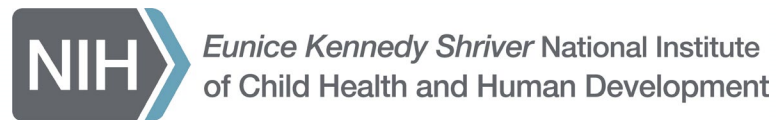


Stillbirth Working Group of Council: Summary of Findings and Recommendations

June 3, 2024





Background



FY 2022 House Report Language



Stillbirth Task Force.—Stillbirth affects one in 160 pregnancies, with 24,000 babies stillborn each year. Despite medical advances, the rate of early stillbirth has remained the same over the past 30 years. The Committee provides \$1,000,000 for the Secretary to develop a task force on stillbirth in the United States. The task force should include the CDC, NIH, outside specialty organizations, and maternal and fetal medicine specialists. The task force should focus on:

- current barriers to collecting data on stillbirths throughout the United States;
- communities at higher risk of stillbirth;
- the psychological impact and treatment for mothers following stillbirth; and
- known risk factors for stillbirth.

The task force should provide a report on these issues within one year of enactment of this Act.

Working to Address the Tragedy of Stillbirth

This process yielded the Report to Congress titled, *Working to Address the Tragedy of Stillbirth*.

The report focused on:

- Addressing current barriers to collecting data on stillbirths throughout the United States;
- Communities at higher risk of stillbirth;
- The psychological impact and treatment for mothers following stillbirth; and
- Known risk factors for stillbirth.



Current Barriers to Collecting Data on Stillbirth in the U.S.

Recommendations from the Working Group

- A. The HHS, led by CDC, should develop and implement revised procedures to address the barriers to collecting representative, comprehensive, reliable, and sufficiently detailed vital records on stillbirth to support the needs of families, public health officials, and researchers. Changes should include:
- procedures to improve the consistency and quality of data collection;
 - standardization of case definitions;
 - training for individuals involved in data collection for fetal death certificates;
 - improved processes for updating vital records once additional information is available, including a clear, uniform process for submission of autopsy data and other test results; and
 - outreach to states and localities to raise awareness of and build public health capacity to collect accurate, timely, and complete stillbirth data.



Current Barriers to Collecting Data on Stillbirth in the U.S.

Recommendations from the Working Group

- B. The CDC should expand current surveillance and data collection efforts involving risk factors for stillbirth specifically and adverse pregnancy outcomes generally. These activities may include, for example:
- conducting population-based stillbirth surveillance in a diverse range of jurisdictions;
 - exploring opportunities to leverage current data collection systems (e.g., expanding PRAMS to conduct population-based surveillance among women with a recent stillbirth to identify risk factors);
 - conducting or supporting validation studies of current data sources;
 - developing new methods to leverage other surveillance data for stillbirth research; and/or
 - linking or enriching existing data.
- C. The HHS and professional societies should work together to improve and expand training in perinatal pathology, genetics, and other areas to advance the practice of fetal autopsy.



Communities at Higher Risk for Stillbirth

Recommendations from the Working Group

- A. The CDC, the NIH, and other HHS divisions should support surveillance and research to investigate health disparities in stillbirth, in conjunction with other adverse pregnancy outcomes. Such research should address racial, ethnic, socioeconomic, geographic, and other disparities.
- B. The NIH should review its data on inclusion of minorities in its pregnancy and stillbirth studies to ensure appropriate representation.
- C. The NIH should expand community-based research in maternal health and adverse pregnancy outcomes and ensure that stillbirth is emphasized as a focus for community-based research. These efforts should focus on the patient experience in at-risk populations.
- D. Efforts to address the barriers to improving data on stillbirth in the U.S. should include geographic areas with strong representation of individuals with diverse racial and ethnic backgrounds and other groups that experience disparities.



Psychological Impact of Stillbirth

Recommendations from the Working Group

- A. The NIH and the CDC should support or conduct systematic research to collect data from individuals with lived experience in the psychological impact of stillbirth. Implementation research should be designed to inform efforts on how to develop culturally-sensitive programs to support families after stillbirth. Results from this research should be shared with the clinical, research and advocacy communities.
- B. Professional societies should consult individuals with lived experience in the psychological impact of stillbirth, as well as providers who care for those patients, to improve provider training and incorporate supportive practices into the care for affected families.



Known Risk Factors

Recommendations from the Working Group

- A. The NIH should convene a group of basic, translational, clinical, and public health research experts, as well as parents who have experienced stillbirth, to develop a research agenda to advance prevention for stillbirth and other adverse pregnancy outcomes. The research agenda should include efforts to identify implications for stillbirth prevention from NIH's Human Placenta Project and related research.

- B. The NIH should conduct or support research to establish baseline normative data on physiology in pregnancy, including potential indicators of health and disease. Such indicators may include, but should not be limited to, placental development and function, fetal movement, fetal growth, and others.



Known Risk Factors

Recommendations from the Working Group

- C. The NIH and the CDC should support additional research on causes and risk factors, as well as prevention of stillbirth more broadly. Specifically, these efforts should:
- focus on un- and under-investigated areas to discover new risk factors and interactions, to help understand the racial disparity in stillbirth, and to assess the preventability of stillbirth;
 - investigate the feasibility and potential usefulness of developing a stillbirth registry;
 - delineate the mechanisms of how specific risk factors affect stillbirth and explain the racial disparity; and
 - develop and test indicators and clinical interventions for the prevention of stillbirth.



Summary of Recommendations

- I. Improve the quality of vital statistics, surveillance, and epidemiologic data on stillbirth at the local, state, and national levels.
- II. Use insights from improved epidemiologic data and conduct additional research to explain and ultimately address disparities in stillbirth and identify prevention opportunities.
- III. Conduct implementation research and develop culturally sensitive interventions to support families who have experienced stillbirth.
- IV. Create and support a full research agenda, including research on known and unknown risk factors and physiologic mechanisms, to support the development of interventions to prevent stillbirth.



FY 2023 House Report Language



Stillbirth Task Force.—The Committee provides an additional \$1,000,000 for the Secretary to bolster the work for the Stillbirth Task Force. The task force should continue to include the CDC, NIH, outside specialty organizations, and maternal and fetal medicine specialists. The task force should work through the Office of the Secretary to identify:

- current knowledge on stillbirth and prevention;
- areas of improvement for data collection;
- current resources for families impacted by stillbirth; and
- next steps to gather data and lower the rate of stillbirth in the United States.

Report Language from Consolidated Appropriations Act of 2023 (P.L. 117-328).

Stillbirth Working Group of Council Members

Co-Chairs

- Lucky Jain, M.D., M.B.A.
- Uma M. Reddy, M.D., M.P.H.

Members

- RADM Wanda D. Barfield, M.D., M.P.H.
- Joanne Cacciatore, Ph.D., M.S.W
- CAPT Amanda Cohn, M.D.,
- Ada Dieke, Dr.P.H., M.P.H.,
- Donald Dudley, M.D.,
- Andrew Fullerton, M.P.P.,
- Karen Gibbins, M.D., MSCI,
- Katherine Gold, M.D., M.S.W., M.S.
- Cynthia Gyamfi-Bannerman, M.D., M.S.
- Isabelle Horon, Dr.P.H.
- Denise Jamieson, M.D., M.P.H.
- Stephanie Leonard, Ph.D., M.S.
- Jenna Nobles, Ph.D.

- Tina Pattara-Lau, M.D.
- Jennita Reefhuis, Ph.D.
- George Saade, M.D.,
- Mikyong Shin, Dr.P.H., M.P.H., RN
- Robert M. Silver, M.D.
- Catherine J. Vladutiu, Ph.D., M.P.H.
- Maeve Wallace, Ph.D., M.P.H.
- Ronald J. Wapner, M.D.
- Jill Wieber Lens, J.D.,
- Monica H. Wojcik, M.D., M.P.H.
- Debbie Haine Vijayvergiya
- Monica Longo MD, Ph.D.

Ad Hoc Consultants

- Alison Cahill, M.D., MSCI
- Carol J. Hogue, Ph.D., M.P.H.
- Mana Parast, M.D., Ph.D.

Sub-Work Groups

I. Improving Data Collection

- Subgroup I – Improving Data Collection – Co-leads Dr. George Saade and Dr. Mikyong Shin

II. Stillbirth Prevention and Strategies

- Subgroup II - Stillbirth Prevention and Strategies – Co-leads Dr. Robert Silver and Dr. Alison Cahill

III. Enhancing Resources for Families Impacted by Stillbirth

- Subgroup III – Enhancing Resources for Families Impacted by Stillbirth – Co-leads Professor Jill Wieber Lens and Dr. Karen Gibbins



General Working Group Recommendations

1. Standardize data reporting and collection to promote accurate and consistent surveillance.
2. Support population-based surveillance such as expanding the CDC Pregnancy Risk Assessment Monitoring System (PRAMS) Stillbirth Project (Study of Associated Risks of Stillbirths (SOARS) survey) to capture diverse voices of those experiencing stillbirth in jurisdictions with high stillbirth burden.
3. Explore artificial intelligence (AI) and machine learning (ML) as ways to improve risk prediction and stratification based on existing data, ensuring that sensitive health care information is safeguarded.
4. Create tools to educate patients and health care professionals on risk factors for stillbirth.



General Working Group Recommendations

5. Create standardized training, appropriate infrastructure, and resources so that complete stillbirth workup (e.g. completion of autopsy, placental pathology, and genetic studies) can become more widespread and standards of care more uniform.
6. Create infrastructure for perinatal audits to enable analysis and discussion of stillbirth and further identification of risks factors and possible prevention strategies.
7. Support research on how structural, institutional, and interpersonal racism contributes to inequalities in stillbirth rates, the offering and completion of stillbirth workup, differential access to health care opportunities, quality of care after stillbirth, and bereavement care.





Findings and Recommendations: Stillbirth Prevention and Strategies

Stillbirth Prevention and Strategies

Summary of the Working Group Findings

- Lack of routine perinatal autopsy and placental examination leads to incomplete pathology/histology information that could improve understanding of causes of stillbirth and potential avenues of prevention.
- Genetic testing is often not done because of the cost and logistical challenges.
- Perinatal audit, the process of capturing information on the causes of stillbirth and analyzing the quality of care received, in a no-blame, interdisciplinary setting to guide action to prevent similar deaths in the future, is not routinely performed.



Stillbirth Prevention and Strategies

Recommendations from the Working Group

- Consider conducting research on timing of delivery to develop personalized recommendations on the optimal time.
 - Induction of delivery may be offered at 39 weeks per ARRIVE trial results.*
- Address health disparities and the social determinants of health (SDOH).
- Support population-based stillbirth surveillance, especially in jurisdictions with high stillbirth rates.
- Provide access to high quality prenatal care and postpartum care.

*Clinical Guidance for Integration of the Findings of The ARRIVE Trial: Labor Induction Versus Expectant Management in Low-Risk Nulliparous Women:
<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2018/08/clinical-guidance-for-integration-of-the-findings-of-the-arrive-trial>



Stillbirth Prevention and Strategies

Recommendations from the Working Group

- Additional research is needed to develop stillbirth prevention bundles that focus on patient and provider education including public health measures such as advice to cease tobacco use, helping people achieve healthier body mass index, optimize chronic medical conditions such as diabetes, hypertension and others, and induction of labor.
- Link maternal and fetal medical records.
- Consider creating a stillbirth registry and collecting stillbirth biospecimens.
- Consider universal use of low-dose aspirin according to the United States Preventive Services Task Force (USPSTF) guidelines*

*The United States Preventive Services Task Force: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/low-dose-aspirin-use-for-the-prevention-of-morbidity-and-mortality-from-preeclampsia-preventive-medication>





Findings and Recommendations: Improving Data Collection

Improving Data Collection

Summary of the Working Group Findings

- Surveillance and medical definitions (including gestational age and birthweight criteria that currently vary by state) for stillbirth, pregnancy loss, and miscarriage are not currently standardized, therefore, data collection is inconsistent.
- Clinical data collected from multiple sources (e.g., electronic health records, monitoring data, imaging studies, genetic testing, pregnancy experience, patient history), are not integrated and linked across data sets so that all information is accessible for research and stillbirth prevention.
- There is a lack of uniform training of individuals completing fetal death certificates which hinders more accurate record keeping.
- Currently, fetal death certificates are required to be filed within days of the fetal death, before results of the full workup are available. These workups may better identify cause(s) of death. Full workup death results are often not incorporated in the fetal death certificate as formal legal amendment is needed. Thus, information from the delivery and from subsequent testing may be delayed and not be integrated into the fetal death certificate, including final cause of death.



Improving Data Collection

Recommendations from the Working Group

- Collect, transform, integrate, and maintain electronic health records and other pertinent data sets in a format appropriate for future use in AI and machine learning to create a maternal child health data ecosystem serving as a major resource for research on stillbirth as well as other adverse pregnancy outcomes.
- Bridge the gap between data available at delivery and data available at workup completion. Specifically, focus data standardization and quality improvement on reporting, follow-up, and workup of stillbirths.
- Design a case-control study by leveraging AI to collect data for prevention measures, maternal experience evaluation, and ascertainment surveillance.
- Enhance regional stillbirth evaluation through telehealth, the creation of Stillbirth Centers of Excellence, and through Fetal and Infant Mortality Review.
- Improve and develop quality indicators for evaluation, counseling, bereavement services, and follow-up.
- Conduct regular audits to improve the quality of data collection.



Improving Data Collection

Recommendations from the Working Group

The recommendations on education were the following:

- State field representatives should provide ongoing, in-person training to collect fetal death data.
- Providers should be encouraged to use guidance documents and e-learning tools developed by NCHS.
- Hospital personnel should be educated on using a flowchart developed by NCHS to understand a fetal death certificate.
- Personnel should receive training to improve overall fetal death data accuracy and completeness, and to ensure the filing of amendments (e.g., for autopsy results) as needed.





**Findings and Recommendations:
Enhancing Resources for Families Impacted by
Stillbirth**

Enhancing Resources for Families Impacted by Stillbirth

Summary of the Working Group Findings

- There is not always appropriate care at the time of bereavement, which is vital to meet the needs of families.
- Often, health care professionals lack standard training in, among other things, cultural sensitivity in how to speak with bereaved parents and families with empathy.
- There are insufficient local and national resources to support families that have experienced stillbirth, especially in smaller hospitals with limited resources.
- Health care professionals are inadequately trained regarding stillbirth.



Enhancing Resources for Families Impacted by Stillbirth

Recommendations from the Working Group

At the time of diagnosis, caregivers should do the following:

- Display empathy (i.e., understand and respect parental choices regarding the stillborn baby).
- Refer to the stillborn infant as a baby and use the name if one has been given.
- Provide families a road map with information about their delivery hospitalization, including items they may need or want in the hospital; what to expect around the delivery; what the baby might look like at birth; options for pain management; information on a cuddle cot, if one is available; options for parenting activities (like reading the baby a book, bathing them, dressing them); and options for mementos and photography.
- Have a bereavement health care professional (e.g., doula, social worker) available to support families during their hospital stay.



Enhancing Resources for Families Impacted by Stillbirth

Recommendations from the Working Group

After delivery, the following steps are recommended to those providing care to the birthing parent:

- Put the patient in a recovery area away from other pregnant people and the sounds of live born infants.
- Place a marker on the door so that health care providers will know that the death of an infant has occurred.
- Conduct a religious ceremony if it is desired.
- Support the parents' decision to hold or not hold the baby.
- Support the parents' decision to engage in parenting activities if they so choose.
- Create photos, videos, or other mementos of the stillborn child.



Enhancing Resources for Families Impacted by Stillbirth

Recommendations from the Working Group

For postpartum workup, the following recommendations were made:

- Create resources to help parents better understand how the information collected from tests and exams can help to determine the cause of their infant's death.
- Identify any immediate health concerns for the birthing parent, guide management for subsequent pregnancies.
- Set expectations for how results for these tests will be communicated to the family.
- Be explicit that testing may not determine cause(s) of death but emphasize that testing is the best that can be done to determine cause(s).
- Emphasize that the baby will be treated with care and respect.



Enhancing Resources for Families Impacted by Stillbirth

Recommendations from the Working Group

For postpartum care, the following recommendations were made:

- Address the physical needs of the person giving birth.
- Provide information on recovery from childbirth, especially for first-time parents. This could include resources (and staff) that address milk production, physical recovery from childbirth, and postpartum depression.
- Risk of depression is high in parents who have experienced stillbirth. Provide close postpartum follow up and mental health support for grief, trauma, and depression.
- Provide national and local resources for support.
- Create standards of care for other professionals, such as social workers and chaplains, who might regularly interact with families experiencing stillbirth.
- States should consider the availability of stillbirth tax credits.





Overall Recommendation Themes

Overall Recommendation Themes

- Standardize data collection and reporting, exploring new technologies such as Artificial Intelligence and Machine Learning.
- Create a stillbirth prevention bundle.
- Create standardized training so that a complete stillbirth workup including autopsies, genetic, and blood tests are performed.
- Conduct perinatal audits after stillbirths so that specific protocols can be developed following fetal deaths.
- Research ways to reduce the health disparities in stillbirth.
- Establish continuing health care provider education related to stillbirth.
- Research the most effective mental health support after stillbirth.
- Make the costs of stillbirth workup more affordable, including access to autopsy and genetic testing, and placental pathology (optimal when done by perinatal pathologist).



