not only did not benefit from the test but, actually, were harmed in their pregnancy chances by using the test (and paying for it out of pocket because insurance companies usually do not reimburse for PGS/PGT-A). Many among those adversely affected patients, moreover, not only discarded healthy embryos but, involuntarily, concomitantly also discarded their chances of genetic motherhood by wrongly assuming they could no longer conceive with use of their own eggs and, therefore, prematurely opting for donor eggs.

The deafening silence of the genetic laboratory industry, which made millions selling a mostly useless and sometimes harmful test, now for the second time in a decade has been described by the ASRM as unproven in its ability to affect IVF outcomes, makes this, however, an even worse transgression. What makes all of this, however, even worse a transgression, is the by now indisputable fact that, as a consequence of utilizing this test, huge numbers of perfectly normal embryos have been discarded. Because so many healthy embryos were mistakenly disposed of, a large number of patients not only did not benefit from the test but, actually, were harmed in their pregnancy chances by using the test (and paying for it out of pocket because insurance companies usually do not reimburse for PGS/PGT-A). Many among those adversely affected patients, moreover, not only discarded healthy embryos but, involuntarily, concomitantly also discarded their chances of genetic motherhood by wrongly assuming they could no longer conceive with use of their own eggs and, therefore, prematurely opting for donor eggs.

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It took quite some time (many, indeed, believe too much time) for the American Society for Reproductive Medicine (ASRM) to, finally, publish an updated opinion of preimplantation genetic screening (PGS) or, as it is now called in its latest reincarnation, preimplantation genetic testing for aneuploidy (PGT-A).

What the ASRM’s Practice Committee concluded (in much more diplomatic language than CHR has been using in these pages), however fully matches with CHR’s longstanding opinion: “The value of preimplantation genetic testing for aneuploidy (PGT-A) as a screening test for in vitro fertilization (IVF) patients has yet to be determined,” which in diplomatic language means that we have been sold a lot of hot air by the genetic laboratory industry over the last two decades because the commercial clinical utilization of diagnostic tests with unknown diagnostic value is not only unethical but, simply, inexcusable!

capacity is limited. We, therefore, recommend early reservations for everybody who is interested in attending. As always, cocktails start at 6pm, followed by the GrandRounds lecture between 7-8pm and, finally, a sit-down dinner, starting at 8pm. For reservations, please email ykizawa@thechr.com.

Practice Committee of the ASRM Publishes Updated Committee Opinion on PGS/PGT-A

ASRM’s Practice Committee Opinion finally puts an official question mark on PGS, but the genetic testing industry still refuses to take responsibility for 2 decades of abuse.
Annual 2018 Conference of the Foundation for Reproductive Medicine

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New Clinical Trial at CHR

Ovarian Rejuvenation Study Approved for an April Start

Women under 40 with POF/POI are needed for the study

CHR is very pleased to announce that the center’s Institutional Review Board (IRB) approved on March 22, 2018 the proposed study, which will involve injection of the patient’s own platelet-rich plasma (PRP) into one of her two ovaries, with the other ovary serving as control. Here is a brief summary of the study:

WHO QUALIFIES? All women under age 40 who suffer from so-called primary ovarian insufficiency (POI), also called premature ovarian failure (POF) or premature menopause.

HOW ABOUT WOMEN ABOVE AGE 40? POI/POF diagnosis requires patients to be under age 40. Women with early menopause (above age 40) will be offered the treatment under experimental consent but outside of the IRB-approved clinical trial.

WHAT IS THE RATIONALE FOR THE STUDY? PRP is a fraction of blood, which contains different bio-active substances called lymphokines and/or cytokines, produced by white blood cells. These cell populations have in various areas of medicine, such as orthopedics, rheumatology, dermatology and others, been demonstrated to exert beneficial effects on mostly inflammatory conditions. The hope is that these substances will reconstitute the ability of remaining follicles within ovaries to respond to stimulation by fertility drugs. (Even women in menopause, still, do have follicles in their ovaries.)

ARE THERE PRIOR DATA SUGGESTING THIS WORKS? There are lots of data published in other areas of medicine that suggest that PRP, indeed, can beneficially affect disease states in the body through local injections. There are, however, no such studies published in the infertility literature, suggesting improvements in ovarian response in POF/POI patients. European colleagues, however, were the first to orally report at meetings the alleged beneficial effects from intra-ovarian injections of PRP in women with POF/POI but absence of written reports is somewhat disturbing (see also Reproductive Medicine in the Media on page 8).

ARE OTHER FERTILITY CENTERS USING PRP? Yes, quite a number of centers around the world have started using PRP in routine clinical practice and with, at times, remarkably high fees, even though not one published study in the literature has so far appeared to suggest that PRP administration in POF/POI really works. Some of these center, indeed, are in the U.S., especially in New York City and Los Angeles. This is exactly why CHR is introducing PRP within a strict protocol-driven prospective clinical trial, and why CHR does not charge for production of patients’ PRP in CHR’s laboratory and the injection procedure.

HOW MANY PARTICIPANTS WILL BE NEEDED? The expectation is that it will take ca. 40 patients to determine whether the treatment works in some patients or not.

HOW CAN I APPLY TO PARTICIPATE IN THE STUDY? The first step is an appointment with one of CHR’s physicians in order to become a CHR patient and to determine whether you qualify for the study. You need to be under the age of 40 and have POF/POI without an obvious cause in order to qualify for the study. An obvious cause of POF/POF disqualifies from the trial. As already noted, if you do not qualify for the study, you, still, may be eligible to receive PRP outside the clinical trial under an experimental consent. If you are under age 40, and suffer from unexplained POF/POI, your only option to receive PRP will, however, be through participation in the trial.

HOW LONG DOES THE STUDY TAKE? Once you received an injection of PRP into one ovary, you will be monitored closely for development of new small follicles for at least 2-3 months. If development of new follicles is observed under ultrasound, those follicles will receive supporting ovarian stimulation with fertility drugs.

WHAT ARE THE COSTS? As already noted, there are no charges for preparation of PRP and for the injection procedure into the ovary. However, there are discounted charges for anesthesia services (provided by an outside physician) and for the operating room facility where the intra-ovarian injection is performed with the patient under mild I.V. sedation. For details about these costs, please inquire at CHR’s front desk. Should your ovaries respond and you, therefore, enter into a ovarian stimulation cycle, possibly even leading to egg retrieval, normal service charges will become due for services provided by CHR.

Continue reading on page 11
Introducing CONFLAM Forte™, new from Fertility Nutraceuticals, LLC

The only comprehensive inflammation-modulating nutritional supplement, designed specifically to improve female fertility*

+ CONFLAM Forte™ is the only comprehensive female fertility supplement designed to calm down immune systems that have become hyperactive due to inflammation*.
+ CONFLAM Forte™ was designed in consultation with the Center for Human Reproduction (CHR), a fertility center in New York City with special expertise in immunology of reproduction. CHR also endorses the product.
+ Every batch undergoes a rigorous triple-step quality assurance process.

Causes of excessive inflammation
Obesity | Infections | Autoimmune diseases | Allergies | Others

Effects of excessive inflammation on female fertility
Excessive inflammation can make the immune systems hyperactive, negatively affecting women’s fertility. Infertile women also demonstrate a higher prevalence of excessive inflammation, which can reduce pregnancy rates and increase miscarriage risks. Physicians and patients are often unaware of immune system hyperactivity, because it can be completely asymptomatic.

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CHR Experts' Perspective: Nutritional Supplements to Improve Fertility

- Most fertility supplements lack scientific evidence of efficacy. CHR recommends just a few, depending on each patient's needs.

So, you are trying to conceive, and your girlfriend told you about all those supplements you immediately should start taking; a long list of at least 10 different ones. Just thinking about swallowing all of these pills every day makes you dizzy. And what about the costs? Insurance rarely pays for supplements and you rightly ask, will they really make a difference?

The honest answer is that, with very few exceptions, they likely make NO difference!

**NOTICE OF POTENTIAL CONFLICT**
We want to point the attention of our readers to a potential economic conflict: CHR and some of its physicians are owners of a number of US patents, which claim fertility benefits in women with supplementation of androgens (male hormones), especially a hormone called dehydroepiandrosterone (DHEA). In the US, DHEA, paradoxically, is considered a food supplement, while elsewhere in the world, like other hormones, it is considered a drug. Since CHR and some of its physicians receive royalties from companies that sell DHEA as a fertility nutraceutical, CHR, in full disclosure, wishes to point out this fact as a potential conflict of interest, readers of this article should consider.

There is very little evidence that in almost any medical specialty nutritional supplements make much of a difference. Studies in various medical fields have shown this over and over again; yet, the industry is growing, and people buy ever increasing numbers of supplements. If anything, in pregnancy and/or in preparation for pregnancy, there is a general feeling that supplementation may be especially useful.

To a degree that is correct. For example, there is considerable evidence in the literature that suggests that supplementing folic acid during pregnancy lowers the prevalence of spinal fusion defects in offspring. Whether full prenatal vitamins make any difference is, however, already much more controversial, unless, of course, specific deficiencies are discovered through objective laboratory testing.

So, for example, if a patient has low Vitamin D levels, it, of course, should be corrected with a supplement, or if a patient is diagnosed with anemia, supplementation with iron may be appropriate.

When it comes to infertility, the considerations are similar. If a vitamin deficiency is diagnosed during a basic fertility evaluation, it makes sense to supplement; if no such deficiencies are diagnosed, automatic supplementation really has to be questioned.

**Vitamin D**
A good example is Vitamin D deficiency. A number of studies recently claimed that abnormally low levels could negatively affect IVF outcomes. A study CHR investigators performed was, however, unable to confirm any adverse effects of low levels of Vitamin D on IVF outcomes. CHR’s physicians, still, supplement abnormally low levels but are much less concerned about them than they used to be before completing their study, which soon should be published.

**Other Vitamins**
Many women in fertility treatments supplement with a whole array of other vitamins as well, including Vitamin C, Vitamin E, Vitamin B-Complex or individual Vitamin B components, etc. There is little, if any, evidence that any of these supplements affect fertility treatments in any significant ways, unless they have been established to be deficient.

**Non-Vitamin supplements for female fertility**
There are also increasing numbers of non-Vitamin supplements being marketed to female infertility
Supplements: Continued from Page 5

patients, either as individual products or in combination products containing multiple ingredients. Single substance promotions one finds all over the web include zinc, magnesium, selenium, beta-carotene, royal jelly, L-arginine, L-carnitine, fish oil and omega 3 fatty acids, acai, nicotinamide riboside, NAC (N-acetyl-cysteine) and melatonin. Among all of these, we are aware of really only one Japanese study, involving Melatonin, which claimed benefit in improving ovarian function in women with low functional ovarian reserve. How all of the other products have become so popular, is really quite amazing because none of them has been demonstrated to cause any positive effects on either female or male fertility.

Herbs
Likely due to the increasing popularity of Eastern (Chinese) medicine, we have in recent years also witnessed a considerable increase in use of herbs. Agnus Castus (Vitex Agnus Castus) is advertised as “restoring hormone imbalances” and “increasing fertility” but we are unaware of studies to prove this point. Moreover, since Chinese herbs often contain hormones, they can interfere with hormone assay results. They, indeed, can also interfere with the function of various medications, such as birth control pills. At least one study in the medical literature, published by European colleague’s, claimed lower IVF pregnancy rates in cycles where patients were exposed to herbs. For all of these reasons CHR, therefore, strongly recommends that patients avoid herbs while in IVF cycles.

What CHR recommends
In contrast to many other fertility centers, CHR does not have a “supplement list” that is prescribed to every patient. Indeed, CHR does not believe in the concept of treating everybody in the same way. Very much to the contrary, one of the cornerstones of CHR’s treatment philosophy is individualization of care, and that also applies to supplements.

Dehydroepiandrosterone (DHEA)
As already noted above, CHR is quite skeptical about use of supplements in fertility treatment since for the vast majority of supplements offered in the market place, there is really no supportive evidence of efficacy in improving fertility. CHR, therefore, concentrates on only a few: The supplement CHR prescribes the most is dehydroepiandrosterone (DHEA) Anywhere but in the U.S., DHEA is really not considered a food supplement but a drug. Indeed, because it is often abused by athletes and body builders, DHEA is a controlled substance in many countries. The reason why in the U.S. it is available without prescription is a long story, involving the usual political interests that so often are responsible for rather strange policy decisions. DHEA, therefore, is available in the U.S. from a large number of resources as an over-the-counter product, and often of quite mixed quality.

Though DHEA is available without prescription, CHR, nevertheless, considers it a pharmacological product that should be produced under strict quality control and prescribed by a physician. CHR readers may be aware that CHR investigators hold a good number of U.S. patents (see Conflict Statement above), claiming fertility benefits from supplementation with DHEA (and other androgen hormones) in female infertility. For that reason, any company that wants to sell a DHEA product for female fertility purposes in the U.S., must be licensed by CHR. This gives CHR the opportunity to exert a certain degree of quality control over products that make fertility-related claims. Currently, only two products have been licensed by CHR: Fertinatal™, produced by Fertility Nutraceuticals, LLC, in NYC, and a DHEA product offered by Theralogix, LLC, in Rockville, MD. CHR prefers the former because it represents the exact composition and particle size of the DHEA CHR investigators used in their initial groundbreaking clinical research projects, reported in the medical literature. Those studies laid the groundwork for the worldwide utilization of DHEA (and other androgens) we now witness in the treatment of hypo-androgenic female infertility.

CHR investigators a good number of years ago reported in collaboration with colleagues from Toronto, Canada, that DHEA supplementation not only enhanced pregnancy chances but also reduced miscarriage rates, and that this reduction, likely, was caused by decreases in embryo aneuploidies. Most remarkably, these effects became only visible after age 35, and increased with advancing female age. CHR, therefore, recommended to combine standard prenatal multivitamins with a low dosage (25mg daily) of DHEA for women above age 35 who were attempting to conceive on their own. Fertility Nutraceuticals, LLC, indeed, started producing such a product, and CHR still recommends it for women above age 35 with no fertility problems who are trying to conceive spontaneously. The dosage of 25mg is only one-third of the therapeutic dosage recommended to women

Continue reading on page 7
who are infertile and hypo-androgenic.

**Coenzyme Q10 (CoQ10)**
CHR also quite extensively prescribes Coenzyme Q10 (CoQ10), though one must acknowledge that there is not a single CoQ10 study in the literature that has shown fertility benefits in women. Studies in small female animals have demonstrated benefits but humans are not mice, and it is always dangerous to uncritically extrapolate animal data to humans. What convinced us at CHR that there may be value in CoQ10 supplementation was that our urology colleagues have been able to demonstrate benefits on semen quality from CoQ10 supplementation. Considering absence of side effects, relatively low costs, supportive animal data and the fact that male gametes appear to benefit from CoQ10 supplementation, CHR’s physicians came to the decision to consider CoQ10 a co-supplement to DHEA in all women with low functional ovarian reserve. At the same time, we would welcome supportive studies in humans to confirm our decision. In males, CoQ10 is the only supplement CHR recommends.

**Anti-Inflammatory Mix**
As CHR recently addressed in these pages, it is becoming increasingly obvious that inflammation plays a much bigger role in female infertility than has been appreciated. CHR investigators associated elevated C-reactive protein (CRP) with significantly lower IVF pregnancy rates and elevated interleukin-6 (IL-6) levels with significantly increased miscarriage rates. Consequently, CHR treats evidence of inflammation with anti-inflammatory prescription medications much more aggressively than in the past. Concomitantly, we are, however, also exploring the use of a new supplement that recently entered the market under the name Conflam Forte™, produced by above noted Fertility Nutraceuticals, LLC in NYC, and made up of a number naturally occurring anti-inflammatory ingredients.

In summary, non-prescription food supplements in our opinion have only a rather finite role to play in modern fertility care. That DHEA is the only such supplement we can wholeheartedly recommend, speaks for itself, since DHEA is a natural hormone men and women produce in their bodies. It, therefore, is a drug and not a food product under any definition. Though now routinely prescribed all over the world, and in its efficacy supported by considerable animal as well as human experimental evidence, even DHEA supplementation has remained, however, somewhat controversial, and there are good as well as bad reasons for that: In medicine it is always better to be skeptical than to jump into unsupported therapies, and it is true that nobody has yet published a properly powered prospectively randomized study of DHEA. CHR has attempted twice but had to abandon both attempts because women did not want to be randomized (i.e., have a 50% chance of receiving a placebo over many months). Studies in various animal models, however, established an excellent biological framework in explaining the clinical effectiveness of androgen supplementation in hypo-androgenic infertile women, and clinical studies in humans with lower levels of evidence also strongly support androgen supplementation in such women.

Not everybody agrees, however, with what research has quite convincingly demonstrated: One colleague with a prominent website, for instance, appears quite unfamiliar with the conversion biology of DHEA to testosterone when making some rather strange statements in warning against DHEA supplementation in infertile women. He, for example, claims that “by causing testosterone overload, such therapy could be highly detrimental to some women at risk for hyperthecosis.”

What makes this warning even stranger is that he specifically refers to older women and women with PCOS as threatened by DHEA supplementation. No sane fertility specialist would, of course, ever treat an already hyper-androgenic PCOS patients with DHEA but we are not sure that this colleague has already read up on the so-called hypo-androgenic PCOS-like phenotype, repeatedly discussed in the VOICE, which greatly benefits from DHEA supplementation. And practically every woman above age 40 is hypo- and not hyper-androgenic, which means that her ovaries would benefit from higher testosterone levels. Finally, we are really wondering about the concept of hyperthecosis, and how one diagnoses this condition in clinical practice in the first place?

So, let us, therefore, explain a few important issues regarding DHEA (or androgen) supplementation in general:

- The recommended dosage of DHEA (25mg TID, p.o.) is roughly equal to the daily DHEA production rate of a young female adult person, therefore quite low and practically never will raise testosterone
Elsewhere in this issue of the VOICE we report on the IRB approval of CHR’s PRP study for the purpose of Ovarian Rejuvenation in women with premature ovarian failure (POF), also called primary ovarian insufficiency (POI). We also in last month’s VOICE noted that PRP has been in clinical use in Europe and in a number of centers in the U.S., though without any published evidence of success.

The authors who reported these 2 patients apparently announced a second phase for their trial, scheduled to include 33 participants. This project is supported by what appears to be a corporate entity, called MD Stem Cells, located in Westport, Connecticut, which describes itself as “sponsor of specialty clinical studies involving ophthalmology, neurology and spinal cord injury” (though no word on infertility). They further note that their “success stems from years of efforts, first in Europe and, beginning in 2013, with US based, FDA compliant, IRB approved and NIH registered studies.” Our research, however, was unable to detect even one treatment the company offered that was “picked up” by any other providers.

Now comes a paper, published by European and U.S. investigators (Sills et al., First data on in vitro fertilization ad blastocyst formation after intraovarian injection of calcium gluconate-activated autologous platelet rich plasma. Gynecol Endocrinol 2018;28:1-5), which does report on 4 cases of intra-ovarian injection of PRP. Unfortunately, however, like above cited study on the use of bone marrow stem cells, this report makes little sense.

Again, there are multiple reasons why caution is, indeed, called for, starting with the fact that the Food and Drug Administration (FDA) recently announced a clamp-down on unapproved “stem cell treatments” because so much false advertisement has been surrounding many clinic offerings in practically all medical specialties. To our surprise, we find ourselves this time in full agreement with the FDA, as we find the described study design seriously lacking.

We, therefore, caution against over-interpreting this report, as many media have done. As of this moment, there is really not enough evidence to suggest that bone marrow stem cells can do anything in ovaries. Monaco interviewed a prominent medical endocrinologist at Mount Sinai’s Icahn School of Medicine who also called for caution.

There are many reasons why caution is, indeed, needed: First, the study involves only 4 women and none of them really suffered from POF/POI. They all, indeed, did demonstrate abnormally low age-specific ovarian reserve but were far from being in menopause. In other words, they are what we here at CHR describe as women with premature ovarian aging (POA) or occult primary ovarian insufficiency (oPOI). Women with POA/oPOI in our opinion do not require Ovarian Rejuvenation and will, even with much less invasive treatments, produce in most cases good egg and embryo numbers. Without appropriate controls, it, therefore, appears very likely that these 4 patients would have had similar IVF cycle outcomes even without PRP treatments.

Stem cell treatment for POF/POI?

Previously on PRP:
http://kaywa.me/2r637

New report of PRP use requires cautious interpretation

Platelet-Rich Plasma (PRP) for Ovarian Rejuvenation

Kristen Monaco, Staff Writer for MedPage Today on March 19, 2018 reported from ENDO 2018, the annual meeting of the Endocrine Society that this year took place in Chicago, Illinois, that colleagues from Augusta University in Georgia claimed success in “rejuvenating” ovaries of women with premature ovarian failure (POF), also called primary ovarian insufficiency (POI) by injecting bone-marrow-derived stem cells in a surgical procedure (laparoscopy) into their ovaries. Two so-treated patients were then followed up at 1 week, 1 month, 6, 9 and 12 months with a variety of hormonal blood tests but apparently not with assessments of follicle growth, attempts at ovarian stimulation or anything that really could attest to the effectiveness of the procedure.

Now comes a paper, published by European and U.S. investigators (Sills et al., First data on in vitro fertilization ad blastocyst formation after intraovarian injection of calcium gluconate-activated autologous platelet rich plasma. Gynecol Endocrinol 2018;28:1-5), which does report on 4 cases of intra-ovarian injection of PRP. Unfortunately, however, like above cited study on the use of bone marrow stem cells, this report makes little sense.
CHR in the News

An alternative to egg freezing to preserve fertility?

WIRED on March 27, 2018 published an interesting article authored by Robin Marantz Hening, suggesting that “Women may have an alternative to freezing their eggs.” She for that purpose interviewed Vitaly A. Kushnir, MD, who is Director of CHR’s Fertility Preservation Program, and also came by to see firsthand CHR’s cryopreservation laboratory where eggs, sperm, embryos and, yes, also ovarian tissue are cryopreserved.

CHR is among a small minority of IVF programs, which are licensed not only to freeze eggs, sperm and embryos but also ovarian tissue. Programs licensed to freeze ovarian tissue for future reimplantation have been doing this now for a good number of years almost exclusively in cases where young women for medical reasons have to undergo treatments (usually either chemo- or radiation therapies) that will wipe out their ovarian function. To preserve their fertility, they, therefore, freeze some of their ovaries (the so-called cortex that contains most of the follicles) before undergoing these toxic treatments.

Once cured of their medical problem, small stripes of their ovaries can then be reimplanted into those patients, where they usually quickly establish vascularity and start functioning as mini-ovaries. Because they are the patients’ own tissues, there is no rejection taking place, as it would with transplantation of another person’s tissues.

Because this procedure, mostly used in cancer patients, has become a successful and routine practice, there has been increasing talk about using the same treatment also in less dire medical situations, like, for example, in women with severe endometriosis, in women who want to delay their menopause or in young women who just want to preserve their fertility.

In other words, proponents of wider use of ovarian issue freezing argue that, if you want to preserve your fertility, wouldn't freezing part of an ovary make more sense than repeated freezing of small groups of eggs? And this was, basically, the subject of the article in WIRED.

This article, indeed, raises a timely question because the number of eggs one retrieval cycle, performed even at relatively young ages, produces is quite small. Patients, therefore, usually have to undergo multiple retrieval cycles to accumulate a desired number of frozen eggs. Instead, they could undergo one ambulatory operative laparoscopy, which would literally yield hundreds of eggs that could be frozen in tiny strips of ovarian cortex, which at any later point could be reimplanted into the patient, even if she already has reached menopause.

There is also another option on the horizon that may make this form of fertility preservation even more attractive: In last month’s VOICE, we reported that Scottish colleagues in collaboration with CHR’s Director of Laboratories, David F. Albertini, PhD, for the first time succeeded in culturing the kind of very immature follicles that sit in the cortex of ovaries (so-called primordial follicles) to maturity.

The efficiency of the procedure was still inadequate for clinical use, but it seems increasingly likely that in the near future we will learn how to efficiently culture such follicles to maturity in our laboratories. Once that has been accomplished, ovarian tissue would not even have to be reimplanted into patients in order to achieve pregnancy. We then will simply thaw out a singles tissue strip with a large number of follicles and culture those follicles in the lab to maturity, fertilize them, make embryos - and voila!

PRP: Continued from Page 9 each ovary in those patients. How that is technically even possible, is unclear, considering that, especially in older women, most ovaries have a much smaller total volume than 5mL. Just to place this point into context, CHR is planning to inject 0.5mL into each ovary. In other words, not a very credible study, and CHR’s study remains much needed!
In the middle of March, Vitaly A. Kushnir, MD, CHR's Director of Continuing Medical Education and Fertility Preservation Program, was invited to present at a medical conference in Guangzhou, China. His two lectures, one on adrenal gland and female reproduction and the other on the efficacy of PGS/PGT-A, were received well by the attendees of the Reproductive Endocrinology Conference held at the Sun Yat-Sen Memorial Hospital. Dr. Kushnir’s trip coincided with one of several conference appearances abroad this spring for Norbert Gleicher, MD, CHR’s Medical Director and Chief Scientist, for a presentation at the Danish Fertility Society’s annual meeting. David H. Barad, MD, MS, CHR’s Director of Clinical ART, held the fort at CHR.

As repeatedly noted in the pages of the VOICE, CHR has always argued in favor of professional self-regulation in the field of IVF. In doing so, we, however, always referred to ethical considerations affecting research in reproductive medicine that should be left to professional self-regulation. This clearly is not the issue here; to the contrary, the reason why PGS/PGT-A has become such a black eye in the, otherwise, rather stellar history of IVF, is that appropriate research was not performed before the procedure was integrated into routine IVF practice.

Whether a commercial clinical test, especially a genetic test with the power to lead to disposal of human embryos, is properly validated for clinical use has never been subject of self-regulation but has always been under the purview of strict Food and Drug Administration (FDA) guidelines and/or, often, under local state department of health guidelines. How, even up to this point, PGS/PGT-A has been able to avoid FDA and/or local department of health scrutiny, is truly astonishing. How much more damage must be done to infertile couples before the FDA and/or local state health departments intervene?

Dr. Kushnir Visits China for 2 Invited Lectures

Mitochondria Study

We are looking for study participants.

Do you carry a mitochondrial disease, or know someone who does?

If you do, please call us at 212-994-4400 for a free consultation. CHR is searching for a way to prevent inheritance of these awful diseases in a collaborative research project with colleagues at the famous Salk Institute for Biological Studies in La Jolla, CA. You may be able to help us find a way to prevent mitochondrial diseases in children!

CHR on self- vs. government regulation: http://kaywa.me/YGH4H

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

PGS/PGT-A: Continued from Page 1

...for medicine as a whole, the history of PGS/PGT-A is unprecedented.

An even larger scandal. The industry not even uttered one “mea culpa” or one “we are sorry” for all the heartache patients encountered for over a decade! Much to the contrary, seemingly without contrition, the industry is, still, pushing the concept of what is now called PGT-A, though, once again, for some new nebulous and unsupported indications. In other words, business is continuing unabated!

Likely not only for the IVF field, but for medicine as a whole, the history of PGS/PGT-A is unprecedented. We are unaware of similar circumstances in any other field of medicine, where a crucial clinical test (ultimately decisive in determining which human embryos should be disposed of) is allowed to enter routine clinical practice without prior validation studies and, indeed, based on completely unsubstantiated claims, is allowed to do this over and over again in three consecutive incarnations of testing technology and interpretation of results.

CHR on self- vs. government regulation: http://kaywa.me/YGH4H

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

Mitochondria Study

We are looking for study participants.

Do you carry a mitochondrial disease, or know someone who does?

If you do, please call us at 212-994-4400 for a free consultation. CHR is searching for a way to prevent inheritance of these awful diseases in a collaborative research project with colleagues at the famous Salk Institute for Biological Studies in La Jolla, CA. You may be able to help us find a way to prevent mitochondrial diseases in children!
Supplements: Continued from Page 7

- The principal advantage of DHEA over direct testosterone administration lies in the fact that different organs (the ovaries included) maintain varying “normal” testosterone levels by picking up only as much DHEA out of circulation as they need to reach those desired levels. DHEA and DHEAS, otherwise, circulate as storage capacity for future testosterone production, while by themselves being mostly inert as androgens because of their very low affinity to the androgen receptor;

- Responsible DHEA (androgen) supplementation, of course, requires baseline level determinations (one treats only hypo-androgenic women) and follow-up testing to determine when testosterone levels have reached the desired range, and an IVF cycle can be initiated;

- Reaching toxic testosterone levels is really not the problem; what sometimes does become apparent with appropriate monitoring of testosterone levels is that a small minority of patients (much more frequently observed in women of African descent than in other races) do not convert DHEA well to testosterone. The genetics of this were well described by Aya Shohat-Tal, PhD and her CHR co-investigators in 2015 in NATURE Reviews Endocrinology [11(7):429-441]. Those patients then require direct testosterone administration by gel or patch.

Ovarian rejuvenation study: Continued from Page 3

physicians. PLEASE NOTE THAT MOST INSURANCE COMPANIES DO NOT REIMBURSE CHARGES FOR EXPERIMENTAL PROCEDURES!

HOW IS THE INTRA-OVARIAN INJECTION OF PRP ADMINISTERED? The procedure is practically almost identical to an egg retrieval in that one of CHR's anesthesiologists administers IV sedation to the patient. Once she is asleep (which happens within seconds), her vagina is cleaned, and an ultrasound probe is inserted to visualize the ovaries. The probe has a needle guide attached to it, through which a long needle is inserted, which then follows a trace-line on the ultrasound machine. This way, it is very simple to direct the needle toward the right spot in the ovary. In a retrieval, the needle aspirates fluid from the ovary (i.e., the follicles). Here, small amounts of fluid are injected under the capsule of the ovary, where remaining follicles are situated. At the end of the procedure, which should take no longer than 5-10 minutes, the needle, followed by the ultrasound probe are withdrawn, and the patient is woken up. Again, like in an egg retrieval, she will be watched in recovery for a little while before being discharged home. Because patients receive IV sedation, they must be picked up.

Should you have additional questions, please write to ykizawa@thechr.com. If you want to be considered for participation in the study, please call for an appointment with one of CHR’s physicians at 212-994-4400, and tell the patient representative that you are calling regarding the PRP study.