

# OB/GYN Clinical [ALERT]

Evidence-based commentaries  
on women's reproductive health

## ABSTRACT & COMMENTARY

### Zika, Revisited

By John C. Hobbins, MD

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Dr. Hobbins reports no financial relationships relevant to this field of study.

**SYNOPSIS:** A new study from Brazil shows a very high rate of fetal central nervous system abnormalities with both first-trimester and second-trimester exposure to the Zika virus, compared with data from the United States and other areas in the world where the rate of fetal abnormalities has been lower.

SOURCE: Brasil P, Pereira JP Jr, Moreira ME, et al. Zika virus in pregnant women in Rio de Janeiro. *N Engl J Med* 2016;375:2321-2334.

Last spring, I wrote a special feature in *OB/GYN Clinical Alert* dedicated to the Zika virus. Since that time, new information is available to help us understand the spectrum of abnormalities this virus can cause in the fetus. Brazil garnered the earliest attention after the association between the Zika virus and microcephaly surfaced. New information from Rio de Janeiro again has shown that microcephaly represents only one late component of a multifaceted process.

Between September 2015 and May 2016, Brasil et al studied women with signs of Zika virus infection (descending pruritic rash, fever, arthralgia, conjunctivitis) presenting for care in a large clinic in Rio de Janeiro. They compared 125 patients who tested positive for Zika virus (RT-ZIKV) by reverse transcriptase polymerase chain reaction (PCR) within five days of symptoms with 51 patients who tested negative after symptoms.

Forty-two percent of Zika-positive and 3% of Zika-negative patients were positive for chikungunya. Fetal death occurred in 7.2% of Zika-positive and in 6% of Zika-negative patients. Overall, adverse outcomes were noted in 46% of Zika-positive patients, with 42% having either obvious clinical or image-diagnosed central nervous system (CNS) abnormalities. Interestingly, brain abnormalities occurred almost equally among those exposed in the first trimester (55%) and second trimester (52%), with 29% occurring after third-trimester exposure. The emergency cesarean section rate for fetal distress was much higher in the Zika-positive patients (23.5% vs. 2.5%).

#### ■ COMMENTARY

The initial reports from Brazil linking Zika with microcephaly sent chills around the world, especially in areas in which the Zika-bearing mosquito, *Aedes aegypti*

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and *Aedes albopictus*, are indigenous. The population in the featured study represented the perfect storm. The women were all symptomatic and lived in an area where the virus had already been known to cause serious fetal CNS damage — and the results bore this out. The biggest surprise was that the devastating effects happened in equal amounts (about 50%) after both first- and second-trimester exposure and occurred even in one out of three patients with third-trimester exposure.

It is important to note that the experience from other areas in the world does not mirror the results from this Zika hot spot. For example, CDC data from 442 Zika-positive women in the United States and Hawaii have shown a 6% chance of birth defects (mostly CNS), with a 4% overall incidence of microcephaly.<sup>1</sup> Unpublished data from Zika-positive women in Puerto Rico and Columbia are now showing similar results, with less than a 10% chance of CNS abnormalities, intrauterine growth restriction, or fetal demise, with, again, mostly first-trimester exposure.

#### New insight from expanded experience:

1. Viremia in most patients is short-lived, generally being gone by nine days. However, the CDC has noted rare pregnant patients to be PCR-positive for Zika up to 50 days. The virus can be found in urine up to 14 days. After this time, one relies on the presence of Zika IgM antibodies for the diagnosis. A troublesome finding is that infected males can have the virus in their semen in huge concentrations for up to 62 days.
2. The well-publicized finding of microcephaly represents only the tip of the iceberg. This finding in infected cases in Brazil and the Polynesian islands provided a dramatic awakening of the effects of Zika, but it is a late development in a process that can cause an assortment of abnormalities such as ventriculomegaly, cortical thinning, generalized brain shrinkage, and dysgenesis of midline structures (corpus callosum, cerebellar vermis, and brainstem).<sup>2</sup> Periventricular calcifications are common. The virus interferes with the ladder-like progression upward of neuronal development, stopping the migration at the white matter/gray matter border and leaving the fetus with a shrunken brain and, ultimately, a small calvarium. A few cases of brain abnormalities have been accompanied by arthrogryposis, probably because of diminished fetal movement.

Virtually all the early signs of Zika can be diagnosed with 3-D ultrasound techniques and MRI.

3. Eighty percent of Zika-positive patients do not have symptoms and some studies suggest that this has no bearing on the chance of CNS abnormalities. The featured study showed that there was a 13% incidence of adverse outcome in symptomatic patients despite negative Zika testing, suggesting that other viruses such as chikungunya could be responsible. Superimposed infection might also have been responsible for the surprisingly high rate of abnormalities in this Brazilian population.
4. There is no currently available treatment for Zika. Inactivated virus (Zika purified inactivated virus) vaccine and a DNA-based vaccine are now being tested in Phase I trials but there is no timeline for their availability. Most importantly, every effort should be directed toward making a timely definitive fetal diagnosis to enable parents to weigh their options as early in pregnancy as possible.
5. Prevention: N, N dimethyl meta toluamide (DEET) is an effective skin preventive and appears to be safe in pregnancy, as well as permethrin for spraying of clothes.<sup>3</sup> Eliminating standing water in vulnerable communities is essential, as well as aerial spraying.

Some suggestions by the CDC and/or Society for Maternal-Fetal Medicine:<sup>4,5</sup>

1. Pregnant women or those contemplating pregnancy should avoid travel to high-risk areas noted in the CDC website.
2. Male partners traveling to these areas either should avoid intercourse or use protection for six months after returning. Women with or without symptoms would benefit from blood testing with Zika RT-PCR within the first five days of possible exposure, blood and urine RT-PCR testing between 5 and 12 days of exposure, and serum IgM for Zika (Elisa) after that time.
3. Ultrasound exams should be scheduled every 2-4 weeks in those testing positive. Since microcephaly is a late sign, the exam should include a detailed evaluation of the intracranial anatomy (preferably with the help of 3-D volume acquisition). A finding of concern can then be backed up with MRI. ■

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## ABSTRACT & COMMENTARY

# Ovarian Cancer Screening: Mortality Results

By Molly A. Brewer, DVM, MD, MS

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Dr. Brewer reports no financial relationships relevant to this field of study.

**SYNOPSIS:** This paper is a 15-year median follow-up of extended mortality of the ovarian cancer screening portion of the Prostate, Lung, Colon, Ovary trial.

**SOURCE:** Pinsky PF, Kelly Yu, Kramer BS, et al. Extended mortality results for ovarian cancer screening in the PLCO trial with median 15 years follow-up. *Gynecol Oncol* 2016;143:270-275.

The recent publication by Pinsky et al provided an updated review of the Prostate, Lung, Colon, Ovary (PLCO) trial and focused on the ovarian screening portion of the trial. This trial was designed to follow patients over time to determine if CA125 and transvaginal ultrasound (TVUS) affected the mortality rate of ovarian cancer. In this randomized, controlled trial that ran between 1993-2001 at 10 U.S. centers, women between the ages of 55-74 years with no history of ovarian cancer were randomized to either intervention (TVUS + CA125) or usual care (observation). The findings were previously presented in 2011.<sup>1</sup> The authors found that there was no decrease in mortality after a median follow-up of 12.4 years in the intervention group when compared to the women in the control group who did not undergo screening. In fact, there were harms associated with screening: 1,080 women with false-positive results from the screening group underwent unnecessary surgery and 15% of these women experienced major complications as a result of this surgery.

The primary endpoint of the 2011 study was ovarian cancer-specific mortality; secondary endpoints of the initial trial included ovarian cancer incidence, cancer stage, survival rates, harms of screening, compliance, and all-cause mortality. The current study only reported ovarian cancer mortality and survival. There were 34,253 (intervention arm) and 34,304 (usual care arm) women randomized, and 187 ovarian cancer deaths (rate 38.2 per 100,000 PY) in the intervention arm vs. 176 (rate 36.0 per 100,000 PY) in the usual care arm (relative risk, 1.06). There was a slight difference in survival at five years in the intervention arm as compared to usual care arm (47.4% vs. 36.0%), but the survival was similar at 10 years (31.3% vs. 27.1%) with no statistically significant difference in survival ( $P = 0.16$ ).

## ■ COMMENTARY

There has been great interest over the years to develop

screening technology to improve mortality from ovarian cancer. The disease typically *is* diagnosed in late stages (III or IV) because of multiple factors. Although recent studies have shown that most women with ovarian cancer have symptoms, the symptoms often are confused with aging or misinterpreted as a gastrointestinal upset, and diagnosis often is delayed.<sup>2</sup> Additionally, there is evidence that some of the high-grade cancers metastasize early and grow rapidly.<sup>3</sup> The two major screening trials for ovarian cancer are the PLCO trial and the UKCTOCS (UK Collaborative Trial of Ovarian Cancer Screening). The UKCTOCS trial showed no real benefit in mortality rates after 10 years, but the trial was underpowered to meet the endpoint of ovarian cancer mortality.<sup>4</sup> After excluding prevalent cases, the UKCTOCS authors found a slight benefit in survival after 12 years, which is contradictory to the PLCO trial. This group patented its multimodal screening algorithm, also known as Risk of Ovarian Cancer Algorithm (ROCA) and was marketing this test for screening, despite what was considered by many to be a negative trial. A previous report of the PLCO trial applied the ROCA algorithm to the PLCO results to try to mimic the UKCTOCS trial, but there was still no statistically significant mortality benefit of ovarian cancer screening.

Hopefully, the role of screening low-risk women for ovarian cancer finally has been laid to rest. Although a slight survival benefit was detected, attributed to more Stage I cancers found in the screening arms of both the UKCTOCS and the PLCO trials, after 10 years that survival advantage disappeared. In addition, screening has been shown to cause harm. In the PLCO trial, 3,285 (9.6%) women in the intervention arm women had false-positive results and had their ovaries removed, with a 15% serious complication rate as a result of surgery.

How should we interpret these findings? The FDA recently

warned that no screening test has been shown to reduce ovarian cancer deaths in average-risk women without symptoms. Subsequently, the ROCA test, marketed by Abcodia and developed by the researchers of the UKCTOCS trial, has been taken off the market. The real problem with screening for ovarian cancer is that it is a rare disease and, thus, any screening test will err on the side of increased false-positive results. Finally, there is cost in unnecessary screening — the cost of the actual test(s) and the cost of the unnecessary surgery. Unfortunately, until we can identify women at increased risk of ovarian cancer or develop an accurate screening test, the cost of screening does not justify the results. ■

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## ABSTRACT & COMMENTARY

# Fertility of Boys Resulting from Intracytoplasmic Sperm Injection

By Robert W. Rebar, MD

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**SYNOPSIS:** The data from a recent study suggest that at least some men whose fathers had male-factor infertility and were born as a result of ICSI also may suffer from male-factor infertility.

**SOURCE:** Belva F, Bonduelle M, Roelants M, et al. Semen quality of young adult ICSI offspring: The first results. *Hum Reprod* 2016; doi:10.1093/humrep/dew245.

Intracytoplasmic sperm injection (ICSI) is used widely as a part of in vitro fertilization (IVF) to help infertile couples in which the male partner has poor semen characteristics (i.e., typically low sperm count or motility) build a family. First used in 1991, the Belgian group pioneering its use has now examined the reproductive health of a cohort of 54 young adult ICSI men compared to 57 spontaneously conceived men of approximately the same age. The ICSI males included in this cohort were conceived with the use of ICSI because of severe male-factor infertility in their fathers. There was no difference in mean testicular volume between the ICSI men and the spontaneously conceived controls. After adjustment for several confounders (including age, body mass index, genital malformations, time from ejaculation to semen analysis, and period of abstinence), sperm concentration was almost doubled in spontaneously conceived peers compared to ICSI men (ratio 1.9; 95% confidence interval [CI], 1.1-3.2), and a two-fold lower total sperm count (ratio 2.3; 95% CI, 1.3-4.1) and total motile sperm count (ratio 2.12; 95% CI, 1.2-3.2) were found in ICSI men compared to the controls. In addition, ICSI men were almost three times more likely to have sperm concentrations lower than the accepted lower normal value of 15 million/mL (adjusted odds ratio [AOR], 2.7; 95% CI, 1.1-6.7) and four times more likely to have total sperm counts below 39 million (AOR, 4.3; 95% CI, 1.7-11.3).

## ■ COMMENTARY

The use of ICSI together with IVF has revolutionized the

treatment of men with impaired spermatogenesis and permitted them to bear children. More recently, ICSI has become widely used even in normal men as a part of IVF. However, the long-term effect of ICSI on subsequent reproductive function in men conceived with ICSI is still unknown. It is important to note that this study involved ICSI men whose fathers had severe male-factor infertility.

The Belgian group has been following the male offspring of fathers with diminished spermatogenesis born as a result of ICSI for several years. They previously reported normal pubertal development,<sup>1</sup> normal inhibin B as a marker of Sertoli cell function,<sup>2</sup> and normal levels of salivary testosterone as an indicator of Leydig cell function.<sup>3</sup> Even with the data reported in this study, we cannot conclude whether ICSI males will have diminished fertility.

It is possible that the subset of men with abnormal spermatogenesis and chromosomal abnormalities are those most likely to have sons born via ICSI who also will have abnormal spermatogenesis. It is known that infertile men have a higher prevalence of chromosomal abnormalities than fertile men, with several microdeletions of the Y chromosome now recognized.<sup>4</sup> Y-chromosomal microdeletions, especially of the AZFc (azoospermia factor c) region, are the most frequently diagnosed cause of impaired spermatogenesis, with a prevalence of 6% in severely oligozoospermic men and a prevalence of 10% in azoospermic men.<sup>5-7</sup> As expected, transmission

of Y-chromosomal deletions from father to son through ICSI has been reported.<sup>7</sup> Men with these deletions who successfully father children as a result of ICSI generally are not deterred by the prospect of having a son with the same difficulties with reproduction.

There is little doubt that the Belgian group will continue to follow this cohort and also will report on the use of ICSI in other circumstances involving men with normal spermatogenesis. Proposed indications for the use of ICSI in the literature now include unexplained infertility, poor quality oocytes retrieved in IVF cycles, low oocyte yield in IVF, advanced maternal age, prior fertilization failure with conventional insemination in IVF, routine use in all IVF cycles, use in IVF cycles that involve preimplantation genetic testing (PGT), fertilization after in vitro maturation (IVM) of immature oocytes as a part of IVF, and fertilization with use of cryopreserved oocytes.<sup>8</sup> In the CDC's 2014 National Summary Report of IVF, the percentage of oocyte retrievals using ICSI in those cycles without male infertility ranged from 67% among patients younger than age 35 years to 78% among those older than age 44 years.<sup>9</sup> Overall, 56% of all ICSI procedures were performed in cycles without a diagnosis of male-factor infertility. The rationale for the use of ICSI even in the absence of a male factor is avoiding fertilization failure in IVF cycles.

In a Committee Opinion, the Practice Committees of the American Society for Reproductive Medicine and of the Society for Assisted Reproductive Technology concluded that there are no data to support the routine use of ICSI with IVF for non-male factor infertility.<sup>8</sup> Further, they noted that more than 30 couples would need to undergo ICSI unnecessarily to prevent one failed fertilization during IVF. The committees also concluded that ICSI might be beneficial in cycles with PGT, IVM, or cryopreserved oocytes, but additional studies are warranted to determine if such is the case. ICSI for low oocyte yield and advanced maternal age has not improved clinical outcomes. Finally, the committees concluded that the safety and cost (which is not trivial) of ICSI in the setting of non-male factor

infertility must be considered.

So what does this particular study tell us and what does it portend for the future? The data reported by the Belgian group suggest that at least some of the men whose fathers had male-factor infertility and were born as a result of ICSI may well suffer from male-factor infertility. Whether ICSI affects the reproductive health of men born after ICSI whose fathers were entirely normal remains to be determined. Having said that, it is difficult to envision that ICSI will increase male-factor infertility in the offspring of normal males. I chose to focus on this paper for this review because of the frequency with which ICSI is utilized together with IVF. ■

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## SPECIAL EDITORIAL

# Reproductive Rights in 2017: Standing Strong for Women

By Jeffrey T. Jensen, MD, MPH

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Dr. Jensen reports that he is a consultant for and receives grant/research support from Bayer, Abbvie, ContraMed, and Merck; he receives grant/research support from Medicines 360, Agile, and Teva; and he is a consultant for MicroChips and Evofem.

The evidence strongly suggests that comprehensive family planning services provided under the Affordable Care Act (ACA) that include subsidized coverage for highly effective long-acting reversible contraception (LARC)

have contributed to a decrease in the rate of unintended pregnancy and a sharp decline in abortions. Policy changes proposed by the Trump administration threaten to dismantle these advances by eliminating the family planning

safety net by defunding Planned Parenthood (PP) and abolishing the contraception coverage mandate of the ACA. Reduced access to contraception could increase unintended pregnancy and abortion. At the same time, an attack on abortion rights threatens access to safe legal services in many parts of the United States, and the new administration has promised to work to overturn the *Roe v Wade* decision. As women's healthcare providers, we should be leaders in standing up to policy changes that will endanger women and threaten our most vulnerable citizens.

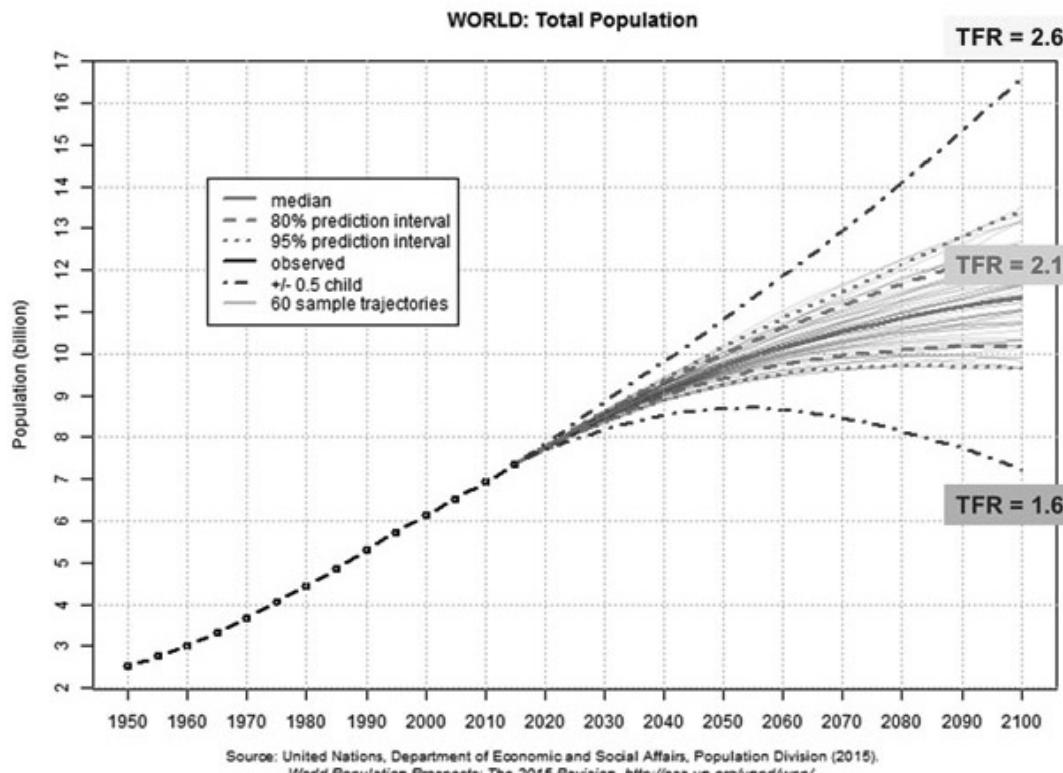
Let's review our current situation. Estimates from the U.S. Census Bureau place the world's human population at slightly less than 7.4 billion, of which more than 1.6 billion are reproductive age women. Although fertility rates in both developed and developing countries have declined, the world population is expected to exceed 11 billion by 2100 before gradually stabilizing. This assumes that we reach an average worldwide total fertility rate (TFR) of 2.1. If half of women add in the "third child" (e.g., a TFR of 2.6), the population will increase to about 17 billion by 2100 with no leveling. Instead, if many women worldwide decided to give birth to a single child (TFR = 1.6), the population would continue to increase, peaking at around 9 billion by 2050 before poetically decreasing to end the 21st century at about 6 billion, the number of humans in 1999. (See Figure 1.) The large number of young people in the prime

reproductive years explains this population momentum. (See Figure 2.) Although most of this youth population bulge exists outside of North America and Europe, these young people have the same hopes and dreams for their families that we have for our own. Many social scientists find that the large numbers of unemployed young men contribute to the increase in violence and terrorism in many regions where political violence is prevalent. In a recent cross-national, time-series study of the period 1950-2000, Urdal et al found a significant increase in conflict outbreak in the presence of youth bulges even when controlling for other factors, such as level of development, democracy, and conflict history.<sup>1</sup> For every percentage point increase in the youth population relative to the adult population, the risk of conflict increases by more than 4%. In most developed countries, 15- to 24-year-olds average about 15% of the total adult population. In contrast, more than 40 developing countries experienced youth bulges of 35% or more. When youth make up more than 35% of the adult population, the risk of armed conflict is 150% higher than in countries with stable youth populations.<sup>1</sup> In short, I worry about a nationalist pronatalistic agenda that turns away from family planning at home and also undermines the importance of international family planning assistance during this critical point in human history.

By the time you read this, President Trump already may

### Figure 1: World Population Growth According to the Median Fertility Scenario

World population growth according to the median fertility scenario (Total Fertility Rate (TFR) of 2.1) with 80% (dashed) and 95% (dotted) prediction intervals. The upper and lower lines indicate TFR of  $\pm 0.5$  (e.g., TFR 2.6 and TFR 1.6).



Source: United Nations Department of Economic and Social Affairs, Population Division (2015).

have signed legislation to make PP clinics ineligible to receive federal funds for providing healthcare services. President Obama prevented this attempt in the last Congress, citing the vital work of PP clinics. Although proponents of defunding PP argue that health departments and other federally qualified health centers (FQHCs) would fill the gaping hole torn in the family planning safety net, the evidence suggests otherwise.<sup>2</sup> PP clinics consistently perform better than other types of publicly funded family planning providers and serve a greater share of women. In many areas, PP is the sole source of publicly funded contraceptive care. Most PP clinics also offer same-day appointments and are more likely to accommodate clients who have difficulty taking time off from work or family.<sup>2</sup> Most importantly, PP clinics offer the full range of approved contraceptive methods (including the most effective LARC methods), while only two-thirds of health departments and only half of FQHCs have this capacity. Also, nearly all PP clinics offer same-day LARC placement, another big difference from both health departments and FQHCs. Finally, PP clinics provide on-site availability of oral contraceptives, and typically will provide a full year supply, a particular benefit for low-income women. Defunding PP clinics while reducing public funding for contraception through the ACA will reduce access for millions of low-income American women. In 2010, PP sites accounted for only 10% of all publicly funded family planning clinics but served 36% of

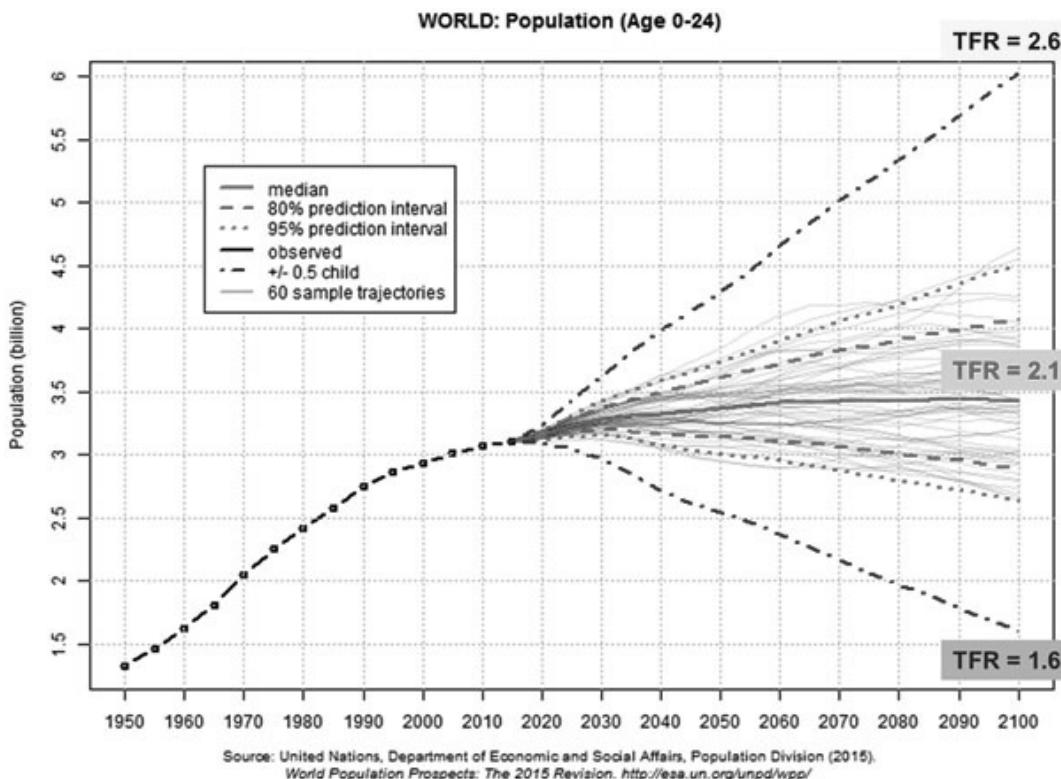
publicly funded contraceptive clients.<sup>3</sup> In more than 300 U.S. counties, PP acts as a primary safety-net health center for family planning. About a third of all women relying on publicly funded contraceptive services live in one of these counties. In 2014, more than 20 million U.S. women required publicly funded family planning services. This represents an increase of 1 million women since 2010.<sup>4</sup> This need won't go away with political rhetoric.

The ACA improved women's lives and made communities better by ensuring access to highly effective contraception.<sup>5</sup> The tens of millions of women who now face few cost barriers to obtaining contraception will see this benefit change with repeal of the ACA. Several studies have shown that the elimination of cost barriers between 2012 and 2014 has resulted in an increase in both use and continuation of prescription contraceptives and, in particular, LARC methods.<sup>6</sup> Increased use of LARC methods has been associated with a decrease in the proportion of unintended pregnancies in the United States (from 51% in 2008 to 45% in 2011).<sup>7</sup> How can a policy that benefits women and communities so directly be under attack?

Some cite opposition to abortion as reasons to defund these programs despite evidence that abortion rates have fallen dramatically as use of LARC methods has increased.<sup>7</sup> Under the Hyde Amendment, federal law currently bans funding

**Figure 2: World Youth Population Growth According to the Median Fertility Scenario**

World youth (age 0 – 24) population growth according to the median fertility scenario (Total Fertility Rate (TFR) of 2.1) with 80% (dashed) and 95% (dotted) prediction intervals. The upper and lower lines indicate TFR of  $\pm 0.5$  (e.g., TFR 2.6 and TFR 1.6).



Source: United Nations Department of Economic and Social Affairs, Population Division (2015).

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for abortion by all federally funded health programs, including Medicare, Medicaid, the Federal Employees Health Benefits Programs, TRICARE (military), Indian Health Service, and Bureau of Prisons. Of the roughly 7.5 million women covered by these programs, a disproportionate number (51%) are women of color.<sup>8</sup> As a former U.S. Navy physician, my heart goes out to the more than 1.4 million military servicewomen and dependents denied abortion coverage. For more than 900,000 of these women, TRICARE is their only source of coverage. This funding ban applies equally to the undesired pregnancy at six weeks and the much desired but severely malformed and genetically abnormal fetus diagnosed at 22 weeks. I am familiar with many heartbreaking stories from active duty women denied abortion coverage for management of an abnormal fetus. More recently, several states have taken steps to restrict private insurance coverage of abortion, and 10 states currently have policies that restrict abortion coverage.<sup>8</sup> We can only expect to see more restrictions and attempts to undermine abortion coverage under the new administration. Will these restrictions ultimately backfire as they affect more and more middle-class Americans?

My wife Robin and I attended the March for Women's Lives event in Hilo, Hawaii, on January 21, 2017, in solidarity with millions of women and men in Washington, DC, and around the world. The event in Hilo on a stormy, rainy day attracted about 2,000 people. In my hometown of Portland, more than 100,000 marched in a pouring rain. My colleagues shared some of their favorite signs. One of the best, held by a 12-year old boy, said "What do we want?...Evidence-based science!"...When do we want it?..."After peer-review!"

Although we may feel sometimes that these mass events in the nation's capital or in local communities make no difference, the prevalence of protests across the country and even in many countries around the world was heartening.

As women's healthcare clinicians, we are leaders in our communities. We need to stand up for science and educate our patients and communities. Our collective voices have great influence. Silence on these matters suggests acquiescence. ■

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**CME/CE QUESTIONS**

- Which of the following is most definitive of the absence of a Zika infection?
  - A serum PCR negative for Zika at seven days postexposure
  - A serum negative PCR at 14 days
  - IgM negative for Zika at five days post exposure
  - A serum PCR negative at five days for Zika
  - PCR negative at the time of diagnosis of a fetal CNS abnormality
- Which of the following is true of ovarian cancer screening?
  - It is highly effective.
  - It is recommended only for high-risk women.
- Intracytoplasmic sperm injection in association with *in vitro* fertilization enhances the chances of pregnancy in couples with:
  - unexplained infertility.
  - male factor infertility.
  - bilateral blockage of the fallopian tubes.
  - low oocyte yield on oocyte retrieval.

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