



Testimony of

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Prematurity and Infant Mortality: What Happens When Babies Are Born Too Early?

Before the House Committee on Energy and Commerce

Subcommittee on Health

Thank you, Chairman Pallone, for holding today's important hearing and inviting testimony from the American Congress of Obstetricians and Gynecologists (ACOG). My name is Dr. Hal Lawrence. I am an obstetrician-gynecologist and ACOG's Vice President of Practice Activities. I am here today representing 53,000 physicians and partners in women's health care and it is my pleasure to offer this statement to the House Committee on Energy and Commerce, Subcommittee on Health on the issues of prematurity and infant mortality.

With the passage of health reform, this is a very good time to examine what more we can do to reduce prematurity and infant mortality rates in the U.S. We look forward to working closely with you, Mr. Chairman, and Members of the Subcommittee on a variety of measures to get us to that goal.

Preterm birth is the leading cause of neonatal mortality in the United States, and accounts for approximately 35% of all U.S. health care spending for infants and 10% for children. According to preliminary 2008 NCHS data, over half a million babies were born preterm representing 12.3% of all live births occur before term in the United States. About two-thirds of all infant deaths are among preterm infants. Slightly more than one-third of which are officially designated preterm-related, i.e., there is sufficient information recorded to ascribe being born preterm as the fundamental contributor to death.

Preterm birth is one of the most complicated and difficult issues in obstetrics. As a Nation, we still don't know very much about the causes of preterm labor. We do know, though, that the rate of preterm births in the United States is a growing public health problem that cuts across social, racial, ethnic, and economic groups. We know that preterm labor is the most common cause of antenatal (before birth) hospitalization. And we know that there is a link between preterm birth and infant mortality.

Unique among all health events, infant death is always viewed as a measure of a community's social and economic well-being, as well as its health. It is also a measure of the organization and capability of a community's health services and community resources. Often infant deaths leave families and communities with few answers, asking: "Can anything be done to prevent this in the future?"

ACOG firmly believes that the answer is a resounding yes, we can make a difference in the future. ACOG will continue its long history of leadership and collaboration with other stakeholders to make this happen.

This year, ACOG President Dr. Gerald F. Joseph, Jr. launched the Making Obstetrics and Maternity Safer (MOMS) Initiative, a multi-pronged campaign to improve maternal and infant outcomes by filling the glaring gaps in research and understanding. ACOG's clinical guidelines that help shape maternity care in America are based on evidenced-based, peer-reviewed science and expert opinion. Our guidelines are limited, though, to clinical areas that have been well-researched. Where the research has not been conducted, clinical guidelines have to wait. **Congress has a unique opportunity to fund research that will provide the underpinnings for our guidance for practicing ob-gyns and other maternity care providers.**

PRETERM BIRTH

In most pregnancies, labor starts between 37 and 42 weeks gestation. Labor before 37 weeks gestation is considered preterm. According to preliminary 2008 data from the National Center for Health Statistics (NCHS), approximately 12.3% of babies born in the United States are born preterm and these preterm births account for most newborn deaths.

Growth and development in the last part of pregnancy are vital to the baby's health. In fact, the earlier a baby is born, the greater the chance he or she will have health problems. Babies born preterm tend to grow more slowly than babies born at term, and often have problems with their eyes, ears, breathing, and nervous system; and experience learning and behavioral problems.

While preterm labor can occur in any pregnancy without warning, we know that some women are at greater risk. Obese women, women who have little or no prenatal care and those who have had preterm labor before are at increased risk. So are women for whom too much amniotic fluid is in the sac that surrounds the baby. Problems with the placenta or birth defects also increase the risk. Certain health factors may be linked to an increased risk for preterm birth, including short cervical length or maternal developmental abnormalities, which are structural abnormalities of the uterus. However, for many women preterm labor occurs without a known cause.

There are medical reasons why the baby is better off being born, even if it is early, including maternal infection, high blood pressure, bleeding, or signs that the fetus is having problems. Sometimes preterm labor may be too far along to be stopped. Preterm babies may need to be cared for in a neonatal intensive care unit (NICU) for weeks or even months.

Women at risk for preterm labor can help reduce their risks by refraining from smoking or abusing drugs. Assuring safe environments to protect women from intimate partner violence is also important. Healthy habits also help ensure healthy pregnancies, including eating healthy food, not skipping meals, and following the doctor's advice.

ACOG'S CLINICAL GUIDELINES

ACOG is the nationally recognized source for developing clinical guidelines and communicating technical and scientific information for our specialty of women's health and obstetrics and gynecology. In a recent membership survey, ACOG found that nearly 98% of respondents were aware of ACOG guidelines, and 96% of respondents reported that they had used those guidelines over the previous five years. Sixty-one percent responded that an ACOG publication or guideline changed their practice within the last two years. ACOG Practice Bulletins were ranked first by ACOG Fellows, followed by ACOG Committee Opinions, as the sources used most often to stay informed about advances in research, practice trends, and ethics in obstetrics and gynecology.

ACOG issues guidelines and recommendations for obstetric-gynecologic practice in four primary vehicles: Committee Opinions, Practice Bulletins, Guidelines, books and reports. We develop our recommendations and guidelines through a rigorous peer review and approval process, utilizing standing committees or special task forces composed of experts in the field that

continually examine and update existing guidelines for clinical practice based on the most up-to-date scientific and medical literature, as well as expert opinion where data are lacking. Representatives from many related specialty societies, voluntary organizations, and federal agencies also serve on our committees and work groups.

ACOG has a number of Committee Opinions and Practice Bulletins addressing premature births, bulleted and summarized here.

- Late-Preterm Births

Late-preterm births, defined as deliveries after 34 and before 37 weeks, make up 71% of all preterm births. Late-preterm infants are at higher risk of developing medical complications, resulting in higher rates of infant mortality, morbidity before initial hospital discharge, and hospital readmission in the first months of life. Late-preterm infants are 4 times more likely than term infants to have at least 1 medical condition and 3.5 times more likely to have 2 or more conditions. The neonatal mortality rate (deaths among infants 0–27 days chronologic age) for late-preterm infants is much higher than the rate for term infants.

ACOG is very clear that deliveries before 39 weeks gestation should occur only when an accepted medical maternal or fetal indication for delivery exists.

- Management of Preterm Labor

It is important to recognize that preterm labor is not the only mechanism leading to preterm birth; numerous preterm births are preceded by rupture of membranes or other medical problems. In fact, 80% of women with presumptive preterm labor do not progress to preterm delivery.

A physician's ability to determine the risk of preterm delivery with clinical accuracy is seriously hampered by the large variations in symptoms of preterm labor and the inability of our current clinical tools to precisely determine a woman's risk. In earlier days, when a patient had symptoms of preterm delivery, her doctor was likely to handle this uncertainty by recommending an abundance of caution, including reduced maternal activity and administering fluids with the aim of stopping the uterine activity. Many of these early interventions have proven to be ineffective.

- Assessment of Risk Factors for Preterm Birth

The functional changes that trigger preterm labor are largely unknown but may include decidual hemorrhage (abruption), mechanical factors (uterine overdistention or cervical incompetence), and hormonal changes, perhaps mediated by fetal or maternal stress.

Risk factors for preterm birth include demographic characteristics, behavioral factors, and aspects of obstetric history. Despite the identification of a number of risk factors, attempts to determine the risk of preterm delivery based on historic and epidemiologic risk scoring systems have been unable to reliably identify women who will give birth preterm. **The ability to predict**

whether a woman is at risk of preterm delivery has value only if an intervention is available that is likely to improve the outcome.

- Obesity in Pregnancy

The prevalence of obesity in the United States has increased dramatically over the past 20 years to the point where, today, one third of adult women are obese. During pregnancy, obese women are at increased risk for several adverse outcomes, including complications related to anesthesia and necessary surgical procedures. Multiple studies have shown that maternal obesity and excessive weight gain during pregnancy are associated with large-for-gestational-age infants who are at increased risk for childhood obesity.

Studies consistently report higher rates of preeclampsia, gestational diabetes, and cesarean delivery for failure to progress in obese women. **Some studies have reported a greater rate of premature delivery for obese women.** Operative and postoperative complications include increased rates of excessive blood loss, operative time greater than 2 hours, wound infection, and endometritis. Surgery in obese women poses anesthetic challenges, such as difficult epidural and spinal placement requiring multiple attempts and intraoperative respiratory events from failed or difficult intubation. Sleep apnea may further complicate anesthetic management and postoperative care for these women.

Obese women who require cesarean delivery are more likely to have an increased incidence of wound breakdowns and infections. Because of the increased likelihood of complicated and emergency cesarean delivery, extremely obese women may require additional blood products, a special operating table, and extra personnel in the delivery room. The success rate of attempted vaginal birth after cesarean delivery is very low in extremely obese women.

- Use of Progesterone to Reduce Preterm Birth

Progesterone is one strategy to reduce pre-term birth. **However, based on current knowledge, it is important to offer progesterone for pregnancy prolongation to only women with a documented history of a previous spontaneous birth at less than 37 weeks of gestation.**

Progesterone supplementation for the prevention of recurrent preterm birth should be offered to women who are carrying only one fetus, not multiples, and who have had a prior spontaneous preterm birth due to spontaneous preterm labor or premature rupture of membranes. Current evidence does not support the routine use of progesterone in women with multiple gestations. Progesterone supplementation may be considered for women with an identified very short cervical length (less than 15 mm) but who have no other symptoms.

ACOG's Committee on Obstetric Practice and the Society for Maternal Fetal Medicine believe that further studies are needed to determine if progesterone therapy can be designed to help prevent preterm delivery in other ways, including optimal preparation, dosage, and route of administration.

CLINICAL and RESEARCH GAPS IN KNOWLEDGE IDENTIFIED

ACOG supported and was intricately involved in the two most recent major initiatives to examine the issue of preterm birth; the Institute of Medicine's (IOM) Report Preterm Birth – Causes, Consequences, and Prevention and the Surgeon General's Conference on the Prevention of Preterm Birth

Institute of Medicine's (IOM) Report Preterm Birth – Causes, Consequences, and Prevention

The Institute of Medicine's (IOM) 2006 Report, Preterm Birth – Causes, Consequences, and Prevention identifies a number of gaps in clinical knowledge. Upon review of the literature assessing the causes and consequences of preterm birth, the diagnosis and treatment of women at risk for preterm labor, and treatments for infants born preterm, the IOM proposed a research agenda for investigating the problem of preterm birth that is intended to help focus and direct research efforts.

The priority areas developed for research include the need to:

- Improve national data, including standardization of birth certificate reporting as advocated by ACOG;
- Study the economic outcomes for infants born preterm;
- Improve the methods of identifying and treating women at risk for preterm labor;
- Study the acute and the long-term outcomes for infants born preterm;
- Study infertility treatments and institute guidelines to reduce the number of multiple gestations;
- Improve the quality of care for women at risk for preterm labor and infants born preterm;
- Investigate the impact of the health care delivery system on preterm birth;
- Investigate the etiologies of preterm birth;
- Study the multiple psychosocial, behavioral, and environmental risk factors associated with preterm birth simultaneously; and
- Investigate racial-ethnic and socioeconomic disparities in the rates of preterm birth.

Surgeon General's Conference on the Prevention of Preterm Birth

To address the serious and seemingly intractable problem of preterm birth, the Surgeon General's 2008 Conference on the Prevention of Preterm Birth convened many of the country's experts from the public and private sectors of research, public health, and health care delivery to discuss preventive strategies.

With the support and participation of ACOG, the Conference adopted the following recommendations:

- Biomedical Research - A better understanding of the basic mechanisms underlying its etiology must be established, including the role of such factors as infection, inflammation, abnormal implantation and placentation, and gene-environment interactions.
- Epidemiological Research - Epidemiologic research must address the heterogeneity of preterm birth and identify methods to characterize preterm births according to underlying causes.

- Psychosocial and Behavioral Considerations - Research on the effects of race, racism, and social injustice for African Americans must be a priority as they bear the highest burden of prematurity.
- Professional Education and Training - The education and training of professionals on preterm birth should be comprehensive, targeted to the discipline, incorporate the social determinants of health, and provide skills enabling them to educate the public and patients.
- Public Communication and Outreach - Several potential audiences should be made aware of the most recent research findings on preterm birth, including women of reproductive age and their families, health care providers, medical/health institutions, and both government and nongovernment policymakers.
- Quality of Care and Health Services – The care and treatment of women before and during pregnancy should be equitable, individualized, and consistent across populations. Health care systems and practitioners should implement practices that are known to be effective and should collect data about the quality of patient care and services provided.

Specific Knowledge Gaps Identified by ACOG

In consideration of the broad recommendations from IOM, the Surgeon General’s Report, and the apparent knowledge gaps evidenced in ACOG’s clinical material, below are important specific gaps that could be addressed with additional research investments.

- Improved assessment tools are needed to address the large variations in symptoms of preterm labor and the inability of routine clinical tools to precisely determine a woman's risk;
- Evidenced-based research on interventions to delay or prevent preterm delivery;
- Comparison studies of the effectiveness of different drugs used to prevent or slow preterm labor and birth;
- Studies to evaluate the optimal preparation, dosage, route of administration, and other indications for the use of progesterone to prevent preterm delivery;
- Studies on the association of multiple gestations, i.e. twins, to the risk of preterm delivery;
- Studies on bacterial infections that have been associated with preterm labor to better understand if their effect and nature of association;
- Research and interventions to address the increased risk for poor outcomes in obese women; and
- Research into the disproportionately higher rate of preterm birth among African American women that cannot be accounted for by known risk factors.

ACOG’S MAKING OBSTETRICS AND MATERNITY SAFER (MOMS) INITIATIVE

Due the magnitude of the problem, it is essential that we address the issue in a comprehensive manner. We must make well-informed and targeted investments to help lower the rate of prematurity, and remember that the health of every baby starts with the health of its mother. For this reason, ACOG developed our MOMS Initiative, a legislative proposal to improve maternal and infant health outcomes through:

- Maternal/infant health research at the NIH to reduce the prevalence of premature births and to focus on obesity research, treatment, and prevention;

- Maternal/infant health research and surveillance at the CDC to assist states in setting up maternal mortality reviews; modernize state birth and death records systems to the 2003-recommended guidelines; and improve the Safe Motherhood Program to better understand maternal deaths;
- Maternal/infant health programs at HRSA to continue the Fetal and Infant Mortality Review (FIMR) which brings together local ob-gyns and health departments to solve a community's problems related to infant mortality; and improve the Maternal Child Health Block grant, the only federal program that exclusively focus on improving the health of mothers and children;
- Comparative effectiveness research into interventions for preterm birth;
- Disparities research into maternal outcomes, preterm birth and pregnancy-related depression;
- The development, testing and implementation of quality improvement measures and initiatives;
- The testing of an obstetric medical home model.

- Maternal Mortality Reviews

National data on maternal mortality is inconsistent and incomplete due to the lack of standardized reporting definitions and mechanisms. To capture the accurate number of maternal deaths and plan effective interventions, maternal mortality should be addressed through multiple, complementary strategies. CDC should fund states to implement maternal mortality reviews that would allow them to conduct regular reviews of all maternal deaths within the state to identify causes, factors in the communities, and strategies to address the issues. Maternal mortality reviews are now conducted in only 15 to 20 states. Combined with adoption of the recommended birth and death certificates in all states and territories, CDC could collect uniform data to calculate an accurate national maternal mortality rate. Results of maternal mortality reviews will inform research needed to identify evidence based interventions addressing causes and factors of maternal mortality and morbidity.

- Electronic Birth and Death Records

Currently, only 75 percent of states and territories use the standardized 2003 birth certificates and 65 percent have adopted the 2003 death certificate. The National Vital Statistics System (NVSS) needs federal support to help states and territories implement the 2003 birth certificate and modernizing their infrastructure to collect these data electronically to expand the scope and quality of data collected on a national basis. NVSS will need \$3 million to phase in the 2003 death certificate and electronic death records in all states and territories. CDC should work with the Centers for Medicare and Medicaid Services and the Office of the National Coordinator to pilot test the integration of electronic birth and death records and electronic medical records.

- National Fetal Infant Mortality Review

Since 1990, the Maternal Child Health Bureau has worked in cooperative agreement with ACOG to run the National Fetal Infant Mortality Review (NFIMR) program. NFIMR provides training and assistance to enhance cooperative partnerships among local community health professionals, public health officers, community advocates and consumers to reduce infant mortality. The goal

is to improve local services and resources for women, infants and families, to remove barriers to care, and to ensure culturally appropriate, family friendly services.

These efforts are crucial to understanding and addressing infant health disparities in communities at highest risk and are a component of many existing Healthy Start Initiatives. A rigorous national evaluation of FIMR conducted by Johns Hopkins University concluded that FIMR is an effective perinatal initiative. The Bureau should continue to use Healthy Start funds to support the NFIMR project and encourage all Healthy Start Programs to implement FIMR.

- Obesity Research, Treatment and Prevention

Obese pregnant women are at increased risk for poor maternal and neonatal outcomes. Additional research and interventions are needed to address the increased risk for poor outcomes in obese women receiving infertility treatment, the increased incidence of birth defects and stillbirths in obese pregnant women, ways to optimize outcomes for obese women who become pregnant after bariatric surgery, and their babies' increased risk of childhood obesity.

- Comparative Effectiveness Research into Preterm Birth and Pregnancy-Related Depression

Support for AHRQ's comparative effectiveness research initiatives is needed in order to better understand the range of interventions for preterm labor, such as different drugs and preventive tools in diverse patient populations. Research evaluating the efficacy of perinatal/postpartum screening tools and whether they can impact the outcome of pregnancy and perinatal depression is also needed.

- Health Disparities Research in Women

Women of racial and ethnic minorities face higher rates of diseases including obesity, cancer, diabetes, heart disease, and HIV/AIDS. There is also a disproportionately higher rate of preterm births among African American women that cannot be accounted for by known risk factors. HHS should conduct research into the causes of health disparities and develop and evaluate interventions to address these causes. Also, the continued and expanded collection of data capturing racial and ethnic information is essential in understanding and eliminating disparities.

- Safe Motherhood/Infant Health

Late-preterm births make up 71% of all preterm births. Funding should be directed to CDC to improve national data systems to track preterm birth rates and expand research that focuses on the causes and prevention of preterm births.

- Preterm Birth Research

According to preliminary NCHS data, over half a million babies were born preterm in 2008, representing 12.3% of live births. NICHD needs increased funding to expand its support of preterm birth research. Congress should help explore the feasibility of establishing integrated

research centers at NIH as recommended by the Institute of Medicine and the Surgeon General's Conference on the Prevention of Preterm Birth. Specifically, NICHD needs additional financial support for planning activities related to the establishment of Transdisciplinary Research Centers for Prematurity.

- Quality Improvement Measures and Initiatives

ACOG urges Congress and the Administration to support these efforts and assist in the dissemination and voluntary adoption of quality measures in both the Medicare and Medicaid programs. ACOG is currently engaged through the PCPI in development of maternity care quality measures. The PCPI process is the gold standard for national development, testing, and maintenance of scientific evidence-based clinical performance measures at the physician/clinician/group level, balanced with stakeholder engagement, public comment, and transparency and spearheaded by clinician ownership, accountability and professionalism. We look forward to maintaining and improving current measures, developing new clinical measures in other facets of obstetrical and gynecologic care and expanding national data collection and aggregation initiatives on all aspects of women's health care through both voluntary data registry participation for physicians and facilities and mandatory certification and accreditation programs like American Board of Obstetrics and Gynecology Maintenance of Certification and The Joint Commission.

- Obstetric Medical Home Model

The testing of a women's medical home, with particular attention to maternity care, is an important opportunity to facilitate the improvement of health outcomes in the United States and reduce duplicate and inappropriate utilization of services. Medical homes are rooted in the principle that care coordination, increasing health care access, patient-provider communication, and collaborative care are fundamental to improving patients' health. This delivery model has the potential to address the unique issues that arise during pregnancy and may be able to address troubling health disparities in certain populations of pregnant women. CMS should test a model in the Medicaid program, which finances approximately 42% of the nation's births.

OTHER ISSUES OF IMPORTANCE

Elective Inductions

In more than 22% of all pregnant women in the U.S. labor is induced, and the overall labor induction rate has more than doubled since 1990 to 225 per 1,000 live births in 2006. The goal of induction of labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. Induction has merit when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy. The benefits of labor induction must always be weighed against the potential maternal and fetal risks associated with this procedure.

ACOG stipulates that unless a medical indication exists, labor induction or a scheduled elective delivery should not be done before 39 weeks of pregnancy. Indications for induction of labor are not absolute, but should take into account maternal and fetal conditions, gestational

age, cervical status, and other factors. Following are examples of maternal or fetal conditions that may be indications for induction of labor:

- Abruptio placentae;
- Isoimmunization, i.e. Rh disease;
- Chorioamnionitis;
- Fetal demise;
- Gestational hypertension;
- Preeclampsia, eclampsia;
- Premature rupture of membranes;
- Postterm pregnancy;
- Maternal medical conditions (eg, diabetes mellitus, renal disease, chronic pulmonary disease, or chronic hypertension); and
- Fetal compromise (eg, severe fetal growth restriction or a deficiency in amniotic fluid.)

Labor also may be induced if the patient is at risk for very rapid labor, if she lives an unsafe long distance from the hospital, or if she has serious mental health indications. Even in these circumstances, at least one of the established gestational age criteria should be met or fetal lung maturity should be established. A mature fetal lung test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances, is not an indication for delivery.

The individual patient and clinical situation must always be considered in determining when induction of labor is indicated.

Maternal Caesarean Delivery Request

Cesarean delivery on maternal request is defined as a primary cesarean delivery requested by the patient in the absence of any medical or obstetric indication. ACOG is clear that **cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity**. Cesarean delivery on maternal request should not be motivated by the unavailability of effective pain management.

Cesarean delivery on maternal request is not recommended for women desiring several children, given that the risks of placenta previa, abnormal placental adherence, and the need for hysterectomy increase with each cesarean delivery. Other risks include a longer maternal hospital stay, an increased risk of respiratory problems for the baby, and greater complications in subsequent pregnancies, including uterine rupture and placental implantation problems.

Literature on elective cesarean delivery without labor shows that the risk of respiratory morbidity, including transient rapid breathing of the newborn, respiratory distress syndrome, and persistent pulmonary hypertension, is higher for elective cesarean delivery compared with vaginal delivery when delivery is earlier than 39–40 weeks of gestation. Because of these potential complications, cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity.

Babies can benefit, too, by medically indicated planned cesarean delivery. Benefits can include lower fetal mortality; lower newborn infection rate; reduced risk of intracranial hemorrhage diagnosis, neonatal asphyxia, and encephalopathy; and fewer birth injuries.

Further research is needed to get direct evidence for better counseling for women in the future. This includes surveys on cesarean delivery on maternal request, modification of birth certificates and Current Procedural Terminology coding to facilitate tracking, prospective cohort studies, database studies, and studies of modifiable risk factors for cesarean delivery on maternal request versus planned vaginal delivery. Short-term and long-term maternal and neonatal outcomes as well as cost need further study.

ACOG's Task Force on Cesarean Delivery Rates

In 1995, ACOG held a focus session to determine ways to reduce cesarean delivery rates. This focus session led to the appointment in 1997 of ACOG's Task Force on Cesarean Delivery Rates, which was convened to assess the factors that contribute to the cesarean delivery rate in the United States, review ways to reduce these rates, and develop guidance material for our members and other concerned institutions.

The Task Force was charged with assisting institutions and individual practitioners assess and, if appropriate, reduce their cesarean delivery rates. The Task Force developed the report entitled the *Evaluation of Cesarean Delivery*.

The factors that have contributed to the increased cesarean delivery rate in the United States over the last 25 years are not completely understood. The report showed a wide variation in cesarean delivery rates between practitioners, hospitals, and geographic regions of the United States, and between patient characteristics including payer type, socioeconomic status, ethnicity, and education. Aspects of physician practice, including solo versus group practice, employment status, in-house coverage, and education, also appear to be associated with variations in cesarean delivery rates.

From this research, it appears that the most dramatic increase in primary cesarean delivery rates was found in patients in their first pregnancy, with normal term single fetuses and with vertex presentations. It was not apparent, though, that higher cesarean delivery rates in these lower-risk patients result in improved outcomes. Accordingly, it would seem appropriate to focus on these patients when evaluating strategies for lowering the primary cesarean delivery rate.

Although cesarean delivery rate analysis may help obstetric institutions and practitioners adjust their practice patterns, cesarean delivery rates alone are not an indicator of quality. All practitioners have some patients in their practices who are at increased risk for needing to be delivered by cesarean, regardless of management practices. Therefore, unadjusted cesarean delivery rates cannot be used to assess the quality or appropriateness of individual institutions or obstetric practitioners. Cesarean delivery rates must be adjusted for case mix to have any value.

The following variables should be examined when cesarean deliveries are performed:

- Cervical dilatation was less than 4 cm;
- In the presence of intact membranes;
- Without appropriate use of oxytocin;
- After the patient has received an epidural when cervical dilatation was less than 4 c;
- After the patient has undergone elective induction of labor at less than 41 weeks of gestation;
- Without trial of labor for suspected macrosomia in nondiabetic women;
- For failed induction of labor for suspected macrosomia in nondiabetic women;
- For the sole indication of twin gestation; and
- For the indication of term fetuses with breech presentations, without offering external cephalic version.

Medical Liability

When addressing the issue of delivery rates, it is impossible to not also mention the medical liability problem that disproportionately targets obstetricians. Our Nation provides exceptional medical education, training some of the world's finest obstetricians and gynecologists. Yet, 90% of ACOG Fellows report they have been sued at least once. On average, ob-gyns are sued 2.7 times during their careers, and nearly 63% have made changes to their practice during the last three years because of the high risk of liability claims. 35% have either decreased the number of high-risk obstetric patients treated or have ceased providing obstetric care altogether; 29.1% reported increasing the number of cesarean deliveries; and 25.9% indicated they stopped performing or offering VBACs due to professional liability concerns.

In the world of childbirth, a “perfect” pregnancy can turn disastrous in a heartbeat, and through no fault or malpractice of the ob-gyn. Vaginal births after c-sections can seem perfectly normal until something goes wrong. At that moment, one and maybe two lives can be on the line and seconds count. It’s often in these scenarios that ob-gyns get sued and result in very large awards, regardless of the physician’s care. The risk is really that great.

A recent study conducted by staff from the Harvard School of Public Health and the Harvard Medical School for the Medicare Payment Advisory Commission showed caps on non-economic damages to be predictive of lower rates of cesarean delivery. Additionally, one study found that states with pretrial screening panels had significantly lower rates of cesarean delivery and higher rates of vaginal birth after cesarean delivery. Finally, another study of obstetrical practice found that joint-and-several liability reform led to decreased use of cesarean delivery and induction or stimulation of labor.

ACOG has for many years advocated reform of our broken medical liability system, including caps on non-economic damages, and other reforms like those found in Texas and California. We will continue to fight for those reforms on behalf of our specialty and our members. At the same time, we strongly support alternatives, including sorry works programs and health courts, that can help reduce the need for defensive medicine and improve patient safety.

ACOG highly recommends exploring ways to reduce rates of caesarean delivery through state and federal experimentation on medical liability reform. We urge Congress to assist states foster **meaningful** alternatives to current medical tort litigation that improve patient safety and quality

of care, provide fair and prompt compensation for medically-related injuries, restore fairness and reliability to the medical justice system, and reduce defensive medicine. These alternatives can include early offer programs, healthcare courts, voluntary alternative dispute resolution, and birth injury compensation funds.

RECOMMENDATIONS

ACOG's MOMS Initiative

ACOG strongly urges Congress to implement the MOMS Initiative to develop and apply evidence-based interventions, and improve maternal and infant health outcomes through funding research to:

- Reduce the prevalence of premature births;
- Focus on obesity research, treatment, and prevention.
- Assist states in setting up maternal mortality reviews;
- Modernize state birth and death records systems to the 2003-recommended guidelines;
- Improve the Safe Motherhood Program to better study pregnancy-related deaths.
- Continue the Fetal and Infant Mortality Review (FIMR);
- Improve the Maternal Child Health Block grant;
- Carry-out comparative effectiveness research into interventions for preterm birth;
- Perform disparities research into maternal outcomes, preterm birth and pregnancy-related depression;
- Test the obstetric medical home model
- Support quality improvement measures and initiatives

Institute of Medicine's (IOM) Report Preterm Birth – Causes, Consequences, and Prevention

ACOG supports the Institute of Medicine's (IOM) 2006 Report, Preterm Birth – Causes, Consequences, and Prevention report. The IOM proposed a research agenda for investigating the problem of preterm birth and is an essential guide for focusing and directing research efforts to:

- Improve national data;
- Study the economic outcomes for infants born preterm;
- Improve the methods of identifying and treating women at risk for preterm labor;
- Study the acute and the long-term outcomes for infants born preterm;
- Study infertility treatments and institute guidelines to reduce the number of multiple gestations;
- Improve the quality of care for women at risk for preterm labor and infants born preterm;
- Investigate the impact of the health care delivery system on preterm birth;
- Investigate the etiologies of preterm birth;
- Study the multiple psychosocial, behavioral, and environmental risk factors associated with preterm birth simultaneously; and
- Investigate racial-ethnic and socioeconomic disparities in the rates of preterm birth.

Surgeon General's Conference on the Prevention of Preterm Birth

ACOG supports the implementation of the following recommendations adopted by the Conference:

- Biomedical Research
- Epidemiological Research
- Psychosocial and Behavioral Considerations
- Professional Education and Training
- Public Communication and Outreach
- Quality of Care and Health Services

PREEMIE Act Reauthorization

ACOG is proud of its support of the 2006 passage of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Act. This legislation was passed unanimously by the House and Senate and signed into law to help identify the causes of prematurity and reduce the episodes of preterm labor and delivery.

With the reauthorization of the PREEMIE Act nearing, ACOG strongly urges Congress to swiftly take up the issue and we look forward to working with you to perfect the reauthorization language.

Medical Liability

ACOG highly recommends exploring ways to reduce rates of caesarean delivery through state and federal experimentation of medical liability reform alternatives. These efforts should include as early offer programs, healthcare courts, voluntary alternative dispute resolution, and birth injury compensation funds, as well as caps on non-economic damages and other reforms like those found in Texas and California law.

Thank you again for the opportunity to provide this statement to the House Committee on Energy and Commerce, Subcommittee on Health on the issues of prematurity and infant mortality. We applaud your commitment and leadership on this issue, Chairman Pallone, and look forward to working closely with you and the Subcommittee.

Appendix

**The American Congress of Obstetricians and Gynecologists' (ACOG's)
Making Obstetrics and Maternity Safer (MOMS) Initiative**

Pregnancy and childbirth is a joyous and safe experience for the majority of mothers in the United States, and ob-gyns play the leading role in delivering this care. Yet the US lags behind other industrialized nations in healthy births, and we know very little about why. While the recently enacted health care reform law will expand access to prenatal care - an essential component to improving birth outcomes - research is critically needed to understand how we can drive down our maternal and infant mortality and prematurity rates. Effective research based on comprehensive data is a key to developing, testing and implementing evidence-based interventions

ACOG is committed to leading this improvement as part of our imperative to make motherhood as safe as possible. Congress and the federal government have important roles to play by helping fund major research initiatives to help us understand the links and effective strategies to help ensure safe births and healthy babies. **ACOG's MOMS Initiative** is a multi-pronged approach that will help the U.S. develop and implement evidence-based interventions to improve maternal health.

- 1) Understand the Causes, Improve Interventions for, and Reduce the Prevalence of Premature Births.**
- 2) Focus on Obesity Research, Treatment, and Prevention.**
- 3) Improve Surveillance and Data Collection On Maternal and Infant Health.**
- 4) Support Maternal/Infant Health Programs at HRSA.**
- 5) Research Disparities in Maternal Care, to Eliminate Disparities.**
- 6) Develop, Test and Implement Quality Improvement Measures and Initiatives.**
- 7) Test an Obstetric Medical Home Model**

1) Understand the Causes, Improve Interventions for, and Reduce the Prevalence of Premature Births.

Between 1990 and 2006, the U.S. experienced a 20% increase in the number of premature births. While in 2008 we saw a 3% decrease in preterm births, preliminary 2008 data from the National Center for Health Statistics (NCHS) show that preterm births still account for 12.3% of all births. In many cases the causes are unknown. Both the Centers for Disease Control (CDC) and the

National Institutes of Health's National Institute for Child Health and Human Development (NICHD) must expand existing research and evaluation of the factors behind these numbers, using improved national data systems to ensure consistent reliable statistics on preterm birth rates and expanding research into the causes and prevention of preterm birth.

NICHD's research activities may be augmented through integrated transdisciplinary research centers, as recommended by the Institute of Medicine and the Surgeon General's Conference on the Prevention of Preterm Birth. Patient-centered outcomes research, also known as comparative effectiveness research, should focus on evaluating the efficacy of interventions in different subpopulations for preterm labor, including different drugs and preventive efforts.

2) Focus on Obesity Research, Treatment, and Prevention.

Obese pregnant women are at increased risk for poor maternal and neonatal outcomes, and the prevalence of obesity in the United States has increased dramatically over the past 20 years. The most recent National Health and Nutrition Examination Survey (NHANES) for 1999–2002 found that approximately one third of adult women are obese. This problem is greatest among non-Hispanic black women (49%) compared with Mexican-American women (38%) and non-Hispanic white women (31%).

Several studies have consistently reported higher rates of preeclampsia, gestational diabetes, and cesarean delivery, particularly for failure to progress, in obese women than in non-obese women. Additional research and interventions are needed to address the increased risk for poor outcomes in obese women receiving infertility treatment, the increased incidence of birth defects and stillbirths in obese pregnant women, ways to optimize outcome in obese women who become pregnant after bariatric surgery, and the increased risk of childhood obesity for their babies.

3) Improve Surveillance and Data Collection Efforts On Maternal and Infant Health.

- Modernize state birth and death records systems to comply with the 2003-recommended guidelines.

Only 75% of states and territories use the 2003 birth certificates and 65% have adopted the 2003 death certificate. Additional funding must be provided to NCHS' National Vital Statistics System (NVSS) to support states and territories in implementing the 2003 birth certificate and modernizing their infrastructure to collect these data electronically to expand the scope and quality of data collected. Funding to support the phasing in of the 2003 death certificate and electronic death records in states and territories must also be made available. CDC should also work with the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator to pilot-test the integration of electronic birth and death records and electronic medical records.

- Assist states in setting up maternal mortality reviews.

National data on maternal mortality is inconsistent and incomplete due to the lack of standardized reporting definitions and mechanisms. To capture the accurate number of maternal

deaths and plan effective interventions, maternal mortality should be addressed through multiple, complementary strategies. The CDC should provide funds to states for implementation of maternal mortality reviews that conduct regular reviews of all deaths within the state to identify causes, factors in the communities, and strategies to address the issues. Combined with adoption of the recommended birth and death certificates in all states and territories, CDC could then collect uniform data to calculate an accurate national maternal mortality rate. Results of maternal mortality reviews will inform research needed to identify evidence based interventions addressing causes and factors of maternal mortality and morbidity. Only 15 to 20 states operate maternal mortality reviews today.

- Improve the CDC Safe Motherhood Program to study pregnancy-related deaths.

To better understand maternal complications and mortality and to decrease disparities among populations at risk of death and complications from pregnancy, the CDC's Division of Reproductive Health's Safe Motherhood Program supports national and state-based surveillance systems to monitor trends and investigate health issues; conducts epidemiologic, behavioral, demographic, and health services research; and works with partners to translate research findings into health care practice, public health policy, and health promotion strategies.

One such program is the Pregnancy Risk Assessment Monitoring System (PRAMS). PRAMS was initiated in 1987 because infant mortality rates were no longer declining as rapidly as they had in prior years, and the incidence of low birth weight infants had not significantly improved in the previous 20 years. Research indicates that maternal behaviors during pregnancy may influence infant birth weight and mortality rates. The goal of the PRAMS project is to improve the health of mothers and infants by reducing adverse outcomes such as low birth weight, infant mortality and morbidity, and maternal morbidity. PRAMS provides state-specific data for planning and assessing health programs and for describing maternal experiences that may contribute to maternal and infant health. Currently 37 States participate in the PRAMS; this program should be expanded to all States.

- Develop a Maternity CAHPS.

Understanding the experience and perspective of mothers is paramount in improving the delivery of maternity care. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) program developed through the Agency for Healthcare Research and Quality (AHRQ) is the gold standard for patient experience surveys at the health plan, hospital, and clinician levels. Survey topics cover the communication skills of providers (important for shared decision making and informed consent) and the accessibility of services. Currently, the CAHPS Consortium has products that cover dental care, primary care, and newly released in 2009, surgical care. ACOG urges AHRQ to fund the development of maternity CAHPS in 2010.

4) Support Maternal/Infant Health Programs at HRSA

- Continue support of and expand the Fetal and Infant Mortality Review (FIMR).

FIMR brings local ob-gyns and health departments together to solve community problems related to infant mortality. Since 1990, the Maternal Child Health Bureau has worked in cooperative agreement with ACOG to run the National Fetal Infant Mortality Review (NFIMR) program. NFIMR provides training and assistance to enhance cooperative partnerships among local community health professionals, public health officers, community advocates and consumers to reduce infant mortality. The goal is to improve local services and resources for women, infants and families, to remove barriers to care, and to ensure culturally appropriate, family friendly services. Such efforts are crucial to understanding and addressing infant health disparities in communities at highest risk and are a component of many existing Healthy Start Initiatives. A rigorous national evaluation of FIMR conducted by Johns Hopkins University concluded that FIMR is an effective perinatal initiative.

- Improve funding for the Maternal Child Health Block Grant.

The MCHB Grant is the only federal program that exclusively focuses on improving the health of mothers and children by ensuring access to quality care, especially for those with low-incomes or limited availability of care.

5) Perform Disparities Research into Maternal Outcomes.

Women of racial and ethnic minorities face higher rates of diseases including obesity, cancer, diabetes, heart disease, and HIV/AIDS, when compared with white women. There is also a disproportionately higher rate of pre-term birth among African American women that cannot be accounted for by known risk factors. HHS must support research into the causes of health disparities and develop and evaluate interventions to address these causes. Continued and expanded collection of data capturing racial and ethnic information is essential in understanding and reducing disparities.

6) Develop, Test and Implement Quality Improvement Measures and Initiatives.

The American College of Obstetricians and Gynecologists is an active leader in the national quality measurement arena. We have a standing executive committee seat on the American Medical Association (AMA)-convened Physician Consortium for Performance Improvement ® (PCPI) and are active members of the National Quality Forum, AQA (formerly Ambulatory Care Quality Alliance), and the Surgical Quality Alliance (SQA). ACOG is currently engaged through the PCPI in development of maternity care quality measures.

The PCPI process is the gold standard for national development, testing, and maintenance of scientific evidence-based clinical performance measures at the physician/clinician/group level, balanced with stakeholder engagement, public comment, and transparency and spearheaded by clinician ownership, accountability and professionalism. We look forward to maintaining and improving current measures, developing new clinical measures in other facets of obstetrical and gynecologic care and expanding national data collection and aggregation initiatives on all aspects of women's health care through both voluntary data registry participation for physicians and facilities and mandatory certification and accreditation programs

like American Board of Obstetrics and Gynecology Maintenance of Certification and The Joint Commission.

ACOG urges Congress and the Administration to support these efforts and assist in the dissemination and voluntary adoption of quality measures in both the Medicare and Medicaid programs.

7) Test an Obstetric Medical Home Model

The testing of a women's medical home, with particular attention to maternity care, is an important opportunity to facilitate the improvement of health outcomes in the United States and reduce duplicate and inappropriate utilization of services. Medical homes are rooted in the principle that care coordination, increasing health care access, patient-provider communication, and collaborative care are fundamental to improving patients' health. This delivery model has the potential to address the unique issues that arise during pregnancy and may be able to address troubling health disparities in certain populations of pregnant women. CMS should test a model in the Medicaid program, which finances approximately 42% of the nation's births.

ACOG looks forward to partnering with Congress and the Administration on the MOMS Initiative to improve maternity outcomes for women and babies. For more information please contact Nevena Minor, Manager, Government Affairs at nminor@acog.org or 202-314-2322.