Research Updates: An Interagency Webinar on Stillbirth
Closed Captioning Transcript

Welcome – Lisa Kaeser

I'm Lisa Kaeser of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development at the National Institutes of Health. And I just want to give a couple of opening remarks. I'm first extremely grateful to my colleagues from the other federal agencies and their own scientific program staff who agreed to participate in this call today.

I'm excited about this webinar, and I think I'll be learning more about stillbirth research as well.

We met with advocacy groups last fall and it became quite clear to us that the larger community of those interested in stillbirth research really might not be aware of what was going on in the federal government. So we have pulled this together and we're hoping this will be really helpful to everybody.

The four agencies that are represented here today are the National Institutes of Health, the Centers for Disease Control and Prevention, the National Center for Statistics which is part of CDC, and HRSA, the Health Research Services Administration.

So thank you again for speaking. The bios of the speakers have been sent out so please refer to those. We won't take a lot of time doing introductions. The way this will work is first we will introduce Lindsey Wimmer from the Star Legacy Foundation and then move to our scientific presentations. Each person will speak for approximately nine minutes and then at the end we will have a question and answer period. I will give each speaker approximately a one minute time warning because we do want to get to some of the Q&A at the end. First I would like to introduce Lindsey Wimmer to say a few words.

Introduction – Lindsey Wimmer

I am the Executive Director from the Star Legacy Foundation, a non-profit dedicated to research awareness and encouraging family involvement. Thanks, Lisa.

It's my pleasure to say a few words on behalf of the Access for Stillbirth Awareness and Prevention (ASAP) Coalition. This coalition began out of a conversation from a summit in 2011 and an international conference in Baltimore in 2012. Star Legacy and First Candle started talking about recognizing the need for a voice and collecting an initiative to encourage the most progress possible in the areas of stillbirth awareness and prevention.

Parents of stillborn babies express similar ideas so that's how the coalition was formed. Being in existence for just over a year today, the coalition has over 800 individual members and over 300 organizational members. Early in our efforts we reached out to people in a variety of institutions involved in stillbirth research. Through these conversations we recognized an incredible passion for the topic and were energized by the efforts. Because the coalition was formed in this spirit we recognized areas that could be strengthened or better utilize precious research resources if more collaboration

were part of the system. The people represented here today share that belief with us. So with this interagency meeting of various federal agencies, that initial concept is being expanded.

We can't thank all the individuals and organizations enough for participating in these presentations and also Lisa, F.L., and Gina for their amazing dedication and work behind the scenes to make this meeting happen. I think we can all say that we are here because we share the belief that 26,000 babies being stillborn every year in the U.S. is not acceptable. That's something we're not content with. We understand that time constraints also will not allow us to hit and solve every issue related to stillbirth today.

We hope that we'll come away with a better understanding of the breadth and depth of the current efforts happening. The work of each of these presenters, and their colleagues, will allow us to hopefully plan for future meetings to allow to further our collaborative goals. With that, I will not take any more time. So thank you again to all of you for joining us and to our speakers for taking the time to present – and I'll turn it back to Lisa.

Thank you so much, Lindsey. Thank you for those kind words. Now I would like to introduce Marian Willinger and Uma Reddy, stellar researchers in terms of this portfolio at NICHD.NICHD – Dr. Marian Willinger & Dr. Uma Reddy

Uma Reddy, NICHD

Thanks, Lisa and to the organizers for the opportunity to present the research from NICHD and the Pregnancy and Perinatology Branch. We will cover basic science, translational metrics, and we're going to touch on studies that focus on stillbirth: SCRN (Stillbirth Collaborative Research Network), New Moms to Be, and then the PASS (Prenatal Alcohol and SIDS and Stillbirth) network. So SCRN, the stillbirth collaborative research network, is a population-based study of stillbirth. We used geographic catchment areas in the U.S. defined by county lines. These areas were selected and they had 59 hospitals delivering women to these areas averaging greater than 80,000 deliveries per year. So in SCRN every woman who had a stillbirth and women who had live births who were representative of those counties were approached about enrolling in the SCRN study. And one of the major goals of screening was to examine risk factors for and causes of stillbirth.

All women who agreed to participate in SCRN did an in-hospital maternal interview, and their medical records were extracted. A standardized autopsy exam was offered to women with a stillbirth, and placental pathology was examined for still births and live births. Indicated tests for stillbirths were performed and biospecimens for both women having stillbirths and those having live births were collected for research purposes. You can see in this pie chart on the left that of the women having stillbirths, 70% of women agreed to enroll in the SCRN protocol and 63% of women who had a live birth agreed to enroll. So we had 663 women who had had a stillbirth and a little over 1900 women with a live birth enrolled in the study.

I'll just show a few brief slides from one or two of our papers. This slide shows anti-partum stillbirth versus intrapartum stillbirth that occurred during the course of labor predominantly between 20 and 24

weeks. In the next slide, we look at the broad category of cause of death. We use rigorous criteria to call a condition a cause of death and you can see the distribution of causes due to obstetric or placental problems, fetal infection, cord, hypertension, and other medical disorders. Here you see obstetric infection as a cause of stillbirth is more associated with intrapartum stillbirth during labor. You can see placental causes and fetal causes were more associated with anti-partum stillbirth. These next three slides are publications from the SCRN study on various aspects of stillbirth. We have analyses ongoing, and we are also looking at the scope of stillbirth comparing the vital stats. This slide talks about future studies for the next couple of years based on what we already learned through our previous analyses and where we want to go. We're interested in infections in stillbirth, we're interested in the microbiome, infectious agents and their association with stillbirth, placental abnormalities in women who had stillbirth, preeclampsia, and thrombophilia where the fetus has grown too small or large for gestation.

Other areas we are interested in are placental abnormalities and corresponding changes in gene expression as assessed by microarray analysis. How are these changes associated with stillbirth, and how do they lead to stillbirth? Why there is still a disparity in stillbirth and the increase in stillbirth among obese women. So this is just a flavor of where we're going.

I will next talk about the New Moms to Be study. This is focused on women in their first pregnancy. So we're interested in this comprehensive look at adverse pregnancy outcomes. Not only stillbirth but pre-term birth, preeclampsia, and fetal growth restriction. These all overlap. They have common pathways, as a woman who has one is at higher risk for the other ones. A lot of attention has already been focused on women who have these in the first pregnancy to prevent recurrence. So this study is to look at women in their first pregnancy; 40% of the American women who are pregnant are in their first pregnancy. We have very little clinically to offer these women to predict and to prevent stillbirth or other complications. So this study is looking at the causes and the pathways for adverse pregnancy outcomes. The aim is to be able to predict who is at the highest risk of having a stillbirth and these adverse outcomes.

So we can predict two of the highest risks early on in pregnancy and then study possible interventions to hopefully prevent the adverse outcome. This is a large prospective study on a cohort of 10,000 women who have single pregnancies being enrolled. The overarching goal is to determine biomarkers and environmental factors that predict adverse outcomes. We are looking at aspects of placental development that influence adverse outcomes and fetal genetic growth parameters associated with these poor outcomes. We're interested in early pregnancy. We have visits throughout pregnancy, and then we do comprehensive clinical biospecimen data collection at all of these visits plus at delivery.

Then there is a new innovative study focused on sleep during pregnancy. There have been a very few excellent researchers who have done a lot of work on this but there's much more to be discovered. So the primary aim of this study is to look at sleep disordered breathing as a risk factor for adverse pregnancy outcomes. Sleep disordered breathing is associated with pathways to hypertension, diabetes, and poor health so these pathways are very similar to the pathways that lead to adverse pregnancy outcomes. Sleep disordered breathing is important because it's a modifiable risk factor we could do

something about. So again, the 10,000 women in the New Moms to Be study are being given specific questionnaires about sleep, what position they sleep in, and questions about quality of sleep. Clinical data are being gathered on them and a control group of 3600 other women; all wear a special device at home that measures sleep disordered breathing apnea episodes, oxygen saturation, and that data is all going to be analyzed. We're very excited;, the last delivery from the 10,000th woman is expected to occur in May. So that's why we're looking forward to information from that study.

Next I want to talk about CMV [cytomegalovirus]. This is part of NICHD's Maternal Fetal Medicine Unit (MFMU) network that has a trial looking at CMV, the most common congenital viral infection. Primary CMV during pregnancy is devastating. Fetal growth restriction and fetal damage occurs so the network trial is looking at using CMV-hyperimmune globulin to diagnose women with primary CMV infection before 23 weeks to see if the primary outcome can be altered. 100 women are enrolled thus far. A trial is coming up that will be conducted by the MFMU network, starting in the next couple of months. The main study question here is: does elective induction of labor in women at 39 weeks improve perinatal outcomes compared with expectant management regarding stillbirth, neonatal death or severe morbidity? The sample size is 6,000 women to be enrolled. Now I'm going to turn it over to my colleague, Marian Willinger.

Marian Willinger, NICHD

I'm going to talk to you about the Safe Passage Study (PASS). These are multi-disciplinary awards, five cooperative agreements, two clinical sites in the Northern Plains and Cape Town, developmental biology and pathology center, physiology assessment center and data coordinating center. We have a cohort study from pregnancy through infancy to assess the role of pre-natal alcohol exposure in stillbirth and SIDS risk, and we do longitudinal assessments from 20 weeks gestation to a year. We have enrolled over 10,000 pregnant women of the 12,000 women target and we are expecting to complete enrollment in 2016. Our primary hypothesis is that pre-natal alcohol exposure increases the risk for SIDS and stillbirth and secondarily we are very interested in the interaction between environmental and genetic factors and how they affect the risk for spectrum of disorders from gestation through infancy. Primary outcomes are SIDS and stillbirth. We adjudicate every case. We get all the autopsy placental pathology, clinical history, seeing investigations where appropriate. We also are trying to get as much information as we can on miscarriages in hospital deaths, FASD and prematurity. As I said, this is a multi-disciplinary approach because we're very interested in the timing and pattern of drinking, for example, women may drink very early on not even know they're pregnant. What is the effect of drinking only early in pregnancy versus women who drink throughout pregnancy? We're interested in the effects of exposure on placental function and structure, as well as on central nervous system and autonomic system function and structure. In the fetal period, how do these exposures relate to poor outcomes such as stillbirth, Sudden Infant Death Syndrome and FAS? We correlate this with the pathology in the placenta and the brain.

This slide gives you a sense of the longitudinal assessments that we do when we enroll as early as six weeks. Then we get exposure information through pregnancy and after birth. As you can see, we have a

number of physiological assessments of the baby and placenta. We gather information about the mother, information about the nervous system, pathology and DNA specimens from the mom and baby.

And my last slide; The PASS study is unique because it's the largest perspective study to understand the regulation of fetal and infant brain development, and the potential public health impact through early identification, even in the fetal period of children at risk for adverse outcomes from pre-natal alcohol exposure. We have a large cohort and we can learn from them what increases the risk for poor outcomes. It gives us a chance to elaborate on our knowledge of genetic susceptibility and molecular mechanisms of stillbirth and the potential to shed light on the etiology of pathogens of SIDS and some unexplained stillbirth and how they may be related. Thank you.

Lisa Kaeser

Thank you, Marian, we really appreciate that. That was an amazing ride through our research. Now I would like to introduce Dr. Joyce Martin from the National Center for Health Statistics.

CDC – Dr. Joyce A. Martin

Good afternoon, everyone. I'm very pleased to have the opportunity to speak with you today about national vital statistics and fetal death data, the foundation of information on stillbirths in the U.S. Following this presentation two CDC colleagues, Drs. Duke and Barfield, will be talking on CDC's newer enhanced surveillance system. I first would like to start with some background on the National Center for Health Statistics (NCHS) and our role in the national vital statistics system. NCHS works with each of the U.S. states and independent reporting areas to develop and disseminate national vital statistics data on all births, deaths and fetal deaths reported in the U.S. We produce the national fetal death data set, and the annual and special reports on fetal death data. We collaborate with the states. We also facilitate the development of the Model State Vital Statistics Act and Regulations (or Model Law as it's known) which recommends best practices for registration and collection of vital events. Despite many collaborations with the states, it's important to note that the federal government has no authority to register vital events. That responsibility lies solely with the states. The NCHS cannot require states to report fetal death or to report any of the data items recommended. NCHS is, however, required by law to work with the states to produce and disseminate national vital statistics data. So this slide just shows the model law definition of fetal death; this is the law that states basically follow. In vital statistics fetal death is a spontaneous death at any point in the pregnancy. The definition includes miscarriages, which are generally considered less than 20 weeks gestation, and stillbirth, which is defined as occurring at 20 weeks and greater.

This vital statistic definition of fetal death explicitly excludes induced termination of pregnancy or abortions which are reported separately. Although all states require reporting of fetal death, they differ on the stage at which reporting is required. This slide shows the different reporting requirements used by states. Fortunately most states require reporting by 20 weeks gestation or 350-grams; this means that national data are available for death occurring at 20 weeks and higher. And accordingly, of course, most NCHS reports focus on death at these stages. Another advantage of vital statistics data aside from the fact that we have information on all vital events reported in the country is that it goes back very far.

We have information on fetal death back for many decades. This slide shows fetal mortality from 1975 to 2004. As you can see we have made substantial progress in reducing risk in the U.S. over this period. This slide shows more current trends. Mortality continued to decline during the 1990s and through the early 2000s. Very disturbingly, rates have been essentially flat since 2003. We're currently working on a report which will attempt to better explain these trends. As many of you may know, U.S. standards reporting, including the U.S. standard report of fetal death, were revised beginning in 2003.

A major focus of the most recent revision to improve data quality is a longstanding concern with birth, vital statistic data, and fetal death data. Improvements in quality were to accomplish improved data items and data collection processes. So these are a few improved collection processes. We developed very detailed specifications for electronic reporting systems including standard work sheets for the moms and hospitals to encourage collection of data and detailed guide books for hospitals with detailed definitions and instructions for the medical and health data. These are a few key items on the 2003 report of fetal death. Many, many other items were reported. Unfortunately the new revision is slowly being implemented across the country, largely because of the cost of the new electronic reporting systems. This map shows the 2011 revisers/non-revisers. You can see that even in 2011, eight years after the new reports were recommended, we still have many states that are not using the new report. This matters because this means we do not have national data on a number of important topics, making these data much less useful. Delayed implementation has also made it much more cumbersome and time intensive for us to produce the national data files and reports and affected the timeliness of our NCHS data. The good news is that most states are expected to be on the new revision by next year. Okay, as I noted, data quality is a long-standing and very legitimate concern with vital statistics. First as Dr. Duke will demonstrate later in the call it appears the event itself is maybe misreported. That is we may not be accurately capturing fetal death incidence in the country. Also the detailed information collected, especially the medical and health data, is undoubtedly underreported. For example information on whether the mom has developed hypertension during pregnancy, an important risk factor for poor outcome, is often unreported. There are also large differences in data quality by state and unfortunately just a few poorly reporting states can negatively affect the quality of the national file.

The good news is that data quality does improve with gestational age. Also, we have seen improvements in data quality over time. So this table shows the percent of unknown data, key to data quality, for fetal death at different times and also for live births. As you can see, the percentage of unknowns tend to be much higher for fetal deaths than live births. On the upside, when we updated the 2005 presentation I did, we found that these levels had declined by one-third and sometimes by one-half since just 2005. There are currently efforts to improve quality of vital signs data. One important effort is statistics data, such as the eVital initiative which is underway for nearly a decade now. NCHS is working with state partners and electronic health records experts and medical experts to develop standards to allow us to capture information directly from electronic medical record systems into the electronic fetal death reporting systems. Implementation will probably be several years from now.

This inter-operability between EHR and vital statistics will improve the accuracy of these data. We also have a new Public Health Service work group tasked with assessing the quality of data and recommending changes; these will include recommendations for cutting back on the volume of data

items collected in the hope that with less to report, hospitals can focus on reporting key items with accuracy and completeness. Also we are working very hard to improve the timeliness of the national data. We have gotten behind as I said because of this slow implementation of revised certificates but are now catching up. We released our 2011 national file and expect to release the 2012 file by the end of the next month. We'll also release a report on fetal trends and mortality in our annual report on fetal death by the end of the month.

We expect strong improvements in the near future. All states will soon be on the 2003 fetal death report revision and finally national data will be available to track trends and identify risk factors. We're also entering new contracts with states which encourage timeliness and we're starting to see improvements. We expect to reduce the amount of data collected at the national level and we'll also work on developing standardized electronic system based on the modified file that states use which should reduce their costs and help. Finally, and perhaps most importantly, we're developing web-based eLearning training for hospital staff to help understand the importance of information and report accuracy. We have detailed outlines accomplished and just established and are looking for funding. While there are challenges to collecting good quality vital statistics data on fetal death, there are efforts underway to improve the quality of the data and reduce recurrence of these tragic events. Thank you.

Thank you very much. Next we have Wanda Barfield, Director of the Division of Reproductive Health at CDC.

CDC – Dr. Wanda D. Barfield

I want to thank the Action for Stillbirth Awareness and Coalition for the profound interest in this important topic, as well as colleagues at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development for leadership in organizing this effort. I want to just briefly discuss an opportunity to understand stillbirth through the use of existing CDC surveillance system. I will discuss background information including barriers, questions, progress and our preliminary results in using the pregnancy risk assessment monitoring system for the surveillance of stillbirth. There's also potential for a contribution to the national surveillance systems. Just to give a quick background on the pregnancy risk assessment monitoring system. It has been conducted for 25 years with the state health departments and it's about the nation's best source on behaviors and experiences of women before, during, and after pregnancy. However, it's mostly among live births. Unfortunately fetal mortality has been overlooked in this surveillance system because of the overshadowing public interest that has focused mostly on infant mortality. Although the efforts of NICHD have increased our understanding about fetal mortality, there's more to be known. We also know there's substantial variation among states and reporting requirements and the completeness of reporting as outlined by Dr. Martin. Recently there was a publication by Dr. Carol Hogue and colleagues that elegantly demonstrated the effect of maternal stressful life events on stillbirth. The study asked questions from March 26 to September 2008, identifying characteristics associated with racial and ethnic disparity, such as interpersonal and environmental stressors that included 13 significant life events. They found increased odds for stillbirth among women reporting all four stressful life event factors which included financial, emotional, traumatic and partner-related stressful life events. The odds ratio was 2.22. How can we ask

women questions to better understand the issue of stillbirth? We know there must be a level of acceptance in a PRAMS-like survey among women who recently experience stillbirth. Also, what is the best time, how soon after loss should women be contacted to participate? It's a very sensitive issue. The third question we asked was what would be the best way or best mode to conduct the survey? More appropriate by phone?, in person?, so these are important questions in terms of thinking about surveillance systems. In collaboration with Emory University again, led by Carol Hogue and Lauren Lundquist, an Emory student at the Rollins School of Public Health, we looked at parent advocacy leader interviews. We identified 30 individual organizations that help us better understand the issues around stillbirths, including support group leaders, bereaved parents, hospital bereavement coordinators, researchers, medical professionals, and then we conducted 60 to 90 minute semi-structured telephone interviews. The other component was to get feedback from mothers. There were 11 women recruited who had a second stillbirth; we conducted four in-person interviews and seven telephone interviews. For phase three, an expert panel of experts in stillbirth research advocacy reviewed findings from phases 1 and 2, including data on qualitative analysis; key themes were identified and a summary of findings prepared. Due to the briefness of this presentation I'll give a few preliminary results. We found that mothers did have a positive response for the PRAMS-like survey. One mother said it's good because people actually care about what we're going through. You're actually trying to fix stuff and make sure others don't go through what we have gone through. In terms of thinking about when to contact them, some women said within 30 days of the occurrence. They told us that way details you want to have are now blocked out. Others thought there was no expiration, telling us "I think you need ample time but as a mom you will never forget any of those things that happened to us. It's burned in our memory." When asked about the appropriate mode - online or mail – they said if you physically mail something it will let us answer it at our own pace and come back to answer things as they are able.

Another mom said, "I know a lot of moms that get emotional especially when it gets to questions about babies and what might scare them off from sitting at a table with somebody. I like talking over the phone." It appears that contacting subjects within three months post-loss seems appropriate. If the loss occurred at 20 to 28 weeks gestation, you don't want to interview any later because that might fall on that anticipated baby's birthday. We also considered the possibility to delay initial contact for five to six months post loss. So our next step was to pilot a PRAMS-based stillbirth questionnaire in Georgia and revise based on feedback from the women. Those results will be presented in June at a CDC Division of Reproductive Health Grand Rounds. We are also considering a possible funding opportunity announcement in 2016 with a pilot implementation of those PRAMS surveys in three states if funding is available. It is important to note this kind of surveillance could provide a potential contribution to understanding women who experience fetal loss. It offers a unique perspective from women who experienced stillbirth with population based sampling. The other added values include understanding the distribution of certain risk factors, understanding the healthcare experiences of these women, monitoring change over time in access and receipt of services, looking at potential new risk factors and gaps in services and how we might work together to prioritize areas for prevention and further research. I would just like to say thank you and now hand the mic over to Dr. Wes Duke.

CDC – Dr. Wes Duke

Thank you for allowing me to talk with you briefly about work being done at CDC's National Center on Birth Defects and Developmental Disabilities. We are looking at a unique approach that uses the infrastructure of birth defect surveillance programs to potentially enhance surveillance data on stillbirths. I will use the term stillbirth to mean loss of pregnancy at 20 or more weeks of gestation. I will start by describing the rationale for this effort. You have already heard a nice presentation and overview on fetal death reporting in the U.S. and though improvements are being made, you understand the limitations of these data with respect to accuracy and reporting as well as quality of data issues. In an effort to address these information gaps and surveillance data on stillbirths, CDC was funded to conduct pilot studies assessing the feasibility of leveraging resources of existing birth defects surveillance programs to include surveillance of stillbirth. The question we asked is whether active case findings and medical record abstraction could improve upon data currently collected on the fetal death report.

The funding for these efforts was used to establish collaborative activities through a cooperative agreement using birth defect surveillance programs in Atlanta and Iowa. I don't have time to discuss each surveillance system in detail but they've similar in a number of respects including the use of trained abstracters who use multiple sources of information to find cases of stillbirth and record demographic clinical pathological and other information on both the mother and the baby. The metropolitan Atlanta congenital birth defects program currently conducts surveillance in three counties, a change from five counties that occurred in 2012, with over 30,000 births per year. The Iowa registry for congenital inherited disorders operates statewide with over 40,000 births per year. In 2010, Iowa further expanded stillbirth surveillance activities to other states by leveraging existing partnerships through a project known as MD Star Net, a multi-state research network that conducts surveillance and research on muscular dystrophy. These expanded areas for stillbirth surveillance include five counties in Colorado, 12 counties in New York, and the State of Iowa.

I want to show a couple of slides to provide a few examples of the impact this type of activity can have enhancing data from fetal death certificates. This slide is looking at data from Atlanta from years 2006 and 2008 showing prevalence estimates of stillbirth in our surveillance population by year. We never received a complete data file for 2007 so that's the reason for excluding that year and is further evidence of the poor quality of data in Georgia. The first two columns show prevalence estimates obtained if all you had were data from fetal death certificates. The middle two columns show estimates using stillbirths ascertained by MACDP which is active surveillance. You can see there's not a lot of difference in the two sources, indicating that there were cases showing up in fetal death certificates that MADCP missed as well as cases in MADCP that has found fetal death certificates. If you combine the sources of causes of death, you can see the impact overall is a 20% increase. As you may know, there is a higher proportion of African-American mothers in our surveillance population so estimates for the sources combined likely yield a truer estimate. These data are presented in greater detail in a paper that is in press with the Journal of Registry Management due out this spring. In terms of data quality and reporting, reports have been published in recent years and describe improvements that can be seen with this type of data collection on the extent and accuracy of information collected as well as issues of misclassification in fetal death reporting.

I'm happy to make these papers available but in short the paper listed on top showed significant improvements in fetal death certificates with respect to reported cause of death and conditions likely contributing to death. What is lacking in population based studies on stillbirth is significant improvements in comparisons of data so that they are meaningful. The second paper is from our partners in Iowa and shows the impact of misclassified induced terminations as fetal death on surveillance data. This is a very brief overview of our work here and the positive impact we believe this type of active case finding and record abstraction can bring to existing surveillance data on stillbirth. I think there are a number of opportunities to further this work in terms of analytic studies using our current data. Some of the broader steps that we envision would be potential expansion to other state based birth defect surveillance programs. Collaborative work with Iowa to date has allowed us to develop a standardized protocol and methods for use in these types of surveillance systems.

We're also developing guidelines to be published in the national birth defects prevention network manual that will further provide assistance to such programs. Last, but equally important, is the need to strengthen partnerships and look for ways to help make use of recommended postmortem evaluation guidelines routine. Thank you.

HRSA – Captain Madelyn Reyes

Thank you for the opportunity to speak about stillbirth from a mortality view perspective. For those not familiar with the Health Resources and Services Administration, I will start with a brief overview of HRSA's vision in healthy communities. Its mission is to improve health and achieve health activity through access to quality services, a skilled work force and innovative programs. It wants to improve access to quality care and services, strengthen the health work force, build healthy communities and improve health equity. MCHB's [HRSA's Maternal and Child Health Bureau] mission is to provide national leadership in partnership with key stakeholders to improve physical and mental health safety and well-being of the maternal and child health population, which includes all of the nation's women, infants, children, and their families including fathers and children with special healthcare needs. MCHB has programs to reduce infant mortality, ensure access to comprehensive pre-natal and postnatal care, improve healthcare for all children, and provide programs for children with special healthcare needs. Some other highlights are that the Bureau administers maternal child health services block grant awards for more than 900 discretionary grants and other key programs such as maternal infant and early childhood home visiting and Healthy Star programs. This is the MCHB organizational chart. We have six divisions and one office under our Associate Administrator, Dr. Michael Lu. Since 1990, the National Fetal Infant Mortality Resource Center is a center working with states and communities to develop fetal infant mortality review programs. It is a cooperative agreement between the American College of Obstetricians and Gynecologists and the MCHB. It's a resource center for 240 programs in 40 states. The Fetal Infant Mortality review is an action-oriented community process that continually assesses monitors and works to improve service systems and community resources for women, infants, and families. The overall goal is to enhance health and well-being of women, infants, and families and to improve community resources and service delivery systems available to them. The FIMR process brings key members of the community together to review information of individual cases of fetal and infant death to identify factors associated with those deaths, establish whether they represent systematic

problems that require a change, develop recommendations for change, assist in the implementation of change and determine community effects. Carrying out the program objectives in a continuing fashion creates a cycle of improvement for the community.

Now, let's summarize what the community gains from FIMR. It offers a warning system that describes the effects of healthcare systems change, a method for implementing continuous quality improvement, and a means to implement needs assessment, quality assurance, and policy development. These are essential public health core functions, and in these times of changing healthcare delivery systems, FIMR may provide an invaluable path towards understanding how changes really affect families trying to access services. The FIMR process includes a standardized home interview with the mother who suffers a loss, if she agrees to convey her story to FIMR members. The team members find this information key to understanding community issues related to disparity. This is a FIMR process from a different view than the cycle of improvement we see on the right. When death occurs, there's case selection, case abstraction, and the review team makes recommendations for systems change based on what could have changed the outcome for the woman. The community action team strategizes to develop initiatives to improve pregnancy outcomes and reduce fetal infant mortality. Improved maternal infant health is the ultimate outcome of FIMR. The most recent survey of programs was completed in March of this year. Out of all the programs that completed a survey, 85% include fetal death in their reviews.

For example, in Marion County, Indiana, a top contributing factor to mortality is maternal substance abuse; the escalating abuse of prescription opioids during pregnancy is particularly problematic. This program conducted one-on-one interviews with opioid-addicted mothers who experience a loss. They convene the multi-disciplinary team to review de-identified medical record data and maternal interview transcripts to prioritize key indicators for systems change. However, barriers to care also emerge. The team found that some mothers avoid prenatal care; moms are not advised of the risk of using opioids during pregnancy even if medication is used legally, and moms are not screened for drug use equally across all socio economic levels. FIMR findings suggest that systemic barriers to addiction recognition, treatment, utilization, and service disparities still exist. These findings were shared with the local consortium; the results were disseminated to the committee and corroborated via the state's Attorney General Drug Task Force's findings related to neonatal abstinence syndrome. FIMR officials went before the state legislature to address substance abuse issues.

Local jurisdictions in Texas, California, and Delaware reported that mothers did not track fetal movement. In Delaware specifically, a social marketing campaign was conducted to target both healthcare providers and pregnant women with the message that fetal movement tracking is an important indicator of fetal health. A fetal kick count program with the March of Dimes was developed after recommendations were made at a case review team meeting, and the kits were distributed to prenatal providers statewide. Delaware was very responsive, and happy with responsiveness of the providers to discuss fetal movement with their clients. They reported fewer deaths but the numbers are too small to suggest a trend. However, they will continue to use the process to monitor results and track the proportion of women with documented prenatal implementation and movement tracking. Maternal interviews also have informed a change in care. Delaware FIMR found fetal death cases occurred before or at 28 weeks gestation. The proportion was higher than infant death at or above 28

weeks gestation. During the period 2000 to 2006, they found that 41% of infant deaths occur in babies born in third trimester. Also of concern was the fetal maternal interviews conducted with women who had fetal death after 24 weeks, only 19% went to the hospital doctor's office the same day when they noticed decrease fetal movement. 42% of women waited one to two days after noticing decreased movements before contacting their health care providers. Knowing the signs of fetal distress was recognized as an early intervention which could be made available to prevent some stillbirths, especially the viable late term fetus.

As I explained in the previous slide, the Delaware program collaborated with the March of Dimes Kicks Count program and conducted an education campaign for providers and parents. The next two slides were submitted by the Delaware FIMR program that talks about the Kicks Count program. If you're interested in more information regarding the programs I just discussed, feel free to contact me or the FIMR staff listed here on the slide. Thank you for the opportunity to speak to you today.

Lisa Kaeser
Thank you so much. I think we had pretty thought-provoking presentations and a lot of data and a lot of acronyms. So I won't be surprised if we get a few questions to explain those. In the meantime we are fortunate to have two people who are really working on the ground on this stuff, Dr. Ruth Fretts and Dr. Robert Silver. We asked the two of them to serve as discussants today but we wanted to hear their thoughts and reactions.

Discussants – Dr. Ruth Fretts (representing the American College of Obstetricians and Gynecologists) and Dr. Robert Silver (representing the Society for Maternal Fetal Medicine)

Dr. Fretts

Well, it's been wonderful to have these presentations and I know that many of the participants are thrilled with some of the progress that has occurred. I wish I could speak as a force in ACOG but would second what Wes Duke mentioned in his talk, that our efforts now are to reach out to providers because I think there we have seen significant gaps in knowledge and awareness. I would like to figure out how to raise the level of education that's provided to the OB-GYN community in forums like their annual meetings.

Dr. Martin:

One of the things we're doing with learning training is developing it so clinicians will be able to get credit for it. So we're hoping that will help them be more likely to actually take the training.

Dr. Duke:

I want to add something I was not able to put in my presentation about some of the work in the state of Iowa with respect to this issue. Hopefully next year they'll have published their findings, but they have been able to leverage statewide perinatal care team to implement a stillbirth evaluation protocol at all birthing hospitals. It’s voluntary but with relatively wide acceptance, these forms are routinely filled out, completed and submitted to the Iowa registry. They're submitted to the Iowa Department of Public

Health that provides the information to their birth defect surveillance programs. So it has added detail in terms of information they collect for their population surveillance of stillbirth. It will be interesting to see the analysis. We have thought about doing a similar activity here in the Atlanta area but, again, those efforts are just in discussion phases at this point.

Dr. Barfield:

I think that you bring up an important point. One of the things that's happening in our quality improvement efforts with Ohio, California and New York, is that data reporting is improving in the context of quality improvement. So as they're doing work around anti-natal steroids, and doing work around prevention of early elective delivery, clinicians are realizing they could do a better job of reporting data on birth certificates in order to inform quality improvement efforts. Hopefully that will be an opportunity to improve surveillance overall.

Dr. Silver:

Thanks for having me and I really appreciate all the talks. We are very enthusiastic about all the attention that the advocacy groups have pointed towards stillbirth. I think there's a lot of awareness raised and it's been really helpful. We still need to keep going and I'm very enthusiastic about research at NICHD and the efforts being done at the CDC to improve surveillance. A few thoughts came to mind in listening to the talks that I wanted to throw out to the group for discussion. One is I think all the strategies that are being used to increase surveillance are terrific. We really need to address underreporting and need to improve the quality of the data in the birth and death certificates. One glitch that remains - I think there are ways around it but it's potentially expensive and that always makes it very hard -- is that when the death certificates are filled out, often there's not a lot of information available regarding testing that's done to evaluate the cause of stillbirth. For example, perinatal autopsy often takes six weeks to come back. If there was a way to get some of that information onto the death certificates, I think that the accuracy and veracity of that information would be dramatically improved if we could have the results of testing back. Now, a separate issue is how to get testing done. I think that's a very important issue as well. Right now, the data we're collecting is often collected before we have some of the information back that may change the diagnosis and some of the details. I'd like to throw that out to the group for discussion if that's okay.

Dr. Duke:

Again, this is Wes Duke. Thanks, Bob, for those comments and that issue. It certainly is an issue when we think about the type of surveillance we're doing using birth defect surveillance programs, which could show some improvement because as you point out, most fetal death certificates are completed before this type of information is available in the medical record. Typically, our cases are ascertained and abstracted anywhere from two to three months after the occurrence. Often, this information is available, though on a small sample of cases and we hope to replicate these findings using more data. When we revise our data collection tool, we pilot tested that abstraction form on a random sample of stillbirths from fetal death records in 2004. Only a hundred or so cases but of those, over half had unknown calls. For those cases, when we reviewed the medical record and applied a classification

protocol known as the “RC” code which stands for relevant conditions at death, we were able to show some sort of potential contributing cause of that fetal death in almost all but ten cases. There are always, at least at this juncture, a handful of cases for which essentially no efforts are made to remember a cause. Or the cause could not be found. So we hope to be able to exploit resources within birth defect surveillance programs to show improvements in those areas.

Unknown:

I agree. Your results are really impressive. I guess my question is how do we get to do that in all states?

Dr. Duke:

A lot of money.

Dr. Fretts:

It's Dr. Fretts, I would like to address the issue of the autopsy, trying to make it more acceptable. I know that in the stillbirth collaborative, they had quite a high autopsy rate, which is not typical for the rest of the country. So we need to make the case to both providers and to parents that we need a thoughtful evaluation of stillbirth of the placenta and the baby together, plus the key tests. They're really key in helping parents understand what happened in the last pregnancy and also for prevention and future pregnancies. The average autopsy rate is probably about 45%. As you know, it's not specifically a covered service. So I see a number of barriers there, cost to providers and making the case to parents. Any thoughts on this issue?

Dr. Duke:

This is Wes again. I would like to add that in the metropolitan Atlanta area we only have two perinatal pathologists. So you can only imagine what some of the more rural areas of many, many states would have in terms of adequacy of trained personnel to perform evaluation so that's an issue as well.

Dr. Silver:

This is Bob again. I wholeheartedly agree and that was on my list of things to raise. We have had good luck with educational programs with patients and providers to increase their willingness to do it. So I think if we try to do some education to patients and providers, I think we can get a higher rate of uptake. But the fact remains that there are too few providers who are well trained in doing this. There's also an expense involved with it. There's typically no expense to the patient, but if your hospital doesn't have one of these perinatal pathologists, you can't get it done. They're all barriers but that's the most difficult barrier we're facing.

Dr. Fretts:

This is Ruth. Wouldn't it be a solution to actually pay the pathologists and then once it's a covered service, you're going to have more people interested in the process or interested in perinatal pathology?

Because right now, there's no incentive to do it unless it's in the goodness of your heart and you happen to know somebody in the stillbirth community.

Dr. Reddy:

Absolutely. I think that's a terrific solution. There's no doubt that it could easily be done. In our own community, we have perinatal pathologists. We have them in two of our four healthcare systems. And the two healthcare systems that have them, the autopsy and placental histology is done. In the two other healthcare systems, they can transport a fetus and/or placenta and it will be a pathologist that accepts the placental transports because they can bill for them and they won't accept the fetal transports because they can't bill for the autopsy. There's no doubt in my mind if people can bill for the procedure that they would gladly take these fetuses and transport. So when a baby dies before 20 weeks gestation, that's a covered service and once it's after 20 weeks, near viable or post term, it's not a covered service. This I never understood. I honestly don't know the answer. It has to do with calling something an autopsy versus specimens. Less than 20 weeks is considered pathologic specimens. Historically autopsies were done in part for medical education and there's some discomfort with charging for that, but that is a one strategy to get at this on a national level. I don't know that this group in this forum can solve this problem today but I certainly think people should be aware we have a shortage of well-trained, perinatal pathologists, and we don't have a good strategy for providing funding for work and expertise that's required to perform this procedure.

I also wanted to add that I agree with a lot of the comments made. In terms of provider education, I think the Society for Maternal Fetal Medicine has done a good job. They have a special targeted monograph on stillbirth. They got a lot of the experts to weigh in on this. They are targeting the fellows, they have a lecture series of core topics and stillbirth is one of the topics. They asked me to give the talk, so I'm going to be giving it to all the MFM fellows in the country. The recent newsletter highlighted stillbirth as an issue. In terms of national meetings, I know Dr. Silver has given talks, and I have given a couple. So I think that even though the Maternal Fetal Medicine is a smaller group than ACOG but these provider education activities have really done a lot. So I agree with Ruth about how we can get ACOG to do more and they have a nice statement in this bulletin on stillbirth. Ruth did a tremendous amount of work helping them write it, making sure that every time a stillbirth occurs, all the information is reviewed with the family. I agree if the fetal death report was filled out later, once all the information was gathered, we could use fetal death reports to do much more informative research. Another problem with stillbirth research is that even electronic medical records are a problem. I'm involved with a study where they collected 200,000 electronic medical records from pregnancies. When you have a newborn, that generates a separate medical record. With a newborn death you can look into the electronic medical record, enter the congenital anomaly, what the cause of death is, and you piece it together. For stillborn babies, there's no separate record, so what happens is they do a complete work up but with autopsy results sometimes added to the mother's record. In this one study I could not, for the majority of stillbirths that occurred out of 200,000 pregnancies, find what lab tests were done because it gets lost. If there was some way every time, like a live birth, when there's a stillborn baby, it gets a separate record, it helps in terms of doing research. That's huge. I don't know how you get that change.

Dr. Martin:

Dr. Reddy, this is Joyce Martin. We're trying to do that vital initiative so there is a separate vital records report required in the electronic health record for fetal death. That should happen. I'm talking about the hospital I know, but if we develop standards the information will encourage the inclusion of the information in the hospitals electronic chart.

Dr. Silver:

This is Bob again. It will be in the future. I agree with everything that Uma said and just want to, number one, say that the Society for Maternal Fetal Medicine is going to do another update of its publication and try to get the word out. Getting back to the records, I think this is a major issue, thinking how we can effect change, we're kind of going with good will and education and those kinds of things. But a lot of times docs respond, providers respond to a lot of initiatives done in hospitals across the country. A major theme in clinical medicine is quality improvement and safety; there are a lot of checklists done for a variety of procedures. To be sure physicians and other providers are complying with generally accepted recommendations. That's being tracked and there is improved quality and safety. And people haven't applied that to things like stillbirth.

Lisa Kaeser:

Terrific. Sounds like we're at a good point to go to the Q&A. We have received piles of very good questions so we'll get to as many as possible, I promise. So do you want to start? Thank you again to all of you for participating. There's a wonderful amount of data and information that's been put out there. Just on housekeeping issues for people listening, there's been a lot of questions whether we're going to post these slides and the answer is somewhat yes, we're waiting for final approval on some of the sets. The intention is to post them. We will have all of your information if you have signed in, we will let y'all know when they are posted. So after all these presentations, a few of the main questions that have come up, is there anything else either might want to highlight about new areas of research and indications of causes and prevention? This is an open question to the presenters.

Dr. Bob Silver:

This is Bob. I'll take that. We are very excited about all kinds of things, but I don't have anything to add beyond the stellar presentation given by the NICHD folks. Dr. Fretts, I wondered about it's a brave new world currently looking at options for pre-natal diagnosis at ten weeks of gestation using DNA. I didn't know but I believe the stillbirth collaborative did look at microarrays and found additional value. But Uma, would you be the best person to answer? Or speak to this?

Dr. Uma Reddy:

I think that whole area is of intense interest in the new mom-to-be study. So as I talked about, we have identified screens for women at the time of delivery. There have been very few studies with increased rates of preeclampsia and fetal growth restrictions. In the New Moms-to-Be study, we want to profile women who are at the highest risk for stillbirth and other outcomes because then we can test

interventions. There's a lot of interest in aspirin, and a lot of literature right now starting as early as the first trimester. We have found placental markers, but the problem is, if you use these markers they have poor predictability. The majority of women in the first trimester will not have a stillbirth. They have a normal birth, so the goal of the New Moms to Be study is to come up with a profile similar to Down syndrome screening. Can we come up with markers? DNA would be one of the markers, and use it in pregnancy, and say this woman is at an increased risk for stillbirth. What can we do to prevent it? Somebody sent a question about whether the New Moms-to-Be study will be identifying risk factors that are arising in the third trimester. So we used early third trimester ultrasound to measure the baby's growth. And the first and second trimester ultrasound to measure placental perfusion. There are ultrasounds that can look at the blood flow to the placenta. So there is interest about early prediction as well as later prediction of stillbirth. The problem with New Moms to Be, though, it's a great study, but the total number of stillbirths we'll have is between 60 and 90 because of the prevalence. Maybe closer to 60 just because these women, after getting these research tests, they're followed more closely than the average pregnant woman. We made the cohorts as large as we possibly could to get a decent number of what might be perceived as rare outcomes though there are many, many stillbirths occurring. In the PASS study we probably will have more than that. We do have ultrasound in the third trimester as well as assessment of other factors so we'll be looking at that as well.

Dr. Bob Silver:

This is Bob. I agree with that, I think that though there's a relatively small number of stillbirths in these cohorts, there is overlap in pathophysiology of stillbirth and other adverse pregnancy outcomes, especially fetal growth restriction, but also preeclampsia. There are larger numbers of those conditions. So I think we have a shot developing reasonable biomarkers in early pregnancy to predict stillbirth and other adverse outcomes. So I will stay tuned.

Lisa Kaeser:

There are questions about ultrasound and what identifies a high risk pregnancy or a woman who is going to have a first pregnancy and why aren't they all considered the same as far as monitoring.

Response:

I can start, and then Ruth and Bob and anyone else can weigh in. In terms of a woman who has had a poor outcome in first pregnancy like stillbirth, she gets monitored differently in the second pregnancy because she's tenfold more at risk of having that happen again compared to a woman who did not have a stillbirth. So we know if she had that outcome, she'll be followed closely; women get ultrasounds to make sure the baby is growing properly. Poor growth is associated with stillbirth and women get fetal testing, monitoring, and told to monitor kick count. So they're watched much closer. Question then, and a very good question, is why don't we do this for all women? Why do we do ultrasounds every four weeks? There are several problems. Because when you do ultrasounds and all this testing you can get tests that are what we call false positives, you deliver the baby, leading to pre-term delivery, but the testing was a false positive meaning that the baby was absolutely fine. So that's the balance that we have to weigh. What to do with the first pregnant schism and that's why New Moms to Be is just one

study. There are international studies with the same population of women in first pregnancy. There is a UK study looking at women in first pregnancy and other European studies looking at how in the first pregnancy when you don't have history to go by, once you have a history of pre-term birth, stillbirth, you're monitored differently in the second pregnancy. How in the first pregnancy can we identify women at higher risk, because if we don't it would be dangerous to do some of these interventions on all women without some triage or figuring out who is high risk.

Lisa Kaeser:

Very helpful answer. Did anyone have anything to add to that?

Response:

Actually I will make a comment. What we found while reviewing stillbirth at Brigham and Women's hospital, was that there were a lot of system problems when you dug into it, which may be picked up on an interview with the parent three or four months postpartum. For example, a woman who is supposed to be getting twice weekly testing and who left a message or dropped by or left a sticky note and the secretary didn't pick it up, and ten days later she presents with fetal demise. Those are things that could be captured in a national inquiry on stillbirth. But we did find it relatively frequently. What we're looking at are data sets and at technologies and genetics. There are basic infrastructure problems that I'm sure occur more often in cities and perhaps the mother's survey would get at those. Every time we do the review we always find something we could do better. I'm encouraged that at the local level an audit can be very helpful. That wasn't the answer to the question but it did come into my head that there's rich information when you review these cases carefully.

Lisa Kaeser:

Okay. Thank you. So we received several questions related to the newer recommendations from ACOG and others based on NICHD research, to the extent possible pregnancies be carried to term, 39 or more weeks. A lot of this is based on our recent research, and Uma and Marian can expand on this, but recent research has shown that babies born even what we call late term or early pre-term, really have differential development and additional challenges. So we are encouraging most women to carry to term. But the questions we received indicate a significant number of stillbirths occur between 36 and 38 weeks, and so folks are wondering if hospitals and Ob-Gyns might be willing to perform scheduled C-sections or early inductions to prevent actual stillbirth. I'm assuming, as Uma mentioned earlier, that women who experienced a previous stillbirth would be monitored more closely and possibly action taken earlier. But I want to throw to it the panel to talk about.

Dr. Bob Silver:

This is Bob. I'll start if that's okay. There's no right answer to this, and it's stressful for families if they have undergone stillbirth. If you deliver the baby prematurely while the baby is still alive, you're not going to have a stillbirth. So it's very rational and reasonable and appropriate to ask the question should we just deliver everybody at 36 weeks and then reduce stillbirth rate. The problem is that between 36

and 39 weeks, the stillbirth rate is still relatively low. The trouble you cause, if you deliver everybody at that gestational age for prematurity, is much higher than the benefits you would have, in terms of preventing stillbirth. What we need is a crystal ball to know who is going to have stillbirth and who isn't. If we had that crystal ball we can say you're going to have a stillbirth at 38 weeks, so we'll deliver at 37 weeks. And if you're not going to have a stillbirth at 38 weeks, we're going to wait until the baby is fully mature. We don't have a crystal ball, but we are trying as hard as we can to be able to predict who might be at high risk for stillbirth. Some based on history, some based on blood tests, some based on information from ultrasound. In individual circumstances, if some of that information indicates a very high risk of stillbirth, it's very appropriate to deliver patients and we do that all the time. Moms with preeclampsia, moms whose babies are small and not getting enough blood and oxygen, moms with abnormal fetal testing. So to sum up an answer it's not appropriate to deliver all patients before 39 weeks, in fact it's not appropriate to deliver most patients before 39 weeks but in the setting of clues that say boy, there's an increased risk of stillbirth or other problems, it's perfectly appropriate and something we do all the time.

Lisa Kaeser:

Thank you. Anyone have anything to add to that? Does anyone, in addition to that, want to talk a little bit about how we got to 39 weeks? That's a fairly recent development.

Unknown:

I'll defer to folks on the call who have done some of the studies. But I think we have always known that 39 weeks is a term gestation and occasionally, while you would have problems prior to 39 weeks, I think we never quantified it well. Most of the time babies are okay at 36 weeks so it wasn't on our radar screen. The past few years we had really good documentation that in fact you really do have very, very important clinical problems for babies born between 36 and 39 weeks, but that just wasn't available before.

Dr. Wanda Barfield:

So this is Wanda Barfield, I think you have made really great points. Increasing understanding again with strong epidemiologic data with good vital records data, has allowed us to look at these issues in terms of the risk of late pre-term birth. The explosion of information that shows when is too early in terms of neural developmental risk and what we're also understanding about these early term deliveries as well. Your point is well taken, I think the other piece was our increasing confidence in neonatal perinatal medicine, perhaps making it seem like a good opportunity to deliver these babies early but we know they also have risk.

Lisa Kaeser:

Thank you. So people are responding to all of this by talking about understanding what the research shows and wouldn't it make more sense to increase the monitoring that goes on? Such as the number of ultrasounds and stress tests.

Response:

I can take that question on. It turns out that for women of advanced maternal age (over 35), there is no ACOG recommendation that these women should have increased monitoring, meaning non-stress tests. So I think providers are taking some of the risk factors identified in the literature like, 15% of women in the U.S over age 35 are delivering. In terms of ultrasound, it's very complicated, because there is very little publicly available data, but looking at insurance companies' data, women are having on the average three ultrasounds per pregnancy. It's clear that having an ultrasound is to look at the anatomy of the baby, and to look for birth defects is important. But what's the right number of ultrasounds? People are saying women are having too many ultrasounds and spending an inordinate amount of money and what are we getting for it, so it's a complicated issue.

Response:

It's hard to explain the concept to people because it kind of goes against human nature, but part of the problem with these tests is not just expense and not just inconvenience but also you can have lots of false positive results so it's common to have a non-stress test be abnormal even when the baby is normal or have an ultrasound be abnormal even when baby is totally normal. That leads to pre-term birth and cesarean delivery. If you're low risk and do these tests you can cause more harm than good so it's not just a matter of not wanting to spend money or time but you can do harm by doing these tests if you're at very low risk.

Response:

Sounds like a real balancing act. But information will continue to be very, very critical in making the difference here.

Lisa Kaeser:

We're going to shift gears for a moment. This is primarily for the CDC folks. People requested or wondered when new statistics are going to be released, knowing that the website showing statistics on stillbirth is from 2006. One very specific question is what percentage of stillbirths remains unexplained?

Dr. Martin:

I'll answer the first question. In my presentation I talked about the fact that we were delayed in our file and our report releases, but we are catching up and we have released 2011 data as of last month and we plan to release our 2012 data file by the end of next month and the accompanying report within the next two months.

Lisa Kaeser:

Great. Can anyone take on the clarification of what percent of stillbirth is unexplained?

Dr. Ruth Fretts:

I can speak a little bit to that. The more thorough evaluation you have, the less likely you will find things unexplained. For instance, in the absence of autopsy, people might miss an infection that wasn't obvious in the baby, so I do think that part of the unexplained has to do with how thorough the review has been. I don't know if there are any other comments.

Dr. Reddy:

This is Uma Reddy. I completely agree with you, Ruth. I think it's clear when a complete work up is followed as recommended by ACOG, you will find the probable cause of death more often in 80% of cases. To say a stillbirth is unexplained, that means that you did a complete work up. A lot of times people say it's unexplained but they didn't do an autopsy or a key piece of testing, which is important. Those where the complete testing hasn't been done shouldn't be considered unexplained. They need to have a complete work up.

Dr. Fretts:

I agree with you.

Lisa Kaeser:

Let me pursue that a little bit further. Several people wrote in asking how do you get that complete work up? One person, for example, asked about pathologists who were doing it, whether it's more appropriate to have an in-house pathologist versus a third-party pathologist, another person wrote in asking about one state having to obtain maternal permission to release the fetal death record, and that can be an obstacle because it's difficult to get that sometimes. So can people talk a little bit more about what it takes to get complete workups?

Dr. Reddy:

I can start; Ruth, Bob, feel free to jump in. I mean, it starts first with explaining to the family what a complete work up entails. So I think the efforts to make sure providers are following that recommendation is important. One rate limiting factor is having pathologists who are qualified and who have the experience to do fetal autopsies. Consulting with a pathologist who may not be at the hospital but who can be sent slides is one way of getting the most expert person you can. It's important also in terms of who explains an autopsy to the parents, and what is the key information you can expect to get out of the autopsy. ACOG has a list of tests they recommend in all stillbirths, and they have a list of tests that are only recommended in some of the stillbirth cases depending on what you find. I don't know, Ruth, Bob, if you want to add anything.

Dr. Fretts:

Again, I think some providers are not up to date and they will make an assumption approaching a parent in this difficult time, which will stress the parent more. There was a study done showing that basically

people are more likely to regret not having an autopsy than having one. There are options for modified autopsies, for instance, ones that are sensitive to the religious requirements of the parent. In the UK there was an issue about whether or not the organs should be kept with the baby or separately. I think all of these can be worked out but there has to be a level of comfort in the provider and some flexibility. There are some good articles on people who have different cultural views on autopsy, and that a lot of these are problems can be overcome but it takes willingness on the part of the provider. When I say provider I also mean the nursing staff. Many times it is the parent who will turn to the nurse and give them this look of what should I do? If nurses aren't educated on this subject there's probably no value in it. So in terms of education I think we have some work to do on all levels.

Dr. Silver:

I agree with you, Ruth. In the stillbirth network that's what we found. One component, a key component, was the maternal interview. We did a focus group before starting the study to see if it was okay to conduct a fairly long interview, which was an hour long. And focus groups are very informative; we learned that in fact it was good to do the interviews and solicit opinions of families and to get these answers. Very useful research information came out of the interview. And other accomplished international researchers were surprised when we said we're doing maternal interviews. They did not think this would be possible because they said it's a difficult time for the family for you to come in and try to do a research interview. It isn't that hard and we found not only do we get great useful information to inform research but we got lots of positive feedback and families saying it was a nice research staff. For the research staff, training is important. 59 staff nurses were involved with the study, where they had gone through specific bereavement training. So lots of positive feedback. We're not just Ob providers. Everyone involved in the care of the family needs to be basically trained as to how to present the work up and provide support.

Dr. Willinger:

This is Marian. We have seen the same in the PASS study where both in Cape Town and the Dakotas there wasn't a big infrastructure for conducting autopsies but by virtue of being present and providing training those rates have gone up significantly. We published an article on consenting for autopsy. And recently, in one of the follow-up studies on grief, one of the graduate students in South Africa showed women appreciated the autopsy. So part of this does come down to education but it also comes down to resources. Being able to invest in that training and infrastructure.

Lisa Kaeser:

A couple of related questions related to that. One is more clinical - is there a specific number of hours after the stillbirth to do the autopsy?

Dr. Silver:

Not really. It doesn't really make a lot of difference. There's really no magic number of hours. For certain kinds of studies obtaining tissues earlier rather than later is helpful. For a subset of specialized studies it

makes a difference. The longer interval between actual death of the fetus and the autopsy, when you get into a long time it can make a difference in the quality of tissue. But on balance there's no absolute amount of time. I want to make another comment about the work. Provider education is the key, getting providers to offer information to the patients. And there's no question that we can do a better job with that. There's no question that having the right conversation with patients can remove barriers. But I think it's also important for some of the advocacy groups to get insurance carriers or whatever our healthcare system is to pay for some of the things. There's a laundry list of tests that are recommended. And in some cases, it's important to do all those tests but for all cases there is a core of four studies that people think are the most important based on some of the studies done. One is perinatal autopsy, one is placental histologic evaluation, one is some sort of genetic assessment of the baby, and one is some sort of assessment whether there's been fetal bleeding or maternal hemorrhage. Of those studies the two expensive ones are autopsy and genetic testing. There's new technology that's wonderful in terms of being able to evaluate genetics and stillbirths but it's expensive technology. In addition to these things, we have to raise provider awareness, we have to get insurance companies to pay for genetic testing and figure out how to compensate the pathologist to do autopsies. If we get parents and docs to want them, we may create a demand.

Lisa Kaeser:

Good point. Let's keep moving along. We're going to switch gears a little bit because there have been quite a few questions about advocacy -- as federal employees, we are not allowed to advocate. But we can talk about education, public awareness and that sort of thing. So there were a number of questions about that. How to accelerate the research, how to continue these discussions, how to educate providers, everyone from Ob-Gyns to hospitals to nursing staff. So I'm going to open that up to the whole group. All of this information is incredibly good, but let's talk how we get it out to the community.

Dr. Barfield:

I think we do have an opportunity to tell stories of women in the context of stillbirth and that's an opportunity for our data partners to share that information. It was said before by one of the participants, the issue of health systems and those that may or may not provide support and services to women who may be at risk for experiencing a stillbirth. We know that many women are high risk for morbidity, and chronic disease is a major factor. Obesity is one of the many issues that affect women. We need an opportunity to think about how we can also better help women in terms of their overall health even prior to pregnancy. So there are some good opportunities I think for the use of the data to be shared with local governments in a way that can help these stories be told.

Dr. Reyes:

Thank you, Wanda. The Delaware example showed one of the ways that one program did go out to the community to educate the providers and parents on the issues that they were facing in the community. So FIMR is a good way, a good avenue to do this. We have a lot of successful stories around that.

Lisa Kaeser:

Where could we find out those stories?

Dr. Reyes:

My last slide second to last, ACOG.org.

Lisa Kaeser:

Okay,so that sounds like one place. I know some of our friends at Star Legacy and First Candle and others can help us with that. So that's helpful. Does anyone else have anything clearly educational? This seems like the major thing. For example, NIH conducts research, we will be doing everything we can to get results out to folks. Some of these big studies have been very informative. One thought occurs to me, though, at the federal level none of us are representatives in state governments. States don't often like us to tell them what to do. A couple of questions came up about how to encourage states to take the lead. Sharing data and results from pilots would be one approach. Anyone have any other thoughts? I'm talking some specifics about death certificates.Do all states require death certificates? Do they require review of medical records? Do all hospitals report the same? Are those things that these pilots can approach?

Unknown:

I'll talk briefly about work in Iowa. I mentioned the state wide perinatal care team and the program they have been able to leverage in that state. They are getting funding from a number of sources within the state, not from the federal government, to develop more training modules, and allowing credits for healthcare professionals where staff from the Iowa Department of Public Health go out to birthing hospitals and provide training on recommended state guidelines for vital event reporting and the importance of accuracy of information on those forms. So we can build upon those templates. Often, it comes down to having the resources to do these sorts of activities.

Dr. Martin:

Just to reiterate, fetal death reporting is required by all states and all states will be on the 2003 certificate within the next year or two. Resources vary widely among the states. And the number of fetal deaths at this time occurring in some states is low, making it more difficult to leverage resources to improve reporting.

Dr. Reyes:

I want to add that FIMR can provide insights into system challenges, such as using the local network to promote systems change.

Lisa Kaeser:

Excellent. So we only have a few minutes left. Several people have asked what's going on in other countries. Particularly Japan was held up as an example where ultrasounds are routinely required. I have mentioned Australia, UK, Norway, what can we learn from those countries? Could anyone address that?

Dr. Silver:

It's a terrific question, I wish I had a terrific answer. I don't. There's a pretty small but enthusiastic community of researchers and docs interested in stillbirth throughout the world and Ruth and others have been quite involved, so people are trying to communicate and collaborate and learn what others are doing to try to see if any countries are doing things that could be applied to our country. But it's very difficult to compare stillbirth rates across countries because each population has a different level of primary risk. Some of it may not have anything to do with the obstetric care rendered. So it is not as simple as saying pick a country with a stillbirth rate lower than ours and then doing everything they do to have the same stillbirth rate. But that being said, it certainly makes sense to look at every country with a low stillbirth rate and ask what they're doing and assess whether those interventions are helpful here. So a terrific question, I think a lot of people are thinking along those lines trying to ask those questions. But I don't know there are a lot of specific things that we could be certain will help us tomorrow. But I think people are working towards exploring those things.

Dr. Fretts:

So ACOG is part of the international stillbirth line and they are actually having a meeting in 2014 in Amsterdam. It's a very unique situation where everyone who is meeting has perinatal loss and stillbirth. There are interesting lessons to be learned, how countries deal with perinatal audit. The other observation which is standard in almost all countries is that women in the lowest quartile or who live in poverty have worse outcomes. The question is how to address these. The parent groups have been instrumental moving the agenda forward. So I would tap into the parent groups through the International Stillbirth Alliance. I think one issue is that we have a very big country and a lot are like 50 countries. And so it's a challenge but every time I go to an international meeting, I find we can make comparisons. I think one that is close to my heart is that before people evaluate the complaint of decreased fetal movement, it was pretty much a clinician who would do an evaluation and send someone out the door without thoughtfully taking the opportunity to do a true risk assessment. Is this a true positive, is this baby trying to tell me something? And in our hospitals, in the Boston area, the ultrasound rate with initial complaint of decreased fetal movement was about 11%. And in the Norway study it was more like 86%. I think we miss the opportunity of identifying growth restriction by not doing ultrasound. But again, those are works in progress. Providers have to be mindful that decreased fetal movement is a risk factor, say a four-fold increase risk for all comers, so the complaint needs to be evaluated thoughtfully.

Lisa Kaeser:

Thank you. That is, to be honest, a sobering statistic so thank you, very much. I think there's plenty to work on. I'm going to ask the presenters if there are any last thoughts they would like to share. And then I just want the say a couple of things in closing. Anyone want to say anything? I want to thank everyone for their excellent questions and support. I think I'm sure the presenters feel the same way. To hear advocacy organizations acknowledge the importance of the research and ask what more can we do, it's important, it's a big motivator for all of us.

Response:

I marvel that the parent groups from a historical perspective have been the ones to ask why did they their baby die and pushed us researchers to get to our jobs

Response:

Couldn't agree more.

Lisa Kaeser:

Thank you. One little announcement, someone sent in a note about the first major motion picture about stillbirth will be aired on Lifetime on May 17th called *Return To Zero*. I'm actually guessing that most of the folks on this call are aware of that. But I wasn't, so I'm glad to know about it. Thank you. Hopefully everyone will let people know about this public health issue. In closing I want to thank Gina and F.L. for helping put this on. I want to extend a huge thanks to those of you who presented today. I realize nine minutes is not a huge amount of time to present all of your good work so I really appreciate it. I appreciate our two discussants who added clinical aspects to this. And most of all, thank you to the coalition and other groups who asked us to do this because I have actually learned a lot in the process and I think it's all good we're all on the same page in terms of understanding what's out there. I'm supposed to mention one more thing. The Stillbirth Summit is in Minneapolis, June 19th through 21. I believe our folks might be going and there will be international researchers sharing their research, so it sounds like an excellent meeting. Again, thank you all so, so much for being on the call today. I think this is just the beginning of the discussion. Looking forward to more. Thank you.