

## LETTERS TO THE EDITOR

### Health Care Costs

#### **To the Editor:**

In response to “The Challenges of Change” written by Dr Burkman, (*The Female Patient*. 2009;34(4): 12–13). I respectfully submit there is probably only one foolproof way to reform administrative costs of health care expenditures in our country: get rid of the administration. If we physicians had enough fortitude to provide some “tough love” to our patients, ourselves, and our country, we would realize the “administration” has not produced one iota of change in our health care system, except to provide the administrators with an unending supply of revenues. Saying “NO” to the insurance companies and the bureaucracy surrounding them would mean eliminating the middle man/ administration from our health care system, and it would allow us to return to the basic premise of our profession: the doctor-patient relationship. Artificial support of our current system with laws and lobbying provide a hindrance to this relationship, which continues to raise our health care costs even further.

**Joseph Gauta, MD**  
Naples, FL

#### **The Author Responds:**

We do have high administrative costs compared with other health care systems in the United States. Perhaps through simplification in a number of ways, such as implementing a single payor system, these costs will decline. Unfortunately, the delivery of health care has become so complex that it is unlikely an “elimination” of administration will ever be feasible.

**Ronald T. Burkman, MD**  
Editor-in-Chief

### Preventing Preterm Labor

#### **To the Editor:**

I read with interest Dr Ross's article (Ross MG. Preventing preterm labor: progesterone and cervical length assessments. *The Female Patient*. 2009;34(3):38–40) on the utility of the CerviLenz device (as noted in his disclosure, Dr Ross serves as Medical Director for CerviLenz Inc.). While he advances several thoughtful points, the author seems to imply a consensus-evolution regarding the utility of routine ultrasonographic cervical length measurement in pregnancy, and that such consensus is in sufficient proximity as to justify use of the CerviLenz by “nurses, nurse midwives, and physicians.” To this, several points should be mentioned: 1) The American Institute of Ultrasound in Medicine recommendation regarding routine cervical assessment in second and third trimesters states, “evaluation of the... cervix should be performed when appropriate. When the cervix cannot be visualized, a transperineal or transvaginal scan may be considered when visualization of the cervix is needed.”<sup>1</sup> This routine screening can be accomplished via transabdominal ultrasound, a modality (along with transperineal ultrasonography) with insufficient data supporting validity when employed for the measurement of cervical length for assessment of risk of prematurity. One supposes that this cervical assessment as recommended might be more for generic purposes, such as determining the presence of absence of anomalies, than solely for the assessment of risk of prematurity. As far as I know, this is the only consensus guideline in the United States regarding the employment of routine ultrasonographic evaluation of the cervix in pregnancy.

2) While new ACOG guidelines permit the possibility of offering progesterone supplementation to women with cervical length measurements from 22 to 26 weeks of less than 15 mm, they also qualify that possibility explicitly with the caveat that routine screening of pregnant women with transvaginal sonographic cervical length measurement is specifically *not* recommended.<sup>2</sup>

3) This allowance by ACOG is in part due to encouraging studies by Fonseca et al, in which 250 women were randomized to receive either placebo (125) or 200 mg capsules of micronized progesterone to be administered nightly from 24 to 34 weeks' gestation.<sup>3</sup> The results showed significant reduction of delivery below 34 weeks' gestation in the treatment group (RR: 0.60, CI: 0.35-0.94), and trends toward improved outcome (albeit not statistically significant) in neonatal deaths, very low birth weight births, neonatal intensive care unit admissions, and need for assisted ventilation in women undergoing treatment over the placebo group. However, relative to the treatment group the placebo group also had more women with previous preterm birth (23 vs. 15), cigarette smokers (10 vs. 6), and multiple gestations (13 vs. 11).

4) The positive predictive value of transvaginal sonography in determining the risk of prematurity for low-risk pregnancies has long been questioned. In several studies surveying women without risk factors, the positive predictive value of a second trimester CL of <2.5 was only about 15%.<sup>4,5</sup> It is likely that further studies will resolve questions regarding which patients might benefit from such screening under which circumstances, but at the present time there is considerable variation in the medical literature on this point.

While Fonseca's study and others show promise in developing future consensus for the utility of cervical length measurement in improving outcome for pregnancies at risk for prematurity, such consensus does not currently exist. Moreover, the lack of consensus guidelines for the use of transvaginal ultrasonography for cervical length measurement in pregnancy, either those at risk for prematurity or as a routine screening measure, surely limits the utility of any surrogate for such studies, such as the CerviLenz device. Finally, the device itself will require validation in clinical use (ie, demonstrating an associated improvement in outcome rather than merely reproducibility when compared to ultrasonography) before its widespread use can be recommended.

**Ian D. MacAgy, MD, FACOG**  
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## REFERENCES

1. American Institute of Ultrasound in Medicine. AIUM practice guideline for the performance of obstetric ultrasound examinations. [www.aium.org/publications/guidelines.obstetric.pdf](http://www.aium.org/publications/guidelines.obstetric.pdf). Updated October 1, 2007. Accessed May 7, 2009.
2. ACOG Committee Opinion number 419 October 2008 (replaces no. 291, November 2003). Use of progesterone to reduce preterm birth. *Obstet Gynecol.* 2008;112(4):963-965.
3. Fonseca EB, Celik E, Parra M, Singh M, Nicolaides KH, Fetal Medicine Foundation Second Trimester Screening Group. Progesterone and the risk of preterm birth among women with a short cervix. *N Engl J Med.* 2007; 357(5):462-469.
4. Iams JD, Goldenberg, RL, Mercer, BM, et al. The preterm prediction study: can low-risk women destined for spontaneous preterm birth be identified? *Am J Obstet Gynecol.* 2001;184(4):652-655.
5. Taipale P, Hiilesmaa V. Sonographic measurement of uterine cervix at 18-22 weeks' gestation and the risk of preterm delivery. *Obstet Gynecol.* 1998;92(6):902-907.

## The Author Responds:

I greatly appreciate the comments of Dr MacAgy in response to the article on preventing preterm labor. Dr MacAgy indicates the article implied a consensus-in-evolution regarding the utility of routine ultrasonographic cervical length measurement in pregnancy, which

justifies the use of CerviLenz. I would argue that consensus in this area is greater than his letter would imply. Our field requires new approaches to the prevention of preterm delivery, the major cause of perinatal morbidity and mortality. While it is true that ACOG has not yet recommended routine cervical length screening, both ACOG and the Society of Obstetricians and Gynaecologists of Canada indicate that progesterone therapy should be considered for asymptomatic patients with a short cervical length. Furthermore, the Fetal Medicine Foundation advocates cervical length measurements every 2 weeks' from 14 to 24 weeks' gestation in women with a previous history of preterm birth.

As a risk factor, a short cervical length at mid-gestation is associated with a markedly increased risk of preterm delivery in asymptomatic patients as compared to previous preterm delivery.<sup>2</sup> Additionally, treating patients only on the basis of a prior preterm birth would have a nominal effect on the rate of preterm birth in the United States.<sup>1</sup> Progesterone has been demonstrated to reduce the preterm delivery rate among patients with a short cervix diagnosed through 24 weeks of pregnancy, while the recent abstract presentation from the NIH Maternal-Fetal Network reported a significant value of cerclage for patients with a short cervix as early as 16 weeks of pregnancy.<sup>3,4</sup> In view of these studies and others, I believe it is likely that cervical length screening, perhaps serially from 16 to 24 weeks, will ultimately become a part of prenatal care. Clearly, a cost effective screening approach that can be done in the general ObGyn office is optimal for identification of patients who may benefit from progesterone, cerclage, or alternative therapies.

I agree with Dr MacAgy in that there is insufficient data supporting the validity of cervical length measurement by transperineal or

transabdominal ultrasound, or digital assessment of cervical length.<sup>5</sup> Following an initial study of CerviLenz that demonstrated a high sensitivity in identifying patients with a short cervix by transvaginal ultrasound (TVU), a multi-center US trial comparing CerviLenz measures to that of TVU is currently being performed.<sup>6</sup> The company is awaiting study completion and analysis prior to commercial marketing.

Most importantly, the article was intended to alert practicing clinicians to the current approaches to prenatal identification of asymptomatic patients at risk of preterm labor. Although neither routine TVU measurements nor routine CerviLenz measurements are currently advocated, the clinician should be aware of the consensus-in-evolution of cervical length assessments.

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## References

1. Petrini JR, Callaghan WM, Klebanoff M, et al. Estimated effect of 17 alpha-hydroxyprogesterone caproate on preterm birth in the United States. *Obstet Gynecol.* 2005;105(2):267-272.
2. Iams JD, Goldenberg RL, Meis PJ, et al. The length of the cervix and the risk of spontaneous premature delivery. National Institute of Child Health and Human Development Maternal Fetal Medicine Unit Network. *N Engl J Med.* 1996;334(9):567-572.
3. Fonseca EB, Celik E, Parra M, Singh M, Nicolaides KH, Fetal Medicine Foundation Second Trimester Screening Group. Progesterone and the risk of preterm birth among women with a short cervix. *N Engl J Med.* 2007;357(5):462-469.
4. DeFranco EA, O'Brien JM, Adair CD, et al. Vaginal progesterone is associated with a decrease in risk for early preterm birth and improved neonatal outcome in women with a short cervix: a secondary analysis from a randomized, double-blind, placebo-controlled trial. *Ultrasound Obstet Gynecol.* 2007;30(5):697-705.
5. Burwick RM, Lee GT, Benedict JL, Ross MG, Kjos SL. Blinded comparison of cervical portio length measurements by digital examination versus CerviLenz. *Am J Obstet Gynecol.* 2009;200(5):e37-e39
6. Ross MG, Cousins L, Baxter-Jones R, Bemis-Heys R, Catanzarite V, Dowling D. Objective cervical portio length measurements: consistency and efficacy of screening for a short cervix. *J Reprod. Med.* 2007;52(5):385-389.