

## **OVERVIEW**

Every year, nearly 500,000 American babies are born too soon. More than 12 percent of U.S. births are preterm—and, most troubling, this rate has continued to rise. Thanks to advances in research and improvements in health care, many of these babies survive and even catch up with their full-term peers. However, a sizeable number of “preemies” are vulnerable to long-term complications that may last a lifetime. The costs associated with prematurity add up to at least \$26 billion per year.

Not only is prematurity a common and costly public health problem, but it is also complicated and difficult to address. At the Surgeon General's Conference on the Prevention of Preterm Birth, held in June 2008, many of the country's foremost experts and leaders from the research, public health, and medical communities convened to discuss strategies for preventing preterm birth. The purpose of the conference was to:

- Increase awareness of preterm birth in the United States;
- Review key findings and reports issued by experts in the field; and
- Establish an agenda for activities in both the public and private sectors to mitigate this problem.

Six working sessions were held among the experts and leaders, and public comments were received throughout the conference. Conference sessions specifically focused on:

- Biomedical research
- Epidemiological research
- Psychosocial and behavioral factors
- Professional education and training
- Communication and outreach
- Quality of care and health services.

The conferees' report to the Surgeon General is organized around these working group topics.

The experts at the conference recognized that preterm birth is a complex and multifaceted public health problem, one that is not likely to be resolved completely or quickly. A large number of goals and recommendations were formed and discussed at the conference, and each represented an important and necessary component of a possible national action plan for preventing preterm birth. By their nature, some of these action steps can be completed quickly. For other recommendations, work can begin immediately but the plan will need to be implemented over the longer term. The working groups distinguished between short-, medium-/mid-, and long-term recommendations, but did not indicate relative priority. Instead, these designations reflect practical considerations, feasibility, and when the goals can be realistically achieved.

Discussions held at this conference will inform a possible national agenda to speed the identification of the causes, risk factors, and treatment of preterm labor and delivery. The translation of such an agenda by researchers, public health officials, clinicians, policymakers, and the interested public will be an important step toward resolving the growing epidemic of preterm birth and ensuring healthy future generations of mothers and children.

## BIOMEDICAL RESEARCH

Co-chairs: George Saade, M.D., and Catherine Y. Spong, M.D.

### Background

In 2006, nearly 500,000 infants (12.8%) were born preterm (at less than 37 weeks of gestation) in the United States. Overall, babies born preterm are at greater risk of death and disability. Although many of the infants born at earlier gestational ages are surviving in greater numbers, they are at a progressively increasing risk of morbidity (e.g., cerebral palsy, intellectual disabilities, and sensory impairments). Although research has been conducted to identify the causes of preterm birth, few definitive etiologies have been determined. However, some biological pathways have been targeted as possibilities, including uterine overdistension, utero/placental deficiency, various infections or inflammation, and implantation errors. In addition, certain maternal conditions have been associated with a higher risk of preterm birth, such as preeclampsia, hypertension, gestational diabetes, and autoimmune diseases. Marked maternal underweight and overweight (obesity) may also be risk factors. Although there is evidence that some environmental toxicants, such as smoking and air pollution, may also increase the risk for preterm birth, there are fewer data on others (e.g., heavy metals, biphenyls, paternal exposures, and gene/environment interactions).

### Current Status

The Institute of Medicine (IOM) report *Preterm Birth: Causes, Consequences, and Prevention* identified many of the needs in research on preterm birth. A strong case was made for research to pursue better predictors of preterm birth for either prevention purposes or for the earliest possible diagnosis so that a determination can be made whether medical or non-medical interventions might be needed. Accomplishing this goal requires studying risk factors both independently and woven together into a constellation of lifestyle factors, including socio-demographic status and community contributions. By identifying these predictors, including pregnant women who have preexisting medical conditions, those at highest risk for preterm birth can then be treated. Further, the integration of new and evolving fields, such as genomics, epigenetics, proteomics, and systems biology, has the potential to provide a greater understanding of the pathways to preterm birth, including the development of new biomarkers. Other important topics include the effects on preterm birth of assisted reproductive technologies and multiple gestations and the mechanisms by which these may be contributing factors. To address the development of improved interventions for preterm labor, the development of improved animal models is necessary to answer specific questions concerning multiple factors, including but not limited to environmental exposures.

### Summary of Working Group Discussion

Our ability to make progress against preterm birth must begin with a better understanding of the basic mechanisms underlying its etiology, including such factors as infection, abnormal implantation and placentation, and gene-environment interactions. To do so, we must take full advantage of advances in genomics, proteomics, and epigenetics and use advanced molecular techniques and systems biology that incorporate multidisciplinary approaches. We must also consider the full range of complex interacting variables and the various maternal and fetal predictors of perinatal morbidity and mortality. This process will entail developing better standards and definitions of perinatal morbidity measures. Success in research and clinically managing preterm birth means going beyond gestational age and improving a wide range of

perinatal outcomes. It will also require enhanced reporting and analysis of key epidemiologic data to inform the development of these measures.

We already know that multiple factors have contributed to the rise in preterm birth. These include a continuing rise in the number of multiple-fetal gestations and an increase in the number of late preterm births. Although the latter has been accompanied by a decline in fetal and neonatal deaths, surviving infants experience increased morbidity. The clinical problems that result in late preterm births are not well studied. Improved understanding will allow us to identify strategies to improve the clinical management of all pregnant women.

We also know that women who have already undergone a preterm birth are at greater risk for subsequent preterm birth, and much research has been conducted in this area. We need to build on this body of knowledge, solving unanswered questions and finding ways to effectively aggregate and bundle various combinations of different interventions. At the same time, we are limited in our ability to assess risk of adverse pregnancy outcome among nulliparous women. Development of biomarkers and predictive information for this group and for women of different races and ethnicities may help to reduce preterm births and improve other birth outcomes. The ultimate goal is to develop the knowledge needed to offer personalized, pathway-specific interventions and therapies.

### **Recommendations of Working Group**

The group recognizes that the designation of short-, mid-, and long-term goals does not equate to a prioritization of action items. Instead, it reflects practical considerations, feasibility, the temporal order in which certain actions must occur, and when the goals can be achieved. The most important research gap that needs to be addressed is our understanding of the mechanism(s) of preterm birth.

Researchers must carefully identify the causes of the rise in preterm birth, focusing on the etiology of late preterm births, the causes of multiple gestations and non-medically indicated preterm birth, and the intricate web of biological and behavioral factors that lead to health disparities in birth outcomes. Studies are also needed on the risks and benefits associated with indicated early- and late-preterm birth in terms of perinatal morbidity and mortality. To accomplish this understanding, researchers and clinicians need more accurate and consistent antenatal indicators of fetal maturity that can best be acquired by early ultrasound dating and through the development of novel techniques to assess fetal well-being. We also need to ensure full implementation of a timely and high-quality national vital records system, emphasizing key biomedical data that can be captured on the 2003 version of U.S. birth certificates.

We should build upon emerging clinical interventions, including better understanding of one of the most promising therapies to date—the use of 17 alpha-hydroxyprogesterone—as well as how various preconception (such as folic acid supplementation) and prenatal interventions can prevent preterm birth. The latter can be accomplished, in part, by testing various combinations of these and other clinical interventions to determine the effectiveness of the best adjuvant therapies.

The identification and development of improved biomarkers, taking advantage of the most advanced laboratory techniques, are key to predicting preterm birth. More advanced techniques also offer hope for determining maternal and fetal innate and acquired responses, which may trigger premature labor, and will help support studies relating preterm birth to other pregnancy

*Surgeon General's Conference on the Prevention of Preterm Birth*  
June 16-17, 2008

outcomes, such as stillbirth, intrauterine growth retardation, preeclampsia, congenital abnormalities, and abruption.

The shortage of scientists and physician-scientists is a major barrier to understanding and preventing preterm birth. There is a need to foster the training and development of researchers through novel and existing programs, including support for mentoring, bridging, and medical liability coverage.

The development and establishment of research aimed at a comprehensive understanding of the basic biomechanisms of preterm birth is an ongoing and critical goal. Genetic, epigenetic, and environmental interactions must all be considered. Multidisciplinary studies will be key in this effort and should include the study of aberrant peri-implantation events and placentation as well as other abnormalities related to preterm birth. Through the identification of accurate predictors of preterm birth, we will be able to develop more personalized interventions to address adverse pregnancy outcomes. This knowledge will be acquired not just by increasing our understanding of pathological processes but by pursuing a greater knowledge of the physiology of normal labor and delivery.

## EPIDEMIOLOGICAL RESEARCH

Co-Chairs: Michael S. Kramer, M.D., and Captain Eve M. Lackritz, M.D.

### Background

Preterm birth is the most frequent cause of infant death in the United States, accounting for more than one-third of all infant deaths. Preterm birth is also the leading cause of severe neurological disabilities, including cerebral palsy and developmental delay, in children and chronic respiratory disease. The preterm birth rate has been rising in recent decades, affecting 13 percent of all deliveries in the United States. Black women have nearly twice the risk of preterm birth compared with white women, regardless of socioeconomic status. The causes of preterm birth and its associated racial and ethnic disparities are multiple and not fully understood. Factors include narrow child spacing; poverty; young and advanced maternal age; psychological, physical, and social/neighborhood stress; changes in obstetrical practices; and multiple gestations, including those due to assisted reproductive technology (ART) and ovulation-inducing agents. Family history and history of prior preterm birth are strong predictors of preterm birth risk, as are infection, inflammation, and preeclampsia. Many other factors remain poorly understood, such as the contribution of pollutants, micronutrients, and psychosocial stressors. Few clinical or public health interventions have been shown to be effective in preventing preterm birth. Smoking prevention and use of progesterone compounds (e.g., 17 alpha-hydroxyprogesterone caproate) have been shown to prevent preterm birth among some populations, though the anticipated impact on a population level is less clear.

### Current Status

The Institute of Medicine (IOM) report *Preterm Birth: Causes, Consequences, and Prevention* called for advancing a comprehensive prevention research agenda addressing, in an integrated fashion, the multiple clinical, social, biological, environmental, and behavioral factors that contribute to the risk of preterm birth and to racial disparities. The report recommended the use of ultrasound early in pregnancy to improve estimates of gestational age, in combination with improved prenatal and postnatal measures of fetal/neonatal maturity. The need for improved epidemiologic data, linked to etiologic investigations of preterm birth, was identified as crucial for understanding the causes of preterm birth, identifying women at risk, and evaluating methods for prevention. Although population-based data are essential for monitoring levels and trends, more detailed data studies are needed to understand the burden of preterm birth and to evaluate contributing factors such as infertility treatments; obstetrical practices and decision-making; maternal, paternal, and infant biomarkers; environmental factors; and categories of the types of preterm delivery based on known or suspected causes.

### Summary of Working Group Discussions

The working group centered most of its discussion on the types of epidemiologic research needed to understand the causes of preterm birth and possible strategies for prevention. Strengthening vital records systems was identified as a national priority for tracking the problem of preterm birth. Resources are needed to assist states in adopting the new birth certificate and to improve data quality and analysis at the state and national levels. Improved training of hospital personnel is needed to improve quality and consistency of birth certificate data. The group agreed that use of ultrasound in the first trimester should be part of routine prenatal care. Professional organizations, such as the American College of Obstetricians and Gynecologists (ACOG), can be instrumental in encouraging their members to increase the use of first trimester ultrasound, coordinated with public and private payers. Research in the fields of engineering,

*Surgeon General's Conference on the Prevention of Preterm Birth*  
June 16-17, 2008

physical science, and biochemistry could further advance new methods for assessing gestational age and fetal maturation.

Epidemiologic research must address the heterogeneity of preterm birth and identify methods to characterize preterm births according to underlying causes. Traditional categories have focused on the major categories of spontaneous preterm birth: medically indicated, and preterm premature rupture of membranes (PPROM). Other categories should be considered based on the timing of the underlying causes (e.g., acute vs. chronic) and pathophysiologic pathways (e.g., inflammatory vs. vascular). The recent rise in late preterm birth rate received considerable discussion. Anecdotal reports suggest a shift in clinical decision making with improved neonatal outcomes of late preterm births, concerns of litigation, increases in elective cesarean sections, and other shifts in provider practices. However, data are not available to assess the role of clinical decision making or other reasons for the rise in late preterm birth.

The working group discussion emphasized the need for prospective cohort studies, population-based studies, and development of multidisciplinary research centers that investigate, in an integrated fashion, the epidemiologic, demographic, social, behavioral, nutritional, clinical, and biological factors that all affect risk of preterm birth. More studies are needed to understand the biology of parturition and preterm birth, to advance research on placental function as well as structure, and to integrate molecular techniques in the epidemiologic investigations of preterm birth, all linked to social and behavioral data. The study of genomics is important (i.e., maternal, paternal, and fetal), with improved understanding of gene function: transcriptomics, proteomics, metabolomics, epigenetics, and gene-gene and gene-environment interactions. Enhanced research infrastructure is needed to link to research and research training in smaller, community care settings. Data that track women's health during pregnancy, including pharmaceutical exposure, are currently limited and are often not linked to data from subsequent pregnancies. More research is also needed to evaluate clinical, social, and public health programs and policies aimed at the prevention of preterm birth.

Infertility treatments (including ART and ovulation stimulation) were identified as a preventable cause of multiple gestation and preterm birth. Epidemiologic studies are needed to evaluate the contribution of these interventions on preterm birth, the effects of single embryo transfer and reproductive health history on fertility and birth outcomes, and the public health impact of insurance coverage for fertility treatment. The lack of data on the contribution of medical ovulation stimulation and preterm birth was identified as an important research gap.

The study of the causes and prevention of racial and ethnic disparities in preterm birth was identified as an immediate priority area of epidemiologic research. Multiple issues were emphasized, including effects of the physical environment, social environment, access and quality of care, cultural perceptions, gene-environment interactions, access to healthy diet, racial differences in clinical management; acculturation of immigrants, program evaluation, behavioral risk factors, and the interactions of infection, inflammation, stress, and vascular pathology. In addition, validated measures of racism, health care biases, and related stress are needed. A multidisciplinary approach was highlighted as a critical element to understanding and reducing racial and ethnic disparities.

**Recommendations of Working Group**

Human and financial resources to advance epidemiologic research in the causes and prevention of preterm birth are urgently needed. Improved vital records that include data from first trimester ultrasound are fundamental to understanding the epidemiology of preterm birth. However, collecting better data is not sufficient; human and financial resources are also needed to analyze, interpret, and report that data to researchers and policy makers.

In recognition of the heterogeneity of preterm birth, the working group recommends that the scientific community study the differential outcomes of preterm birth by cause. Emphasis was placed on epidemiological research that addresses clinical, biological, social, genetic, and behavioral factors simultaneously. More research also is needed on the impact of various types of infertility treatments and to evaluate programs aimed at decreasing multiple gestation rates. In addition, research was recommended to better understand the growing incidence of medically indicated late preterm births and the professional and individual decision-making processes that precede them (including the possible role of racism in that process). Research in racial and ethnic disparities was identified as a priority, again with an emphasis on a multidisciplinary approach.

## PSYCHOSOCIAL AND BEHAVIORAL CONSIDERATIONS

Co-Chairs: Dawn Misra, Ph.D., and Lynne Messer, Ph.D.

### Background

The complex nature of preterm birth led the Institute of Medicine (IOM) Committee on Understanding Premature Birth and Assuring Healthy Outcomes to consider multiple potential causes in an integrated manner and across the life course. The powerful and complex interactions among risk factors have been understudied. The Committee specifically considered frameworks that encompass a broad range of psychosocial and behavioral factors, linking these to preterm birth. Psychosocial and behavioral factors are not hypothesized to influence preterm birth alone, but rather are proposed as possible mediators or moderators of biomedical determinants of preterm birth. Furthermore, psychosocial and behavioral factors may contribute substantially to racial, ethnic, and socioeconomic disparities in preterm birth. These risk factors often occur simultaneously and are more frequent among more vulnerable populations.

### Current Status

The IOM report *Preterm Birth: Causes, Consequences, and Prevention* summarized the evidence on a wide range of psychosocial and behavioral risk factors, calling for research on both individual behavioral risk factors as well as multiple, interconnected risk factors to be studied across the life course. One critical cross-cutting topic is racism, which is largely considered a psychosocial stressor, but may function more potently through its socioeconomic consequences. Moreover, the importance of experiences and exposures *prior to conception* was highlighted by the IOM with regard to all risk factors, including psychosocial and behavioral factors. The IOM recommended that studies consider multiple risk factors simultaneously. In particular, development and application of models, measures, analytic methods, study designs, and data sharing/pooling agreements were suggested to achieve progress in reducing preterm birth rates and related health disparities.

### Summary of Working Group Discussions

Participants with a wide range of expertise gathered to propose, discuss, and prioritize recommendations related to psychosocial and behavioral considerations in the prevention of preterm birth. Working group members were asked to contribute recommendations in four broad areas: substantive (e.g., specific psychosocial or behavioral factors), methods, interventions, and policy analysis. Participants were then asked to prioritize these recommendations within each area, and to then identify each recommendation as achievable within in a short-, mid-, or long-term time period.

## **Recommendations of Working Group**

### Key Issues:

- Needs identified in research, screening, and clinical care should be addressed in a timely fashion.
- Research and services for African Americans are a priority because they bear the highest burden of prematurity.
- Research on the effects of race, racism, and social injustice is a priority.

### Short-term Goals

- Develop a blue-ribbon panel for studying stress—including its definition, conceptualization, measurement, and biological correlates—in prematurity research.
- Invest in the collection and analysis of data that enable high-quality evaluation of existing large-scale intervention programs.
- Improve the measurement of psychosocial and behavioral risk factors.
  - Achieve consensus on gold standards of measurement for research.
  - Promote consistency in measures used for screening of these risk factors.
- Maximize use of existing data to better understand psychosocial and behavioral determinants of preterm birth.
- Analyze potential barriers to care for identification and management addressing psychosocial and behavioral risk factors.

### Mid-term Goals

- Determine what drives individual decision making on health behaviors along the life course and develop interventions that target that decision-making process.
- Promote community-based participatory research on preterm birth, utilizing both qualitative (e.g., ethnography) and quantitative research methods.
- Promote research on nutrition and physical activity interventions.
- Improve screening for psychosocial risks and responses.
  - Set gold standards for reliable, consistent screening.
  - Address identified needs.
  - Include high-risk sub-populations.

### Long-term Goals

- Shift from a risk-based approach to an assets-based approach to identify protective factors that mediate and alleviate stress and other factors in the pathway to preterm birth.
- Develop methods to study preterm birth across the life course in a multiple-determinants framework.
  - Better data infrastructure for longitudinal studies, whether across a woman's reproductive "career" or across generations
  - Improve measurement, including methods to assess cumulative and clustered exposures
  - Promote study of interactions
  - Develop statistical techniques that test causal pathways
  - Identify mechanisms for sharing/linkage of neighborhood- and individual-level data
- Promote research on interventions that go beyond the mother to target the family and/or community, especially fathers, to address psychosocial and behavioral risk factors.

*Surgeon General's Conference on the Prevention of Preterm Birth*  
June 16-17, 2008

Final Thoughts

- Multiple working groups produced several identical recommendations (e.g., the need for quality, national-level data).
- The Surgeon General should give these recommendations extra weight when prioritizing actions for implementation.

## PROFESSIONAL EDUCATION AND TRAINING

Co-Chairs: Hal C. Lawrence, III, M.D., and Carolyn Aoyama, C.N.M., M.P.H.

### Background

Fewer medical students are choosing to specialize in obstetrical/gynecological care, and of those, even fewer are choosing careers in research. To address this problem, both the public (NIH) and private sectors have responded by establishing and supporting a range of programs to assist and train new and mid-career scientists and offer them sufficient reason to continue their research careers. Institutions, faced with paying liability insurance even for those clinical scientists who only conduct research a portion of their time, require those scientists to spend larger periods providing clinical care, which helps to provide greater funding. In addition, because no single definition exists or cause has been identified for preterm birth, clinicians must rely on their own experience to treat their patients, including sometimes prescribing needed drugs for pregnant women that have not been tested for use in pregnancy.

### Current Status

Because of a lack of data on the causes of and diagnostic markers for preterm birth, gaps exist in the education and training of all professionals who may be involved in preterm birth, including not only those clinicians who are conducting research, but also advanced practice professionals, nurses, social workers, and allied health professionals. Both research and training, some of it multidisciplinary, need to be conducted in the settings where pregnant women who are at risk for a preterm birth may be cared for, such as maternal and child health clinics. According to the Institute of Medicine (IOM) report *Preterm Birth: Causes, Consequences, and Prevention*, the lack of researchers who focus on this area is a major roadblock to progress. Even though some programs exist to assist researchers, more targeted career development programs were identified as being critical, as well as mentoring programs in both obstetrics/gynecology (ob/gyn) and pediatric departments, especially programs led by those researchers who have successfully received federal research funds. In addition, specific assistance with ethical concerns (e.g., balancing the interests of fetus and woman) and liability insurance were noted as being particular issues that must be addressed before the numbers of individuals interested in this area of research will increase. For the development of and collection of data on prescription drugs used by pregnant women, individuals who are trained in both basic science and clinical medicine are also essential.

### Summary of Working Group Discussions

Educating professionals includes enabling them to educate the public and patients. We need to begin by teaching what we now know with regard to preterm risks: maternal age, parity, prior preterm labor, multiple gestations, and behavioral (i.e., substance abuse/use, violence in patient's life) and psychosocial factors. Professionals should understand why preterm birth is an important problem. All types of clinicians must be knowledgeable about core preterm birth issues because patient contacts with pediatricians, cardiologists, pharmacists, dental professionals, and others represent prevention and intervention opportunities. Health sciences curricula should be targeted to the discipline. The curricula for the clinicians and public health professionals responsible for primary and reproductive health care will need to be more comprehensive.

Behavioral and addictions health care should be integrated into primary care for women so that these services are immediately available to patients. The community should be a source for

identifying the relevant issues that women are dealing with. For example, federally qualified health centers should be both sources of training content and sites for training. Training should incorporate social determinants of health. Statistics indicate that 84 percent of pregnant women initiate prenatal care in the first trimester, representing an important opportunity for early ultrasound dating.

### **Group Priorities for Provider Knowledge**

Core risk factors: history of preterm birth, short cervix, parity, maternal age, interconceptional interval, and co-morbidities (e.g., psychosocial, environmental, medical). Elective deliveries should not be performed before 39 weeks of gestation, consistent with American College of Obstetricians and Gynecologists (ACOG) clinical guidelines. Because not all preterm birth is preventable—it may be indicated to save the life and/or protect the health of the mother and/or baby—the human consequences of preterm birth, such as the heavy financial and emotional impact on families and the morbidity (short- and long-term) and mortality risk for the infant—must be communicated. Risk factors do not necessarily predict outcomes for individual patients. In addition, prenatal care has not been shown to prevent preterm birth; however, there is evidence that preconceptional and interconceptional care may reduce preterm birth risk. There are misconceptions outside of the ob/gyn community that preterm birth (especially late preterm) is not a major problem; therefore, content on preterm birth risks and the consequences of preterm birth needs to be included in the curricula of all medical specialties, as well as in training for allied health and public health professionals. Clinician training should incorporate a life-course perspective that emphasizes the different psychosocial behavior risk factors experienced by different groups. Providers should be trained to identify patients at risk. Clinical team education is also very important. For example, if no medical indication is evident, labor and delivery nurses should question inductions before 39 weeks of gestation. Accurate dating of gestational age is also essential. The National Quality Forum could be tied into education. Employment law is an issue because employers and employees want a certain date for delivery, and new parents want to maximize time with their newborn. Because various operative and other medical procedures may increase risk of preterm birth, basic and clinical research on the etiology of preterm birth are essential and outcomes of such research should direct practice.

### **Recommendations of Working Group**

**Short-term Goals—Who should be taught:** All health professionals, including but not limited to physicians, dental professionals, pharmacists, nurses and advance practice nurses, physician assistants, teachers, social workers, nutritionists, health educators, etc., with more detailed content for those in ob/gyn, family practice, pediatrics, midwifery, nurse practitioners, physician assistants, and obstetric nursing. **What should be taught:** Core factors, including: only medically indicated deliveries before 39 weeks of gestation; outcomes for infants born before  $\leq 38$  weeks of gestation (financial, emotional, family and societal costs); risk factors (medical, psychosocial, demographic/racial, social determinants) for preterm delivery, including efforts to explain the difference between a risk factor and predictor for an individual patient; importance of preconceptional and interconceptional care (including ongoing wellness care/primary care plus specifics that deal with pregnancy); methods of translating evidence into practice. **How should it be taught:** Include in curricula for all health professions (more detailed content for those in ob/gyn, family practice, pediatrics, midwifery, nurse practitioners, physician assistants, and obstetric nursing). Provide online training (possibly using existing programs, such as the March of Dimes). Encourage organizations and government agencies to develop and disseminate educational programs and materials and to conduct and incorporate ongoing evaluation. Conduct continuing medical education and training through professional organizations. Identify key stakeholders who can promote the importance of knowledge about

*Surgeon General's Conference on the Prevention of Preterm Birth*  
June 16-17, 2008

preterm labor/birth to other specialties/disciplines. Use clinical sites for educational opportunities.

**Mid-term Goals—Who should be taught:** All health care professionals and professionals who educate the public (see audiences listed earlier); elected officials, hospital administrators, policy makers, higher education leaders, business community, insurance providers. **What should be taught:** New research findings (integrate them into curricula); skills related to promoting health literacy as part of behavioral change; preterm birth state of the science; ways to discuss a reproductive life plan with both women and men (to decrease the incidence of childbearing at the extremes of reproductive age); and awareness of the need to have psychosocial/behavioral health services immediately available to perinatal and women's health care providers and their patients and to have those services supported by health care funders. **How should it be taught:** Encourage professional organizations to inform policy makers of core issues in preterm birth and on the impacts of curricular and policy changes. Monitor incorporation of evidence-based knowledge by linking evidence-based management of preterm labor to certification, re-certification, and Maintenance of Certification. Convene a follow-up conference(s) on the state of the science of preterm delivery.

**Long-term Goals:** Ensure ongoing educational efforts for all levels of health care providers (assuming that curriculum goals will be fully implemented, and new research will have been included in curricula). Conduct research to document change in preterm delivery rates, especially late preterm deliveries. Develop an integrated, interdisciplinary, evidence-based model of care that addresses medical and social issues and health disparities. Identify the core etiologies of preterm labor, and incorporate this research into training and practice. Ensure that all health care professionals practice patient-centered care incorporating a life-course perspective that emphasizes the different psychosocial/behavioral risk experienced by different groups. (These goals assume that research will have identified a final common pathway for preterm birth.)

## **PUBLIC COMMUNICATIONS AND OUTREACH**

Co-Chairs: Nelson Adams, M.D., and George Strait, M.S.

### **Background**

The Institute of Medicine (IOM), for its report on preterm birth, *Preterm Birth: Causes, Consequences, and Prevention*, conducted a detailed cost analysis of both the immediate and outyear costs for the most common outcomes. It found that the cost of preterm birth in the United States was \$26.2 billion in 2005, or \$51,600 per infant born preterm that year. Ongoing societal costs include special medical care, early intervention programs, and special education. Combined with the less quantifiable social and emotional costs of the consequences of preterm birth, the resulting burden to individuals, families, and society offers researchers a good incentive to find ways to prevent preterm birth. In turn, families who experience preterm birth may be facing these emotional and economic burdens without having the most up-to-date information available to them.

### **Current Status**

The IOM report identified many potential audiences who should be aware of the most recent information and research findings on preterm birth, including women of reproductive age and their families, health care providers, medical/health institutions, and policy makers (both government and non-government). Gaps in available evidence-based information warrant further investigation to quantify the economic consequences of preterm birth, because the long-term medical, educational, and productivity costs borne by individuals, families, and society are not well understood. In addition, because preterm birth occurs disproportionately in lower socioeconomic populations, who are largely served by public programs and hospitals, the costs to the general public are substantial, a fact that is often not appreciated. In addition, research needs to address the distribution of costs by gestational age and across public and private payers. Communication mechanisms to inform all relevant audiences are not fully in place, so as new information on the development of the impact of healthy lifestyles, preventive measures, interventions, and treatments becomes available, it is not being disseminated as quickly as it could be.

### **Summary of Working Group Discussion**

The chair charged the group to craft messages and develop community outreach programs that will promote the prevention of preterm birth. These messages and programs must be clear and understandable and received by various publics in a way that will ultimately motivate a behavior change. A set of three principles guided the discussion: (1) Translating of knowledge and new information into clinical practice and public health practices; (2) Maintaining a strong foundation in science; and (3) Encouraging the participation of partner organizations in message dissemination. Next, the group set out to identify who will be the intended publics for which the messages will be crafted. Once the audiences are identified, the messages can be tailored so that they will have the most impact on behavior.

When thinking about what messages need to be communicated, there were some general core themes that emerged. There is a lack of awareness of risk among most women. Therefore, there is a need to communicate that risk in terms of poignant statistics or percentages that will resonate with the intended audiences. There is also not a clear understanding that "building a human being" during pregnancy is a very complex and elaborate process that is most successfully done over a 40-week or nine-month period. In light of these themes, it was decided

that there is a need to communicate the critical importance of actions such as maintaining a healthy lifestyle and seeking early prenatal care; conversely, there are negative effects on maternal and fetal outcomes when these things are not done.

There were also some over-arching themes discussed about what should be done to tailor messages to appeal to discrete audiences. The idea of increasing awareness and the adoption of best practices are important messages for health care providers. The significant disparity that exists in the incidence of premature birth highlights the need for all messages to be culturally sensitive. Also, for those women who are in the at-risk groups, the working group recommended a message of empowerment that they can take actions such as preconception care, family planning, and early prenatal care to reduce their risk. In order for messages to have the greatest impact, health care systems, non-health care entities, and policymakers must also be involved in every aspect of reaching various publics. Several themes were identified that would best speak to these audiences, including the cost of care for preterm infants versus the savings with prevention efforts, the increasing prevalence of preterm birth despite current best efforts, and an awareness of the impact that preterm birth has on the entire community.

Once the messages are crafted, the effective dissemination of those messages must be timely and distributed in a way that achieves the best outreach efforts. The group believed that it was important to identify partners who work together to achieve cohesive outreach efforts. These groups include federal agencies (i.e., Centers for Disease Control and Prevention, Health Resources and Services Administration), professional societies (i.e., American Academy of Pediatrics, American College of Obstetricians and Gynecologists, National Medical Association, National Hispanic Medical Association, American Medical Association), patient advocacy and voluntary groups (i.e., March of Dimes), and private groups (i.e., sororities, fraternities). The media can also be viewed as a partner in outreach activities; however, media do not always reflect the complete story of preterm birth in terms of the life-long morbidity and effects on the families. The group agreed that there is a great need to tell the complete story because most women want to know and because it is crucial to raising awareness. The tools that can be employed to communicate messages include traditional media such as television, radio, and print; new media, such as Web tools; and social media, as well as finding the most appropriate person to deliver the message.

Finally, there must be a way to evaluate the communications strategy. Several ways were discussed for to do this, including surveys and Gallop polls. An initial screening survey could be used to help craft messages to ensure that they resonate with the intended audiences. There may even be research opportunities to discover what women know about pregnancy. The results of such studies can also aid in the crafting of an effective message.

### **Recommendations of Working Group**

The consensus of the group was that the center of the communications strategy for the prevention of preterm birth be a national education and action program to communicate what we know about preterm birth and how to reduce its incidence. This program would initially involve the high-risk population groups, which include patients with a history of preterm birth, ethnic and racial groups, and those patients with a low socioeconomic status. Partnerships that encourage collaboration and shared dissemination networks would be formed to help implement communication strategies, treatment plans, and best practices. Other products of the group would be an instrument that helps to an individual to understand her risk for preterm birth and culturally appropriate health literature that communicates the risk and consequences of preterm birth and the best practices to improve birth outcomes.

*Surgeon General's Conference on the Prevention of Preterm Birth*  
June 16-17, 2008

The strategy would also include the reactivation of the Interagency Coordinating Council on Prematurity and Low Birthweight and the establishment of a Surgeon General's Task Force on Preterm Birth. Through the task force, best practices and scientific knowledge can be communicated. It can also identify opportunities for future research and public outreach priorities at periodic intervals.

## QUALITY OF CARE AND HEALTH SERVICES

Co-Chairs: Susan Allan, M.D., J.D., M.P.H., and Denise Dougherty, Ph.D.

### Background

The societal burden of preterm birth is heavy, 75 percent of perinatal mortality and half of the cases of permanent neurological morbidity. The estimated monetary cost of preterm birth in the United States annually is \$26.2 billion. Health disparities remain significant: African American women are twice as likely to deliver infants at less than 37 weeks of gestation as women of other races. Many strides have been made in obstetrical care, often making it possible to delay labor long enough for the pregnant woman in preterm labor to be transported to a more appropriate care setting, and for the delivery of antenatal steroids to allow for maximum fetal lung maturity. Nonetheless, the incidence of preterm birth remains static.

### Current Status

The Institute of Medicine (IOM) report *Preterm Birth: Causes, Consequences, and Prevention* identified many clinical gaps needing attention before preterm birth can be adequately prevented or treated. Basic research to develop biomarkers in order to accurately identify those women at risk for preterm labor and therapies to prevent it was among the most urgent needs. Currently, no sequence of assessment measures exists to accurately predict preterm labor in women at increased risk (those with a prior preterm birth, race or ethnicity with a higher incidence, or physical measure such as a shortened cervix). The development of these measures may warrant a revision in the content and structure of prenatal care to include an assessment for and potential prevention of preterm birth, along with other conditions currently assessed. Once better prevention and intervention are available, incentives encouraging health care providers to reduce preterm births could be considered.

### Summary of Working Group Discussions

The working group addressed the following issues: economic consequences of preterm birth; impact of the health care delivery system on preterm birth; research that will inform public policy; and Medicaid, State Children's health Insurance Program (SCHIP), Medicare, and private insurance. In exploring the role of health services research and quality, the group agreed that its guidelines for development of recommendations would be: evidence based, actionable, strategic, systems based, and bold. The general principles to be applied included: that all care be family centered, including care coordination and support services. Care and treatment should be equitable and individualized for individual and community. Working group members agreed to an approach that looks for the following attributes from health care systems. Health care systems and practitioners should implement practices that are known to be effective and the care of women prior to and during pregnancy should be consistent across populations. Health care systems should collect data about the quality of patient care and services provided. Information collected should inform measure development and be added to existing and emerging databases for research purposes. Health care systems and practitioners should participate in clinical research and be prepared to translate new biomedical knowledge and technology, and funding should promote better outcomes, quality processes, and research.

## Recommendations of Working Group

### *Recommendation #1: National Priority*

Make prevention of preterm delivery, management of preterm labor, and care of preterm infants and their families a national health priority, with a focus on the following items: access, financing, research, and quality measures. Federal, state, and local agencies should make this a programmatic priority and coordinate across sub-agencies and agencies.

### *Recommendation #2: Access*

The health system should assure access to appropriate preventive and intervention measures for all women of reproductive age and infants. These should include: access to health care coverage and care for all women of childbearing age; preconception, interconception, and early prenatal care; and access to health care coverage and care for all children.

### *Recommendation #3: Payment*

Payers for health services should align with recommended clinical practice, including private health insurance, Medicaid, SCHIP, Medicare, and other publicly supported programs. Reimbursement needs to include equity in reimbursement.

### *Recommendation #4: Quality/Accountability*

Quality measures related to prevention and management of preterm birth should be developed and implemented for systems of clinical care. Preconception and interconception care for high-risk patients, assessment, discharge, referral and home-based care, neonatal intensive care units (NICUs). Health care delivery systems should implement processes for tools. Accountability measures to utilize appropriate clinical practice for providers.

### *Specific clinical practices for which there is sufficient evidence*

Smoking cessation has been demonstrated to reduce risk for preterm delivery. A sonogram in early pregnancy to determine gestational age improves information for clinical management. Reproductive endocrinologists and practitioners engaged in fertility treatment should reduce frequency of multi-fetal gestation. Implement the longstanding American College of Obstetricians and Gynecologists (ACOG) guideline (since 1999) to avoid elective inductions or C-sections prior to 39 weeks of gestation unless there is documentation of fetal lung maturity. Ensure that preterm infants or high-risk pregnant women have access to appropriate level of NICU services.

### *Recommendation #5: Gestational Age*

Prematurity as determined by gestational age should be a major focus for clinical and research investigation. Gestational age should be determined by an accurate method in the first trimester. Gestational age, in addition to birth weight, should be included in all reporting systems that collect health data about infants, children, and pregnancy status and outcomes.

### *Recommendation #6: Data*

Convene appropriate group to identify common data elements with definitions to be used in all health reporting systems. Sustain, expand, enhance, and link data and surveillance systems. Use health care data to conduct and inform clinical research.

*Surgeon General's Conference on the Prevention of Preterm Birth*  
June 16-17, 2008

*Recommendation #7: Health Services Research*

Include assessment of long-term morbidity, mortality, and quality of life to inform policy. The National Children's Study is a potential data resource. Remove malpractice insurance costs as a barrier to research. Increase resources for transdisciplinary, collaborative research mechanisms, research mission and mentoring.

*Recommendation #8: Economic Evaluation*

Collect primary data and link databases for analyses of medical and non-medical costs and family consequences, both economic and non-economic. Utilize appropriate economic evaluation methods for preterm interventions, including return on investment and cost-effectiveness analyses.

*Recommendation #9: Healthy People 2020*

Healthy People 2020 objectives should include at least the following related to preterm birth: increase gestational age reporting on the birth certificate, and specifically set and publish goals to reduce the frequency of preterm birth and reduce morbidity and mortality from preterm birth.

## **CONCLUSION: CROSS-CUTTING ISSUES**

Alan Fleischman, M.D.

All working groups agreed that there were several cross-cutting issues critical to the proposed action plan to prevent preterm birth. First, the need for the acquisition of new knowledge through the establishment of a national agenda for research to:

- Conduct basic research to understand the mechanisms of preterm birth;
- Implement and evaluate a spectrum of evidence-based interventions implying multi- and trans-disciplinary approaches and encouraging community engagement; and
- Establish a continuum of quality assessment through the development of quality measures; data collection; and provider-, hospital-, and system-based levels of accountability.

Second, there is a need for surveillance data. A national vital record system to provide accurate, timely, and consistent information is required in order to identify opportunities for effective interventions. In addition, the collection of data regarding the use and outcomes of assisted reproductive technologies (ART) and ovulation induction practices is required to optimize recommendations and quality improvement approaches for achieving singleton pregnancies.

Third, in order to decrease health disparities and move toward achieving equity in health outcomes, we need to ensure that there is an alignment of payment with evidence-based practice within the public and private sectors of health care systems. This should include providing long-term follow-up services and support for affected patients and families.

Finally, the establishment of an inter-agency coordinating council on prematurity is critical in order to implement the proposed action plan from this conference. The charge to the coordinating council should be to monitor and report on the progress of the implementation of the action plan and disseminate research findings and effective interventions to ultimately reduce preterm birth.