

## Ending preventable stillbirths 5



## Stillbirths: ending preventable deaths by 2030

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Efforts to achieve the new worldwide goals for maternal and child survival will also prevent stillbirth and improve health and developmental outcomes. However, the number of annual stillbirths remains unchanged since 2011 and is unacceptably high: an estimated 2·6 million in 2015. Failure to consistently include global targets or indicators for stillbirth in post-2015 initiatives shows that stillbirths are hidden in the worldwide agenda. This Series paper summarises findings from previous papers in this Series, presents new analyses, and proposes specific criteria for successful integration of stillbirths into post-2015 initiatives for women's and children's health. Five priority areas to change the stillbirth trend include intentional leadership; increased voice, especially of women; implementation of integrated interventions with commensurate investment; indicators to measure effect of interventions and especially to monitor progress; and investigation into crucial knowledge gaps. The post-2015 agenda represents opportunities for all stakeholders to act together to end all preventable deaths, including stillbirths.

## Introduction

This Series paper is the final in the *Lancet* Ending preventable stillbirths Series, aimed to increase the concern of the worldwide community about this neglected area in public health and to identify actions for accelerated progress.<sup>1</sup> Since 1990, deaths of children younger than 5 years and maternal deaths have decreased more rapidly than ever,<sup>2</sup> yet have not reduced enough to achieve Millennium Development Goals 4 and 5 for women's and children's health. Newborn mortality and stillbirths, health indicators external to

these goals, have seen much slower progress.<sup>3</sup> In September, 2015, the UN member states committed to a post-2015 framework—the Sustainable Development Goals—which includes the unfinished agenda for maternal and child health supported by the Global Strategy for Women's, Children's and Adolescents' Health 2016–30 (Global Strategy).<sup>4,5</sup>

The new Global Strategy also focuses on additional priorities, including newborns and stillbirths, family planning, and adolescent health.<sup>6</sup> Inclusion of these groups shows the obstetric transition, in which countries

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## Key messages

**Stillbirths comprise a large proportion of preventable deaths**

Too many women and children die in pregnancy and childbirth including the estimated 2·6 million third trimester stillbirths worldwide. Efforts to end preventable stillbirths and maternal and newborn deaths will improve maternal and newborn morbidity outcomes and have positive, long-term effects on child development and non-communicable diseases.

**The burden of stillbirths is overlooked**

Stillbirths are absent in worldwide data tracking, social recognition, and also in investment and programmatic action. The burden on families, especially women, is severe and long lasting, yet stigma and taboo hides this burden even in high-income countries.

**Five priority actions can change the trend for stillbirths**

These actions include intentional leadership; increased voice, especially of women; implementation of integrated interventions with commensurate investment; indicators to measure effect of interventions and especially to monitor progress; and investigation of critical knowledge gaps.

**Leadership is a critical prerequisite for progress**

The network of organisations working on stillbirth issues has the potential to improve collaboration and cooperation through existing connections with maternal and newborn health activities, but deliberate efforts are needed to strengthen the role and involvement of affected parents within this network.

**Stillbirth rate is a marker of quality of care in pregnancy and childbirth**

Indicators to measure effect and to monitor progress are needed to count every stillborn baby, track programmes, and measure coverage. These indicators will enable improvements in data coverage to track content and quality of care for relevant programmes and interventions with the greatest effect on stillbirths, such as intrapartum monitoring and management and syphilis treatment in pregnancy.

**Respectful and supportive care is needed**

In the event of any death in pregnancy or childbirth, contextual, respectful, and supportive care is an important yet still neglected component of care. Increased voices from community and women can address issues of stigma associated with stillbirth.

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### Panel 1: Analyses and methods

#### Mapping of post-2015 women's and children's health initiatives

The objective of this mapping exercise was to review all relevant global post-2015 initiatives to explore content related to recommended criteria for inclusion of stillbirths based on the themes identified in the first paper of the Series.<sup>17</sup>

Documentation selection streamlined with the first paper in this Series included papers that supported Every Woman Every Child or were mentioned in the call to action from the 2011 *Lancet* Stillbirth Series. Additionally, several themes were identified by the Advisory and Study Series Groups as important yet under-represented—global mental health, raising women's voices, stigma, and human rights—and related documents were identified for each theme.

For each initiative, the original action plan or most recent updated report was selected, resulting in a total of 16. Each document was reviewed in full to identify the number of mentions of stillbirth and other relevant terms, evidence of the criteria identified to assess inclusion of stillbirth, and opportunities for the future to incorporate these criteria (appendix).

#### Organisational network analysis

Organisational network analysis assesses the structure of relationships between actors in a network. This organisational network analysis, implemented to better understand present patterns of interactions related to stillbirths and develop the way forward to strengthen momentum and action for stillbirths, included 33 organisations associated directly or indirectly with stillbirth-related issues, selected by the *Lancet* Stillbirth study group (appendix). Respondents from multilateral agencies, professional associations, academia or

research organisations, the donor community, non-governmental organisations, partnerships, parent groups, and the private sector provided structured information on their organisation's interactions in the past year with each of the other 32 organisations, and qualitative information on successes and challenges for the community of organisations working on stillbirth issues. Similar analyses have been used for the community of organisations working on newborn health worldwide.<sup>18</sup>

Analysis, using UCINET version 6.547, included network density (to measure realised vs potential connections between organisations), degree centrality (to measure the number of direct links each organisation has, weighted for interaction level), betweenness centrality (the extent to which an actor is connecting two actors not currently interacting), and network centralisation (to measure how equally or unequally degree and betweenness centrality are distributed in the network). With the study's 100% response rate, analysis results are based on confirmed ties (ie, those in which both organisations stated they had interacted in the past year; appendix).

Limitations to this analysis include its small sample size, little distinction between individuals and their organisations, respondent knowledge, and an inability to capture changes over time (data show interactions only in the past year). We intentionally sampled globally affiliated organisations rather than country-specific organisations in view of the global nature of the analysis. However, this restriction prevented the consideration of some active country-based organisations that engage at a global level as well. The 33 organisations included are a sample of the global network and not inclusive of all organisations working in this sphere.

shift from a pattern of high to low maternal mortality, from a predominance of direct obstetric causes of maternal mortality to an increasing proportion of indirect causes and other relevant health and non-health factors.<sup>7</sup> Relevant worldwide plans emphasise this transition, for example Strategies for Ending Preventable Maternal Mortality,<sup>8,9</sup> and many countries have followed, albeit at differing paces. Countries further along the obstetric transition pathway have subspecialisations, such as in maternal-fetal medicine or in perinatal changes, which deal with fetal health outcomes predominantly in high risk pregnancies. However, specific attention to improve the baby's health and survival along with the mother's health should not have to wait for an obstetric transition because common preventive measures are linked to survival, particularly high quality midwifery and obstetric care, which should occur in all settings.

The progress for maternal and child mortality has resulted in greater attention on morbidity, stillbirths, newborn deaths, and the long-term effects of adverse

birth outcomes on development and non-communicable diseases.<sup>10-14</sup> To tackle these challenges, optimisation of the health of the mother-baby dyad is needed. The worldwide epidemiological transition for mortality of children younger than 5 years led to a shift in focus to newborn health and the resulting Every Newborn Action Plan with specific targets for ending preventable stillbirths and maternal and newborn mortality.<sup>15,16</sup>

This final paper aims to: (1) synthesise evidence from the Series on actions to accelerate progress for ending preventable stillbirths and to promote respectful, supportive care, which includes bereavement care after a death; (2) assess opportunities for greater integration of stillbirth prevention and care in relevant global health initiatives and reports and national plans; (3) report on an organisational network analysis examining relationships among 33 organisations working to prevent stillbirths; and (4) renew a measurable call to action for the integration of stillbirth prevention and response as part of women's and children's health. Data and methods are summarised in panel 1 and the appendix.

See Online for appendix

## Synthesis of the evidence from the Ending preventable stillbirths Series

Strategies for maternal and newborn health emphasise universal access to high quality care.<sup>8,16</sup> This Series argues that stillbirth prevention and response is founded on respectful, high quality care for mother and baby, which must be part of women's and children's health programmes. Frøen and colleagues<sup>17</sup> use the term prenatal health to refer to antenatal and intrapartum care that protects and supports the mother–baby dyad.<sup>17</sup> At the same time, specific attention to stillbirths in advocacy, policy formulation, research, and monitoring is required as countries move through the obstetric transition. Stillbirths in the USA, for example, now outnumber infant deaths<sup>19</sup> and therefore the issue is gaining greater attention than previously.<sup>20</sup>

As an expansion of the *Lancet* Stillbirths Series in 2011,<sup>11</sup> this Series debunks myths around stillbirth and presents new evidence, updated stillbirth estimates, and a call to action in the post-2015 era (panel 2).

The estimated 7200 stillbirths that occur every day are neglected in global public health and women's rights initiatives,<sup>17,21,24</sup> despite the evidence shown in 2011.<sup>32,33</sup> Half are intrapartum stillbirths, which are highly preventable with high quality care at birth<sup>26,34,35</sup> and early identification of at-risk pregnancies.<sup>27</sup> The high numbers of stillbirths and slow progress show that the 2011 call to action<sup>36</sup> is mostly unrealised despite impressive global media visibility;<sup>37</sup> Frøen and colleagues<sup>17</sup> assess the reasons for lack of progress and effective action. Use of the term stillbirth is infrequent in reporting, research, and funding with some exceptions.<sup>8,13,16,34,38</sup> Countries have committed to ending preventable stillbirths with the adoption of the Every Newborn Action Plan,<sup>16,39</sup> yet few have taken this commitment forward in national plans.<sup>17</sup> Stillbirths have received little political attention, defined by Hafner and Shiffman<sup>40</sup> as occurring when “leaders of organizations express concern about issues publicly and privately, and back up this concern by allocating resources”. Stillbirths have had even less political attention than other important public health issues, such as HIV or malaria, even though the burden is greater and solutions exist that would benefit women and children.<sup>41</sup>

Stillbirth rate data are increasingly available through national civil registration and vital statistics, birth registries, and health management information systems,<sup>21,25</sup> and the indicator is included in core health indicator lists.<sup>42</sup> Lawn and colleagues<sup>21</sup> summarise the burden of stillbirths with updated national and worldwide stillbirth rates and projections for 2015 and with a focus on intrapartum stillbirths, risk factors (eg, infections in pregnancy, especially syphilis; non-communicable diseases; and lifestyle risks), and other metrics for disadvantaged populations. Most stillbirths occur in low-income countries and mostly in rural settings. In high-income countries, marginalised groups are particularly affected.<sup>25</sup> Unlike previous *Lancet* Series on maternal,

newborn, and child health,<sup>13,38</sup> the importance of bereavement care after a stillbirth is assessed in this Series. Heazell and colleagues<sup>24</sup> consider the economic and social costs of stillbirths, especially for women, including stigma associated with stillbirth. Flenady and colleagues<sup>25</sup> identify challenges of stillbirth prevention in high-income countries, including socioeconomic disparities, the need to improve data quality, and provision of bereavement care.<sup>25</sup> A matrix of themes from the papers in the Series is available in the appendix.

## A mother–baby dyad approach to stillbirth prevention and response

A healthy mother and baby are the markers of successful management of pregnancy, labour, and childbirth. Stillbirth prevention and response cannot be stand-alone issues and need an integrated programmatic approach. Likewise, neglect of stillbirths would restrict the full potential of an integrated approach for women's, children's, and fetal health that averts deaths (maternal, newborn, and stillbirth), improves child neurodevelopmental outcomes, and reduces maternal morbidities.<sup>11,12,29–31</sup> Investment in and effective implementation of high quality care and health promotion along the continuum of women's and children's health is one of the most effective ways to protect mother and baby and promote healthy child development outcomes.<sup>43</sup> This approach is further strengthened with functioning health systems, woman-centred, compassionate care, and trusting relationships between women and their care providers.<sup>44</sup> Interventions for respectful and supportive care provided in the table could be the core elements of the bereavement care package, but this group of interventions needs to be studied, defined, and agreed by stakeholders.

The stillbirth rate is a key indicator of quality of care during pregnancy and childbirth, defined by WHO as: “the extent to which health-care services provided to individuals and patient populations improve desired health outcomes...health-care needs to be safe, effective, timely, efficient, equitable and people-centered.”<sup>45</sup> The *Lancet* Midwifery Series suggested a framework for quality maternal and newborn care that incorporates the values on which care should be based—respect, open communication, and tailoring to women's needs. Additionally, this framework should include components of the health system needed to enable this provision of quality care—adequate resources, accessible and acceptable quality services, and integration between communities and facilities.<sup>46</sup> High quality is necessary throughout the continuum of care and can only be ensured when appropriately educated and skilled health-care professionals are in place and well supported by a functional health system.

The table shows the interventions and requirements at each stage of the health continuum,<sup>48</sup> including in the case of a death of a baby. Heazell and colleagues<sup>24</sup> provide an updated review of evidence-based interventions. Highly

**Panel 2: Debunking myths about stillbirths****Myth 1: stillbirth is not an important global health problem in comparison to maternal and child mortality, and other more pressing health issues**

Fact: an estimated 2.6 million stillbirths occur every year,<sup>21</sup> which should be added to the global burden of deaths for women and children: 5.9 million deaths of children younger than 5 years (including 2.87 million newborn deaths) and 303 000 maternal deaths.<sup>22,23</sup> In most high-income countries, stillbirth numbers outnumber infant deaths.<sup>19</sup> The costs of stillbirths go beyond the loss of life and include maternal depression and financial costs to parents as well as long-term economic costs to society.<sup>24</sup> Even in countries where the overall stillbirth burden is low, the equity divide is great (eg, rural vs urban, ethnicity, age, and poverty) in terms of stillbirth rates.<sup>25</sup>

Action: intentional leadership is needed from global and country leaders to count the global burden of stillbirths together with maternal and child deaths. Not only will this inclusion acknowledge stillbirth as a death to families and help to break the silence but also the full potential of investments in preventable deaths will be then accurately measured. Indicators to monitor progress and to measure inputs will ensure every death is counted and actions to prevent these deaths can be tracked and monitored.

**Myth 2: stillbirth is inevitable**

Fact: half of stillbirths occur during birth, of which three-quarters are preventable with equitable access to quality care<sup>26</sup> and early detection of at-risk pregnancies.<sup>27</sup> Stillbirths due to non-preventable congenital abnormalities account for less than 10% of stillbirths after 28 weeks.<sup>21</sup> Infections during pregnancy are important preventable factors, especially in sub-Saharan Africa where malaria in pregnancy is estimated to be associated with about 20% of stillbirths and syphilis is associated with 11% of stillbirths. Addressing other risk factors such as non-communicable diseases, nutrition and lifestyle factors, fetal growth restriction, preterm labour, and post-term birth will also reduce preventable stillbirths.

Action: implementation of high quality care for every woman during pregnancy, labour, and birth will prevent most intrapartum stillbirths nowadays. Family planning and safe abortion will prevent unintended pregnancy and promote adequate birth spacing. Social and political actions to address poverty and discrimination as well as health care in adolescence and before pregnancy can also reduce stillbirths. The focus must be to deliver measures that are known to work, especially in the highest burden settings, to reduce equity gaps, and to scale up evidence-based interventions through the strengthening of national capacity, to remove health system bottlenecks, and to support health workers. Investigation into essential knowledge gaps will improve understanding and increase effective innovation for stillbirth prevention. Data are crucial for accelerating progress. Quality of care during labour also relates to data collection because the capacity for effective data collection implies a level of functionality that is associated with good quality of care (and vice versa). Data are urgently needed, especially for intrapartum stillbirths.

**Myth 3: stillbirth prevention is not affordable, especially for low-income countries**

Fact: investment in stillbirth prevention will also prevent maternal and newborn deaths as well as improve child neurodevelopmental outcomes,<sup>28</sup> and long-term adult wellbeing,<sup>12</sup> and reduce maternal morbidities.<sup>29-31</sup> An integrated programmatic approach is needed to prevent and to respond to stillbirths.

Action: increased investment for high quality antenatal and intrapartum care must be strengthened and targeted in order to achieve the bold targets for ending preventable deaths in the Global Strategy for Women's, Children's and Adolescents' Health 2016–30. Affordability of interventions will be maximised if countries count stillbirths in addition to maternal and newborn deaths.

(Panel 2 continues on next page)

effective interventions in pregnancy, such as syphilis detection and treatment, and during labour and birth, such as assisted vaginal delivery and caesarean section for fetal indication, are essential for stillbirth prevention.

Prevention of stillbirths starts with protection of the girl through addressing hunger, violence, and discrimination and ensuring equal access to education and health care.<sup>49</sup> In adolescence, comprehensive sexual education, delayed marriage, access to sexual and reproductive health information and services including family planning, and access to safe abortion services when legal, are crucial. Access to primary health care before pregnancy helps to address nutritional deficiencies and enable diagnosis of hypertensive disorders and diabetes, which can help to reduce stillbirths. Community mobilisation and gender empowerment, including engagement with men on women's health issues, play a role in women's general

health and wellbeing and thus contribute to a reduction of stillbirths. Care in pregnancy, labour, and birth must include attention to both mother and baby—the principle of “survival convergence”.<sup>50</sup>

Although most stillbirths, like most neonatal deaths, do not have death certificates,<sup>21</sup> stillbirths matter to women and their families.<sup>24,25,51</sup> When any death happens, bereaved families will typically need some form of support because evidence shows that mothers of babies who are stillborn are at greater risk of negative psychological symptoms, including depression, than those who have liveborn babies.<sup>24</sup> Evidence also shows that families might be stigmatised,<sup>24,25</sup> and that, despite evidence-based solutions and guidelines,<sup>24,26,52</sup> a sense of fatalism exists whereby women and even health workers do not see stillbirths as preventable; therefore societies continue to accept these deaths as inevitable.<sup>25</sup>

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**Myth 4: talking about stillbirth is inappropriate and insensitive; stigma and taboo associated with stillbirth are a part of culture that must be accepted**

Fact: no mother in any society can forget that she had a baby who was stillborn. Many do not even want to forget. Moreover, many parents and other family members find going forwards easier if they are given the opportunity to share their stories and remember their babies in settings with respectful and supportive family members or caregivers. Addressing loss forthrightly can help to bring out concealed stillbirth and reduce the stigma. Culture changes constantly. For example, maternal deaths were accepted a century ago as a normal outcome of pregnancy and childbirth. As countries have advanced along the obstetric transition,<sup>7</sup> maternal deaths are no longer viewed as inevitable and accepted. This same shift must take place for stillbirths as well as neonatal deaths, which are also deemed acceptable in some societies. When deaths of babies do occur, respectful care is necessary during the remainder of the pregnancy, as well as during childbirth and after.

Action: an increased voice, especially of women, will support women to demand improved quality of life and health care. Cultural change requires intentional leadership, coordinated partnerships, nurtured champions, and robust data and evidence to build a case. Culturally appropriate protocols and support programmes need to be developed and implemented for respectful care after a death in pregnancy and childbirth.

Stigma relating to stillbirth must be defined, assessed, and tracked at country, regional, and global levels, and support coordinated with action to reduce stigma.

**Myth 5: a vertical approach is needed to end preventable stillbirths**

Fact: ending preventable stillbirths is not achievable without an integrated approach. Stillbirth prevention and response is respectful, quality and interlinked antenatal, intrapartum, and postnatal care, and not isolated vertical programmes. To ensure inclusion of stillbirth in worldwide and national policy formulation, research and monitoring for women's and children's health, specific advocacy, and attention are required.

Action: intentional leadership is needed to raise the profile of stillbirth prevention and care within the continuum for women's and children's health, to make the case for the full potential of returns on investment, and to show stillbirth from the perspectives of rights, equity, and vulnerability. Increased accountability will result from use of key indicators of relevance to stillbirth, including quality of antepartum and intrapartum care, and especially incorporation of the stillbirth rate as a marker of quality maternity care. Investigation is also key for effective and recommended interventions, with a focus on what works in different settings—for example, low resource and conflict settings, as well as for marginalised groups and under-researched countries and regions.

More details in appendix.

**Proposed criteria for integration to truly address stillbirths**

Promotion of women's and children's health inherently includes the prevention of stillbirths. Frøen and colleagues<sup>7</sup> have identified themes relating to stillbirths in global women's and children's health platforms since the *Lancet* Stillbirths Series in 2011. Based on the findings of these authors, we propose three ways to effectively and appropriately incorporate stillbirths into post-2015 initiatives for women's and children's health. These criteria include: acknowledge the burden of stillbirths; address actions needed to prevent stillbirths with high quality antenatal and intrapartum care; and monitor stillbirths with a target or outcome indicator, or both. We assessed relevant post-2015 initiatives for these criteria (panel 1, appendix). The Every Newborn Action Plan meets the criteria, although the component for antenatal care is not emphasised sufficiently for stillbirths. Seven of the 16 initiatives identified and assessed, including the Global Strategy, mentioned quality care and acknowledged the burden, but did not include a target or indicator to monitor progress for stillbirth prevention. Half the initiatives reviewed met only one or none of these criteria. The inclusion of these criteria needs to be linked to the continuum of women's and children's health promotion, but specific advocacy for the inclusion of stillbirth prevention within new

women's and children's health initiatives might be needed to ensure no opportunities are missed.

**Priorities based on evidence, opportunities, and gaps**

Findings from this Series show that stillbirths should be integrated and tracked within initiatives for women's and children's health as well as women's rights and empowerment.<sup>17,24,25</sup> Building on existing calls to action from the *Lancet* Every Newborn Series<sup>13,15</sup> and the *Lancet* Midwifery Series,<sup>38</sup> which called for women's right to available, accessible, acceptable, and good quality care, and supplemented by evidence from this Series, five issue areas were identified to change the trend for stillbirths. These themes included: intentional leadership; increased voice, especially for women; implementation of integrated interventions with commensurate investment; indicators to measure effect of interventions and especially to monitor progress; and investigation into crucial knowledge gaps. Integration into women's and children's health as measured by the three criteria, proposed previously in an earlier section of this Series paper, cuts across all these areas.

**Intentional leadership**

Global health issues are prioritised in part because of "actor power" exercised by individual champions,

	Interventions with proven effect on stillbirth prevention	Interventions with potential effect on stillbirth prevention and care	Legislative and policy actions
Reproductive health: planning and preparing	Family planning information and services, including for adolescents (fewer pregnancies among women who are younger than 16 years and older than 35 years, and birth spacing); folic acid fortification or supplementation; <sup>*,47</sup> prevention of, testing for, and management of syphilis	Maintenance of good health and nutrition, promotion of healthy behaviour such as good nutrition, physical activity, and no tobacco, alcohol, and drugs; prepregnancy checks for hypertensive disorders, cardiac disease, anaemia, undernutrition, and obesity;† prevention of, testing for, and management of sexually transmitted infections (eg, hepatitis B and HIV); prevention of child and forced marriage; detection and management of hazardous and harmful substance use; prepregnancy detection and management of risk factors (nutrition, tobacco, alcohol, and environmental toxins) and genetic disorders	Legislative and programmatic interventions to delay marriage; legislative and programmatic interventions to ensure completion of secondary education for girls and boys; provision of comprehensive sexuality education for boys and girls; planning pregnancies with modern contraceptive methods; strategic thinking about quality of care, including availability, equitable access, acceptability
Pregnancy: ensuring a healthy start	Effective antenatal care and support visits;‡ folic acid supplementation; prevention and management of malaria, including insecticide-treated bednets or intermittent preventive treatment; <sup>*</sup> prevention and management of syphilis; <sup>*</sup> interventions for cessation of smoking; screening for and management of maternal illness and risk factors (obesity, hypertensive disorder, <sup>*</sup> diabetes); detection and management of fetal growth restriction <sup>*</sup>	Iron supplementation; calcium supplementation (prevention of hypertension); dietary counselling for healthy weight gain and adequate nutrition; detection and management of risk factors (nutrition, tobacco, alcohol, environmental toxins) and genetic disorders; management of chronic medical conditions (eg, hypertension and diabetes); low-dose aspirin to prevent pre-eclampsia; antihypertensive drugs; magnesium sulphate for severe pre-eclampsia and eclampsia; external cephalic version; counselling for domestic violence	Maintenance of good health and preparation for pregnancy, childbirth, and the early months as a new family; receiving at least four quality antenatal care visits, which include essential clinical components:‡
Childbirth: supporting a safe beginning	Facility childbirth with a skilled birth attendant; antibiotics for PPRM; induction of labour to manage PROM at term; surveillance of labour (partograph), including fetal monitoring; post-term labour induction; <sup>*</sup> assisted vaginal delivery and caesarean section for fetal indication (comprehensive emergency obstetric care) <sup>*</sup>	Psychosocial support and companion of choice during labour; appropriate procedures for delivery after stillbirth diagnosis (eg, induction of labour, embryotomy, and caesarean section)	Access to midwifery services with the companion of choice; mothers participate in decisions about how they and their baby are cared for and have the privacy and space to experience birth without unnecessary disturbance and interventions
When a death of a baby occurs: respectful and supportive care	NA	Quality postnatal care to the mother, including management of complications (eg, haemorrhage, eclampsia, sepsis, and anaemia), and prevention, early detection, and management of obstetric fistula; family planning advice and contraceptives; initiation or continuation of antiretroviral therapy for HIV; nutrition counselling; postnatal contact with a skilled health-care provider, at home or in a health facility at about day 3, day 7, and at 6 weeks after birth; screening and management for post-partum depression; maternal and perinatal death or near-miss case review or audit; compassionate support and counselling for all family members after a stillbirth, maternal, or neonatal death; provision of emotional support and specific information to assist in decision making and access to financial support when possible	Respectful support to all the family members after death as appropriate in context, which might include accurate information on options (eg, seeing and holding the baby) and decisions (eg, funeral arrangements and autopsy); continuing support after a death (eg, information on where to go for help, counselling support, financial support for lost income and extra expenses, and listening); information and education to reduce the stigma and taboo associated with stillbirth, maternal or newborn death; support to community groups, which can reduce stigma and support bereaved families; education and training of health-care workers in respectful care for bereaved parents; creation of safe spaces to support health-care workers caring for the bereaved; encouragement of autopsy where feasible

PPROM=preterm premature rupture of the membranes. PROM=premature rupture of membranes. NA=not applicable. \*Interventions proven to reduce stillbirth from the *Lancet* Stillbirth Series in 2011.<sup>28</sup> †We suggest investigations are needed to study the effectiveness of primary health-care prepregnancy visits aimed to detect health problems having a potential effect on maternal mortality, morbidity, and stillbirth, to adapt treatments (antihypertensive drugs), and discuss post-partum contraception. ‡Quality antenatal care visits should include assessment of gestational age, definition of the estimated date of delivery (first half of the pregnancy), body-mass index measurement, blood pressure measurement, urine test (albumin), syphilis and HIV screening, and information provision for birth preparedness (eg, danger signs, including fetal movements, and decision making by a health-care professional competent in midwifery). Additionally, as needed, visits should include context specific interventions such as intermittent presumptive treatment for malaria and a repeated HIV test in late pregnancy. The effect on stillbirths of use of ultrasounds in poor settings to measure gestational age, to monitor fetal growth, and to inform the mother of possible complications (eg, placenta location, fetus number and position, amniotic liquid) should be tested.

**Table: Interventions and action to prevent and respond to stillbirths along the continuum of women's and children's health care<sup>2,24,48</sup>**

“guiding organisations” that help to develop networks and movements, and a mobilised civil society.<sup>53</sup> An organisational network analysis was conducted to better understand how a group of 33 organisations working in maternal and newborn health are interacting in relation to stillbirths and how to maximise their associations to advance stillbirth prevention and response (panel 1, appendix).

Our results suggest that these organisations have fairly dense interactions for maternal, newborn, and stillbirth issues (47% of potential interactions realised). However,

these organisations are missing opportunities to collaborate more effectively for stillbirth prevention and response: stillbirth-specific interactions are much less dense (21%; figure 1). The obvious centralisation of the stillbirth-only network indicates the network is highly dependent on the most central actors (appendix). The network could be strengthened with expansion of existing interorganisational work for maternal or newborn issues (which probably already includes activities relevant to stillbirth prevention); an increase in the level or intensity of interactions on stillbirth issues; and further integration

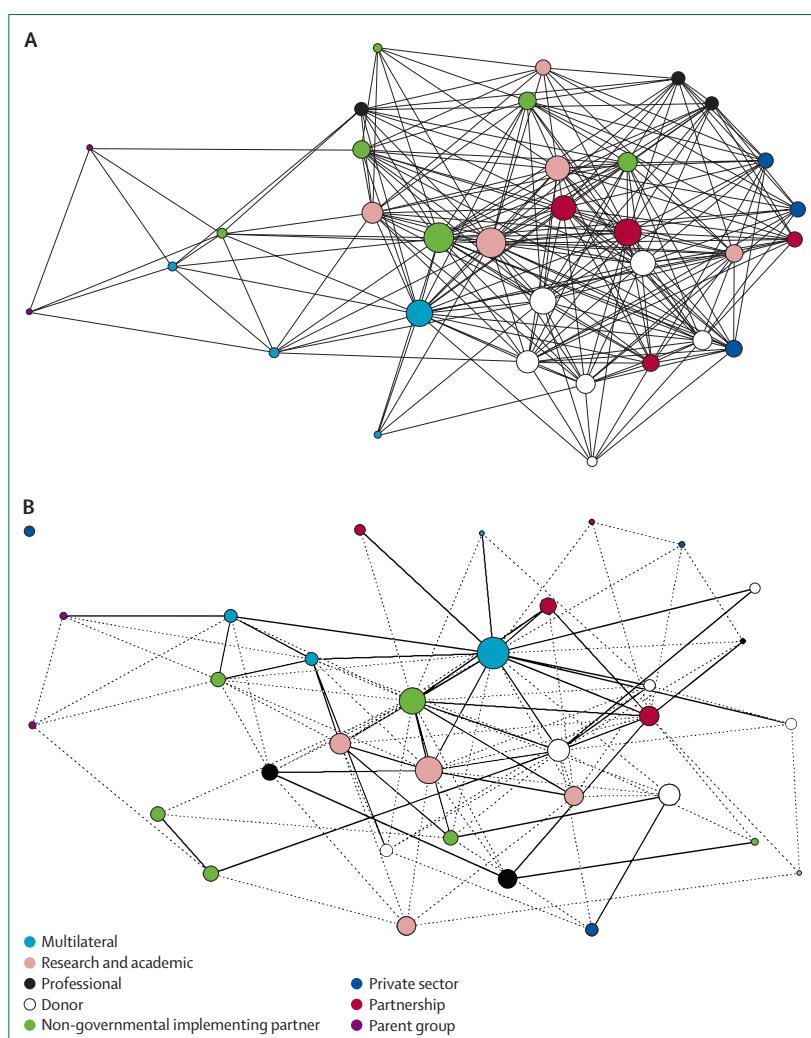
of those organisations focused on stillbirths into the network by increasing their interactions with highly connected maternal or newborn organisations.

To build a strong network, the few central organisations responsible for most stillbirth interactions (notably academic institutions and large non-governmental organisations) who serve as connectors, need to find new ways to bring in less connected organisations (figure 1B). This target is especially important to integrate the main global organisations with relevant mandates and also parent groups, which are more peripheral. These connections will need intentional institutionalisation in the other organisations but this process can only happen if those organisations are open to linkage and have people time allocated to bring in the stillbirth agenda. Otherwise the network of those working on stillbirth related issues will remain weak.

Intentional leadership needs agencies with adequate capacity, skills, and funding to assume responsibility and lead policy and programme change, while supporting countries. WHO should develop guidelines, set priorities for research, and implement large-scale research. The UN Population Fund should lead scale-ups of midwifery and emergency obstetric services. The professional associations (ie, the International Federation for Obstetrics and Gynaecology and the International Confederation of Midwives) should enable their national organisations to speak up for improved services. Academic institutions should lead on research. Civil society should be advocating for policies to hold global and national stakeholders accountable for ending preventable deaths, including stillbirths, providing respectful care and support to bereaved families, and leading behaviour change and community engagement. Specific efforts will be needed to support agencies in leadership roles including funding, strategy assessments, and adaptable approaches to implementation. A powerful advocacy mechanism will be needed to open dialogue about stillbirths and count these babies as deaths.

Little information is available about leadership or champions for stillbirth. Countries that have adopted a national stillbirth target often have done so through the efforts of a few individual champions.<sup>17</sup> All interested stakeholders, including parent-based organisations, should be given an opportunity to regularly convene and exchange information for new evidence, funding, and prevention strategies, to increase the strength of the network.

Culturally appropriate supportive care in the case of a death is particularly difficult without leadership. WHO's joint statement for respectful maternity care,<sup>54</sup> echoed by the UN Women's 2015–16 progress report, calls for the protection of a woman's "right to dignified, respectful health care" and "ending disrespect and abuse during childbirth". Although this agenda does not include care after a death,<sup>55</sup> supportive, respectful care in pregnancy and childbirth including after a death



**Figure: Visualisation of organisational interactions among 33 organisations in 2015 by organisation type** (A) Any reported interactions related to maternal, newborn, or stillbirth issues. (B) Stillbirth interactions only, medium and high level of interactions depicted with bold lines, low level interactions shown with dotted lines. The placement of organisations varies between the plots; for both plots, nodes are sized according to degree centrality. For details on the organisational names, see appendix.

should be deemed to be part of care along the life-course of women and children.

### Increased voice, especially of women

The *Lancet* Stillbirth Series in 2011 provided evidence of stigma and marginalisation of women who had stillbirths<sup>51</sup> and called for empowerment of communities and families.<sup>36</sup> This new Series shows that no specific or notable action has been taken against stigma or for support of affected families,<sup>17</sup> and stigma persists.<sup>24</sup> Change needs to include women's and parents' voices to call for change,<sup>17,21,24</sup> to demand accountability, to take action against stigma, and to provide support to the bereaved, as culturally appropriate.<sup>24</sup>

To enable women to demand high quality health care, they must be supported to realise their fundamental

human rights,<sup>49</sup> including “the highest attainable standard of physical and mental health”.<sup>56</sup> Cultural barriers often disempower women; for example, young brides might have to get pregnant early to prove their fertility, and expectant mothers might be delayed from care seeking. For sustainable development, women need to be healthy, valued, enabled, and empowered.<sup>49</sup> Empowerment of women, through education, equitable decision making, woman-focused care, and access to resources, can improve health outcomes, including the prevention of stillbirths, yet more research is needed to understand these linkages.

Health workers’ and communities’ norms of complacency and fatalism related to pregnancy and childbirth need to be addressed. Community-based interventions are one method of changing norms and should be tested for scale-up.<sup>57,58</sup>

Respectful support is fundamental to increase women’s voices, starting with an acknowledgment of death and help for families to respond in their own ways. The respectful maternity care agenda is an entry point for support after any death—maternal, newborn, or stillbirth.<sup>55</sup> Dignified care is important to grieving families and communities,<sup>24,25</sup> and culturally acceptable support should be an integral part of this process.<sup>55</sup> Parents should be given the option to hold a baby who has died, yet the bodies of stillborn babies are often disposed of without any recognition, name, clothes, or funeral.<sup>25,51</sup> Context-specific approaches are needed for supportive, respectful care in pregnancy and childbirth, including after a death. Little knowledge is available from low-income and middle-income countries but in some settings, some support is available for affected families from the community. Around half of families affected by stillbirth in high-income countries reported substandard levels of bereavement care.<sup>24,25,44</sup> Acknowledgment of a family’s right to respectful care during and after childbirth can give rise to a common understanding of, and commitment to, respectful care during and after death as well. Programmes are also needed to support affected health workers and avoid the blame culture that is often associated with stillbirth.<sup>59</sup>

Parent groups have the potential to raise stillbirth awareness, as noted for preterm birth,<sup>60</sup> but the network of stillbirth-affected families is small, disconnected, and under-resourced. Only a small number of parent organisations are active in more than one country.<sup>61</sup> The organisational network analysis suggests that parent-based organisations are less connected with the broader global maternal and newborn health community. Parent groups mainly focus on local provision of information, advice, and support, or advocacy locally or nationally, for instance lobbying for legal recognition of stillbirths, or seeking to raise awareness of stillbirths’ burden. Successful examples of parent group advocacy in the USA provide some lessons learned, such as Group B *Streptococcus* advocacy, but these occurrences are small

scale and more engagement is needed,<sup>62</sup> especially in low-income and middle-income countries.

Monitoring of progress of respectful, supportive care and raising the voice of affected parents needs a clear definition of models and content of care, and indicators. However, concepts such as stigma and taboo for these deaths have not yet been well quantified, making measurement of progress a challenge.

### Implementation of integrated interventions with commensurate investment

Health services for women and children, including those with the most effect on stillbirth prevention and response, should be delivered together whenever possible without compromising the quality of care for mother or baby.<sup>8,50</sup> Evidence-based, cost-effective interventions exist despite reports of a knowledge gap for interventions and low awareness of risk factors among some health providers and women.<sup>24–26</sup> Linking stillbirth prevention to programmes for HIV, malaria prevention and treatment, nutrition, immunisation, and antenatal care packages is crucial. Programmatic and clinical guidance and additional research are necessary to design appropriate and innovative policies and to implement interventions. These interventions could include prevention of unwanted pregnancies, especially in adolescents, or support to shift the epidemiological, social, and medical contexts (thereby reducing the incidence of risk factors, such as obesity),<sup>63</sup> health promotion before and in pregnancy (eg, preconception care,<sup>64</sup> early and focused antenatal care visits, and ultrasounds), labour surveillance (eg, fetal monitoring),<sup>65,66</sup> and correct use of interventions during labour and birth (eg, labour induction, amniotomy, fetal monitoring, assisted delivery, or caesarean section, when appropriate<sup>67</sup>). Some maternal and newborn interventions reduce the number of stillbirths,<sup>26,68</sup> although not always,<sup>58,69</sup> and more research is needed to better understand why. For example, the number of antenatal care visits does not give an accurate assessment of quality of care, the effective provision of essential interventions, or whether stillbirths and other adverse outcomes are being reduced (table, appendix).

Stillbirth prevention does not need a separate set of intervention programmes from antenatal and intrapartum care, although specific interventions must achieve high quality—eg, fetal heart rate monitoring and syphilis treatment. The Saving Mothers, Giving Life programme shows that stillbirths can be prevented when good quality maternal and newborn care is improved with reductions in stillbirth rates of 20% in Uganda and 19% in Zambia (appendix).<sup>70</sup> Improved coverage of 13 already recommended interventions reduced stillbirth and was cost effective in the South African setting.<sup>71</sup> Countries recognised as fast-progressing for newborn deaths show that many pathways exist for improvement,<sup>72,73</sup> from investment in the workforce and family



planning to community leadership, health insurance, and greater accountability than at present.<sup>21</sup> Reductions in stillbirth rates require similar pathways.

Successful integrated interventions for prenatal care should be reflected in essential indicators in guidelines and intervention lists. Implementation needs a full range of competent and motivated health professionals, including midwives and specialists, within functioning health systems. Major bottlenecks of quality care at birth include health financing, workforce, and service delivery.<sup>72</sup> Incentives for demand creation for accessing quality care and strengthening of implementation must also be explored.<sup>74,75</sup>

Incorporation of stillbirths into investment cases for women's and children's health strengthens the cost-effectiveness argument;<sup>34</sup> however, supporting programmes often do not use stillbirth rates to monitor progress and document the full return on investment.<sup>76</sup> Scarce mention of stillbirth in the Organisation for Economic Cooperation and Development's database of donor funding reflects another missed opportunity to integrate stillbirth into existing programmes for women's and children's health.<sup>17</sup> The hidden costs to families and societies might partially explain why the investment case for stillbirth is not more widely used.<sup>24</sup>

#### Indicators to measure effect and especially to monitor progress

Data are crucial to accelerate progress for implementation efforts as well as advocacy for more political attention and funding.<sup>77</sup> Efforts to improve antenatal, intrapartum, and postnatal care data are underway through the Every Newborn metrics work,<sup>78</sup> and quality improvement will benefit from the forthcoming WHO perinatal mortality audit and review tool. Associations between stillbirth, maternal death, and near-miss reviews (as defined by WHO) are recommended, when appropriate, within the maternal death surveillance and response mechanism.

Stillbirth reporting has had some improvements, with more data at the national level available and advancements in worldwide updates.<sup>21</sup> Data for intrapartum stillbirths are the weakest of all outcome-level data assessed.<sup>21</sup> Investment in civil registration and vital statistics and maternal death surveillance provides a key opportunity to improve counting of births and deaths, including stillbirths. A perinatal mortality rate indicator, based on intrapartum stillbirths and pre-discharge neonatal deaths, needs more research as a measure of quality of care at birth in low-income settings.<sup>79,80</sup> Recordings of all birth outcomes using comparable definitions and with details on timing of stillbirths (intrapartum *vs* antepartum) would increase data quality, and accountability,<sup>41,81</sup> and can be used to drive change when linked to clinical review and audit discussions without blame on staff.<sup>82</sup> The proposed classification of causes of death by the International Classification of Diseases (ICD)-perinatal mortality is a step towards development of a global

classification system that includes programmatically relevant stillbirth causes as called for in the 2011 Stillbirth Series (Allanson E, Tunçalp Ö, Chou D, et al, unpublished).<sup>36,83</sup> WHO should harmonise its ICD-perinatal mortality efforts with a re-revision of the verbal autopsy tool and the ICD, to ensure greater relevance of ICD to stillbirth than in previous versions.

Although evidence exists for effective interventions, programmatic coverage indicators are scarce.<sup>17</sup> Identification and tracking of intrapartum and antenatal care, including content, quality, coverage, and equity, is urgently needed. Indicators must address specific actions to prevent stillbirths and monitor care after death. Data disaggregation, including by timing, cause, and for marginalised groups, might enable countries to target strategies to reach the most vulnerable people. Data collected through routine health management information systems or intermittent assessments for quality of health facilities can strengthen accountability for stillbirths when used in national or subnational score cards to track coverage of care as used in a number of countries, for example Tanzania.

#### Investigation of crucial knowledge gaps

The Stillbirth Series in 2011 prioritised research themes to reduce stillbirth rates in different settings.<sup>36</sup> Frøen and colleagues identified only 11% of new research studies since 2011 that could be linked to themes from the call to action.<sup>17</sup> Since 2011, some research into effective interventions to prevent stillbirth has emerged, for example on obesity prevention and diabetes screening.<sup>21,25,84,85</sup> Many themes are being researched, with new gaps being identified.

Although the volume of implementation research is increasing, investigation into the generalisability of present interventions to different settings is needed to avoid unintended consequences and to reach a high level of effective coverage, particularly with respect to obstetric emergencies.<sup>86</sup> Relevant research should record many adverse outcomes, including stillbirths<sup>17</sup> and preterm births.<sup>87</sup> Identification of additional knowledge gaps, such as an improvement in the understanding of causes, stillbirth predictors, and placental pathological abnormalities, and reprioritisation of research questions are crucial to increase support and funding. Many key questions, such as the frequency of stillbirth with obstetric fistula, are unanswered.<sup>88</sup>

Heazell and colleagues<sup>24</sup> identified large gaps in the evidence base for interventions to mitigate the effects of stillbirths for women and other family members and call for research to establish stillbirth's costs, particularly in low-income and middle-income countries and for marginalised families. Research is needed to quantify all costs related to stillbirths, including economic and psychosocial costs, years of life lost, and both direct and indirect costs, to communicate effectively to the public, funders, national governments, and others about the

For the WHO verbal autopsy see <http://www.who.int/healthinfo/statistics/verbalautopsy/standards/en>

For the Organisation for Economic Cooperation and Development's database see <http://stats.oecd.org/Index.aspx?DataSetCode=CR51>

**Panel 3: Call to action—an integrated approach for ending preventable stillbirths; building on existing global strategies and plans**<sup>2,16,90,91</sup>

**Mortality targets by 2030**

- National stillbirth rate: as called for in the Every Newborn Action Plan,<sup>16</sup> every country should achieve a rate of 12 stillbirths or fewer per 1000 total births (resulting in a global average of nine stillbirths per 1000 total births)
- Equity stillbirth rate: as called for in the Every Newborn Action Plan, every country, particularly those where stillbirth rates are already less than 12 per 1000, should set and meet a national target to reduce equity gaps in stillbirth rates
- Intentionally nurture champions especially from high burden settings, and from professional organisations, including building technical capacity to implement interventions and to research
- Convene regular stakeholder events, including affected parents
- Raise the profile of stillbirth prevention and promote a healthy start in life within the continuum for women's and children's health, making the case for the full potential of returns on investment and showing stillbirth from the perspectives of rights, equity, and vulnerability

**Universal health-care coverage by 2030<sup>90</sup>**

- Family planning: by 2020, 120 million more women and girls to have access to contraceptives;<sup>91</sup> by 2030, ensure universal access to sexual and reproductive health-care services, including family planning, information, and education, and the integration of reproductive health into national strategies and programmes<sup>90</sup>
- Antenatal care: by 2030, universal quality, comprehensive antenatal care for all women in all countries (table)<sup>90</sup>
- Care during labour and birth: by 2030, effective respectful intrapartum care should be given to all women in all countries, including high quality intrapartum monitoring; timely and appropriate obstetric interventions, including caesarean section; and adequate, context-appropriate clinical and respectful management of stillbirth<sup>16</sup>

**Milestones by 2020**

This call for action also supports the milestones already stated in the Every Newborn Action Plan's global and national milestones to be reached by 2020 including the Measurement Improvement Roadmap (appendix).<sup>16,78</sup>

- Respectful care, which includes specifics for bereavement support after death: global consensus on a package of care after a death in pregnancy or childbirth (of a mother, newborn or stillborn baby) for the affected family, community, and caregiver in all settings
- Reduce stigma: all countries should acknowledge the effect of stillbirths and identify mechanisms to reduce associated stigma for all stakeholders, including health workers and communities

**Priority actions to achieve national and global stillbirth targets**

*Intentional leadership*

- Maximise existing leadership, ensure global organisations include stillbirths when taking action for women and children
- Ensure relevant global organisations act on their mandates related to stillbirths

*Increased voice, especially among women*

- Empower women to demand quality of life and health care, and support those affected by the burden of stillbirth to raise their voices for change
- Engage women, families, and communities in research, prevention, support, and convening opportunities
- Develop and implement culturally appropriate protocols and support programmes for respectful care after a death in pregnancy or childbirth
- Reach consensus on how best to define, assess, and track stigma relating to stillbirth at country, regional, and global levels, and support coordinated action to reduce stigma

*Implementation of integrated interventions with commensurate investment*

- Increase high quality coverage of priority interventions for respectful maternity care and promotion of prenatal health during pregnancy, labour, and birth, and provide culturally appropriate, supportive, respectful care after a death
- Focus on the highest impact interventions, especially intrapartum care in the highest burden settings; reduce equity gaps; strengthen national capacity to end preventable deaths, and severe morbidity; and increase funding commensurate with the scale of 2.6 million deaths a year
- Promote innovation to improve prenatal, maternal, and neonatal health
- Scale up and act on mortality review and audit data through national perinatal review and audit policies
- Overcome health system bottlenecks, especially the need for skilled and supported health workers, particularly midwives, and promote an enabling working environment
- Promote these actions within national processes supporting the Global Strategy for Women's, Children's and Adolescents' Health

(Panel 3 continues on next page)

personal cost of stillbirth borne by parents, caregivers, and other stakeholders. Additional issues needing further research include respectful, woman-centred care,<sup>54,89</sup> such as choice of companion during labour, choice of position during labour, and respectful, supportive care for bereaved people in all income

settings.<sup>24</sup> Evidence is very scarce for interventions; agreement on definitions and indicators is a prerequisite to research that could build the evidence base (table).

To increase research capacity, investment and an integrated approach are needed. A harmonised set of criteria for context, population, inputs, outputs, outcome,

(Continued from previous page)

*Indicators to measure impact and especially to monitor progress*

- Count every baby, including stillborn babies, track programmes, and measure coverage, linking with the Every Newborn Measurement Improvement roadmap and metrics work for Ending Preventable Maternal Mortality<sup>78</sup>
- Institutionalise stillbirth registration in every country as part of the routine Civil and Vital Registration Systems
- Promote the use of comparable definitions of stillbirth (based on gestational age before weight) and of causes
- Support the completion and wide use of perinatal audit tools and a global classification system for causes of stillbirth
- Identify and track coverage and content indicators for stillbirth prevention and supportive, respectful care after a death
- Strengthen accountability with key indicators of relevance to stillbirth, at a minimum including stillbirth rate, intrapartum stillbirth rate, antenatal care, identification and management of syphilis in pregnancy, management of hypertension, and effective intrapartum monitoring and response
- Promote stillbirth investigation as part of maternal or perinatal death review and response mechanism

*Investigation of crucial knowledge gaps*

- Address gaps in knowledge by setting research priorities of what is needed to prevent, manage, and monitor

- stillbirths and provide bereavement support; build the evidence through increased investment in discovery, translational, and implementation science to drive better understanding and effective innovation; learn through implementation research; develop research capacity
- Revisit research priorities for prenatal, maternal, and newborn health to address knowledge gaps for stillbirth prevention and respectful, supportive care
- Build the research evidence on outstanding questions related to effective and recommended interventions, focusing on what works in low-resource and conflict settings, for marginalised groups in all settings, and under-researched countries and regions
- Support and invest in implementation research and robust monitoring and evaluation of programme activities, ensuring integration of stillbirth outcomes as well as other pregnancy and birth outcomes, as appropriate
- Develop research capacity that serves specific contexts and communities with emphasis on highest burden settings
- Research and assess needs of women and families after death due to pregnancy or childbirth complications (maternal and newborn deaths and stillbirths), and for best practices in supporting health-care workers affected by their care of women undergoing stillbirth

and effect will improve interpretation of study findings to inform programme design. Collaboration among organisations should be expanded to align and increase resources. The extent of parent involvement in the research agenda has not been assessed but needs serious consideration.

### A turning point for stillbirths

As the Millennium Development Goals era came to an end in 2015, the sustainable development era must be a turning point for ending preventable deaths—stillbirths, and maternal, newborn, and child deaths. We outline a renewed call to action to end preventable stillbirths based on the evidence (panel 3, appendix)<sup>2,16,78,90,91</sup> in support of women's and children's health, including criteria for successful integration.

Leadership, coordination, and accountability are needed at all levels to address health system failures and denials of the human right to health, which cause preventable deaths. One of the most important contributions to ending preventable stillbirths will be the intentional incorporation of stillbirths into global, regional, and national policy frameworks for women's and children's health. This integration will help to break the silence and will cause a ripple effect, adding stillbirth outcomes to research, policies, and programmes. Training and support for health-care

workers, particularly midwives; strengthening of health systems; funding of research that strengthens prenatal interventions; and education and empowerment for women, are all examples of investments to prevent deaths. Additionally, the movement for respectful care during childbirth provides a framework on which to build supportive care when death occurs; indicators for respectful care and reduction of stigma still need to be developed, validated, and launched. The stillbirth rate is a marker of high quality antenatal and intrapartum care,<sup>17</sup> and a sensitive marker of a health system's strength.<sup>1</sup>

Strengthening of the network of organisations working on stillbirth prevention and care has potential to move forward the agenda. Stillbirth prevention and response must involve women and thus depends on their health, education, and equality. Intensive efforts are needed to improve support to women, men, and others after stillbirth, newborn or maternal death and to bring the voice of affected parents and communities into global and national policy platforms.

Every Woman Every Child called for prioritisation of stillbirths post-2015<sup>2</sup> and has included stillbirths in its vision: “ending preventable maternal, newborn and child deaths, and stillbirths”.<sup>92</sup> Stillbirth prevention and response will need to be done differently than at present to reach the full potential of 2030 with 126 million more

mothers and children alive, including 21 million stillbirths prevented.<sup>76</sup>

#### Contributors

The manuscript was drafted by MVK, LdB, SHL, PtH-B, WS, and JEL. LF led the organisational network analysis. SHL reviewed and analysed reports and initiatives. MVK coordinated the paper contents and consultation with the advisory group. LdB and MVK had full access to all the data in the study and had final responsibility for the decision to submit for publication. All authors commented and contributed to the content of the report, and read and approved the final version.

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#### Declaration of interests

We declare no competing interests.

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