THE LANCET’S ENDING PREVENTABLE STILLBIRTHS SERIES

Stillbirths: Recall to action in high-income countries

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1.6 Abstract

Variation in stillbirth rates across high-income countries (HIC) and large equity gaps within HIC persist. If all HIC achieved stillbirth rates equal to the best performing countries, 19,439 late gestation stillbirths could have been avoided in 2015. Unexplained stillbirths remain high and can be addressed through improvements in data collection, investigation and classification, and better understanding of causal pathways. Substandard care contributes to 20-30% of all stillbirths, and the contribution is even higher for late-gestation intrapartum stillbirths. National perinatal mortality audit programmes need to be implemented across all HIC. Reducing stigma and fatalism around stillbirth and improving bereavement care are also clear, ongoing priorities for action. In HIC, a child has twice the risk of being stillborn due to adverse socioeconomic circumstances. Community- and country-level programs to improve health among disadvantaged families are needed to address these inequities.

1.7 Key words

Stillbirth; Perinatal mortality; High-income countries; Quality of care; Implementation; Perinatal audit; Classification; Bereavement care
1.8 Key messages

- **Late gestation stillbirth rates vary** across HIC from 1.3 to 8.8/1000 births, showing that further reduction in stillbirths is possible. Setting and monitoring targets in all HIC are important for reducing preventable stillbirths.

- **Socially marginalised and disadvantaged women** often have twice or more the risk of stillbirth. **Social determinants** of maternal and fetal wellbeing should be monitored in all HIC, and addressed through education and alleviation of poverty, as well as better access to health care, especially timely, culturally appropriate antenatal care.

- **Stigma and fatalism** continue to exacerbate trauma for families and impede progress in stillbirth prevention. Stronger parent and care provider partnerships are needed to dispel misperceptions and negative attitudes that persist in communities.

- It is the responsibility of all countries to implement high quality **national perinatal mortality audit** that translates into improvements in quality of care. Key performance indicators of quality maternity care should be measured and reported, with the aim of eliminating **substandard antepartum and intrapartum care** - too often present when a stillbirth occurs.

- **Bereavement care** commonly fails to meet the needs of parents, often with devastating consequences. Immediate bereavement care should be provided by appropriately trained health care professionals with sensitive and seamless transition to community support services in all settings.

- **Poor quality data on stillbirths is a major problem across HIC.** Access to high quality investigation into the causes of stillbirth, including **autopsy and placental histopathology** by a skilled perinatal pathologist, should be made available to all parents following stillbirth. Consensus on a **classification system** for stillbirth, which addresses the contribution of placental pathology, and **standard a definition for reporting stillbirths** that makes it possible to report comparable early and late stillbirth rates across HIC are needed.

- Future research must focus on **stillbirth prediction**, understanding **placental pathways** to stillbirth and causal pathways to **unexplained stillbirth**. Effective strategies to reduce the prevalence of **obesity and smoking** in women of reproductive ages are needed. Understanding pathways leading to **early stillbirth** and **spontaneous preterm birth** at early gestation is also important to pursue.
1.9 Introduction
As stated across this Series, stillbirth rate is a key indicator of women’s health and quality of care in pregnancy and childbirth.\textsuperscript{1,2} While high income country (HIC) rates are relatively low compared with low- and middle-income countries (LMIC), stillbirth is a major health burden with rates over double neonatal mortality rates,\textsuperscript{3} and often equal to all deaths in the first year.\textsuperscript{4} Neonatal death rates continue to fall,\textsuperscript{4} whereas stillbirth rates remain steady, and have increased in some regions.\textsuperscript{5} The death of any child is a tragedy for families, often with profound, long-lasting psychosocial and economic impact.\textsuperscript{6} The 2011 Lancet Stillbirth Series (LSS) drew attention to the slow progress in reducing rates across HIC and highlighted prevention.\textsuperscript{7} In this fourth paper of the Lancet’s Ending Preventable Stillbirths series, we summarise the current status of stillbirths in HIC, and present strategies to maintain momentum in reducing deaths and meeting parents’ needs when their child is stillborn.

1.10 Methods
We used the range of methods described in Panel 1 with further details provided in the webappendix. We also assessed HIC stillbirth rates and annual rate reductions (ARR) from 2000 to 2015 (Blencowe and colleagues).\textsuperscript{8}

1.11 Stillbirth rates – Is progress good enough?
The latest global estimates\textsuperscript{8} show an average stillbirth rate (using the 28 weeks’ gestation definition) across 49 HIC of 3.5 per 1000 total births. Country-specific rates varied widely from 1.3 to 8.8 (Figure 1). The ARR from 2000 to 2015 varied, with nine countries demonstrating ARRs of <1%, and five countries >4%. Cross-country comparisons are hindered by data capture issues including reporting practices for termination of pregnancy after the gestational age threshold, variation in data capture mechanisms including the use of cross-linkages between birth and death certificate data and birth registry data, and variation in definitions for reporting.\textsuperscript{8} Use of the WHO recommended lower gestational age limit of 28 weeks likely reduces the influence of these issues on reported rates. Regardless of data capture issues, real epidemiological variation in rates is present,\textsuperscript{9} and shows further reduction is possible. Stillbirth rates for disadvantaged groups are around double those of
greater advantage, with recent evidence indicating these gaps can be narrowed. While intrapartum stillbirths comprise a small proportion (<10%) across HIC, variability in this indicator is also evident, as presented by Lawn and colleagues. Nonetheless, it is important that countries monitor and understand their own temporal trends rather than assess performance based on rankings with other countries.

As shown in Figure 1, 6 of 49 countries (12%) demonstrated third trimester rates of 2.0/1000 births or lower, showing that this is achievable. If all countries had achieved a stillbirth rate ≤2.0, in 2015, 19,439 late gestation stillbirths could have been avoided.

### 1.11.1 Early gestation stillbirth

Depending on definition, 35% to 50% of HIC stillbirths occur below the WHO recommended cut-off for international comparison of 1000 g (or 28 weeks). Due to variability in definitions (e.g. inclusion of terminations), comparisons of early gestation stillbirth rates between and even within countries are difficult. When crude stillbirths rates were compared, Sweden ranked 3rd and Australia 28th in a comparison of 28 HICs, but Sweden dropped to 10th and Australia improved to 11th when rank was based on stillbirths >1000 g. Under-reporting of stillbirths <28 weeks is also evident in some regions. Ascertainment may be influenced by perceptions of viability. Despite these difficulties, stillbirth rates <28 weeks’ in HIC are not falling, and some increases are evident. In Canada, pregnancy terminations for congenital anomalies at 20-23 weeks gestation explain the increasing stillbirth rate. In the USA, spontaneous preterm birth at early gestations made a significant contribution to higher stillbirth rates in black non-Hispanic women. Thus, in HIC, stillbirths at <28 weeks comprise an important component of all adverse pregnancy outcomes, particularly among some racial/ethnic groups.

### 1.11.2 Perceptions of stillbirth - Are they holding back progress?

Fatalism and stigma around stillbirth persist in HIC, both across communities and in the healthcare workforce (as reported in the LSS). In the International Stillbirth Alliance (ISA) surveys (see Panel 1 for methods), 2 in 3 respondents felt their community believed that most stillbirths are not...
preventable (Figure 2). Around 1 in 2 parents felt their community believed that “parents should not talk about their stillborn baby because it makes people feel uncomfortable”. One parent said “…many women told me that my son’s death was likely ‘nature taking care of mistakes’”. Perceptions and actions that denigrate grief, dismiss the significance of a stillborn child, or support notions that a child was “never supposed to live”, are harmful to bereaved parents and devalue efforts towards prevention. Parent organisations provide powerful mechanisms to challenge stigma and fatalism around stillbirth (“Parents bringing about change”, webappendix).

1.12 Factors leading to stillbirth

1.12.1 Risk factors - Are we sufficiently aware?
Risk factors including demographic and lifestyle factors and medical/pregnancy conditions were reported in the LSS. In the ISA survey of care providers, we asked respondents to select 10 out of 23 risk factors and associated conditions they believed posed the highest risk. We present the survey rankings alongside the adjusted odds ratio (aOR) as reported in the LSS and recent systematic reviews (Figure 1, webappendix). Perceptions were generally consistent with the evidence, but care providers underestimated of the risks of advanced maternal age (>35 years), IVF, and multiple gestations, and overestimated of the risk of preeclampsia, smoking and substance misuse.

Risks associated with maternal obesity were also underestimated. In the survey of community members, 72% (n=1113) rated community awareness of overweight and obesity as very low to moderate (Figure 2, webappendix). With increasing prevalence of overweight and obesity, interventions to increase the number of women beginning pregnancy with a normal body weight are critically important to improving pregnancy outcomes and longer-term health. Modelling of a large Canadian cohort indicates a 10% decrease in pregnancy BMI could decrease stillbirth risk by 10%. However, targeting behavioural change alone fails to recognise the complexity of this problem, resulting in ineffective interventions and added stigma for women who are overweight. Antenatal care that “problematises” women by focusing on weight rather than a healthy pregnancy can produce feelings of embarrassment, guilt and shame, leading women to avoid or delay care.
1.12.2 Classification of causes – Where do we need to focus?

Despite the call in the LSS for a uniform approach to the definition and classification of stillbirths,27 a recent systematic review of causes of stillbirth globally28 showed continued use of disparate approaches across HIC (Table 4, webappendix), rendering interpretation difficult. Despite this, placental pathologies were clearly important, accounting for around 50% of stillbirths in systems designed to capture them. Wide variation was shown in capture and definition of these pathologies, consistent with a recent review.29 The contribution of other important factors varied widely; congenital abnormalities ranged from 6-33%; infection 2-22%; and spontaneous preterm birth/preterm ruptured membranes (PROM) 1-14%. In one high quality study, spontaneous preterm birth/PROM was a key factor in 41% of stillbirths <28 weeks.17

Studies using hierarchical approaches showed higher proportions of FGR30 and congenital abnormalities,31, 14 depending on the system used. The categories “Other unspecified” and “Unexplained” showed the widest variation and highest proportions; up to 76% and 53% respectively.

1.12.3 Diagnostic tests for finding the cause of stillbirth

The evidence for many routinely performed stillbirth investigations is limited. While ongoing studies in the Netherlands and Australia will help to address this, the value of placental histopathology, autopsy, and genetic analysis is clear.31, 32 Nonetheless, in the ISA parent survey (n=3503), almost one quarter reported not being counselled or given information about autopsy. Failure to offer autopsy denies parents a chance to understand the cause of their baby’s death, increases the proportion of unexplained stillbirths, and hinders the effectiveness of subsequent audit. A critical shortage of perinatal pathologists also hampers efforts.33, 34 Such a shortage was shown in our surveys, where only 26% of care providers reported that autopsies were performed or supervised by perinatal or paediatric pathologists. Resources continue to be diverted away from perinatal pathology,33, 35 despite stillbirths and neonatal deaths outnumbering deaths from cancer.9, 36 In our survey of care providers, only 33% reported that autopsy was routinely performed upon consent (Figure 3, webappendix).

Parental consent and cost were frequently cited barriers to investigations (Figure 4, webappendix),
despite evidence that identifying the cause of stillbirth may reduce costs in subsequent pregnancies. As stated by Heazell and colleagues,\(^6\) the cost of care for subsequent pregnancies following stillbirth with an assigned cause is less than for women whose stillbirths were of unknown cause.\(^37\)

Changes in diagnostic testing may lead to revisions of causes of stillbirths. Chromosomal microarray is now preferred to karyotype since it overcomes the problem of non-viable tissue. Microarrays also identify abnormalities, such as microdeletions and microduplications, that are not identified by karyotyping.\(^38\) However, adoption of diagnostic advances is slow, with 30% of care providers from the ISA survey unsure how frequently microarray was performed; only 4% indicated that microarray was routine. Whichever test is used, it is important to have a perinatal pathology service to determine phenotype to assess the significance of newly described genetic variations.\(^39\),\(^40\)

### 1.12.4 Addressing data quality in causes of stillbirth

Classification of cause of death in stillbirth needs to be standardised, especially with regard to placental pathology. Collective agreement of definitions of placental lesions and their significance is also needed. Although the same lesions may be seen in stillbirths and in livebirths, high quality studies suggest that specific placental lesions are significantly more common in cases of stillbirth.\(^41\) This is also true for other “causes” of stillbirth. In a recent review, not a single classification systems met the criteria of a quality system.\(^42\) Development of the WHO’s International Classification of Diseases Perinatal Mortality (ICD-PM), presented in a commentary to this series,\(^43\) aims to address this. While HIC are likely to continue with detailed classification based on sophisticated diagnostics not accessible in LMIC, approaches must be consistent with the ICD-PM system, and HIC must reach consensus on such a system. Underpinning accurate data on causes is the availability of thorough history and diagnostic testing. Standardised perinatal death datasets are essential. Such datasets are in place nationally in The UK, Ireland and New Zealand, and under pilot-testing in Australia.

### 1.13 Understanding and tackling disparities in stillbirth risk

Disparities reflect larger systems of structural inequality, including racism and systematic inequities in opportunities and power.\(^44\) Consequently, health disparities reflect social and political determinants
rather than biological origin.\textsuperscript{45,46} Within HIC, stillbirth rates for disadvantaged groups are often double those of more advantaged groups, and are likely to be underestimated, as health disparities are often only measured by comparing the most advantaged with the least advantaged.\textsuperscript{47} The relationship between stillbirth and social disadvantage is complex, with probable links across preconception, pregnancy pathways and risk factors (Figure 3).

1.13.1 Access to, and quality of, antenatal and maternity care
Disadvantaged women are less likely to receive adequate antenatal care.\textsuperscript{48} Access to, and quality of antenatal care also differs by populations served,\textsuperscript{49} and amongst ethnicities.\textsuperscript{50} There are clear and specific circumstances where differential access or uptake of services contributes to disparities. These include antenatal diagnosis and pregnancy termination for congenital anomalies; timely diagnosis and treatment of preeclampsia; and labour induction for post-term pregnancy. Rural-urban differences in access to services are also likely to contribute, especially among vulnerable populations in remote areas.\textsuperscript{51,52} Institutionalised racism is commonly reported by women accessing antenatal care.\textsuperscript{53}

1.13.2 Beyond health care delivery
Health disparities are only partly explained by disparities in maternity care.\textsuperscript{47} Complex social determinants, termed “causes of the causes”, include: poverty; experiences of discrimination; incarceration; addiction; chronic stress; inadequate education, child care, employment, transportation, and living conditions.\textsuperscript{54} Intimate partner violence,\textsuperscript{55} mental health issues,\textsuperscript{56} and the cumulative impact of stressful “life events”\textsuperscript{57} are also hidden but potent risks. In a systematic review of nearly 1,000,000 births in the UK from 1993-2005, stillbirth rates were 1.5-2 fold greater between the highest and lowest area deprivation quintiles.\textsuperscript{58,59}

In a recent study, women migrating to HIC had stillbirth rates double host country averages, particularly when their country of birth was a humanitarian source country.\textsuperscript{60} Adjusted for age, parity, socioeconomic status and BMI, these differences disappeared,\textsuperscript{60} suggesting ethnicity may not always be a pathway to increased stillbirth. However, disparities in pregnancy outcomes continue between women of differing racial or ethnic background accessing the same healthcare services.\textsuperscript{61-63} Stillbirth
rates for women of South Asian and African origin giving birth in Europe or Australia are 2-3 times higher than those of Caucasian women. The challenge is to understand why, and how we can manage the excess risk of stillbirth correlated with ethnicity within routine and comprehensive antenatal care.

1.13.3 Addressing disparity

To understand and address socioeconomic disparities in stillbirth, it is critical that all HIC monitor and report SES in vital statistics. Maternal education is one relevant and feasible indicator for within-country and cross-country comparisons. Across 19 European countries with a median population attributable risk of 26% (IQR 16 to 31), Zeitlin and colleagues showed 1,606 out of 6,447 stillbirths would not have occurred in 2010 if rates for all women were the same as for women with post-secondary education. School completion for pregnant women could therefore have a substantial impact on reducing disparities. Structural issues such as housing, employment and food security policies must also be addressed.

Antenatal care, home visiting services and financing of contraceptive services are examples of interventions with capacity to address reproductive health strategies and therefore to prevent stillbirths. Universal service platforms should be supplemented with efforts to engage vulnerable populations, including outreach strategies and transportation to health services. In 2011 we nominated quality, accessible, culturally responsive and appropriate preconception care among priorities to reduce disparity. Improving preconception care remains an enormous challenge. Innovative community programs addressing refugee maternal and child health inequalities and antenatal care programs involving partnerships between midwives and Aboriginal health workers are underway in Australia. Universally, women whose first language differs from dominant national languages should be offered care and information in their own language, with choice of interpreter gender. The US Affordable Care Act will provide services such as free contraception, screening for infections and alcohol and smoking cessation programs.
1.14 Quality of care

1.14.1 Uptake of interventions in stillbirth prevention

Through the ISA survey of care providers we assessed uptake and perceived barriers to implementation of LSS recommended interventions in stillbirth prevention (Figures 5 and 6, webappendix). Only 60% of respondents said they always provided smoking cessation advice. The most frequently cited barriers were lack of time and/or resources (20%) and acceptance to women (35%). Only 36% said they always provided culturally-appropriate care, with lack of time and/or resources the most common barrier (17%). Serial fundal height measurements were performed not at all or only sometimes by 14%, with 10% identifying lack of evidence as a barrier. Most providers said they always or mostly used early ultrasound assessment of gestational age (83%), with cost and acceptance to women cited as barriers by around 12%. Screening for gestational diabetes at 28 weeks was always or mostly performed by 77%, with 12% citing acceptance by women as a barrier. Use of Doppler velocimetry in high-risk pregnancies had reasonably high usage (68%), with lack of evidence (11%) and cost (9%) the most frequently cited barriers. The least commonly used intervention (used always or mostly by 43%) was low dose aspirin for high-risk pregnancies, with 13% reporting lack of evidence as a barrier. Low dose aspirin and heparins have been used to improve placental function and decrease stillbirth, but a high number needed to treat (aspirin) and uncertain efficacy has prevented widespread adoption of these interventions. While evidence is limited, preconception care is a potentially valuable intervention in stillbirth prevention, yet only 28% of care providers said that preconception care for women with risk factors was performed mostly/always in their facilities.

1.14.2 Antenatal and bereavement care - Information, communication and support

In addition to clinical care, quality maternity care incorporates interpersonal and emotional aspects of care. Since stillbirth is an indicator of quality care, women’s experiences of care around stillbirth can be considered an indicator of quality of care processes. Just as actions can be taken to prevent stillbirth, actions can be taken to prevent adverse psychosocial outcomes following stillbirth and, in both instances, suboptimal interpersonal care can undermine even the best clinical care and produce harm.
The ISA surveys asked parents and care providers eight questions designed to capture components of quality care consistently identified as important to women (webappendix). The data (Figure 7, webappendix) show that care providers viewed various aspects of care more positively than bereaved parents. At least 4 in 5 providers (83-95%), but only 3 in 5 parents (54-70%), considered these aspects of quality care to be present always or most of the time. Not spending enough time with parents in antepartum care was a point of agreement for parents and care providers. Critically, more than one-third of parents believed their concerns were not taken seriously or felt not listened to, either before or after their baby was stillborn.

Ratings of information-provision and parental involvement in decision-making after stillbirth were lower for parents and care providers alike compared with before stillbirth, underscoring the challenge of providing quality bereavement care. Parents’ views of the comprehensibility of information were also less positive; barely half felt the time spent with care providers was adequate. Many of the questions parents had at this time could be readily answered and procedures to answer such questions would be easy to implement (Panel 1, webappendix). Missed opportunities to answer parents’ questions might be avoided by measures that recognise parents’ need to know more about their child.

These survey findings corroborate the results of a systematic review on parents’ and care providers’ experiences of bereavement care. Care providers were found to “hide” behind ritualising guidelines and checklists; they were frequently not trained to expect and manage parents’ reactions and individual needs. In our survey of care providers, only 23% reported being satisfied with training opportunities in bereavement care at their facility, and 30% had no opportunities. As found in the meta-analysis, care providers urgently need emotional, knowledge and system-based support, and training in verbal and non-verbal communication skills.

### 1.14.3 Addressing quality of care

Stillbirth prevention requires emphasis on quality maternity care that is respectful of a woman’s rights and tailored to her needs. Quality can be improved through better communication and information-provision, and timely delivery of evidence-based interventions. Quality bereavement care must also
be emphasised, with greater access to training a crucial first step. Maternity units must decide whether this is best accomplished via training and certification of competencies for all staff, or whether to assign the role of bereavement support to a dedicated group. Access to clinical practice guidelines is imperative, but active implementation and evaluation are required. The UK provides an extensive range of national clinical guidelines acknowledging every aspect of the key messages of the LSS HIC paper but, for other HIC with a high stillbirth burden, such resources are far less comprehensive (webappendix). Publicly available reports of maternal satisfaction with care and other indicators of women’s maternity care experiences should be developed, as done in Queensland, Australia, New Zealand and across The UK. Audit and feedback and benchmarking programs that include explicit targets for change and suggestions for how change can be achieved are also effective.

1.14.4 Perinatal mortality audit - Why and how?

Perinatal audit has been described as: “The systematic, critical analysis of the quality of perinatal care, including the procedures used for diagnosis and treatment, the use of resources and the resultant outcome and quality of life for women and their babies.” Audits in the Netherlands, The UK and New Zealand show substandard care factors are present in an unacceptably high proportion of cases (20-30%, and up to 60% for intrapartum stillbirths). In New Zealand, stillbirth rates at term have declined over the seven years since national perinatal audit began (Figure 8, webappendix). This decline was specifically attributed to a reduction in stillbirth at 37-40 weeks’ gestation and >41 weeks’ gestation. Despite their value, few countries have implemented national-level perinatal audit programs (webappendix). Norway, which originally introduced it in 1984, has now abandoned this practice. Among the care providers we surveyed, only 37% reported that their facility conducts regular perinatal audit meetings; these were most commonly held only monthly (34%) or quarterly (26%), and used case discussion only as opposed to formal audit methodology (61% vs 12%).

There is a clear need for greater focus on effective, sustainable implementation of perinatal audit to ensure health services identify areas of suboptimal care. Establishing perinatal mortality audit requires both service- and ministerial-level support, and quarantined time for multidisciplinary team
engagement. Other critical components include an agreed set of definitions, adoption of a formal audit methodology, and appropriate indicators for monitoring and evaluation, and effective data systems (Panel 2). Innovative e- and m-health solutions currently being implemented hold promise, as well as structured education programs around institutional perinatal mortality audit and classification such as the IMPROVE program.

1.15 Antenatal screening and interventions to prevent stillbirth – Are we getting closer?

1.15.1 Early delivery

Routine induction of labour (IOL) at term and post-term reduces the risk of perinatal mortality and caesarean birth. However, birth prior to 39 weeks increases the risk of morbidity and is associated with increased risk of long-term mortality. Therefore, prior to 39 weeks, early delivery requires balancing any reduction in stillbirth risk against these risks, and should only be considered in the presence of significant risk for maternal and neonatal complications. When IOL is undertaken, adequate information-provision to women is essential, as women have reported not being aware of the risks of induction or the implications for future pregnancies until after the induction had been performed.

The ARRIVE trial in the US comparing elective IOL at 39 weeks with expectant management among singleton uncomplicated term pregnancies may help to clarify the risks and benefits of term induction.

1.15.2 Ultrasonic and biochemical prediction of stillbirth risk

Multiple pathophysiological processes result in stillbirth, making it difficult to predict. A test is likely to perform poorly when assessed against all stillbirths, but possibly more specific for a given cause of stillbirth. A systematic review of biomarker and ultrasonic tests found none of 16 single, or 5 combined, tests performed well as predictors of stillbirth. However, stillbirth attributed to placental dysfunctional disorders was moderately to strongly associated (positive likelihood ratios between 5 and 15) with low first trimester pregnancy associated plasma protein A (PAPP-A), and abnormal uterine
artery Doppler velocimetry in the second trimester. More studies are needed to determine whether closer vigilance or any treatment is effective to prevent stillbirth in this increased-risk group.

### 1.15.3 Routine late pregnancy ultrasound to screen for fetal growth restriction

Of the estimated 30-50% of stillbirths related to FGR; most are undetected and many occur in women lacking risk factors. Ultrasonic fetal biometry is widely used in high risk pregnancies as a means of detecting FGR, thus universal ultrasound is one potential approach to screening low-risk women. However, high-quality evidence on the diagnostic effectiveness of ultrasound is lacking. A recent prospective cohort study found universal scanning was associated with approximately 3-fold increase in the detection of small for gestational age (SGA) (20-57%). Further, SGA fetuses with reduced abdominal circumference growth velocity were at increased risk of morbidity, whereas SGA fetuses with normal growth velocity were not. This study confirms universal ultrasound is effective in identifying FGR. However, the costs and potential adverse iatrogenic consequences of implementing such an intervention require consideration.

### 1.15.4 Challenges in gaining high quality evidence for screening

Sample size calculations demonstrate that even if a screening test has a positive likelihood ratio of 10 and was coupled with an intervention that reduced stillbirth by 50%, a study of screening and intervention would still require approximately 130,000 women to be adequately powered (Figure 9, webappendix). Possible approaches to address this problem are the inclusion of stillbirth as part of a composite outcome and the use of study designs with randomisation at the hospital level, including cluster randomised controlled trials (RCTs) or stepped wedge RCTs, such as the trials of fetal movement awareness interventions mentioned below.

### 1.15.5 Promising antenatal interventions?

Raising awareness of decreased fetal movements (DFM) may aid stillbirth prevention via timely detection and reporting, though concerns exist over the potential to increase anxiety and health service utilisation. Two large-scale trials of fetal movement awareness interventions are ongoing in Australasia, and Ireland and The UK. In a large non-randomised study, an educational program of
standardised measurement of fundal height, plotting on customised charts and referral protocols, has also been associated with reduced stillbirth.\textsuperscript{97} Data from RCTs are required to confirm or refute these findings.\textsuperscript{98} The adverse impact of supine sleep position in late pregnancy has recently been highlighted as a potentially modifiable risk factor.\textsuperscript{99-102} Although these findings are biologically plausible, results from further studies in The UK\textsuperscript{103} and New Zealand\textsuperscript{100} study are awaited.

1.16 The research agenda
The LSS identified 30 questions derived from opinions of professionals and researchers. Research priority setting methods have since developed to include patient and public views. As part of the ISA surveys, over 7,000 parents, care providers and community members provided stillbirth action and research priorities. While the ISA project is ongoing, preliminary data indicate agreement with the LSS and a recent UK project.\textsuperscript{104} Major topics included: stillbirth prevention by application of current tests and development of novel investigations with optimal timing of delivery, understanding placental pathways in stillbirth and the causes of unexplained stillbirth, optimal bereavement care, and subsequent pregnancy care.

Perinatal mortality audit programs, interventions to reduce the prevalence of overweight and obesity, and initiatives to increase the coverage of smoking cessation programs in pregnancy are also priorities. With static rates of stillbirths <28 weeks across HIC, and with spontaneous preterm labour and/or preterm ROM a major contributor, ongoing efforts in prediction and prevention of preterm birth are important in stillbirth prevention. Strengthening collaborations between researchers and parents to address priorities using similar protocols is key in addressing stillbirths in HIC.

1.17 Conclusions
Stillbirth remains a major public health problem in HIC and reductions in rates have not matched those for neonatal mortality. Variation and socio-economic disparities in stillbirth rates, suboptimal uptake of interventions, low proportions of stillbirths attributed to congenital abnormality and high proportions classified as unexplained, and the contribution of substandard care factors suggest
stillbirths are not inevitable, and that further reduction in HIC is possible. Ending preventable stillbirths in HIC can be achieved through improvements in the health status of women, through improvements in quality of maternity care, and by reducing social inequities. High quality perinatal mortality audit informed by thorough investigation is attainable in all HIC and holds the key to (relatively) rapid reductions in stillbirth rates.

The death of a child before birth is a tragedy for families, and stigma and fatalism must be eliminated to optimise bereavement care and to reduce the number of these deaths.
1.18 Contributions

V Flenady was responsible for overall development and writing of the manuscript; A Wojcieszek assisted with development and writing of the manuscript and coordination of author contributions; D Ellwood and P Middleton assisted in editing; V Flenady, A Wojcieszek, D Ellwood, F Boyle, D Horey, A Vanacci, C Ravaldi, J Cassidy, P Cassidy, J F Frøen, L Farrales, M Gross, P Middleton, J J Erwich, G Smith, T Y Khong, R M Silver, S Leisher, L McCowan, D Siassakos, A Heazell and S Petersen contributed to the development and dissemination of the web-based surveys; A Wojcieszek coordinated the dissemination of surveys and S Leisher and A Wojcieszek coordinated the survey translations; A Wojcieszek lead the quantitative survey data analyses with V Flenady, M Coory; F Boyle, D Horey, undertook qualitative survey data analysis; J E Lawn and H Blencowe conducted data analyses for stillbirth rates and risk factors; T Y Khong, R M Silver, S Leisher, JJ Erwich developed the diagnostic test section; D Ellwood developed the risk factor and interventions sections; V Flenady, M Coory, and H Reinebrant undertook the causes of stillbirth analysis; JJ Erwich, C Farquar, L Sadler developed the perinatal mortality audit section; P Middleton, L Farrales, S Brown, K S Joseph, J Zeitlin, E Wallace developed the disparity section; D Siassakos, A Heazell, C Storey contributed a meta-synthesis on experiences of bereavement care; G Smith and L McCowan assisted to develop the antenatal screening and interventions to prevent stillbirth section; F Bloomfield, G Smith, J F Frøen, and R Goldenberg contributed to framing and drafting of the manuscript. All authors read and approved the final version of the manuscript.

1.19 Conflicts of interest

HB received grants from Saving Newborn Lives, Save the Children, during the conduct of the study. SB received salary support via a Future Fellowship from the Australian Research Council, during the conduct of the study. LS received personal fees from Health Quality and Safety Commission NZ, during the conduct of the study. DS received grants from Sands, outside the submitted work and is a member of the Executive Committee of the Stillbirth Clinical Study Group, UK (RCOG & Sands), the Department of Health Stillbirth task-and-finish groups, and the PROMPT Maternity Foundation. GS received non-financial support from GE, personal fees and non-financial support from Roche, grants and personal fees from GSK, outside the submitted work. All remaining authors have nothing to disclose.

1.20 Acknowledgments

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supported the dissemination of surveys. Finally, we thank Translators Without Borders for assisting with survey translations.

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1.2 References


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Panels

Panel 1. Methods

ISA web-based surveys

We developed three web-based, multilanguage surveys of bereaved parents, care providers and general community members to assess practices around stillbirth prevention, awareness of stillbirth risk factors, quality of antepartum and bereavement care, uptake of stillbirth investigations, audit and classification of stillbirths and more. A mix of categorical items, open-ended items, ranking items and rating scales were included. Surveys were disseminated chiefly via the International Stillbirth Alliance (ISA) member organisations and additional relevant professional societies between December 2014 and February 2015. Surveys were available in English, Dutch, German, Italian, Spanish and Portuguese. The survey of care providers was also available in French and Japanese.

In total, 6,636 responses were received across 32 HIC. Quantitative data were analysed in SPSS and were weighted to account for uneven distribution of responses across countries (see webappendix). Qualitative data were sorted in NVivo.

Surveys were approved by the Mater Health Services Human Research Ethics Committee, within the guidelines of the Australian National Statement on Ethical Conduct in Human Research and the University of British Columbia Office Of Research Ethics.

Stillbirth rates in HIC / analysis of avoidable deaths

The number of potentially preventable stillbirths across all HIC for the year 2015 was calculated from stillbirth rates and total births in Blencowe and colleagues\(^4\) by subtracting the anticipated numbers of stillbirths applying the 2015 stillbirth rates from the numbers derived using a rate of 2/1000 births for all countries with a rate above 2/1000.

Summary of disparities in HIC

Socioeconomic disparities in stillbirth rates in HIC were investigated via narrative review, by searching for papers on health inequities and social disadvantage as they relate to stillbirth, by snowballing from those papers, and from citations made to the LSS HIC paper.\(^7\) We also contacted experts in the field for details of programs addressing disparities in stillbirth and ways of reducing stillbirths in HIC.
Review of national policies and clinical practice guidelines

National policies on perinatal mortality audit

We searched for policies national policies on perinatal mortality audit across the top 36 HIC according to number of annual stillbirths (equating to 99% of the known stillbirth burden in HIC).

Perinatal audit was defined as per Dunn and McIlwaine as “The systematic, critical analysis of the quality of perinatal care, including the procedures used for diagnosis and treatment, the use of resources and the resultant outcome and quality of life for women and their babies”. Specifically, we searched for policies for national perinatal data collection that is coupled with mandatory in-depth review of care by a multidisciplinary team following a stillbirth (see webappendix for further search details). We also consulted a local key informant to confirm findings and gain further information.

National clinical practice guidelines

National clinical practice guidelines and recommendations addressing stillbirth prevention and investigations were identified across the top five developed countries according to number of annual stillbirths (Russian Federation; United States, Japan, France, The United Kingdom). Guidelines of interest included those addressing the key messages of the 2011 LSS HIC paper, namely overweight and obesity, alcohol and substance use, smoking cessation, training of health professionals to provide care to disadvantaged pregnant women, and stillbirth investigations protocols to assess cause of death. A structured search was conducted specific for each country using a customised list of organisational websites providing national health care guidelines (see webappendix for further search details). We also consulted a local key informant.
Panel 2. Essential steps to establish perinatal mortality audit at the national level

- Execute an information-plan to ensure it is known that stillbirths are not inevitable and that many stillbirths can be prevented by increasing quality of care, particularly around term.
- Obtain support and budget from national bodies, including ministries of health and professional colleges.
- Develop a national network to coordinate the data collection and identify missing cases through a check system using births and death certificate; and to lead timely reporting and analysis.
- Establish a national multidisciplinary leadership/steering group to drive the process, agree on national priorities, develop and monitor formal audit-methodology, establish consistent and robust definitions, ensure consistency across jurisdictions, and ensure perinatal audit remains on the national agenda while it remains relevant.
- Identify clinical champion(s) at service delivery level.
- Develop a system for clinical and process data collection, preferably web-based, to be completed by the clinical staff.
- Ensure that the underlying philosophy of data collection is based on shared ownership of the data to optimise data quality. This includes the ability of units to access their own data in a format that they can use for their own surveillance and perinatal mortality reviews.
- Allocate human resources to support local or regional audit initiatives.
- Conduct local review of perinatal cases with multidisciplinary teams that have allocated time.
- Develop a method to provide useful, automatically-generated feedback to clinicians and facilities of the suggested improvements to support local quality and audit processes.
- Conduct effective monitoring and evaluation of the audit program with relevant and feasible performance indicators.
- Implement processes to ensure that disclosure of information cannot be used for disciplinary action.
- Ensure there is support/funding to support implementation of recommendations.
Figures

Figure 1. Current stillbirth rates and reductions since 2000 in HIC

<table>
<thead>
<tr>
<th>Country</th>
<th>ARR Stillbirth rate 2000-2015 (%)</th>
<th>Stillbirth rate 2015 (≥28 week definition)</th>
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ARR: Annual rate reduction  *Countries with <5000 annual births
Figure 2. Survey data on perceptions of stillbirth in high-income countries

“In the community I live/work, people/my colleagues generally think that:”

- There is a lack of awareness of stillbirth
- Parents should be able to grieve openly after their baby is stillborn
- A stillborn baby is the same as the death of a child
- Many stillbirths are preventable
- Parents get the care and support they need when their baby is stillborn
- The death of a baby to stillbirth is “nature’s way”
- Parents should try to forget their stillborn baby and have another child
- Parents should not talk about their stillborn baby*
- The death of a baby to stillbirth is usually the mother’s fault

% agree or strongly agree

*Full statement: “Parents should not talk about their stillborn baby because it makes people feel uncomfortable”
Figure 3. Disparity pathways for stillbirth

Social disadvantage and stillbirth: DOUBLE the risk

Preconception
- Pregnancy intention
- Lack of access to contraception
- Poverty
- Social status
- Economic status
- Nutrition
- Interpregnancy interval

During pregnancy
- Lack of access to care
- Delays in care
- Placental pathology
- Poorer quality care
- Institutional racism
- Lack of involvement and empowerment in own care
- Lack of community involvement

Major risk factors
- Smoking
- Obesity
- Fetal growth restriction
- Pre-existing diabetes
- Illicit drugs
- Pre-eclampsia
- Hypertension
- Maternal mental health
- Infection
- Previous stillbirth

Figure depicts complex relationships and associations for social disparity in stillbirth rates. Stillbirth rates can be double for African-American women, Aboriginal and Indigenous women in Canada, Australia and New Zealand, women who have migrated, especially those coming as humanitarian entrants/asylum seekers or refugees, low income women, women with low educational achievement, and teenage women under 15 years.