**Lives Saved Tool Technical Note**
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# Revisions to Stillbirth Impact calculation

## Background

In addition to estimates of child and maternal mortality, LiST includes estimates of intervention impact on stillbirths. Stillbirths are defined as late-gestation fetal loss, typically encompassing births with no sign of life that occur at or after 28 weeks gestation. There is little comprehensive data on stillbirths in most low- and middle-income countries due to 1) births occurring outside of the health system, 2) incomplete HMIS and vital registration systems, and 3) difficulty classifying stillbirths (1). As a result, modeling plays a vital role in estimating not only changes in stillbirth related to intervention coverage but also baseline stillbirth rates. LiST populates baseline estimates of country-specific stillbirth rates using data from UN-IGME, which are updated every few years (1).

## Interventions impacting on stillbirth

The last significant set of revisions to the stillbirth interventions included in LiST occurred in 2017 (2). In this revision, we have included one additional intervention – folic acid fortification – as data on the prevalence of stillbirths related to neural tube defects have become available. Multiple micronutrient supplementation has been removed from the stillbirth model due to a new Cochrane review that showed no significant effect of MMN supplementation in preventing stillbirths (3).

| **Intervention** | **Up to Version 5.88** | **Revised 2020** |
|---|---|---|
| Periconceptional | | |
| Folic acid fortification | | X |
| Pregnancy | | |
| Balanced energy protein supplementation | X | X |
| Multiple micronutrient supplementation | X | |
| Prevention of malaria in pregnancy (IPTp / ITNs) | X | X |
| Syphilis detection and treatment | X | X |
| Diabetes case management | X | X |
| Hypertension case management | X | X |
| Childbirth | | |
| Induction of labor for pregnancies +41 weeks | X | X |
| Assisted vaginal delivery (proxy for BEmOC care) | ~ | X |
| C-section (proxy for CEmOC care) | ~ | X |

### Antepartum / Intrapartum Split

In the absence of information on cause of stillbirth, LiST incorporates the proportion of stillbirths that occur in the antepartum and intrapartum period. Some interventions, specifically those delivered during childbirth, only impact intrapartum stillbirths. However, due to the inclusion of all stillbirths in most intervention efficacy studies, these interventions are modeled to impact equally on both antepartum and intrapartum stillbirths. Estimates of the proportion of stillbirths occurring in the intrapartum period are periodically updated and provided by UN-IGME. These estimates are calculated by SDG region and underlying stillbirth rate. The most recent unpublished country estimates were provided in conjunction with "A Neglected Tragedy: The global burden of stillbirths. Report of the UN Inter-agency Group for Child Mortality Estimation. 2020" where the estimates of SDG regional average intrapartum stillbirths were presented.

## Updates to efficacy and affected fraction

### Interventions during the Periconceptional Period

#### Folic Acid Fortification

Neural tube defects, including anencephaly, spina bifida, or encephalocele, can result in early pregnancy loss, miscarriage, stillbirth, neonatal death, or life-time disability. Folic acid (FA) fortification can prevent stillbirths due to neural tube defects (NTDs). Fortification of staple foods, such as maize or wheat flour and rice, can ensure women of reproductive age receive the 400 micrograms of folic acid (vitamin B9) needed to prevent NTDs. Folic acid supplementation after confirmation of pregnancy occurs too late to prevent NTDs (4). Estimates of the prevalence of NTD-related stillbirths have recently become available, and FA fortification has been reintroduced to the model.

Efficacy: Imdad and colleagues estimate FA fortification in the periconceptional period can reduce the incidence of NTDs by 41% [Relative risk 0.59; 95% CI 0.52-0.68] (5). This estimate was based on the pooled results from 11 fortification studies. We apply the overall impact of fortification on NTDs as a proxy for the reduction in stillbirths. Imdad and colleagues calculated the efficacy of fortification on the overall incidence of NTDs. We, therefore, apply the impact to both antepartum and intrapartum births.

AF: We calculated the proportion of stillbirths that could be impacted by folic acid fortification based on the prevalence of NTD-affected stillbirths. Blencowe and colleagues conducted a systematic analysis to estimate the regional prevalence of neural tube defects among live births, stillbirths, and electively terminated pregnancies (6). We divided the regional average prevalence of NTD-affected stillbirths (per 10,000 livebirths) by the regional average prevalence of all stillbirths (per 10,000 livebirths) to calculate the proportion of stillbirths affected by NTDs at a regional level. We apply this value as the folic acid fortification stillbirth affected fraction.

Default coverage: We calculate the coverage of folic acid fortification using data from the Food Fortification Initiative (7). Using each county's fortification standard and estimated daily fortified food intake (adjusting for the proportion of grain industrially fortified), we calculated the proportion of women receiving at least 400 mcg of FA a day from fortification.

## Interventions during Pregnancy

### Balanced Energy and Protein Supplementation

Women undernourished at conception and during pregnancy have an increased risk of adverse perinatal outcomes. Balanced protein energy (BEP) supplementation (i.e. supplements in which protein provides less than 25% of the total energy content) can reduce this risk.

Efficacy: A Cochrane review by Ota and colleagues estimates BEP supplementation can reduce the risk of stillbirth by 40% (RR 0.60, 95% CI 0.39 to 0.94) (8). This estimate was based on evidence from five trials. The trials enrolled pregnant women, regardless of their underlying nutritional status. However, the study populations were considered chronically undernourished.

AF: We use the country-specific proportion of women of reproductive age with low BMI (<18.5) as a proxy for the proportion of stillbirths potentially affected by BEP supplementation (9).

Default coverage: No default data on BEP supplementation coverage are available.

### Syphilis Testing and Treatment

Congenital syphilis, resulting from the transmission of syphilis from mother to fetus during pregnancy, is a preventable cause of stillbirth. Syphilis transmission to the fetus can occur early in pregnancy and is most common in women with an active case (an infection occurring in the past 5 years that is not adequately treated). Early detection and treatment with parenteral penicillin can prevent transmission to the fetus or clear a fetal infection.

Efficacy: In a meta-analysis, Blencowe and colleagues estimated detection and treatment of syphilis in pregnancy reduced the risk of stillbirth by 85% (RR 0.15: 95% CI 0.10 – 0.21) compared to infected and untreated pregnancies (10). Efficacy was calculated for stillbirths occurring in both the antepartum and intrapartum periods. We subsequently apply the impact to both antepartum and intrapartum stillbirths.

AF: We calculated the proportion of stillbirths attributable to syphilis infection based on the prevalence of active syphilis and relative risk of stillbirth with infection. We adjusted 2016 WHO regional estimates of syphilis in women of reproductive age (derived mainly from estimates of prevalence in pregnancy) (11) by the proportion of syphilis cases that are likely active (65%) (12). The relative risk of stillbirth in pregnancies with versus without untreated congenital syphilis was assumed to be 10.89 (13).

We then calculated the proportion of stillbirths who could benefit from the intervention using a two-step process previously established to estimate stillbirth affected fractions in LiST (2):

1) We calculated the stillbirth rate in the absence of the risk factor (the counterfactual – baseline stillbirth rate if congenital syphilis did not exist):

$$Baseline\ SBR = \frac{observed\ SBR}{(Prevalence * risk) + (1 - Prevalence)}$$

2) We calculated the proportion of stillbirths attributable to the underlying cause or risk factor:

$$Attributable\ fraction\ of\ stillbirths = \frac{Observed\ SBR - Baseline\ SBR}{Observed\ SBR}$$

Example using data from Nigeria:

$$Baseline\ SBR = \frac{22.24\ SB\ per\ 10000\ LB}{((0.016 * 0.65) * 10.89) + (1 - 0.016)} = 20.17$$

$$Attributable\ fraction\ of\ stillbirths = \frac{22.24 - 20.17}{22.24} = 0.093$$

Default coverage: We derive default coverage of syphilis testing and treatment from country-specific ANC coverage rates adjusting for facility readiness to provide the intervention.

## Prevention of Malaria in Pregnancy

Malaria infection during pregnancy can result in fetal growth restriction, preterm delivery, and fetal loss. A fetus can be impacted by a peripheral infection in the mother, resulting in anemia and inflammatory response, and placental sequestration of parasites. While treatment of malaria infections in pregnancy reduces the risk of adverse outcomes, prevention of infection has the greatest potential to avert stillbirths and other adverse perinatal effects.

Efficacy: A pooled analysis by Ishaque and colleagues found that ITN use during pregnancy was associated with a 33% reduction in fetal loss due to malaria (RR 0.67, 95% CI 0.47 to 0.97) (14). This meta-analysis found no effect of intermittent preventive treatment in pregnancy (IPTp) on stillbirth and no synergistic effect in using both IPTp and ITNs. We apply the efficacy of ITN use as a proxy for all malaria prevention interventions, including sleeping under a net and use of IPTp.

AF: To estimate the proportion of pregnancies exposed to malaria, we used the Malaria Atlas Project's country-specific estimates of clinical malaria incidence in 2015 (15). These estimates are weighted by population to represent the incidence across the entire country, regardless of malaria endemicity. We assume malaria incidence is similar in pregnant women in the absence of interventions to prevent malaria in pregnancy. These estimates align with the subregional estimates of the prevalence of malaria exposure in pregnancy presented in the 2019 World Malaria Report (16).

A systematic review by Moore and colleagues found an increased risk of stillbirth associated with malaria infection in pregnancy (17). Associations with both *P. falciparum* and *P. vivax* infection were examined. However, there were too few studies to establish a significant association between *P. vivax* infection and stillbirth. The risk associated with *P. falciparum* varied by the duration and severity of infection, including infection diagnosed and treated

during pregnancy (OR: 1.47), peripheral malaria infection at birth (OR: 1.81), and placental malaria at birth (OR: 1.95). Additionally, the odds of stillbirth were greater in areas of low-to-intermediate endemicity than in areas of high endemicity (Table 1). In the absence of robust data on the prevalence of each severity of malaria infection, we applied the OR associated with peripheral malaria infection to our estimate of the prevalence of malaria in pregnancy. We applied the OR associated with low-to-intermediate malaria endemicity to countries with a malaria prevalence of less than 10% in endemic areas. These estimates were calculated for all pregnancies and did not differentiate for the higher risk associated with primigravidae.

We then calculated the proportion of stillbirths affected by malaria using the same two-step process detailed in calculating the AF for syphilis. For each country, we calculated the SBR in the absence of malaria (accounting for malaria incidence and associated risk), and then applied this value to assess the proportion of stillbirths attributable to malaria infection.

**Table 1. Association between severity of malaria in pregnancy and stillbirth**

| Association by malaria parasite | P. falciparum | P. vivax |
|---|---|---|
| | OR (95% CI) | OR (95% CI) |
| In pregnancy* | 1·47 (1·13–1·92) | 1·09 (0·76–1·57) |
| Peripheral at delivery | 1·81 (1·42–2·30) | 2·81 (0·77–10·22) |
| Placental at delivery | 1·95 (1·48–2·57) | |

| Association by endemicity | Low to intermediate endemicity | High endemicity |
|---|---|---|
| | OR (95% CI) | OR (95% CI) |
| In pregnancy* | 1.88 (1.35, 2.62) | 1.16 (0.83, 1.62) |
| Peripheral at delivery | 2.59 (1.92, 3.50) | 1.32 (1.04, 1.68) |
| Placental at delivery | 3.11 (1.83, 5.30) | 1.49 (1.12, 1.98) |

*detected and treated

Default coverage: Country-specific 2-dose coverage of IPTp and/or ITN use by pregnant women is calculated from household survey data based on maternal report.

## Management of Diabetes in Pregnancy

Uncontrolled or poorly controlled diabetes in pregnancy can result in macrosomia (babies large for gestational age) and birth complications resulting in stillbirth. Both pre-existing (diagnosed or undiagnosed) diabetes and gestational diabetes can impact fetal outcomes. Diagnosis and careful management, resulting in stable blood sugar levels, can prevent these adverse outcomes. Appropriate management includes early diagnosis of diabetes, appropriate counseling, and routine monitoring.

Efficacy: A review by Syed and colleagues found an insignificant impact of diabetes management on stillbirth. In lieu of sufficient published data to establish intervention efficacy, a Delphi process of health area experts established a median effect size of 10% reduction in diabetes-

related stillbirths in both the antepartum and intrapartum period with optimal diabetes recognition and management (18).

AF: We derived estimates of the prevalence of diabetes in pregnancy from the 2019 International Diabetes Federation (IDF) Diabetes Atlas (19). The prevalence of diabetes was estimated based on data from 41 countries and presented by IDF region. Globally, they estimate most cases of diabetes in pregnancy are gestational diabetes (83.6%), followed by pre-existing but newly detected cases of type I or type II diabetes (8.5%), and pre-existing, diagnosed diabetes (7.9%). Greater risk of stillbirth is associated with uncontrolled pre-existing diabetes compared to gestational diabetes. However, data on the relative risk of uncontrolled pre-existing diabetes was unavailable. We based our estimate of the relative risk of undiagnosed or uncontrolled diabetes on a case-control study in the UK. The study found women with elevated fasting plasma glucose, indicative of gestational diabetes, who were not screened and diagnosed with diabetes, had 4.22 fold greater odds of stillbirth than women with normal plasma glucose levels (20). We then calculated the proportion of stillbirths affected by diabetes using the same two-step process detailed in calculating the AF for syphilis.

We derive default coverage of diabetes testing and treatment from country-specific ANC coverage rates adjusting for facility readiness to provide the intervention.

## Management of Hypertension in Pregnancy

Hypertension in pregnancy can result in intrauterine growth restriction, preterm birth, and fetal loss. Pre-existing chronic hypertension, pregnancy-induced hypertension, pre-eclampsia (hypertension with proteinuria), and eclampsia can all result in stillbirth. Diagnosis and appropriate management of hypertension can avert these adverse outcomes.

Efficacy: We derived our estimate of the effectiveness of hypertension management from a review by Jabeen and colleagues. This review found inconclusive evidence related to the use of aspirin, maganesium sulphate, antihypertensives, and calcium supplementation on stillbirth. A Delphi review estimated a package of interventions for managing hypertension (antihypertensives, magnesium sulphate, and C-section if needed) could avert 20% of hypertension-related stillbirths in both the antepartum and intrapartum period.

AF: We derived our estimates of intervention prevalence from Abalos and colleagues' re-analysis of the WHO Multicountry Survey on Maternal and Newborn Health (21). This analysis presented the prevalence of chronic hypertension in pregnancy, pre-eclampsia, and eclampsia by WHO region (Table 2). The paper also estimated the odds of fetal death associated with pre-eclampsia (AOR: 3.12; 95% CI 2.77–3.51) and eclampsia (AOR: 3.92; 95% CI 3.16–4.87). Chronic hypertension increases the risk of a woman developing pre-eclampsia. We estimated the odds of stillbirth associated with hypertension, independent of pre-eclampsia, was 2.04 ( 95% CI 1.48–2.82) (22). We then calculated the proportion of stillbirths affected by hypertension using the same two-step process to calculate the AF for syphilis.

**Table 2. Prevalence hypertensive conditions by WHO region**

| Prevalence by Region (%) | AFRO | EMRO | EURO | AMRO | SEARO | WPRO |
|---|---|---|---|---|---|---|
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Hypertension | 0.21 | 0.26 | 0.43 | 0.45 | 0.22 | 0.32 |
| Pre-eclampsia | 1.56 | 1.39 | 2.99 | 3.88 | 1.51 | 2.43 |
| Eclampsia | 0.55 | 0.18 | 0.23 | 0.21 | 0.26 | 0.14 |

Default coverage: We derive default coverage of hypertension management from country-specific ANC coverage rates adjusting for facility readiness to provide the intervention.

## Interventions during Childbirth

### Induction of Pregnancies Post-term

Pregnancies that last beyond 41 weeks gestation are at greater risk of stillbirth due to placental failure. Induction of labor can effectively avert these stillbirths. However, accurate data on gestational age is required to implement the intervention safely.

Efficacy: A Cochrane review by Middleton and colleagues found a 70% (RR 0.30, 95% CI 0.12 - 0.75) reduction in stillbirth associated with induction after 41 completed weeks of gestation versus expectant management based on data from 22 trials (23). This efficacy value was calculated for both antepartum and intrapartum stillbirths.

AF: Globally, we estimate that 7.5% of all pregnancies will go past term in the absence of intervention (24). The increased risk of stillbirth associated with the delivery after 41 weeks of gestation is 1.94 (95% CI 1.72-2.19) (25). We then calculated the proportion of stillbirths affected by advancing post-term using the same two-step process to calculate the AF for syphilis.

Default coverage: We derive default coverage of post-term pregnancy induction using country-specific facility delivery rates adjusted for facility readiness to deliver the intervention.

### Assisted Vaginal Delivery and C-Section

Since the previous publication on the LiST stillbirth model, the tool has shifted away from estimating childbirth care as a proportion of women delivering at BEmOC- and CEmOC-ready facilities. The revised model now includes estimates of coverage of individual childbirth interventions, based on the proportion of women delivering at a facility and utilization-weighted facility readiness to provide the intervention. As a result, the impact of BEmOC delivery and CEmOC delivery are now captured under assisted vaginal delivery and C-section coverage, respectively. Both assisted vaginal delivery (AVD) and C-section are types of operative delivery that can reduce stillbirths in the intrapartum period resulting from obstructed or prolonged labor. Both interventions can expedite delivery and reduce the risk of fetal asphyxia, infection, and birth trauma.

Assisted vaginal delivery includes delivery with the assistance of forceps or vacuum suction. AVD is a component of BEmOC, and the only BEmOC intervention directly associated with the

prevention of stillbirth. Despite being a component of BEmOC, the use of AVD is low due to lack of training and practice, fears over injuring the newborn, and the availability of necessary equipment (26). Where available, clinicians often precede directly to C-section rather than attempting AVD. However, compared to C-section, vacuum extraction is associated with a lower risk of infection and hemorrhage, shorter time to birth resulting in lower rates of asphyxia and intrapartum stillbirths, and fewer complications post-delivery and in subsequent pregnancies (26). Where AVD fails, attempted AVD decreases the time to C-section and improves C-section outcomes (26).

Efficacy: BEmOC includes the use of IV/IM antibiotics, oxytocin, and anticonvulsants, manual removal of retained placenta and retained products of conception, AVD, and basic newborn resuscitation. CEmOC extends the content of BEmOC to include c-section and blood transfusion. A review by Yakoob and colleagues found insufficient data related to the impact of the provision of BEmOC and CEmOC on stillbirth (27). A Delphi was used to establish that provision of BEmOC could avert 45% of intrapartum stillbirths. As AVD is the only component of BEmOC directly tied to averting stillbirths, AVD assumed the full efficacy of provision of BEmOC. The Delphi process implemented by Yakoob further established that the provision of CEmOC could avert 75% of intrapartum stillbirths. C-section assumed the additional efficacy of CEmOC, beyond the impact of BEmOC. To prevent double-counting the impact of BEmOC when scaling-up both interventions, we calculated the disaggregated effectiveness of C-section was 55%.

AF: We assume both AVD and c-section can impact all intrapartum stillbirths in a country. The source of data used to define this split is presented in the section “Antepartum / Intrapartum Split”.

Default coverage: We derive default coverage of AVD using country-specific facility delivery rates adjusted for facility readiness to deliver the intervention. We estimated C-section coverage using household survey data on C-section births. An estimated 10-15% of births are expected to occur via medically-necessary C-sections. In some countries, and particularly in higher-income groups, non-medically necessary elective C-sections may be common. To estimate the proportion of women in need of a C-section who accessed care, we attempted to adjust for the contribution of elective C-sections in the overall C-section delivery rate. Using maternal report of C-section birth from household surveys, we estimated the proportion of women within each wealth quintile accessing C-section, assuming 12.5% of births required C-section. We capped coverage within a wealth quintile at 100%. We then weighted the quintile-specific coverage by the proportion of births within the wealth quintile, based on either CBR or TFR, to estimate the coverage among all births at a national level.

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