

National aggregate data for SGA are lacking, with just eight countries reporting on SGA rates and, among these countries, various growth references were used. Therefore, population-level estimation approaches used for preterm birth or LBW cannot currently be used for SGA (Okwaraji Y and colleagues, unpublished; Ohuma EO and colleagues, unpublished). Given these gaps in knowledge and the imperative for burden estimation, we estimated overall SGA from the modelling of SVN types using a Bayesian approach with individual-level data, applying a single, common, international standard (figure 2B).[35,36] We estimated 23·4 million (17·4%) liveborn babies were born SGA in 2020 (figure 2B). There was marked regional variation in SGA, with more than a third (40·9%) of all newborns in southern Asia being SGA compared with 10·7% in sub-Saharan Africa

	Preterm non-SGA		Term and SGA		Preterm and SGA		Total (any type of SVN)	
	% (50% credible interval)	Number in thousands (50% credible interval)	% (50% credible interval)	Number in thousands (50% credible interval)	% (50% credible interval)	Number in thousands (50% credible interval)	% (50% credible interval)	Number in thousands (50% credible interval)
Latin America and the Caribbean	8·1 (7·9–8·2)	794·9 (770·1–808·9)	7·0 (6·1–8·6)	687·0 (599·6–846·5)	0·8 (0·6–1·0)	75·0 (61·0–99·8)	15·9 (15·0–17·5)	1556·8 (1469·5–1716·3)
Eastern Asia, southeast Asia, and Oceania*	6·2 (6·0–6·3)	1569·6 (1517·1–1602·6)	7·3 (5·9–10·0)	1831·5 (1485·9–2519·7)	0·6 (0·5–0·8)	148·1 (115·1–200·6)	14·1 (12·7–16·8)	3549·2 (3203·5–4237·3)
North America, Australia and New Zealand, central Asia, and Europe	7·2 (7·0–7·4)	949·8 (920·5–968·1)	5·9 (4·1–8·6)	769·7 (544·8–1133·2)	0·7 (0·5–0·9)	89·2 (71·0–118·6)	13·8 (12·1–16·5)	1808·7 (1583·9–2172·3)
Southern Asia	11·2 (3·7–12·2)	4037·3 (1339·2–4400·0)	38·8 (34·9–42·9)	14 022·3 (12 608·8–15 472·3)	2·1 (1·0–9·5)	740·8 (378·1–3438·9)	52·1 (48·2–56·1)	18 800·4 (17 386·9–20 250·4)
Sub-Saharan Africa	9·2 (8·9–9·4)	3575·6 (3463·5–3647·2)	9·8 (8·0–13·2)	3798·9 (3097·1–5126·9)	0·9 (0·7–1·2)	338·1 (266·6–450·3)	19·9 (18·1–23·3)	7712·7 (7010·9–9040·7)
Western Asia and northern Africa	8·3 (8·0–8·5)	964·9 (935·0–988·5)	7·2 (4·3–11·7)	833·8 (499·8–1365·5)	0·8 (0·6–1·0)	91·3 (67·6–121·2)	16·2 (13·4–20·8)	1890·0 (1555·9–2421·7)
Global	8·8 (6·8–9·0)	11 892·0 (9138·4–12 155·7)	16·3 (14·9–18·9)	21 943·2 (20 064·6–25 462·6)	1·1 (0·9–3·1)	1482·6 (1218·9–4236·3)	26·2 (24·8–28·8)	35 317·9 (33 439·2–38 837·2)

SGA=small for gestational age. SVN=small vulnerable newborn. *Excluding Australia and New Zealand.

Table 1: **Estimates of prevalence of three SVN types per 100 livebirths by region for 2020**

	Number of countries and areas in NMR group (2020)	Term non-SGA (neonatal mortality rate per 1000 livebirths; reference group; median, IQR)	Neonatal mortality RR		
			Preterm SGA (median, IQR)	Preterm non-SGA (median, IQR)	Term SGA (median, IQR)
6 subnational studies (100 913 livebirths, 4016 deaths)					
30 to <45 deaths per 1000 livebirths	15	13·8 (7·5, 14·5)	12·4 (8·8, 18·7)	11·6 (5·7, 19·9)	3·4 (2·2, 4·9)
5 subnational studies (40 339 livebirths, 1078 deaths)					
15 to <30 deaths per 1000 livebirths	48	10·1 (7·3, 11·6)	12·7 (6·0, 14·4)	10·6 (5·1, 11·8)	2·7 (2·5, 2·7)
5 subnational studies (96 860 livebirths, 1247 deaths) and 2 national studies (26 906 355 livebirths, 182 454 deaths)					
5 to <15 deaths per 1000 livebirths	65	6·3 (3·4, 7·0)	10·4 (7·3, 39·6)	4·0 (2·6, 11·7)	2·7 (1·5, 4·1)
13 national datasets (96 020 388 livebirths, 286 777 deaths)					
<5 deaths per 1000 livebirths	67	0·6 (0·4, 0·6)	76·8 (70·3, 89·1)	36·5 (32·7, 40·9)	5·9 (4·6, 6·8)

NMR=neonatal mortality rate. RR=relative risk. SVN=small vulnerable newborn. See the appendix (pp 31–34).

Table 2: **Neonatal mortality RR for three SVN types by neonatal mortality rate group**

and less than 10% in other regions. Time trends for SGA could not be estimated due to insufficient data but should be a future priority.

SVN types worldwide

Given the imperative for addressing overlaps between preterm and SGA babies, *The Lancet* Small Vulnerable Newborn Series team proposed a novel framework to categorise newborn types on the basis of gestational age (ie, term *vs* preterm), size for gestational age (ie, SGA *vs* AGA), and birthweight (ie, LBW *vs* non-LBW).[10] The original framework had six types, but in this Series paper we present a simplified grouping based on three mutually exclusive SVN types not including the dimension of LBW: preterm non-SGA, term SGA, and preterm SGA. We combined preterm AGA and preterm LGA into the preterm non-SGA group as the mortality risk associated with these types is very similar and the prevalence of preterm LGA was low (appendix pp 6–8).[40,41,43] No previous multicountry analyses have been published with these SVN types.

To conduct these analyses, large, individual-level datasets were required from around the world. The Vulnerable Newborn Measurement Collaboration[41] was

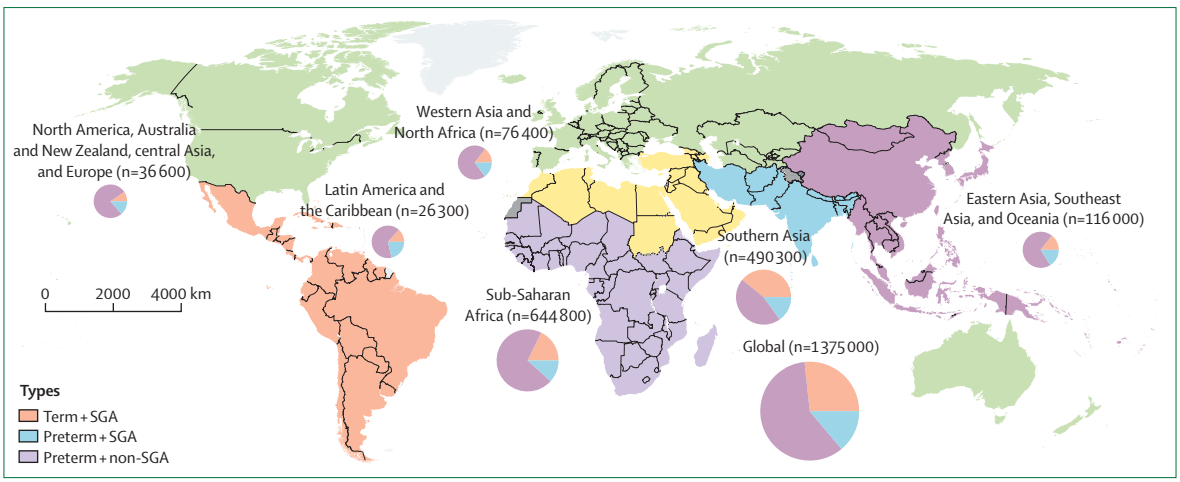


Figure 3: **Distribution of attributable neonatal deaths by three SVN types by SDG regions**
The map is coloured to show SDG regions. The areas of the pie charts are proportional to region-specific numbers of attributable deaths. Each pie chart presents neonatal deaths by vulnerable newborn type. Dotted and dashed lines on maps represent approximate border lines for which there might not be full agreement. The boundaries shown on this map do not signify any official endorsement of borders or the legal status of any country or territory. For more details, see the appendix (pp 35–36). SDG=Sustainable Development Goal. SVN=small vulnerable newborn.

initiated in 2020 to identify datasets meeting inclusion criteria and collate both national datasets and subnational studies (figure 1B; appendix pp 9–15). Details of sourcing, data quality, and analyses are given elsewhere.[40,41] The national datasets and some study datasets were analysed by the relevant teams using shared code and standardised tables. Most of the study datasets were analysed by the central study team. Each livebirth was characterised into one of three SVN types on the basis of gestational age (ie, preterm <37 weeks *vs* term ≥37 weeks) and size for gestational age and sex according to the INTERGROWTH-21st newborn standards (ie, SGA <10th centile or non-SGA ≥10th centile).[40,41] The comparison was term non-SGA newborns.

Using these data inputs, but restricted to 2010–20, combined with the WHO and UNICEF preterm birth estimates for 2020, we developed a Bayesian framework to estimate the prevalence of the three SVN types at a national level for 195 countries and areas. The Bayesian approach for SVN modelling is outlined in the appendix (pp 21–30). SGA estimates were then derived from the Bayesian-modelled estimates of the SVN types.

Overall, of 135 million livebirths worldwide in 2020, 35·3 million (26·2%, 50% CrI 24·8–28·8%) were classifiable into one of the three vulnerable newborn types, with 11·9 million (8·8%, 6·8–9·0%) preterm non-SGA, 21·9 million (16·3%, 14·9–18·9%) term SGA, and 1·5 million (1·1%, 0·9–3·1%) preterm SGA (table 1). The distribution varied by geographical region (table 1). The highest rates of SVN types are in southern Asia, where more than half (52·1%, 48·2–56·1%) of all newborns are affected, and sub-Saharan Africa, where 19·9% (18·1–23·3%) of all newborns are affected. The lowest rates of SVN newborns were in countries and areas with low neonatal mortality, such as in the SDG region of North America, Australia, New Zealand, central Asia, and Europe (13·8%, 12·1–16·5%).

Neonatal mortality and stillbirth risk for SVN types

Neonatal mortality effects

Data from 15 national datasets (125·5 million livebirths) in high-income and middle-income settings and 16 subnational, population-based cohort studies (238 000 livebirths) in low-income and middle-income settings with exposure data and linked neonatal survival between 2000 and 2020 were included. National data had a high degree of completeness for sex, gestational age, and birthweight required to estimate newborn types. However, for subnational (ie, study) data, we used multiple imputation for birthweight and the recalibration of infant weight measured after birth to the time of delivery in view of higher rates of missing birthweight data (appendix pp 31–33).[43–45]

Given that within-region variation can be wide in obstetric and newborn care over time, we grouped countries and areas by neonatal mortality rate (NMR) bands using NMRs in the input dataset so that risks were applied to a similar context for estimation (appendix p 33). We used NMR bands that have been previously used for epidemiological and health system analyses.[8,46,47]

We estimated the relative neonatal mortality risk for each of the three SVN types compared with term non-SGA within each NMR band. The relative risk (RR) was highest for babies who were preterm, SGA or not, compared with term non-SGA (table 2; appendix p 34). Risks associated with being both preterm and SGA were higher than for preterm alone in all mortality settings (table 2). The highest RRs were observed in

the lowest mortality settings due to the very low mortality risk in the comparison group (ie, term SGA). More accurate counting of preterm neonates and deaths at the extremes of viability might also contribute.

More than half (almost 1·4 million, 55·3%) of the 2·4 million neonatal deaths in 2020 were attributable to SVN types, with 32·8% (50% CrI 23·1–33·7%) attributed to preterm non-SGA, 14·7% (12·5–15·8%) attributed to term SGA, and 7·7% (6·2–16·9%) attributed to preterm SGA (figure 3; appendix pp 35–37). The regions of North America, Australia, New Zealand, central Asia, and Europe had the highest population attributable fraction of deaths to SVNs (68·0%), of which 90·8% were attributed to preterm babies (appendix pp 36–37). Term SGA has a lower RR (2·7–3·4) than preterm non-SGA (4·0–11·6; table 2), but given the high SGA prevalence, does account for 14·7% (50% CrI 12·5–15·8%) of attributed mortality globally and 21·1% (16·0–21·8%) in southern Asia, where more than half of the world's term SGA babies are born.

Stillbirth effects

Stillbirth is an extreme outcome of the SVN aetiological pathways. Small vulnerable babies frequently die before or during labour before 37 weeks of gestation, resulting in preterm stillbirth. There were an estimated 1·9 million late-gestation stillbirths (ie, at ≥28 weeks of gestation) worldwide in 2021 and the overall burden, including all stillbirths from 22 or more weeks of gestation, is even higher.[3] Despite this large burden, most of which is preventable, there has been little attention to stillbirths and progress in reducing them has been slow.[4,48] Stillbirths have not been included in most burden estimates and indicators for small babies, including LBW and preterm birth. Few previous analyses have estimated gestational age distribution for stillbirths and the contribution of suboptimal fetal growth to stillbirths with comparable multicountry data. We sought to close these gaps using stillbirth data from 12 of 23 high-income and middle-income countries and areas participating in the Vulnerable Newborn Measurement collaboration, including 605 557 stillbirths after 22 weeks of gestation (figure 4A; panel; appendix pp 38–39; Okwaraji Y and colleagues, unpublished).

In this analysis, three-quarters of the stillbirths were preterm. Approximately a fifth of term stillbirths were SGA, although this value varied by country (figure 4A). Compared with term non-SGA, the median stillbirth rate ratio was 86·8 for preterm SGA, 24·2 for preterm non-SGA, and 5·9 for term SGA. Future analyses with data from lower-income contexts would be important, notably southern Asia given the very high prevalence of SGA babies (figure 4B).

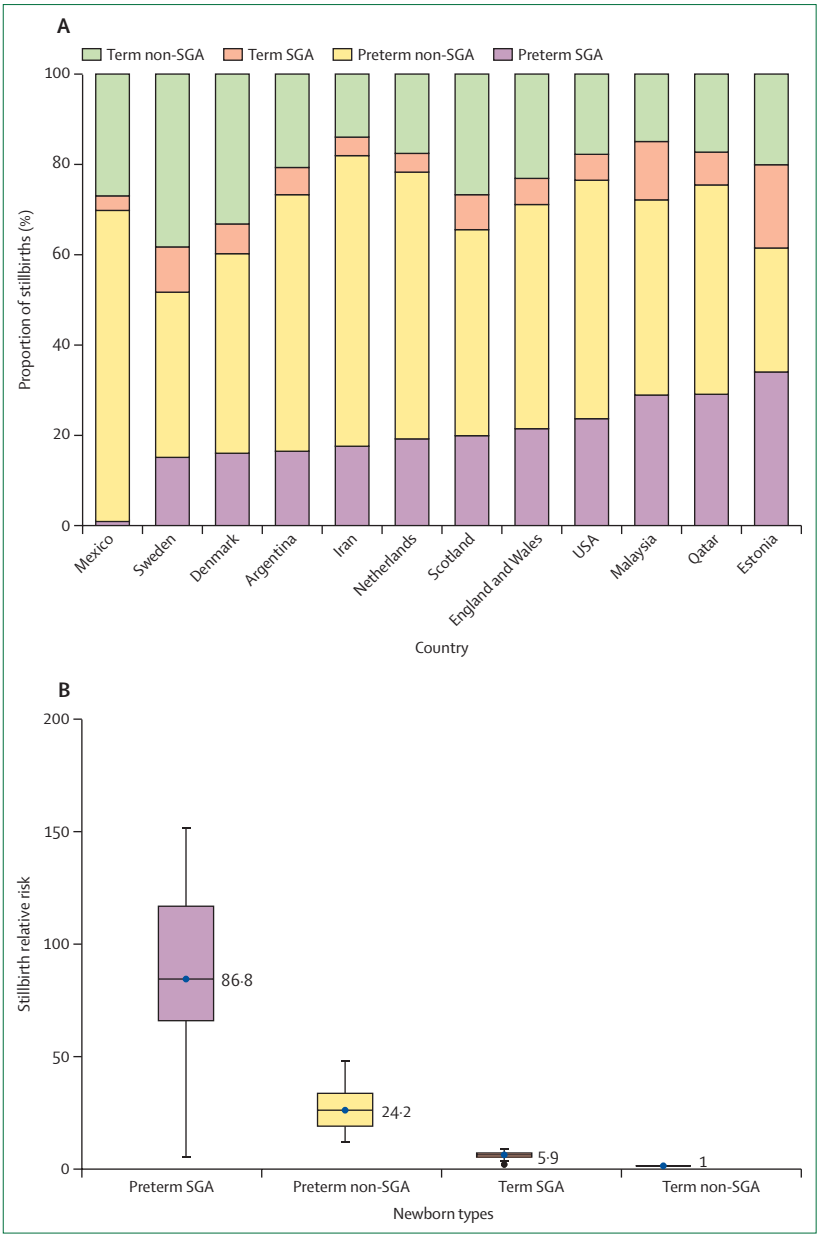


***Figure 4*: Stillbirth rates and rate ratio by vulnerable newborn type**
(B) Stillbirth rate ratio for 12 countries and areas (n=605 557). Box and whisker plots show median rate ratio and IQR. SGA=small for gestational age.

Implications for programmes

Our findings show that, in 2020, around one in four liveborn newborns worldwide (26·2%) were estimated to have at least one SVN type, which is a larger number at risk than when the LBW threshold alone is used. Globally, 13·4 million of these liveborns were preterm and 21·9 million were term SGA newborns (figure 5). Southern Asia has higher rates of preterm birth than the global average and very high rates of SGA, and accounts for 26·8% of global livebirths, but 63·0% of all SVNs. This high number of SGA newborns is multifactorial, including intergenerational.[49]

SVNs were estimated to account for 1·7 million (67·0%) of the 2·4 million neonatal deaths worldwide in 2020, of

Panel: Stillbirths and vulnerability related to being preterm and small for gestational age (SGA)

Methods

We included 605 557 stillbirths beyond 22 weeks gestation and 119 644 788 total births between 2000 and 2020 from 12 countries and areas in three SDG regions: North America, Australia, New Zealand, and Europe; southeast Asia; and western Asia (Okwaraji Y and colleagues, unpublished). Some countries and areas have variation in their threshold for stillbirth definition; for example, at 20 or 24 weeks of gestation. However, these analyses used 22 weeks and standard measures including standards for size by gestational age and sex according to the INTERGROWTH-21st project. All births were classified according to the three small vulnerable newborn (SVN) types (ie, preterm non-SGA, term SGA, and preterm SGA) or the reference type (term non-SGA).

Results

Around three-quarters of stillbirths included were born preterm, with a fifth being preterm SGA (figure 4A). Approximately one-fifth of term stillbirths were SGA, although this value varied by country. The median rate ratio (RR) for the association of stillbirth with SVN types was highest for preterm (preterm SGA RR 86·8 [IQR 71·9–115·7] or preterm non-SGA 24·2 [20·0–29·3]) compared with babies born term non-SGA (figure 4B). The risk was highest for the most preterm (<28 weeks gestation, RR 146·3 [110·7–200·7] and 28–31 weeks gestation, RR 59·4 [49·9–66·9]), but remained raised even in the late preterm period of 34–36 weeks gestation (RR 7·7 [6·9–8·6]). Babies born SGA remained at increased risk of stillbirth even after term (5·6 [2·8–13·8]).

Implications

Our analysis has strengths, including high data quality and comparability of standards and approach, but the data included were all from high-income and upper-middle-income countries and areas; more data are needed from other contexts. Improved data on the timing of fetal death in relation to gestational age, and the relative contribution of fetal growth restriction to these deaths, could inform interventions now and in future research towards ending preventable stillbirths. Improved data use at the individual and population level is possible now.

which the majority (~1·0 million) were preterm. Globally, over half (55·3%) of neonatal deaths were attributed to being SVN, with preterm births accounting for 73·4% of these attributable deaths. In the highest mortality settings, there is still an excess of newborn deaths who were not within the small vulnerable types, but in regions with lower rates of mortality a higher proportion of deaths are attributable to SVN types.

Neonatal mortality is only part of the overall burden associated with SVN types. Small babies are at increased risk of complications throughout their life course, including stunting, non-communicable disease, long-term disability, and reduced learning potential (figure 5). Southern Asia's exceptionally high SGA newborn rates have many implications, including fuelling the epidemic of non-communicable conditions in later life, particularly diabetes and hypertension.

At the individual-level, more investment is needed in closing major survival gaps for newborns in low-income settings. Most of the progress in reducing neonatal deaths in middle-income and high-income settings can be attributed to improved neonatal care,[50] and there is potential to save an estimated 742 700 lives per year in low-income and middle-income countries and areas with more investment in the care of small and sick newborns, including respiratory support and other neonatal care.[51]

Primary prevention is crucial, given the large numbers, high risk, and slow progress in reduction; yet, few countries and areas have shown convincing reductions. With high-income and many middle-income countries reaching the thresholds of viability, more progress for survival and, importantly, disability-free survival will be increasingly dependent on primary prevention. Research on mechanisms, diagnostics, and interventions might benefit from more specific evaluation against these three specific vulnerable newborn types.[49] Including stillbirths is crucial to assessing the full loss of human capital due to small babies because most of these 2·0 million annual stillbirths are likely to be preterm or associated with suboptimal growth in utero (figure 5).

Measuring better for every newborn, everywhere

Improving aggregate data in routine systems

Data availability in national routine systems has increased over the last two decades, notably with higher facility births rates and expanded data systems, including both health information systems and birth registration (Ohuma EO and colleagues, unpublished). Of 195 countries and areas, 117 have data on stillbirth rates, but still have a reliance on surveys.[3,4] For LBW data, 113 countries and areas have national routine data included in estimates for 2000–20 (Okwaraji Y and colleagues, unpublished). All babies born in health facilities should have a birthweight recorded, therefore collating national LBW data should be possible. In most regions, there is a gap between countries with more than 80% facility births, but missed opportunities for reporting LBW data that is usable for national estimates. This is notable in southern Asia, where most countries have high facility birth rates, yet few have useable national LBW data (figure 6).

National routine health information systems collect aggregate data through tallies at the facility level; for example, from labour ward registers counting each woman and her baby. Routine birthweight data in labour ward registers have been shown to have good completeness and be valid with little heaping, with even less heaping when digital scales are used.[52] Aggregated

data are collated at facility, district, and national levels in electronic platforms, such as DHIS2, which is operational in over 80 low-income and middle-income countries and areas. In countries and areas with high levels of facility births and functional national electronic data systems, closing data gaps should be achievable (figure 6). In countries and areas with low facility birth rates or weak routine information systems (eg, in humanitarian contexts), other strategies might be needed.

Preterm birth data have more gaps, with only 64 of 195 countries and areas having national routine data meeting inclusion criteria for the latest WHO and UNICEF preterm birth estimates (Ohuma EO and colleagues, unpublished). Although dating by the first-trimester pregnancy ultrasound is the gold standard, sonography up to 22–24 weeks is considered acceptable.[53,54] Innovations in late pregnancy ultrasound might increase the accuracy of dating after 24 weeks.[29,55] With the indicator of four antenatal care (ANC4) contacts, large data gaps were evident in all regions between ANC4 and the availability of national data on preterm birth rate (figure 6). ANC4 is very high in almost all countries and areas and closing these gaps requires wider use of dating ultrasound technology. Improvements in gestational age data are important for both individual clinical care and improving national routine preterm birth data.

Regarding SGA data, almost no national data were available in the public domain with only eight countries reporting. National SGA data quality was further impeded by variation in standards for SGA classification (Ohuma EO and colleagues, unpublished). For countries and areas already collecting data on both LBW and preterm birth, closing the gap for SGA data should be feasible (figure 6) and innovations could help (eg, electronic medical record systems that automatically calculate Z-scores and percentiles, software applications, or smartphone-based apps).[56]

Survey data from households every 3 to 5 years, such as the Demographic and Health Surveys, are still used in low-income contexts for LBW national estimates and will continue to be important in contexts with few facility births or with humanitarian emergencies. Although these surveys have biases for birthweight data, notably missingness and heaping,[57] some can be adjusted in a standardised way with individual-level datasets.[14] Current survey tools are not sensitive for accurate gestational age information, but there is potential for improvement; notably, if women have and know their gestational age.[58] In view of the shift towards facility births, investment in improving the data of routine health information systems for small babies could be the most sustainable way to ensure high-quality, timely data for every birth.

Improving and the use of individual-level data for SVN types

Improving SVN data will require counting every baby, whether liveborn or stillborn, with information on

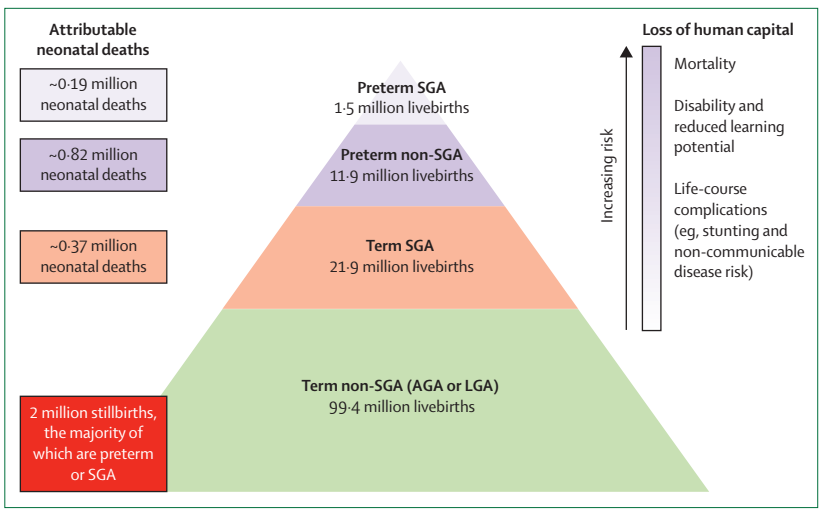


Figure 5: **Population-level implications of the burden of SVNs and neonatal mortality by SVN type**
For more details, see the appendix (pp 35–36). AGA=appropriate for gestational age. LGA=large for gestational age. SGA=small for gestational age. SVN=small vulnerable newborn.

birthweight, sex, and gestational age. Information systems require aggregate data at a national level, but being able to link the aggregate data to individual-level data, ideally electronically, is crucial; for example, on maternity or newborn care wards. Having multicountry, standardised, electronic-data platforms is key for tracking individual care for the improvement of quality and linking for longer term outcomes. Such systems enable inbuilt data checks and timeliness to accelerate action and improve outcomes for all babies, liveborn and stillborn.

The SGA assessment has additional challenges and is influenced by the choice of standards, which might result in an apparent varying of SGA rates.[59] Differences observed in growth patterns in low-income and middle-income countries arise largely due to socioeconomic and health constraints on fetal growth, such as maternal nutritional status, pregnancy morbidity, and environmental exposures. To compare across multiple populations requires an international standard,[39] of which the most widely used is the INTERGROWTH-21st newborn standards.[35]

We originally proposed six newborn types, including a birthweight dimension (ie, LBW *vs* non-LBW), preterm birth, and SGA.[10] The types have been simplified by focusing on three SVN types in this Series paper, noting that 99·5% of LBW newborns are in the three categories of preterm, SGA, or preterm SGA.[41] Combining preterm AGA and preterm LGA is justifiable because the mortality risks are very similar (appendix pp 7–8).[43] Given that a short length of gestation is the strongest predictor of mortality risk and long-term adverse neurodevelopmental outcomes,[43,60] splitting the preterm categories into subgroups based on maturity could provide useful additional information for policy and programming and individual care. Further categorisations of severity of SGA (eg, <3rd centile) could be informative.[61] Although the smallest newborns have the highest mortality risk, the

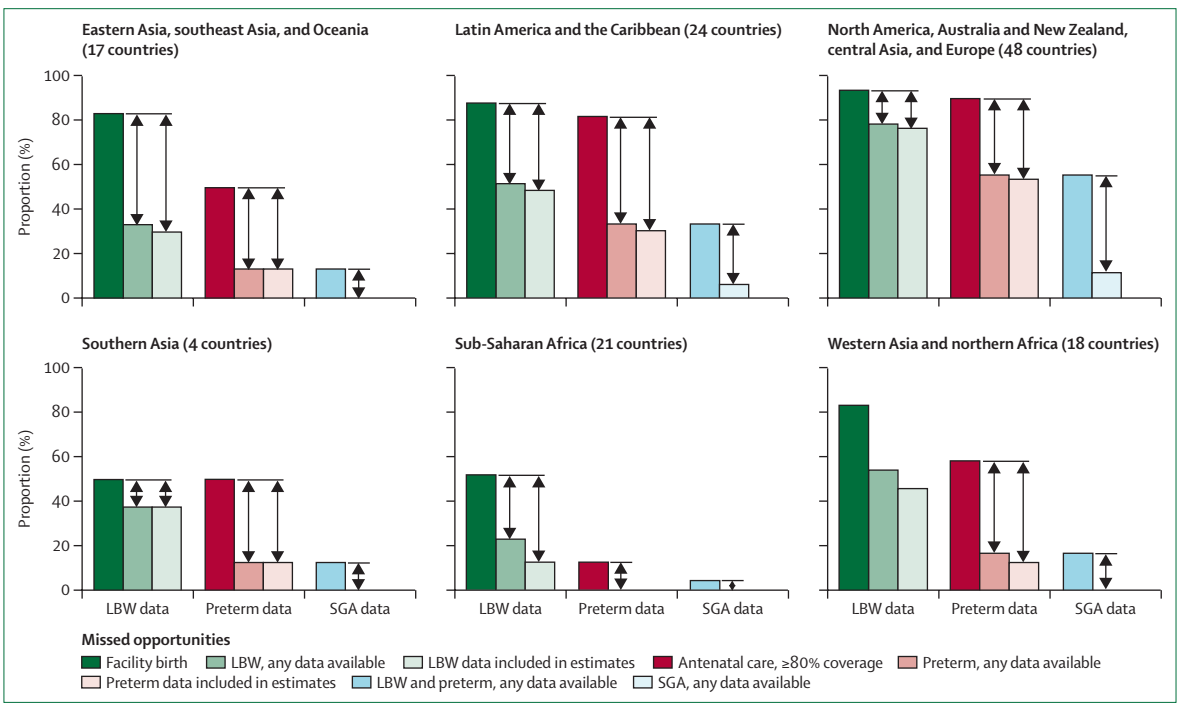


***Figure 6*: Missed opportunities for improved data on LBW, preterm birth, and SGA based on national data for 195 countries and areas by region**
No national SGA data were available from the Asian or African regions. Countries included have >80% facility births by region. For more details, see the appendix (p 40). LBW=low birthweight. SGA=small for gestational age.

prevalence of LGA newborns is increasing and might, in some settings, be associated with an increase in risk; including LGA also provides a more complete overview (Suárez-Idueta L and colleagues, unpublished). More work is still needed to better understand and link these types of newborns, including LGA, to life-course outcomes. More granular types according to gestational age could be useful for specific questions, notably research on aetiological pathways or interventions, but are likely to be too complex for programmatic use. In addition, other data on both causes and outcomes will be needed to inform action. Individual-level data mortality risk ratios were not possible to adjust for confounders due to multicountry variation in the measurement of potential confounders. The unadjusted mortality is likely to have led to biases in the calculation of population-attributable risk with Levin-type formulas instead of alternatives,[62] which is an acknowledged limitation.

Research gaps for better measurement, including long-term consequences

Improving quantity, quality, and the use of SVN data will require having information systems that count every baby and ensuring data from every facility flow into national aggregate data with interoperability so that individual-level datasets can be linked to track later outcomes (eg, mortality or disability). Innovations are available for the measurement of gestational age, but more are needed, with an evaluation of the cost and the feasibility of implementation at scale and the accuracy in different populations. Implementation research in various contexts is required to inform efforts to improve data quantity, quality, and flow to enable SVN-type characterisation at individual, national, and global levels. A parsimonious, standard dataset is needed for every newborn at birth and to track quality and outcomes for the care of small and sick newborns.[7] As well as improving data availability and data quality, more focus is required on increasing data use at all levels, including building the capacity to recognise implausible data and gaps in reporting (eg, caused by missing the smallest babies). Evidence regarding the full effect of SVN, including long-term life-course outcomes and the effect on human capital, such as morbidity, education, and socioeconomic outcomes, could be generated with these more granular SVN types from routinely collected data.

International approaches to assess size for gestational age include the use of a prescriptive or descriptive approach.[63] Prescriptive fetal growth standards are the only option that enables international comparisons, whereas descriptive charts are commonly used to produce a reference based on the anthropometry of a given population at a particular time and place, such as a hospital, region, or country, with varying risk-factor exposures and access to care.[63–65]

Studies to examine aetiological pathways and basic mechanisms could benefit from measuring these specific

SVN types rather than crude markers, such as LBW. The third paper in this Series examines current evidence and notes the challenges of inconsistent outcomes, as well as multiple exposures including nutrition, infectious and obstetric conditions, and congenital anomalies.[49]

Intervention research would also gain from assessing these more specific SVN types and including stillbirths as an outcome when relevant.[66] For example, most studies of insecticide-treated bednets in pregnancy measured LBW, yet omitted outcomes of preterm, SGA, or stillbirths.

Conclusions

In every country worldwide, large numbers of SVNs each year—almost 35 million—disproportionately contribute to early deaths and long-term loss of human capital. Vulnerability for small babies was identified centuries ago and for the last 30 years the world has set, and missed, global targets for LBW reduction. These more specific SVN types enable us to advance beyond the crude marker of LBW, now measuring the two underlying pathways of preterm birth and FGR. Stillbirths also need to be included in counting. With these SVN types, we can better inform individual-level care, enable more precise research on aetiological pathways and interventions, and accelerate unacceptably slow progress on primary prevention, thereby improving outcomes for every baby, everywhere.

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Contributors
JEL and REB conceptualised the Vulnerable Newborn Measurement Collaboration. LSI, YBO, EH, DJE, EOO, and MD did descriptive analyses of the pooled datasets. EBr did the analyses of Bayesian modelling and mortality risk estimates with statistical oversight by EOO, epidemiological oversight by HB and JEL, SGA and population-attributable risk oversight by ACCL, and reviewed by MS and REB. A-BM, CH, and EBo were part of the WHO/UNICEF estimation group for preterm birth and LBW. JEL, HB, EOO, and REB drafted the manuscript. All authors reviewed and revised the manuscript and approved the final version. The content of this Series paper represents the position of the authors and does not constitute the official position of any of the relevant institutions.

Declaration of interests
We declare no competing interests.

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