

Stillbirth Working Group of Council: Findings and Recommendations

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Presentation Outline

- Introduction
- Findings and Recommendations in 4 focus areas
 - Data collection
 - Communities at higher risk
 - Psychological impact of Stillbirth
 - Known risk factors – moving towards stillbirth prevention
- Next Steps and Discussion





Introduction

Introduction

- Stillbirth is a tragedy and a major public health concern in the U.S. Between 2016 and 2020, stillbirth affected between 20,000 and 24,000 families each year.*
- NICHD formed the Stillbirth Working Group of Council in 2022 in response to an HHS request to lead a task force to examine stillbirth in the U.S.
- Creation of this task force was described in the Fiscal Year 2022 (FY22) House appropriations report language.
- The working group was funded in the Consolidated Appropriations Act of 2022, which was enacted on March 15, 2022.

* CDC Vital Statistics Fetal Death data, <https://wonder.cdc.gov/fetal.html>, accessed January 17, 2023.



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.

Stillbirth Working Group of Council: Members

- Lucky Jain, M.D. (co-chair)
- Uma M. Reddy, M.D., M.P.H. (co-chair)
- RADM Wanda Barfield, M.D., M.P.H.
- CAPT Amanda Cohn, M.D.
- Deborah Conway, M.D.
- Carla DeSisto, Ph.D., M.P.H.
- Ada Dieke, Dr.P.H., M.P.H.
- Donald Dudley, M.D.
- Andrew Fullerton, M.P.P.
- Isabelle Horon, Dr.P.H.
- Denise Jamieson, M.D., M.P.H.
- Stephanie Leonard, Ph.D.
- Jenna Nobles, Ph.D.
- Tina Pattara-Lau, M.D.
- Sonja Rasmussen, M.D., M.S.
- Jennita Reefhuis, Ph.D.
- Robert Silver, M.D.
- Catherine Vladutiu, Ph.D., M.P.H.
- Maeve Wallace, Ph.D., M.P.H.
- Monica H. Wojcik, M.D.



Stillbirth Working Group of Council: Meetings

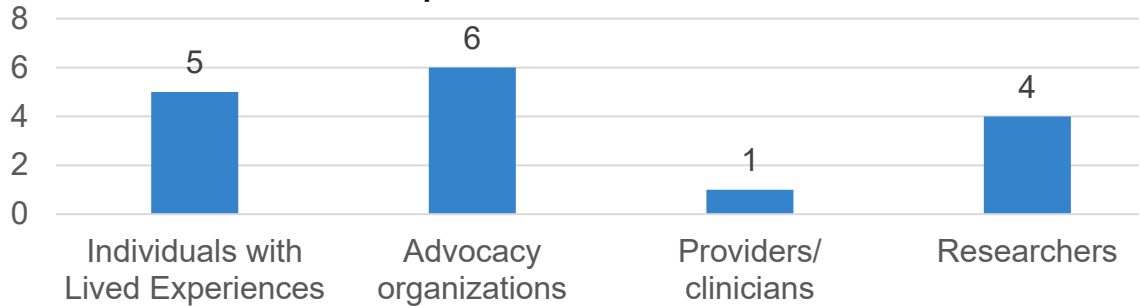
4 Working Group Meetings:

- October 20, 2022: NIH research; data collection procedures
- November 22, 2022: Barriers to data collection; communities at higher risk; environmental risk factors
- December 9, 2022: Role of federal agencies; psychological impact; known risk factors
- January 5, 2023: Impact of stillbirth on families and communities (presentations from members of the public)



Stillbirth Working Group of Council: Request for Information (RFI)

- Published November 10, 2022
- Responses due January 6, 2023
- 11 Distinct Responses Received



Some respondents are represented in more than one category.

- All responses addressed current barriers to data collection and known risk factors for stillbirth. About half of the responses addressed high-risk communities and/or psychological impact.
- Information from RFI responses was similar to content presented at working group meetings, and was incorporated in overall findings and recommendations.

Request for Information (RFI): Developing Strategies to Strengthen Research on Stillbirth Prevention

Notice Number:
NOT-HD-22-054

Key Dates

Release Date: November 10, 2022

Response Date: January 06, 2023

Related Announcements

None

Issued by

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Purpose

This is a Request for Information (RFI) to solicit input regarding the development of strategies to improve the impact NIH-funded biomedical, behavioral, and clinical research on stillbirth.

Background

Stillbirth—the death of a fetus at or after the 20th week of pregnancy—is devastating for expectant parents and families. Unfortunately, it remains all too common in the United States, with more than 21,000 occurrences annually, according to the Centers for Disease Control and Prevention (CDC).

Since the 1940s, improvements in maternity care have dramatically reduced the occurrence of stillbirth, but these improvements have slowed in recent years. Stillbirth remains a devastating reality for many families and takes a severe toll on families' health and well-being. Stillbirth has many possible causes, including pregnancy complications, infections, and birth defects. Unfortunately, often health care providers cannot identify the exact cause of a stillbirth, and families are left sadly wondering why. Stillbirth affects families from all demographics across the United States, although rates are higher among certain populations, including Black and American Indian/Alaska Native communities.

NICHD and other NIH Institutes and Centers support research on the causes of stillbirth, its occurrence in populations, risk factors, and prevention methods. The U.S. Department of Health and Human Services (HHS) recently asked NICHD to lead a congressionally mandated task force on stillbirth. The stillbirth working group will focus on the barriers to collecting data on stillbirth in the United States, communities at higher risk, the psychological impacts of stillbirth, and known risk factors for stillbirth. They will present their recommendations to the National Advisory Child Health and Human Development Council in January 2023, with a report due to HHS in March 2023.





Findings and Recommendations: Data Collection

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

Summary of the Working Group Findings

- The current system for obtaining, updating, validating, analyzing, and releasing data on stillbirth in the U.S. needs substantial improvement.
- Accurate, timely, and detailed vital statistics data on stillbirth are essential to enable researchers to advance the scientific knowledge on stillbirth and stillbirth prevention.
- These data are also urgently needed by families affected by stillbirth.



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

Findings of the Working Group

1. Current methods for collecting and recording data on stillbirth are not always fully standardized at the state and local levels, and do not always follow best practices for the collection of vital statistics data.
2. Stillbirth data are typically based on incomplete underlying information due to lack of autopsy, placental analysis, genomic analysis, and other types of assessments necessary to obtain sufficient information to determine a cause of death.
3. Few individuals have the combination of skills necessary to assess a cause of death in the case of stillbirth, and for many stillbirths, a cause of death is never identified.



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

Findings of the Working Group

4. Stillbirths are typically not linked to the electronic medical records of the mother, and typically, no electronic medical records are created for the baby.
5. Stillbirth records are often not amended or updated after additional autopsy or other information becomes available, limiting records' usability to researchers and public health officials.
6. Barriers to effective collection of stillbirth data may include lack of legal authority to require specific types of standardization, limited awareness, lack of appropriate training for individuals involved in gathering and/or reporting data, state and regional differences, and lack of research surrounding best practices.



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

“...very few pathologists ... are able to conduct full perinatal autopsies (in conjunction with placental pathology) and thus evaluate cause of death ...”

“Stillbirth is an issue that we cannot solve without accurate and timely data.”

“A substantial barrier to conducting clinical stillbirth investigations is a lack of insurance coverage.”

“She died of repeated cord compressions. I paid a lot of money out of pocket to learn that.”

“Fetal death certificates (from which state and national stillbirth statistics are compiled) are filled before autopsy, placental pathology, and other testing is even completed, and are difficult or impossible to amend after the fact.”

“We have never received a reason for [my son’s] death and it is very difficult to obtain closure.”

“Even when placental pathology is performed, the quality of the placental evaluation varies widely by hospital.”

“I was told that an autopsy wouldn’t bring my baby back and I would probably never know the answer ... nobody acknowledged my need to know why my baby just died.”



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.





Findings and Recommendations: Communities at High Risk

Communities at Higher Risk for Stillbirth

Summary of the Working Group Findings

- Survey and vital records data from CDC on stillbirth indicate that individuals of diverse racial and ethnic groups face higher risk of stillbirth, as well as higher risks of other adverse pregnancy outcomes. Other disparities across racial, ethnic, geographic, sexual/gender identity, and socioeconomic groups are evident or highly probable.
- The danger of stillbirth in the U.S. can not be addressed unless stillbirth is significantly reduced in communities at highest risk.



Communities at Higher Risk for Stillbirth

Findings of the Working Group

1. In the U.S., individuals of color face substantially higher risk of stillbirth. Fetal death rates in the non-Hispanic Black group are more than twice as high as rates for non-Hispanic Whites.*
2. Elevated risk of stillbirth is associated with higher risks of other adverse pregnancy outcomes.
3. The reasons for stillbirth disparities are not fully clear, but structural factors contribute to differences in stillbirth risk across racial, ethnic, geographic, and socioeconomic groups.

* ECW Gregory, CP Valenzuela, and DL Hoyert. *Fetal Mortality: United States, 2020. National Vital Statistics Report, 71(4), August 4, 2022.*



Communities at Higher Risk for Stillbirth

“Provider bias merits a stand-alone research focus ...”

“There needs to be more research on exactly why minorities, especially Black women, are at such high risk.”

“Racial disparities hold true even for wealthy and educated parents who identify as Black or Brown, many of whom report being treated differently once their providers realize that they hold advanced degrees or prestigious titles.”

“Some marginalized populations with high stillbirth rates are left out of most stillbirth research.”

“If we simply close the gap between black and white women, we would avert 4000 stillborn deaths in this country.”

“My history of having 4 pregnancies and 2 losses is unfortunately a very common one when it comes to Black women.”



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.





Findings and Recommendations: Psychological Impact

Psychological Impact of Stillbirth

Summary of the Working Group Findings

- Stillbirth has a devastating, lifelong impact on affected families.
- The overwhelming aftermath of stillbirth is felt not only by mothers, but also by fathers, siblings, grandparents, and others.
- Improvements in clinical practice and public health care are essential to ensure that families receive the support they need.



Psychological Impact of Stillbirth

Findings of the Working Group

1. Stillbirth takes a devastating, lifelong psychological toll on families.
2. Women have reported experiences of having their concerns dismissed or being blamed for stillbirth.
3. Families report that obtaining information on cause of death is important.
4. Best practices, like procedures used in specialty clinics for women who have experienced stillbirth, are available but not widespread.
5. Women who have experienced stillbirth often do not receive timely, sensitive, and effective support.
6. Fathers, siblings, grandparents, and other family members also need support, but seldom receive it.
7. Research on the psychological impact of stillbirth has documented the need for psychological support and bereavement care, but further research is needed to develop more effective interventions.



Psychological Impact of Stillbirth

"I had called two health professionals who specialized in grief and child loss and was told they weren't accepting new patients, or I didn't receive a call back. My postpartum appointment wasn't until 8 weeks after and that's when I was finally referred to speak with someone."

"What goes unnoticed after a stillbirth occurs is that marriages fail, families fall apart, friendships dissolve, and careers are lost."

"I was not advised of what to expect my body to do following a birth. I was given little resources to help with address what happened and any signs of PPD and grief. I was not advised of my options and what could be done to figure out what happened to [baby] and brushed aside as if she didn't matter and I could just have another one."

"Make no mistake; stillbirth is horrific. And its devastating impacts extend far beyond just the parents, to an entire family and community, and to our society as a whole."

"In a few weeks our family will honor the memory of [the baby's] 10th birthday with a cake but no [baby]. Families shouldn't have to celebrate a birthday without the birthday child being there."

"I was incredibly lucky that I had the sense of mind to get into therapy immediately but I know that that isn't the case for all, part of which is due to financial reasons."



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.





Findings and Recommendations: Known Risk Factors

Known Risk Factors

Summary of the Working Group Findings

- A wide variety of risk factors – including pregnancy complications, chronic health conditions, genetics, environmental factors, and social determinants of health – have been associated with stillbirth and other adverse pregnancy outcomes.
- However, known risk factors account for a limited proportion of the variation in stillbirth rates.
- Additional research is needed to discover additional risk factors, delineate the mechanisms of how these risk factors affect stillbirth, explain the racial disparity, and to translate knowledge of risk factors into interventions.



Known Risk Factors

Findings of the Working Group

1. Known risk factors are insufficient to explain why stillbirths occur. In many cases, a stillbirth occurs without any known risk factors.
2. Improved ascertainment of risk factors for stillbirth is needed for risk stratification, prediction, and ultimately stillbirth prevention.
3. Risk factors associated with stillbirth are often also associated with other adverse pregnancy outcomes, suggesting common underlying mechanisms. Research into the pathophysiologic underpinnings of risk factors is needed.
4. Numerous risk factors and potential causes are associated with stillbirth. A few examples include:
 - Placental conditions
 - Cord issues
 - Infection
 - Maternal conditions, both pregnancy-associated (like preeclampsia) and chronic pre-existing conditions
 - Genetic conditions
 - Environmental exposures
5. For many known risk factors, interventions addressing the risk are not yet available.



Known Risk Factors

“I was told I had a perfect pregnancy ... up until the moment they told me my baby didn't make it.”

“We need to do more than know the risk factors – we need to know how to move towards prevention.”

“Methodological issues specific to stillbirth pose a challenge to investigating risk factors.”

“... maternal conditions need to be examined in association with each other and with the stillbirth outcome.”

“Genomics and epigenomics are promising realms for reducing unexplained stillbirth numbers but are under-researched.”

“...very few pathologists ... are able to conduct full perinatal autopsies (in conjunction with placental pathology) and thus evaluate cause of death ...”

“... more research is needed to better understand the role of social determinants on health on the risk for stillbirth.”



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.





Overall Summary of Recommendations

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.





Next Steps

Next Steps

- Today (1/24): Discussion and Feedback for Incorporation into Report
- February: Develop Report of Working Group
- March: Working Group Report submitted and published
- Spring-Summer 2023: Work begins on implementing recommendations



Thank you!

