Uncertainty in Medicine: Zika, Alcohol & Fertility

We decided to address uncertainty in this month’s VOICE as the issue of the month. A discussion of the many uncertainties that seem to engulf us, and of the resulting multiple insecurities we rightly perceive, appears timely because this is where the nation finds itself today in practically all aspects of life, starting with national policies and politics, the economy, terrorist threats and foreign policy and, yes, health care.

And we are not only referring to the increasingly apparent shortcomings of the Patient Protection and Affordable Care Act (also in brief referred to as Obamacare) but to the perception that the nations in unprecedented fashion, and apparently completely unprepared, rather hysterically swoons from one potential health care catastrophe to the next. We just survived Ebola, and now there is suddenly the Zika virus which, only a few weeks ago, most of us, even within the medical community, did not even know existed. Not surprisingly, what gnaws at many of us is, therefore, the question, what will come next?

Constantly increasing connectivity, increasing media competition, the Internet with its huge number of more or less serious contributors are all responsible for steadily increasing, unwarranted risk exaggerations in our society. Whether it is the risk of a now well-prognosticated blizzard that leads the mayor to completely shut down New York City, when the city weathered well (no pan intended) much...

Continue reading about these two issues:

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Fertility Business News

We have on prior occasions lamented the excessive commercialization of some aspects of the so-called “fertility business.” Here are two additional stories deserving attention.

Read about “industrialization” of infertility: http://kaywa.me/

Settlement for egg donation lawsuit

It is hard to believe that anybody would file a lawsuit against the American Society for Reproductive Medicine (ASRM) for violating anti-trust laws in the first place, but even more incredibly, the ASRM, as reported in early February, decided to settle the case.

Here is what happened: As the principal professional organization representing the infertility field in the U.S., one of the more important functions of the ASRM is to set guidelines for ethical behavior and clinical practice. In that function, over 10 years ago, the ASRM set guidelines in the range of $5,000-10,000 for what it considered to represent appropriate reimbursements for efforts and time of eggs donors.

The lawsuit filed on behalf of four plaintiff donors claimed that, by issuing these guidelines, the ASRM “restricted trade” since, as ASRM members, most IVF centers follow these guidelines, thus depriving egg donors of a free market for their services.

Here is a little background to understand the ASRM action better: Under the U.S. law, and supported by most ethicists, it is illegal and unethical to “sell” body parts, which includes eggs. The law and ethical considerations, however, permit “appropriate reimbursement” for time, expenses and efforts a donor faces. What represents “appropriate reimbursement” was, however, neither defined by law nor was there unanimity until the ASRM stepped in, and asked a committee of experts to define this issue. The consensus reached by the committee of experts was then issued as a “guideline” by the ASRM.

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worse unannounced snow storms in the past without such draconic steps, or whether it is the constant exaggeration of risks in public health, government appears to believe that it is supposed to strive for a risk-free life. But risk-free existence does not exist, and risk avoidance, therefore, has to be proportional and make sense!

Physicians, probably better than many other professions, understand that every intervention carries risks. The goal of good medicine is not to avoid all risks at any price but to find the correct balance between risk and benefit, for that reason in medicine called the risk/benefit ratio. Observing how government and the media sensationalize public health risks is, therefore, disheartening. All such exaggerations achieve, is to create more uncertainties and increase the insecurity of the public.

We are trying to help, and this issue of the VOICE attempts to offer some clarity on some issues that, recently, made headlines in the media.

How big is the Zika virus problem?

The American Society for Reproductive Medicine (ASRM) in a Bulletin, released on February 9, 2016, succinctly noted: “at this point it seems clear that the virus has implications for reproduction, and that it can be transmitted through sexual activity and reproductive tissues.” The Bulletin then continues: “We urge patients who are pregnant, who are considering becoming pregnant or those who may be involved as donors or recipients of reproductive tissues to exercise caution.”

So here is what this means for everybody who already is pregnant or is planning on pregnancy in the near future (of course, including all patients in fertility treatment): The Zika virus is not a new virus. It was already present in Africa years ago but its significance to reproduction was only recently recognized, when Brazilian physicians noted a remarkable increase in neonates born with microcephaly (small head circumference). In trying to determine what may be the cause, investigators stumbled on the Zika virus.

It is important to note that, as of this moment, the association between the virus and microcephaly is just that: an association. This means that there is considerable reason to believe that the virus is causing the microcephaly but there is no direct proof, and how the virus may cause this very significant birth defect is not understood. It, for example, is entirely plausible that a co-factor of the virus rather than the virus itself (which could be anything, including, for example, a pesticide used against the mosquito that transmits the virus) is the real villain. Since they also identified specific eye pathologies in newborns directly attributable to the virus, and for other reasons, Brazilian investigators in recent days appear increasingly convinced that the virus, indeed, is the primary culprit.

What are the infection risks?

The Zika virus, in principle, like a good number of other viruses, is transmitted to humans through mosquito bites. Getting bitten by an infected mosquito makes such an infection likely in both sexes. There is, however, now also considerable evidence that the infection can be transmitted through sexual intercourse from men to women. Transmission from women to men has, so far, not been reported but has to be considered a possibility, as viral transmission during intercourse is usually more pronounced from men to women than women to men (see also, for example, the HIV literature).

Not all mosquitoes transmit this virus. Transmission is restricted to only two Aedes species, A. aegypti and A. albopictus, both of which also are the carriers of dengue and chikungunya viruses. Dengue fever has in recent years increased in the U.S. but is not endemic in most of the country as it is in parts of Mexico and the Caribbean. It, therefore, is unlikely that Zika virus infections will become endemic in the continental U.S. in the near future. Consequently, pregnant women or those planning to conceive in the continental U.S. really do not have to worry about being infected by this virus, unless they or their sexual partners travel to areas where the virus is endemic.

The Centers for Disease Control and Prevention (CDC), therefore, issued the so-called “Level 2 Practice Enhanced Precautions,” urging pregnant women and those seeking to become pregnant “to avoid travel to endemic areas or use enhanced prevention and follow up activity if such travel cannot be avoided.”

It is now clear that the Zika virus can be transmitted via semen. Any suspicion that a male may be infected, therefore, warrants condom uses with intercourse throughout pregnancy and, of course, interrupts potential conception attempts (for more detail, see...
New Monthly Case Report

The Hypoandrogenic PCOS Patient

As a service to patients and colleagues who are readers of this newsletter, we are initiating here a new section in THE VOICE, in which we report brief case summaries, we believe may be educational for patients and colleague. We invite colleagues from outside of CHR to participate in this monthly feature by contributing interesting cases. If you think that you may have an interesting case to report, please contact this newsletter’s editor, Ms. Yu Kizawa, at ykizawa@thechr.com.

Case: A 43-year-old woman with normal BMI presents with desire to conceive. She has previously failed 5 IVF cycles, including 3 involving preimplantation genetic screening (PGS) attempts. None of the 3 PGS cycles reached embryo transfer. Her FSH is 11.4mIU/mL with normal range estradiol; her AMH is 2.9ng/mL; her total and free testosterone are mildly below midpoint of normal range; her DHEA is 246 ng/mL, her DHEAS is, however, 64ug/dL; and her sex hormone binding globulin (SHBG) is 134nmol/L. The patient had a history of Hashimoto’s thyroiditis, had abnormal elevations of IgM and IgE immunoglobulins and, based on elevated IL-6, evidence of inflammation.

Analysis: This is a woman of advanced age with normal BMI who presents with repeated IVF failures. Her FSH is within expected range for age, though somewhat elevated. Her AMH is, however, unusually high for her age. This discrepancy between FSH and AMH, both reflecting functional ovarian reserve (FOR), is one key point in resolution of this case.

Total and free testosterone as well as DHEA appear in normal range; DHEAS is, however, abnormally low, while SHBG is abnormally elevated. This is a fairly typical presentation of what we, here at CHR, have come to call the hypoandrogenic polycystic ovary syndrome (haPCOS).

Background: The discovery of this new haPCOS phenotype was initiated at CHR with a study published in 2013 in the prestigious Journal of Clinical Endocrinology and Metabolism (Gleicher et al., Clinical relevance of combined FSH and AMH observation in infertile women, 2013;98:2136-45). This study revealed that, amongst all possible FSH/AMH combinations, the combination of high/high overall resulted in best IVF outcomes. Yet, at the same time, a combination of abnormally high FSH and abnormally high AMH was contradictory because, as FOR declines, both hormones are expected to go into opposite directions (FSH up, and AMH down). This unexpected finding initiated further research at CHR, which, ultimately, led to the discovery of the new haPCOS phenotype.

It is characterized by exactly the hormone profile above described patient demonstrates: Her FSH as well as AMH are abnormally high. While her testosterone and DHEA appear in normal range, they actually are not. This can be assumed because her DHEAS is very low, and especially because her SHBG is very high (it usually goes into the opposite direction to testosterone). Combined, these data suggest that the patient’s seemingly normal testosterone and DHEA levels are actually, likely, relatively hypoandrogenic.

This conclusion should not surprise: Her still very high AMH of 2.9ng/mL at age 43 strongly suggests that, when this patient was younger, her AMH probably was at PCOS levels. Since she has a normal BMI, and never was obese, she at younger years, likely, was a non-obese (“skinny”) PCOS phenotype, which in the literature has been differentiated from the “classical” PCOS phenotype with truncal obesity and obvious signs of hirsutism.

In continuing the investigation, CHR investigators then discovered that PCOS patients at CHR were almost exclusively of the “skinny” phenotype. Since over 90 percent of CHR patients failed prior fertility treatments elsewhere, this observation suggested that “classical” PCOS patients, likely, conceive more easily and earlier during fertility treatments than “skinny” PCOS patients (For further details, please see Kushnir et al., Relative importance of AMH and androgen changes with aging among non-obese women with polycystic ovary syndrome, J Ovarian Res 2015;8:54).

Like women with “classical” PCOS, “skinny” PCOS patients at young ages, however, are also hyperandrogenic; yet, older women with likely haPCOS, as ours studies revealed (same Kushnir et al reference), usually had become severely hypoandrogenic and, at best, barely reached mid-range normal levels, as here presented case. However, even haPCOS patients...
Hypoandrogenic PCOS: Continued from Page 3

with seemingly normal testosterone levels, have to be considered functionally hypoandrogenic because their ovaries’ tissue memory is, likely, expecting higher testosterone levels of their younger years. Therefore, we consider this PCOS phenotype to be hypoandrogenic and coined the term haPCOS.

We, since, have had the opportunity to see quite a number of relatively younger haPCOS patients and were able to add additional clarifications. For example, we now know that the hypoandrogenism of haPCOS is not the classical age-dependent decline in androgens seen in women after age 40. haPCOS patients suddenly drop their androgen levels already at relatively young ages (late 20s to mid-30s).

Why that happens is still unknown, though CHR’s strong suspicion is an autoimmune attack on the zona reticularis of the adrenals, where adrenal androgen production takes place. The principal reason for our suspicion is, like in the here reported case, low DHEAS, which is almost exclusively an adrenal product. Autoimmunity is suspected because, as in the here reported case, haPCOS phenotypes almost always demonstrate significant evidence for autoimmunity and/or inflammation. Moreover, in a small number of haPCOS patients, we actually diagnosed previously unknown autoimmune-induced classical adrenal insufficiency. Confirmation of an autoimmune anti-adrenal immune response causing the observed hypoandrogenism in haPCOS patients, however, awaits experimental confirmation.

Adrenal gland and zona reticularis

Adrenal cortex consists of three layers: Zona glomerulosa, zona fasciculata and zona reticularis. Zona reticularis, the innermost layer of the adrenal cortex, converts cholesterol into androgen precursors, including DHEA. Image from Wikimedia Commons, by OpenStax College under Creative Commons license.

Treatment: Low intra-ovarian testosterone levels adversely affect early stages of follicle maturation. haPCOS patients, therefore, require androgen supplementation, which we in most cases provide with dehydroepiandrosterone (DHEA), though sometimes with testosterone directly, following in principle the same protocol as in women with low FOR. Since in haPCOS patients higher levels of “normal” testosterone are likely required than in non-PCOS patients with low FOR, the one difference is that we carefully watch testosterone as well as SHBG levels, and will not initiate IVF cycles until SHBG drops below 80.0nmol/L.

Conclusions: Once the features of the new haPCOS phenotype were identified, it was quite surprising how often patients with haPCOS are seen in daily practice at CHR. Here described case report represents the fairly typical clinical presentation of these patients. The patient conceived in her second IVF attempt at CHR, and delivered, after receiving immunosuppressive therapy during her IVF cycle and into early gestation.

Since CHR for over 10 years has been routinely supplementing women above age 40 with DHEA, we, for all of this time, unknowingly, have been treating women with haPCOS correctly. When we reported in 2013 CHR’s outcome experience in IVF based on FSH and AMH combinations, we were unable to explain our findings (see above reference Gleicher et al). It took CHR’s investigators over three years to figure out the mystery. We now fully understand why women with elevated FSH and high AMH do so well at CHR, and are in the process of preparing a manuscript for publication, describing statistical outcome data for a few hundred haPCOS patients.

Mitochondria Study

DO YOU CARRY A MITOCHONDRIAL DISEASE OR KNOW SOMEBODY WHO DOES?

If you do, please call us at 212-994-4400 for a free consultation in person, by phone or via Skype. CHR is searching for a way to prevent inheritance of these awful diseases in collaboration with colleagues at the famous Salk Institute for Biological Studies in La Jolla, CA. You may be able to help!

Contact us to learn more about the study: http://kaywa.me/43Mdn

The Salk investigators are on the forefront of genetic editing, which has significant potential in eliminating genetic diseases and help infertile women conceive. CHR is looking forward to a long and fruitful collaborative effort between the two institutions, and hope you will consider participation in the study.
Such guidelines are exactly that; they are not the law, nor are they rules. Physicians may or may not follow them. Indeed, most professional organization that publish guidelines stress that such guidelines should not be rigidly applied to all patients but should be selectively applied, according to each patient’s circumstances.

It, therefore, appears puzzling to us that this lawsuit was not outright dismissed, though we do understand to a degree why the ASRM agreed to a settlement: The settlement was cheaper than a prolonged court battle. Plaintiffs’ lawyers, according to media reports, were paid $1.5 million in fees and costs. And, yes, the four plaintiff donors, each also received $5,000 (it is certainly better to be a lawyer than a plaintiff). In addition, ASRM agreed to remove the recommended payment range from the guideline.

So, if you see egg donor fees increasing in the coming years, you know where it all started: Egg selling is now considered commerce, subject to free market rules!

Corporate take over of IVF centers
We previously noted in these pages that, especially in Europe, publicly traded companies and/or investment trusts are increasingly interested in acquiring IVF centers. A similar trend appears to be developing in the U.S., with investors recently making a major investment into the Colorado Center for Reproductive Medicine (CCRM) to fund its national expansion.

Australia, a scientific pioneer in IVF, in recent years also became a pioneer in the commercialization of IVF by fostering some of the first IVF chains that became public companies. Now media from Australia report on some of the darker sides of these developments: Consumer watchdog organizations are apparently reviewing the advertising practices of these companies. Genea, one of the county’s largest chains of clinics, advertises itself as giving couples “an almost 40% greater chance of taking a baby home” in comparison to the average of other Australian clinics. City Fertility Centre in beautiful Brisbane claims that “of the people who do require IVF treatment and have had a baby through CFC, 90% fall pregnant in 1-3 cycles.” A number of leading academics in the field have criticized these advertisements as highly misleading, which they are, because even a statistician will have a hard time figuring out what they mean.

First U.S. Uterine Transplant
Colleagues from the Cleveland Clinic reported in late February the first successful uterine transplant operation in the U.S. We congratulate our Cleveland colleagues to a major surgical milestone, first achieved by colleagues in Sweden. The Cleveland Clinic department of Gynecology has a long and well-deserved reputation for superior surgical skills.

The most difficult part of their work, however, now only awaits them. After a year of waiting to let the transplanted uterus “recover,” our colleagues will have to be successful in achieving pregnancy in this uterus through IVF, and in bringing the pregnancy to a healthy, viable delivery. The Swedish colleagues, who developed the concept of uterine transplantation in humans, and so far have transplanted the largest number of uteri, already have reported healthy births.

A statement from the American Society for Reproductive Medicine (ASRM) noted that “it is important to note that, as impressive an accomplishment as this is, there is much work to do before we can properly assess its safety and efficacy.” We could not agree more!
Currently there is really little reason to worry about Zika.

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never will be. If you live in Brazil (or if you plan on visiting there for the Summer Olympics), it may be a different story, though!

On February 2, the Centers for Disease Control and Prevention (CDC) released a report on the effects of alcohol use on pregnancy, which concluded that women who do not use effective birth control should completely abstain from alcohol. The CDC’s principal Deputy Director, Anne Schuchat, commented: “The risk is real. Why take the chance?”

As is usually the case when a very sensational report of this kind is published and gets widespread media attention, our phones for a few days did not stop ringing. Concerned patients, many, as one would expect in a fertility center, in a relatively early stage of pregnancy, were fearful of having caused irreparable harm to their unborn children for daring to have had a glass of wine at a recent family celebration or at an intimate dinner with their significant other.

We were not the only ones who found the CDC’s recommendation and Schuchat’s comments somewhat surprising. Quite a number of prominent voices, indeed, spoke up, and considered the recommendation quite offensive toward women. Like others, we were stunned by the breadth of the brushstroke with which the CDC addressed this issue. Implying that women in reproductive years endanger every potential pregnancy by having a glass of wine or a drink is, simply, untrue.

Though crossing the street at red certainly creates risk, it, of course, does not put everybody into the hospital. A vast majority of people crossing the street at a red light will face no adverse outcomes, while saving time and, maybe, even having fun doing it.

From our point of view, the CDC’s position on this subject was far too alarmist and, therefore, inappropriate; and especially a Deputy Director of a federal health agency should know better!

This is, however, just one more example how government misunderstands its function in public health, which certainly is not to frighten people into what government considers best (and/or healthiest) behavior. Instead, it is the government’s responsibility to correctly, and without exaggerations, inform the public of potential risks and, by doing so, encourage the public to pursue healthy life styles. In other words, government should not make public statements on health-related behavior, unless such statements are based on solid science and reliable quantitative data.

Avoiding all alcohol - really?

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Dear Colleagues and Friends,

This Conference has the principal goal of offering an authoritative 2016 update for reproductive scientists and clinicians about important new translational developments in reproductive biology/physiology and clinically relevant patient care issues, while at the same time pointing out paradigm changes and imminent new potential developments of significance. By targeting clinicians as well as basic scientists as audience, this Conference will offer both groups a unique and intimate framework for interaction and exchange of ideas.

David F. Albertini, PhD | Ali H. Brivanlou, PhD, MD | Norbert Gleicher, MD | Zeev Shoham, MD

June 15, 2016 Abstract deadline for inclusion in the Journal of Assisted Reproduction and Genetics (JARG) and eligibility for Young Investigator Award of $5,000

Due to limited space and limited numbers of discounted hotel rooms available during the pre-Christmas season, we recommend early registration and hotel reservation.

Pre-Conference Workshops:

In vitro follicle/oocyte maturation age: From primordial stages | A new paradigm in clinical IVF: Age-specific stimulation and embryology | An in vitro implantation model: Peeking into the “black box” of implantation | The biological basis for the demise of preimplantation genetic screening (PGS)

Sessions:

The future of fertility care | Paradigm change I: Expanding infertility treatments from the gonadotropin-sensitive to earlier stages of follicular maturation | Paradigm change II: Early diagnosis of premature ovarian senescence, offering women more and better reproductive options | Paradigm change III: Reconsidering embryo selection | Paradigm Change IV: Individualization of infertility care | Skeptical of current clinical practice? Here are some answers!

For the full Conference program, registration, and abstract submission, visit the official Conference website: http://frm.cme-congresses.com/
Uncertainty: Continued from Page 8

alcohol has in the third trimester of gestation been routinely used as treatment for premature labor.

Olga Khazan in The Atlantic said it possibly best when asking, “why is it that whenever public health officials talk about alcohol, they act like they’re Puritan robots from outer space who could never understand earthlings’ love of distilled spirits?” What makes this CDC announcement even more incredulous, however, is that all of this is happening while state after state with government support is legalizing pot!

By being excessively alarmist in pronouncements and recommendations, public health officials are running the risk of desensitizing the public to really dangerous situations. After too many false alarms, nobody reacts to a real alarm when fire breaks out.

The amount of circulating misinformation affecting pregnant women appears to grow exponentially: Coffee is one day bad, and the next day healthy; exercise in pregnancy is healthy today and forbidden tomorrow. Suddenly all seafood is dangerous in pregnancy, and one has to wonder what women eat in countries where seafood is the nutritional mainstay.

But then again, governments rarely act logically, and often are more concerned with pretending than with achieving results. Having public media and the Internet available as largely uncritical megaphones allows them never to miss an opportunity as long as they can grab headlines. It is the public that is left wondering what is right and what is wrong, while physicians receive the phone calls from totally confused patients!

Driving patients crazy

Research programs at the CHR bring many opportunities for young doctors and scientists to investigate important areas of infertility with our professional staff of scientists and physicians. We do this because we recognize the importance of exposing future specialists to solid research and motivating them to pursue careers with rigorous standards that we use on a day-to-day basis at the CHR. This month’s image was taken by one of our most recent trainees, Margarita Agarsheva, who is finishing her medical training at Moscow State University in Russia and spending 6 months of research at CHR. She is studying the energy producing mitochondria in granulosa cells we retrieve from our patients as possible indicators of egg and embryo quality. Her research is being done at the CHR in our 4th floor imaging center under the supervision of Vitaly A. Kushnir, MD, CHR’s Director of Continuing Medical Education and Associate Scientist, and David F. Albertini, PhD, Senior Scientist and Director, Division of Laboratories.

A welcome back to CHR

Senior Embryologist and Assistant Scientist, Emanuela Lazzaroni-Tealdi, MS, is coming back to CHR after spending roughly a year away, attending to her young daughter, a CHR baby, and family matters in Italy. We are happy to welcome her back!

A welcome back to CHR

“-The CHR

Fighting for every egg and embryo!”

Staying Connected

New informational material on treatments or news coverage on fertility breakthroughs, the best way to stay up to date on CHR’s activities is via our social media channels. Follow us, and never miss important news!

Visit CHR on Facebook: https://www.facebook.com/thechr
Follow CHR: http://twitter.com/infertilityNY
Check out our video resources: https://www.youtube.com/user/CenterForHumanReprod

IN FOCUS

This feature presents microscopic images from CHR’s laboratories, edited by our Director of the Division of Laboratories and Senior Scientist, David F. Albertini, PhD.

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News on a CHR publication

We are very pleased to report that CHR’s 2015 paper, Wu et al., Aging-related premature luteinization of granulosa calls is avoided by early oocyte retrieval, in the prestigious Journal of Endocrinology (2015;226:167-180), according to a letter received from the Managing Editor of the journal, was “one of the top downloaded articles from the journal’s website during 2015.” We have to acknowledge that this did not come as a surprise because we consider this one of the most important papers CHR published in the last few years, which will change IVF practice globally.

Visit CHR on Facebook: https://www.facebook.com/thechr
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Check out our video resources: https://www.youtube.com/user/CenterForHumanReprod

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