



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS



August 13, 2014

Sylvia Mathews Burwell, Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Mathews:

On behalf of the undersigned organizations, congratulations on your recent confirmation as Secretary of the U.S. Department of Health and Human Services (HHS). We are writing to update you on our efforts and guidance on the prevention of preterm birth, and to ensure that the U.S. Department of Health and Human Services' (HHS) efforts with respect to this and the related endeavor to reduce the rate of infant mortality in the U.S. include consideration of our organizations' 2012 guidelines with respect to cervical length measurement and use of progesterone.<sup>1,2,3</sup> We believe that the inclusion of these important guidelines in HHS' efforts – both at the public health program and the health coverage levels will lead to a reduction in the rate of infant mortality and provide safer, more effective care for pregnant women and their babies. These strategies that have been proven by research<sup>4,5,6</sup> conducted by many of our members and the *Eunice Kennedy Shriver* National Institute of Child Health and Development will go a long way in tackling this issue.

According to the United Nations, the United States ranks 55<sup>th</sup> in the world in infant mortality - far below many developing nations.<sup>7</sup> The Center for Disease Control's National Vital Statistics reports tally over 26,000 annual infant deaths; a rate of 6.4 deaths per 100,000 live births. Importantly, there are significant racial disparities.<sup>8</sup> We can and must do more to solve this crisis.

The leading cause of infant morbidity and mortality is preterm birth. Preterm infants account for nearly 70% of infant deaths.<sup>8</sup> Women in the U.S. suffer among the highest preterm birth rates in the world: one in nine babies born in the United States (11.5%) is delivered before 37 completed weeks of gestation.<sup>9,10,11</sup> Moreover, while babies born before 32 weeks represent only 2% of all births, they result in half (54%) of infant deaths.<sup>8</sup> The rate of infant mortality for babies born very low birthweight (less than 1,500 grams) is 100 times higher than that for babies born weighing more than 2,500 grams. Preterm babies who survive are at significant risk of developmental and physical disabilities including cerebral palsy and developmental delays, chronic respiratory disease, blindness and deafness – all problems which can last a lifetime, severely affecting these children and their families, and adding significant cost to the healthcare system.<sup>12</sup> Awareness and education are desperately needed to expand risk screening and preventive treatment. Reducing the rate of preterm birth is the most important means of reducing infant mortality.

There are significant racial disparities in both infant mortality and preterm birth. The rate of infant death for non-Hispanic black babies (12.40/1,000) is more than twice that for non-Hispanic white (5.33/1,000) babies.<sup>8</sup> The March of Dimes recently reported a preterm birth rate of 16.8% for African Americans compared with 11.7% for Hispanics and 10.5% for White women.<sup>9</sup>

Preterm birth is extraordinarily expensive and accounts for 50% of all pregnancy costs. The Institute of Medicine examined the cost of preterm birth and estimated the economic toll in 2005 to be \$26.2 billion, or \$51,500 per infant born preterm.<sup>12</sup> With sky rocketing health care costs, the total today is surely much higher. A disproportionate share of this cost results from Neonatal Intensive Care Unit

(NICU) admissions for very preterm babies. As an example, the average NICU expense for babies born before 32 weeks of gestation is \$280,000.<sup>13</sup> Incremental medical costs remain much higher for very preterm infants for at least the first 7 years of life. Overall, the cost of a preterm birth is ten times that of a full term birth.<sup>12</sup>

In 2010, Medicaid provided coverage for 45% of the births in the United States, and over 60% in several states.<sup>14</sup> On average, this rate has increased 19% nationally increase since 2008. With the Affordable Care Act and Medicaid expansion, these rates are expected to rise. Moreover, Medicaid pays for twice as many adverse outcomes as do private insurers. For most Medicaid payers, NICU admissions are at the top of the list of most expensive hospitalizations. Quality improvement initiatives to prevent preterm birth can bring significant savings to Medicaid budgets.

Growing adoption of evidence based strategies has helped bring the rate of preterm birth and infant mortality down slowly. For example, earlier identification of pregnancies, better access to prenatal care, improved education, smoking cessation programs, innovative care delivery models such as Centering Pregnancy, 17  $\alpha$ -hydroxyprogesterone (17-OHCP) to prevent recurrent preterm birth, quality initiatives to reduce early elective deliveries, and inter-conception care have each made a difference. Despite our best efforts, though, the nation is not on pace to reach the March of Dimes' goal to reduce the rate of preterm birth to 9.6%.

Both CMS and HRSA have identified preterm birth as an important issue. Pilot programs to help define best practices and quality measures have been instrumental in creating road maps for rolling out such strategies to benefit pregnant women across the country. We wholeheartedly support these efforts being made at the federal level.

We believe that much more could be done, and we urge HHS to include our own guidelines that were published in 2012 as you work toward a cohesive, collaborative national infant mortality strategy. We have attached here the guidelines published in 2012: May 2012, SMFM published "Progesterone and Preterm Birth Prevention: Translating Clinical Trials Data into Clinical Practice" (Am J Obstet Gynecol 2012;206:376-386.); June 2012, ACNM published "ACNM Position Statement on Preterm Labor and Preterm Birth"; and from October 2012, ACOG published "ACOG Practice Bulletin No.130: Prediction and Prevention of Preterm Birth" (Obstet Gynecol 2012 Oct;120(4):964-73.). These publications include comprehensive reviews of clinical trials and provide detailed recommendations for progesterone treatment in select high risk pregnancies. In sum:

- For singleton pregnancies with a history of prior spontaneous preterm birth, 17-OHCP is recommended to prevent recurrent preterm birth
  - Re-affirms recommendations in a 2008 ACOG Practice Bulletin
  - Utilization needs to improve
- For singleton pregnancies without a history of prior spontaneous preterm birth, vaginal progesterone is recommended to prevent preterm birth in patients diagnosed with a cervical length less than or equal to 20 mm by transvaginal ultrasound between 18 and 24 weeks gestation
  - New guidelines require a change in practice
  - Universal cervical length screening is supported to identify patients eligible for treatment
- Progesterone is not recommended for multiple gestations

Vaginal progesterone is readily available at a low cost. Using the generic drug, a full course of treatment is approximately \$350.<sup>15</sup> Universal cervical length screening can be added to routine prenatal care using existing technology.

Economic analyses show that universal screening and vaginal progesterone treatment for those diagnosed with premature cervical shortening is cost saving. For every 100,000 pregnancies screened, \$19.6 million can be saved by treating the high risk patients.<sup>16,17</sup> In a recent Journal of Perinatal Medicine article, Dr. Roberto Romero, Chief of the Perinatal Research Branch of NICHD, estimated that widespread adoption of this risk assessment and treatment could bring a net savings of \$500-750 million annually to the U.S.<sup>18</sup>

Experts note that this combination of risk screening – obstetric history and cervical length measurement – can identify more than 50% of pregnancies destined to deliver early.<sup>19</sup> Identification allows progesterone treatment, and that can help reduce the incidence of preventable preterm birth. A slew of meta-analyses and articles continue to be published in the medical literature with an urgent call for adoption of risk screening and treatment for all eligible pregnant women. It is broadly agreed that cervical length measurement meets the WHO standards for a screening test.

We firmly believe that more attention, education and prioritization is needed to help realize the potential of both 17-OHCP and vaginal progesterone to improve maternal and infant outcomes and reduce cost. There is no more devastating or expensive problem in obstetrics. The evidence is clear. We have all the necessary tools. We must not wait any longer to take all necessary steps to accelerate adoption. We respectfully request that you take a leading role in this regard.

As you move forward with realizing the goal of reducing infant mortality, we hope that you will consider the adoption and inclusion of our guidelines in this strategy. We fully support the work of the Secretary's Advisory Committee on Infant Mortality (SACIM), but think the SACIM's report in January 2013 made note of many, but not all, of the above statistics and strategies. Most notably, progesterone treatment to prevent preterm birth in select high risk populations was missing.

Research conducted by NICHD on 17-OHCP dating back to 2003 showed a 33% reduction in preterm birth for singleton pregnancies with a history of spontaneous preterm birth.<sup>5</sup> This therapy has been in use since then, and an ACOG Practice Bulletin recommending it was published in 2008. Identification of the eligible patient population relies on maternal history at the first prenatal visit but can be supplemented with data tracking systems. Sadly, this intervention is still profoundly under-utilized in many places – and that means pregnant women are missing opportunities for healthier outcomes. This is unacceptable.

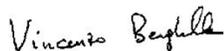
There is also now another progesterone strategy to add to our arsenal: universal cervical length screening and vaginal progesterone treatment for prematurely short cervix. A worldwide study conducted by the NICHD<sup>6</sup> and published in 2011 demonstrates the efficacy of this strategy, validating and expanding upon the results of prior clinical trials. For singleton pregnancies without a prior preterm birth with a mid-pregnancy short cervical length, vaginal progesterone treatment showed significant reductions in preterm birth and improvements in infant outcomes, which translate to significant reductions in short- and long-term costs, including:

- 45% reduction in preterm birth  $\leq$  33 weeks<sup>6</sup>
- 50% reduction in preterm birth  $\leq$  28 weeks<sup>6</sup>
- 43% reduction in neonatal morbidity and mortality<sup>6</sup>
- 61% reduction in respiratory distress syndrome<sup>6</sup>
- 25% reduction in NICU admissions<sup>20</sup>

Beyond ACIM, HHS's ability to bring leaders together and encourage states to include these evidence-based strategies is fundamental to improving the health and well-being of our mothers and babies. We look forward to working with you as HHS works to expand and execute a national strategy to

reduce infant mortality. Again, infant mortality cannot be addressed without addressing preterm birth – and our guidelines are a major piece of this puzzle. HHS’s work on this matter thus far is commendable, and it is well positioned to help obstetrics providers and payers add universal cervical length screening and vaginal progesterone treatment as recommended by SMFM, ACOG, and ACNM in the future. The lives and livelihood of our nation’s babies are at stake. We appreciate your consideration of this, and should you have any questions please contact the Society for Maternal-Fetal Medicine’s Washington Representative, Katie Schubert, at (202) 484-1100 or [kschubert@dc-crd.com](mailto:kschubert@dc-crd.com).

Sincerely,



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Hon. Richard Shelby  
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- <sup>1</sup>Society for Maternal-Fetal Medicine Publications Committee with the assistance of Vincenzo Berghella, MD. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. *Am J Obstet Gynecol* 2012;206:376-386.
- <sup>2</sup>American College of Obstetricians and Gynecologists (ACOG). ACOG practice bulletin no.130: prediction and prevention of preterm birth. *Obstet Gynecol* 2012 Oct;120(4):964-73.
- <sup>3</sup>American College of Nurse-Midwives, Division of Standards and Practice, Clinical Standards and Documents Section. ACNM position statement on preterm labor and preterm birth. Approved by the ACNM Board of Directors, June 2012.
- <sup>4</sup>Iams JD, Goldenberg RL, Meis PJ, et al. The length of the cervix and the risk of spontaneous premature delivery. *N Engl J Med* 1996;334:567-572.
- <sup>5</sup>Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. *N England J Med*;384(24):2379-2385.
- <sup>6</sup>Hassan SS, Romero R, Vidyadhari D, et al. Vaginal progesterone reduces the rate of preterm birth in women with a sonographic short cervix: a multi-center, randomized, double-blind, placebo-controlled study. *Ultrasound Obstet Gynecol* 2011;38:18-31.
- <sup>7</sup>United Nations, Department of Economic and Social Affairs, Population Division. *World Population Prospects: The 2012 Revision*. New York, 2013.
- <sup>8</sup>Matthews TJ, MacDorman MF. Infant mortality statistics from the 2009 period linked birth/infant death data set. U.S. Department of Health and Human Services, National Vital Statistics Reports: 2013;61(8).
- <sup>9</sup>March of Dimes 2013 Premature Birth Report Card: United States. Available online: <http://www.marchofdimes.com/peristats/pdflib/998/premature-birth-report-card-United-States.pdf>
- <sup>10</sup>March of Dimes, PMNCH, Save the Children, WHO. *Born Too Soon: The Global Action Report on Preterm Birth*. Eds CP Howson, MV Kinney, JE Lawn. World Health Organization. Geneva, 2012.
- <sup>11</sup>Hamilton BE, Martin JA, Ventura SJ. Births: preliminary data for 2012. U.S. Department of Health and Human Services, National Center for Health Statistics: 2013;62(3).
- <sup>12</sup>Behrman, RE and Stith A (Editors). *Preterm birth: causes, consequences, and prevention*. Institute of Medicine Committee on Understanding Premature Birth and Assuring Healthy Outcomes. National Academy of Sciences, 2006.
- <sup>13</sup>Special care nursery admissions. March of Dimes Perinatal Center: 2011. Available online: [www.marchofdimes.com/peristats/pdfdocs/nicu\\_summary\\_final.pdf](http://www.marchofdimes.com/peristats/pdfdocs/nicu_summary_final.pdf).
- <sup>14</sup>Markus AR, Andres W, West K, et al. Medicaid covered births, 2008 through 2010, in the context of implementation of health reform. *Women's Health Issues* 2013;23(5):e273-e280.
- <sup>15</sup>Kowalski JT. A guide to the cost of progesterone for prevention of preterm labor. *Proceed Obstet Gynecol* 2011;1(3):Article 9[4 p.].
- <sup>16</sup>Werner EF, Han CF, Pettker CF, et al. Universal cervical length screening to prevent preterm birth: a cost-effective analysis. *Ultrasound Obstet Gynecol* 2011;38:32-37.
- <sup>17</sup>Campbell S. Universal cervical length screening and vaginal progesterone prevents early preterm births, reduces neonatal morbidity and is cost saving: doing nothing is no longer an option. *Ultrasound Obstet Gynecol* 2011;38:1-9.
- <sup>18</sup>Romero R, Yeo L, Miranda J, et al. A blueprint for the prevention of preterm birth: vaginal progesterone in women with a short cervix. *J Perinat Med* 2013;41:27-44.
- <sup>19</sup>Sotiriadis A, Papatheodorou S, Makrydimas G. Perinatal outcome in women treated with progesterone for the prevention of preterm birth: a meta-analysis. *Ultrasound Obstet Gynecol* 2012;40:257-266.
- <sup>20</sup>Romero R, Nicolaidis K, Conde-Agudelo A, et al. Vaginal progesterone in women with an asymptomatic sonographic short cervix in the midtrimester decreases preterm delivery and neonatal morbidity: a systematic review and meta-analysis of individual patient data. *Am J Obstet Gynecol* 2012;206:124.e1-19.

