

# STILLBIRTH WORKING GROUP OF COUNCIL MEETING SUMMARY

October 31, 2023 (Virtual)



*Eunice Kennedy Shriver* National Institute  
of Child Health and Human Development

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Eunice Kennedy Shriver National Institute  
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## Working Group Members

### Present

#### Co-Chairs

Lucky Jain, M.D., Emory University

Uma M. Reddy, M.D., M.P.H., Columbia University Irving Medical Center, representative of the American College of Obstetricians and Gynecologists

#### Members

RADM Wanda D. Barfield, M.D., M.P.H., Centers for Disease Control and Prevention (CDC)

Joanne Cacciatore, Ph.D, M.S.W., Arizona State University

Alison Cahill, M.D., MSCI, University of Texas at Austin

CAPT Amanda Cohn, M.D., CDC

Ada Dieke, Dr.P.H., M.P.H., CDC

Donald Dudley, M.D., University of Virginia

Andrew Fullerton, M.P.P., March of Dimes

Karen Gibbons, M.D., M.S.C., Oregon Health and Science University

Katherine Gold, M.D., M.S.W., M.S., University of Michigan

Cynthia Gyanmfi-Bannerman, M.D., M.S., FACOG, UC San Diego School of Medicine

Debbie Haine Vijayvergiya, The 2 Degrees Foundation

Carol Hogue, Ph.D., Emory University

Isabelle Horon, Dr.P.H., CDC

Denise Jamieson, M.D., M.P.H., Emory University

Stephanie Leonard, Ph.D., Stanford University

Jenna Nobles, Ph.D., University of Wisconsin–Madison

Mana Parast, M.D., Ph.D., University of California, San Diego

Tina Pattara-Lau, M.D., Indian Health Service

Jennifer Reefhuis, Ph.D., CDC

George Saade, M.D., Eastern Virginia Medical School

Mikyong Shin, Dr.PH., M.P.H., R.N., CDC

Robert M. Silver, M.D., University of Utah Health Sciences Center

Catherine Vladutiu, Ph.D., M.P.H., Health Resources and Services Administration (HRSA)

Maeve Wallace, Ph.D., M.P.H., Tulane University School of Public Health

Ronald J. Wapner, M.D., Columbia University

Professor Jill Wieber Lens, J.D., University of Arkansas School of Law

Monica H. Wojcik, M.D., Boston Children's Hospital

### Absent

### Others Present

Speakers

NICHD Staff Members

Members of the public

## Welcome and Introductions

**Natasha Williams, Ph.D., J.D., L.L.M., M.P.H.**, NICHD, Chief of Legislation and Public Policy

**Alison Cernich, Ph.D.**, NICHD, Deputy Director

Dr. Williams and Dr. Cernich welcomed participants to the meeting. Dr. Cernich reviewed the scope of stillbirth in the United States (U.S.), which affects more than 24,000 families each year and disproportionately impacts non-Hispanic Native Hawaiian or other Pacific Islander, non-Hispanic Black, and American Indian/Alaska Native communities. Over the past year, the Stillbirth Working Group of Council (WG) had examined barriers to data collection on stillbirth for at-risk communities, the psychological impact on mothers following stillbirth, and the known risk factors for stillbirth. In March 2023, the Working Group developed a set of recommendations that were outlined in a report to Congress.

NICHD was committed to addressing the tragedy of stillbirth by implementing these recommendations. Dr. Cernich outlined some examples of NICHD activities, including:

- Launching the Rapid Acceleration of Diagnostics Technology (RADx® Tech) Fetal Monitoring Challenge that will award up to \$2 million to spur innovation in fetal diagnostic and monitoring technologies.
- Supporting the alignment of data collection efforts between the Maternal-Fetal Medicine Units network and the Neonatal Research Network to yield insights into the mechanisms underlying stillbirth.
- Issuing new funding opportunities for stillbirth research through initiatives such as the Road to Stillbirth Prevention Initiative.

Dr. Cernich thanked WG members for their ongoing efforts. Dr. Jain and Dr. Reddy led WG member introductions.

## Overview of Stillbirth Working Group Report to Congress: Summary of Findings and Recommendations

**Lucky Jain, M.D.**, Co-chair, Emory University School of Medicine, Department of Pediatrics

**Uma Reddy, M.D., M.P.H.**, Co-chair, Columbia University Irving Medical Center; American College of Obstetricians and Gynecologists (ACOG) Representative

Dr. Jain and Dr. Reddy provided an overview of the WG findings and recommendations outlined in their report to Congress: *Working to Address the Tragedy of Stillbirth*. There were four major areas requiring federal action and coordination. These were:

- Improving the quality of vital statistics, surveillance, and epidemiological data on stillbirth at local, state, and national levels.
- Using insights from improved epidemiological data and additional research to explain and address disparities in stillbirth and identify prevention opportunities.
- Conducting implementation research and developing interventions to support families that have experienced stillbirth.
- Creating and supporting a full research agenda on known and unknown risk factors and physiologic mechanisms to support the development of interventions to prevent stillbirth.

The 2023 House Report provided an additional \$1 million in appropriations to continue the WG's charge. The WG will use these additional funds for a deeper dive into their recommendation topics. To that end, the WG formed three Subgroups: 1) Improving Data Collection, 2) Stillbirth Prevention and Strategies, and 3) Enhancing Resources for Families Impacted by Stillbirth. Each Subgroup will consider the evidence, develop action items, and identify opportunities for implementation.

## Question and Answer Session

**Question:** Has there been any discussion on linking bereavement outcomes in families across stillbirth, infant mortality, and maternal mortality?

**Answer:** Dr. Reddy answered that it was clear that adverse mental health outcomes associated with infant death and stillbirth could contribute to maternal mortality. Dr. Cacciatore added that the research on traumatic grief and bereaved parents as a whole did indicate that there was a hazard mortality ratio, which likely extended to parents whose babies had died.

## Current and New Activities

### CDC Stillbirth Activity Update

**Jennita Reefhuis, Ph.D.**, CDC, Branch Chief, Division of Birth Defects and Infant Disorders

Dr. Reefhuis provided an overview of data collection efforts across CDC divisions and centers. In collaboration with state Offices of Vital Records, the National Center for Health Statistics collects a standard dataset on all fetal deaths in the U.S. that occur at 20 or more weeks of gestation. These data were used to monitor trends and risk factors for fetal deaths. The Division of Reproductive Health runs the Pregnancy Risk

Assessment Monitoring System (PRAMS), which collects perinatal experiences from individuals who have delivered a live birth. These data were leveraged to conduct the Study of Associated Risks of Stillbirth (SOARS), which collected information from individuals in Utah who experienced a stillborn infant to better understand needs such as grief support. The Division of Birth Defects and Infant Disorders has been conducting a Study to Evaluate Pregnancy Exposures (BD-STEPS) of pregnancies that ended in stillbirth in Arkansas and Massachusetts in order to assess risk factors and develop prevention messaging. The division was also working on population-based stillbirth surveillance in hospitals.

Dr. Reefhuis reviewed updates on recent CDC activities related to stillbirth. The National Center for Health Statistics formed a new Fetal Death Data Quality Improvement Workgroup that was working on a new report of provisional fetal death data, which they aim to release in November 2023. The center also provides in-person training for state field representatives, as well as guidance and tools to support data providers. The Division of Reproductive Health will be expanding SOARS-like studies across multiple sites with a high stillbirth burden to capture a more diverse range of experiences in stillbirth. The Division of Birth Defects and Infant Disorders added a third site (New York) to BD-STEPS and funded four states (Illinois, Georgia, Nevada, and Indiana) to conduct active surveillance of stillbirths.

### **NICHD Stillbirth Activity Update**

**Monica Longo, M.D., Ph.D.,** NICHD, Pregnancy Perinatology Branch

Dr. Longo reviewed recent NICHD activities in stillbirth. The institute recently released a Notice of Special Interest (NOSI) on The Road to Prevention of Stillbirth, which is focused on identifying risk factors, strategies for high-risk communities, racial and ethnic disparities, normative pregnancy physiologic data, real-time placental imaging, targeted clinical interventions, risk models, and the psychological burden on families. NICHD's Maternal-Fetal Medicine Unit and the Neonatal Research Network were working on a joint Parent and Infant Registry (PAIR) to record stillbirth and other adverse fetal outcomes. The data from PAIR may yield insights into the causal and mechanistic underpinnings of stillbirth. PAIR will include 29 centers across the U.S.

In collaboration with the National Institute of Biomedical Imaging and Bioengineering and in partnership with the Bill and Melinda Gates Foundation, NICHD launched the RADx® Tech Fetal Monitoring Challenge, a \$2 million prize competition aimed at accelerating the development of diagnostic and monitoring technologies to reduce the risk of fetal morbidity and mortality.

Finally, NICHD continues to lead the WG in its congressional mandate.

## Resources for Families Impacted by Stillbirth

**Debbie Haine Vijayvergiya**, Working Group Member and Advocate

Ms. Haine offered her perspective as a stillbirth parent and advocate and outlined the need for resources for parents, extended families, and providers after stillbirth. She talked about how families were often not in a position to make important decisions that they may later regret, suggesting that they were often not offered options or support. Ms. Haine emphasized the need for a bereavement doula and outlined several resources that would be helpful, including:

- Information about useful items to bring for the labor and delivery of a stillbirth infant.
- An explanation of the different delivery options, including pain management and the costs/benefits of vaginal versus cesarean section delivery.
- Meaningful options to assist the bereavement process at the hospital, such as self-care boxes, cuddle cots, hand or footprints or molds, and blankets or clothing. There should also be options to hold, name, bathe, dress, sing to, or read to their infant, as well as an opportunity to hold religious or ritual blessings.
- A description of what to expect after delivery of a stillborn infant including lactation, delivery pain, and postpartum depression, as well as options for suppressing or donating milk.
- Information about blood tests, placental examinations, genetic counseling, and autopsy, as well as the potential of these tools to determine causes and identify any risk to the mother.
- Information about cremation and burial options, as well as information about how to obtain a fetal death certificate.
- Information about financial assistance, such as stillbirth tax credits and family leave.
- Bereavement resources for siblings, grandparents, and other family members.
- Extended support resources, such as counseling, support websites, and crisis hotlines.
- Opportunities to make a meaningful difference through peer support groups, stillbirth advocacy, sharing birth stories, and becoming certified as a bereavement doula.
- Provider resources to support them through the stillbirth process and training to inform them of how best to interact with families.

## NIH Portfolio Analysis: Research Literature Update

**Sarah Glavin, Ph.D.**, NICHD, Deputy Director, Office of Science Policy, Reporting, and Program Analysis

Dr. Glavin provided an update on a recent research literature review on stillbirth. This literature review expanded on a previous review to include research published between January 2022 and August 2023. Similar to their first research literature review, they organized findings based on three categories: 1) stillbirth-focused research, 2) stillbirth-inclusive research, and 3) stillbirth-adjacent research. Interestingly, they found that the majority of research published was stillbirth adjacent (51 percent), followed by stillbirth inclusive (34 percent) and stillbirth-focused (15 percent). Dr. Glavin emphasized that much of what was needed to understand about stillbirth was often contained in research that was not originally designed to focus exclusively on stillbirth.

Publications were placed into three subgroups: 1) epidemiology, 2) risk and prevention, and 3) families. The overwhelming majority of publications focused on risk and prevention. Studies in the epidemiology and data collection category were even less than what was indicated because many of the publications focused on other countries and the challenges of data collection in limited resource settings. There was very little published on health disparities. Overall, there had been an increase in stillbirth research, until 2021 when that trend began to plateau.

Within the risk and prevention category, the most common research topic was infection, followed by congenital abnormalities, preterm birth, genetics, placenta, and preeclampsia. There were very few publications on families and bereavement, and two-thirds of these were focused on the mother—despite the understanding that bereavement research needed to include family members and other involved individuals. There was also little research on provider needs, and most of these were focused on clinical support and less on non-clinical or follow-up support.

Dr. Glavin reviewed some NIH-supported research advances on stillbirth. Much of NIH research was focused on the causes and mechanisms of stillbirth, such as pathogens and protein levels. There were also a number of studies on maternal history and risk of stillbirth—for example, one study found that traumatic brain injury prior to pregnancy was associated with increased risk. Interpregnancy intervals was another focus area, which generally found that intervals were not associated with risk, but that there was variability in what providers were communicating to their patients. There were a number of studies on risk factors such as COVID-19 antibodies, pregnancy outcomes across sex and gender orientation, and pregnancy outcomes in low- and lower-middle-income countries. There were also studies focused on placental factors, but there was only one study that focused on family support.



Dr. Glavin added that network programs and cohort studies played an important role in NIH-funded stillbirth research.

### **Question and Answer/Discussion Session**

**Question:** One area that is strikingly deficient is the genomic basis of stillbirth. Do you have any information about studies that considered either whole genome or whole exome sequencing?

**Answer:** Dr. Wojcik agreed that it was an area that needed further study, but there had been some looking at highly selected phenotypes that were high yield for genetic diagnoses. More population-based and large cohort work was needed.

**Question:** Can you comment on the lack of autopsy data in published research?

**Answers:** Dr. Wojcik said that the challenge was related to discussing autopsy and parental wishes and that those discussions and decisions could often take place at a later time. However, even if the immediate opportunity for autopsy was lost, only a small amount of genetic material was needed to investigate genomic causes, and could often come from the placenta. Genomics could therefore complement traditional autopsy and fill some research gaps.

Dr. Glavin added that most of the autopsy studies focused on how autopsy helped enhance the ability to identify the cause of death. However, genetics and genomics was a rapidly increasing topic of interest.

Dr. Wojcik noted that the costs of genetic sequencing and counseling were rapidly decreasing and may become a more cost-effective strategy than autopsy. Dr. Glavin commented that there was little in the research on cost and its influence on available data.

Dr. Parast said that an autopsy did not have to be complete to garner useful information. For example, an autopsy could be limited to a biological system that had been identified as problematic, such as a heart- or lung-only autopsy. Standardized placental pathological examinations could be very useful, but there were few people with expertise. NICHD could encourage perinatal pathology training to help fill this gap.

Professor Lens talked about the restraints related to collecting state data on autopsies. Fetal death certificates were often required to be filed within days, and autopsy results may not come for weeks or months. There were state legal constraints in terms of amending fetal death certificates and other restraints about when to issue fetal death certificates.

**Question:** Will the Subgroup on Enhancing Resources for Families Impacted by Stillbirth address these financial and policy issues?

**Answers:** Dr. Jain expressed a hope that all Subgroups would make recommendations about financing the initiatives they want to move forward. It would be important to know, for instance, the cost of whole genome sequencing and the impact on state and federal budgets. It was important for the Subgroups to be bold in seeking this information, as well as information about where the data could be housed and made accessible.

Dr. Wapner said that the problem with genomic studies was that stillbirth was rare and the genes associated with stillbirth were also potentially rare. Therefore, one would need large sample sizes from stillbirths for a genomics study. A biobank of stillbirth samples would be helpful, but collecting those data would require permission at the time of stillbirth. It would be helpful to have not only a biobank but also a standardized permission form that could be utilized at the time of stillbirth so that patients could grant permission to use tissue for genomic studies.

Dr. Saade requested that unintended consequences should be considered when making recommendations. For example, if there was a recommendation to test the placenta or conduct genetic studies, but nothing could be done about a test result, it may have a negative impact on the clinical care of the patients. There would be a need to counsel these patients about the results of the test, and providers may not know how to do this.

Dr. Reddy suggested that NICHD's Parent and Infant Registry would be an opportunity to leverage the amount of data needed for in-depth testing and to learn about patient and provider preferences.

**Comment:** Dr. Saade said that it would be important to consider gestational age and find clarity on what group the WG was addressing. Testing or causal studies may involve preterm birth, for instance. It would be important to define the focus, whether it was on the intrapartum period, stillbirth in the hospital, or stillbirth with indeterminant cause.

Ms. Vijayvergiya noted that these data were collected by the hospital at the time of stillbirth and that birth clerk training was lacking. It was important for the WG to raise awareness among these groups about the value of the data being collected.

**Comment:** Dr. Silver advocated for collecting as much information as possible, even if not used right away. There were competing issues in terms of the amount of information versus cost, but the focus should be on data collection. In terms of gestational age, 20 weeks was an arbitrary definition with no real scientific or clinical utility. There was tremendous overlap in the pathophysiology of losses at different time periods. He added that there was an effort to change the nomenclature that was worth reconsidering.

**Question:** Are the Subgroups focused on the research agenda that was outlined in the report? Are they supposed to focus on policy and funding rather than research? What exactly is the charge?

**Answers:** Dr. Jain said this his understanding was that the focus should be on both and not limited to one or the other. He encouraged the WG members to be bold and focus on both as much as possible.

Dr. Williams added that the congressional mandate charged the WG to address the three topic areas. She also encouraged WG members to be bold and address how to implement the recommendations.

Dr. Longo agreed and suggested that WG members consider the tools needed to reach the recommendations. She added that one common challenge seemed to be definitions, which could be a starting point for discussion.

Dr. Jain said that while the charge was routed through NICHD, the congressional mandate was directed to HHS to develop recommendations. Therefore, the recommendations should not be limited to a research lens. Ultimately, the implementation of the recommendations may go through the Centers for Medicare & Medicaid Services (CMS) or other HHS agencies.

**Comment:** Dr. Dieke commented on Ms. Vijayvergiya's recommendations for families and said that the SOARS questionnaire aligned with many of those, largely because they had incorporated input from people with lived experience.

## Subgroup Report Out

### Improving Data Collection

Dr. Shin reported on the Improving Data Collection Subgroup discussion. Their discussion focused on standardized data element definitions, specifically gestational age; actionable steps for data collection, such as integrated data sources; and a data registry or hub, specifically in terms of collecting additional data sources, data sharing agreements, and consent. The Subgroup discussed the fetal death certificate and improvements needed to increase data quality, such as addressing state reporting issues, personnel training, and certificate completeness.

The Subgroup also talked about population-based surveillance and the active data surveillance program at the CDC's Division of Birth Defects and Infant Disorders. They talked about the importance of leveraging data from existing studies and prenatal testing data. They also discussed data improvements from a clinical standpoint in terms of coverage for fetal death or autopsy, provider incentives, and data from genetic counselors. The Subgroup also considered practices outside of the U.S.

Dr. Saade added that surveillance was only as good as the clinical workup, and if that was hampered by resources such as compensation or reimbursement, then it was a challenge that should be considered. There was often talk about a final visit to counsel the patient and review results, but this visit often did not occur because of reimbursement. All of these challenges affected data surveillance.

### **Stillbirth Prevention and Strategies**

Dr. Silver said that the Stillbirth Prevention and Strategies Subgroup divided their discussion into recommendations for implementation and recommendations for research. Under implementation recommendations, one idea was a standardized evaluation for all stillbirths, which would need funding at the national level and a centralized office because there were not enough trained perinatal pathologists across the U.S. Another suggestion was perinatal audits, similar to maternal mortality or neonatal mortality reviews, in which a case would be discussed by a multidisciplinary panel of experts. Although this would be an important opportunity for reducing stillbirth, it would also be very expensive.

A stillbirth bundle was another implementation suggestion, which could entail reviewing stillbirth bundles from other countries and identifying the evidence-based practices to include. The bundle should provide education to help providers communicate with their patients. There were also two somewhat controversial recommendations including a mandatory offer of induction at 39 weeks and the universal use of low-dose aspirin.

In terms of research recommendations, the Subgroup considered topics such as managing decreased fetal movement and identifying practices on fetal growth restriction. There was also a recommendation to research the assessment of placental function to predict outcomes using imaging, biomarker, or histopathology data. The Subgroup also discussed the need for antenatal surveillance, particularly among at-risk groups, studies using surrogate data such as placental insufficiency, and a large screening study of patients at 36 weeks. There were also suggestions to identify new biomarkers or ultrasound measures, risk stratification at 36 weeks, and different kinds of stillbirth registries including data on social determinants of health.

### **Enhancing Resources for Families Impacted by Stillbirth**

Dr. Gibbons reviewed the Enhancing Resources for Families Impacted by Stillbirth Subgroup's discussion. One major theme was the lack of standard care for bereaved parents and families, particularly in terms of postpartum care, follow-up, and psychosocial support. They discussed the potential for an AIMS bundle that included training for medical providers, how to provide information to families to help them prepare, and follow-up that included a comprehensive review of the workup. They emphasized the need for this model of care delivery to include multiple options for cultural- and language-concordant care for marginalized communities.

The Subgroup also discussed the types of training currently available, which seemed to be ad hoc and not standardized. They considered how to fit standard training into current curricula and whether there needed to be a maintenance of certification involved. They also talked about challenges related to insurance coverage and the economic burden of the costs of stillbirth, workup, funeral care, medical leave, autopsy, and genetic counseling. They also considered an awareness campaign similar to the preterm birth or the Back to Sleep campaigns, and the need to ensure that the campaign reached everyone, not just pregnant women. The Subgroup talked about a survey of treatment during stillbirth to have a better understanding of what was happening in the U.S. and what supports were needed.

Finally, the Subgroup discussed potential research opportunities such as the information that families actually want, screening for postpartum mental health, a differentiation of trauma versus grief responses, and the impact of insurance coverage on maternal outcomes.

## **Adjourn**

Dr. Reddy and Dr. Jain thanked the participants for their thoughtful input and NICHD staff for their support.