



THE WORLD
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Spring 2014 Newsletter

Thank you for your interest in The World Egg Bank.

We would like to share some of our exciting new developments with you. We are pleased to announce that Dr. Kim Pomeroy has joined our team as our Scientific Director, and look forward to the value he brings to The World Egg Bank. We also are now working with Dr. Masashige Kuwayama as our Scientific Advisor and utilizing his Cryotec Method, a new technology that we anticipate will increase our already superior warming rates. Our impressive 2013 pregnancy data is below.

The World Egg Bank is working with a growing number of clinics in the US and worldwide. We have screened and registered a large number of new donors in the last few months to accommodate your patients. We are delighted that we have brought such great outcomes to so many recipients with the help of their local fertility specialists! Please don't hesitate to contact us with any questions.

Best,
Diana Thomas, CEO &
Dr. Patricia McShane, Medical Director

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The World Egg Bank

43067 N. 112nd Street, Suite 1

Phoenix, Arizona USA 85018

Toll Free: +1-877-331-2427

US: +1-402-670-1906

Fax: +1-602-678-0326

www.TheWorldEggBank.com





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The World Egg Bank Pregnancy Rates

The World Egg Bank takes great pride in collecting and reporting direct and clear pregnancy outcome data for our prospective patients and their fertility clinical staff. We are happy to report the following data from our US verified clinics during 2013:

Thaw survival rate per warmed oocyte* 87%
Pregnancy rate per oocyte warming (heartbeat) 64%
Implantation rate (heartbeat per transferred embryo) 29%
Average number of embryos transferred 2.1

2013 Australia Data

The outcome data for Australia during 2013 is reported separately due to the practice of transferring a single embryo in most instances, consistent with the practice with fresh embryos, in order to minimize twins. For comparison, pregnancy rates of approximately 35% are noted with fresh embryo transfers.

Thaw survival per warmed oocyte* 83%
Pregnancy rate per oocyte warming (heartbeat) 38%
Implantation rate (heartbeat per transferred embryo) 33%
Average number of embryos transferred 1.1

The World Egg Bank Guarantee

The World Egg Bank Guarantee assures patients that at least 60% of oocytes will survive the warming when a minimum of six (6) oocytes are warmed and the embryology staff have been trained and verified by The World Egg Bank trainers.

*Survival is defined as warming of the vitrified egg and placing it into culture. Due to the inability of The World Egg Bank to account for sperm quality and other aspects of ICSI, growth protocols, and lab equipment quality controls for each clinic, we can only guarantee what we can control, which is our proven training and verification process for the thawing of the eggs.

The World Egg Bank

4202 N. 32nd Street, Suite 1

Phoenix, Arizona USA 85018

Toll Free +1 877.331.2427

US: +1 602.678.3906

Fax: +1 602.678.0328

www.TheWorldEggBank.com



Welcoming Dr. Masa Kuwayama as our Scientific Advisor

Dr. Masashige Kuwayama, known to all as Masa, has joined our organization as Scientific Advisor this spring. A pioneer in cryobiology, he has advanced vitrification techniques, initially in animal species but ultimately moving into human medicine when the technique proved robust in other species. He is responsible for the world's first vitrification pregnancy in a woman who had her oocytes cryopreserved prior to cancer chemotherapy. She subsequently married, had both of her oocytes warmed, inseminated and gave birth to a baby.

Dr. Kuwayama has perfected the new Cryotec vitrification system and is providing training for embryologists in workshops around the world. He is currently the CEO of a private research institute, Repro-Support Medical Research Center in Japan, and the academic and technical supervisor of the embryology laboratory at Kato Ladies Institute, one of the largest IVF centers in the world.

Dr. Kimball Pomeroy Joins The World Egg Bank as Scientific Director

Kimball O. Pomeroy is a clinical embryologist who has directed several clinical laboratories throughout the United States. He was trained in Bristol, England as a human embryologist and prior to that was educated at Colorado State University, where he received a PhD in Animal Physiology, and then worked at the Salk Institute for Biological Studies, where he did post-doctoral work in molecular biology. At the Salk Institute, Dr Pomeroy was a molecular biologist and worked with Dr Glen Evans on the Human Genome Project (chromosome 11) and did work in transgenics.

Dr Pomeroy has worked as a consultant for several projects in Mexico, Nepal, China, Bolivia and the Bahamas. He has served as a member of the SART Executive Board, chair of the Reproductive Laboratory Technician's Group, chair of the College of Reproductive Biology and a founding member of the Regulatory Task Force and the Southwest Embryologist Summit.

Dr Pomeroy has lectured at many scientific meetings and has been involved in the organization and presentations at several symposia for the education of embryologists. He has coauthored numerous papers, mostly dealing with the detection of embryo toxins and cryopreservation. Recently, he has coauthored several papers on the

The World Egg Bank

43232 N. 27th Street, Suite 1

Phoenix, Arizona USA 85018

Toll free +1 877 331 2427

US: +1 602 678 1906

Fax: +1 602 678 0729

www.TheWorldEggBank.com



risks of cross-contamination of microbes during storage of tissue in liquid nitrogen, the usefulness of embryo morphology in predicting pregnancy and the source of microbial contamination during embryo culture.

The World Egg Bank at ASPIRE/FSA

The World Egg Bank was well represented at the 5th Congress of the Asia Pacific Regional Initiative on Reproduction (ASPIRE 2014) in Brisbane Australia, April 2014. The meeting was held in conjunction with the Fertility Society of Australia.



View of Brisbane from the Conference Center.

Our exhibit booth was staffed by our founder Diana Thomas, medical director Patricia McShane, embryologist and vitrificationist *par excellence* Brian Lomanto and administrative staff person Caderina Carrizosa. Many visitors from the Pacific basin stopped by the booth and learned about our current technology and outcomes. We are proud of our compliance with Australian rules and regulations. There was a lot of interest from practices in New Zealand where the current regulations are interpreted as being prohibitive of almost all donor oocyte services. It is expected that newer interpretations will allow donor egg as has been carried out in the UK and Australia (<http://acart.health.govt.nz/consultations>).

The World Egg Bank

4202 N. 22nd Street, Suite 1

Phoenix, Arizona USA 85018

Toll Free +1 677.331.2427

US +1 602.678.1906

Fax: +1 602.678.0328

www.TheWorldEggBank.com



THE WORLD
EGG
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The World Egg Bank

4202 N. JAZZ STREET, SUITE 1

PHOENIX, ARIZONA USA 85018

Toll Free: +1-877-331-2197

US: +1-602-678-1906

Fax: +1-602-678-0326

www.TheWorldEggBank.com



Brian, Ken, and Diana at the ASPIRE booth.

Unveiling a New Vitrification Technology for The World Egg Bank

Dr. Masashige Kuwayama, world renowned embryologist and leader in the field of cryopreservation, has introduced his newest vitrification system, Cryotec. This innovative method has been adopted by The World Egg Bank for oocyte and embryo vitrification and warming. Speaking to interested guests at The World Egg Bank's cocktail reception at FSA/ASPIRE, Dr. Kenichiro Hiraoka, a close associate of Dr. Kuwayama, outlined the 100% survival rate and high pregnancy rates of oocytes that have been vitrified and warmed with the Cryotec method.

What makes this system so successful are the years of dedicated research and innovation Dr. Kuwayama has been able to achieve. Cryotec takes advantage of three critical factors: high viscosity, minimal volume and direct touch. The medium is also chemically defined, making it very stable and consistent. Finally, the manufacturing process is highly quality controlled and each lot is tested to be endotoxin free.

In order to introduce this technique, Diana Thomas and Brian LoManto visited Drs. Kuwayama and Hiraoka at their laboratory in Japan. Brian was trained in the Cryotec vitrification technique that he then started performing at the retrieval center in Phoenix, Arizona. Internal studies with the method have been extremely positive with excellent results.



The World Egg Bank

4202 N. 32nd Street, Suite 4

Phoenix, Arizona USA 85018

Toll Free +1.877.331.2022

US +1.602.278.1906

Fax +1.602.278.0325

www.TheWorldEggBank.com



Dr. Kuwayama and Diana Thomas at the lab in Japan.

Dr. Kuwayama has performed comparison studies and has determined that oocytes vitrified using other systems will warm with similar, if not slightly better, results. Therefore, oocytes remaining in The World Egg Bank's inventory will also be warmed using the Cryotec warming system. Dr. Hiraoka is scheduled to visit Phoenix in June to instruct The World Egg Bank's group of trainers in the warming techniques. Shortly thereafter, we will switch to this warming method and retrain all of our recipients' clinics. The warming kits will now be sent with the oocytes for convenience and to reduce variability. Although our current survival rate is outstanding at >85% with multiple end users, we believe that the Cryotec method will afford the opportunity to increase that even further.

New Website

Our new website went live the first week in May! New sections include special entry points for Australian and UK recipients. Compliant donors are easily accessible (with their height and weight in metric figures). Under the physicians section, the Australia outcome data are separate, with reference to the fact that most of the transfers are ESET.

The remainder of the content has been extensively updated and the new look is fresher and more dynamic. Take a look at www.theworldeggbank.com.



The World Egg Bank

42021 N. 32nd Street, Suite 1

Phoenix, Arizona USA 85018

Toll Free +1 877.331.2427

US: +1 602.678.1906

Fax: +1 602.678.0328

www.TheWorldEggBank.com

Endometrial Preparation by James W. Akin, MD, TWEB Board Member

When using thawed frozen oocytes, the overall pregnancy success rate is improved if a programmed cycle is used over a natural cycle. There are many different protocols for this purpose. Some protocols utilize oral estrogen while others use transdermal patches. Some protocols utilize leuprolide to prevent spontaneous ovulation while others do not. My personal preference is to start with the estrogen patches in a stepwise fashion(see attached protocol). If the patient does not develop an adequate endometrium, then I will induce a menses and begin with an oral estrogen preparation.

In my IVF program, I batch the cycles together for efficiency purposes. Patients are started on oral contraceptives for 2-3 weeks to reduce ovarian cysts and lower ovarian androgens. The patients stop the oral contraceptives then have a withdrawal period. I do not use leuprolide as a first line to reduce overall cost since most patients will not develop a dominant follicle with the added estrogen. The patient comes into the office for a vaginal sonogram on cycle day 12, 13 or 14. At time of the sonogram, the endometrial thickness and quality is accessed and if adequate, progesterone is begun on cycle day 15. If the patient has a dominant follicle, the cycle will be cancelled and leuprolide is then added in the next months' attempt.

As far as progesterone, all forms are likely the same. Some patients prefer the intramuscular progesterone at 50mg per day, but most are pleased to avoid injections and choose vaginal progesterone. To lower overall cost, I use Prometrium tablets (200mg) 3 times daily in the vagina starting on cycle day 15. The eggs are thawed on day 15 and fertilized by ICSI. Embryo



transfer is subsequently performed on either day 3 or day 5. I also give 100 mg twice daily of doxycycline the day before and day of embryo transfer

Frozen Egg Thaw Protocol

1. Take the birth control pills as directed, taking the last pill on the date given.
2. On first day of period start Minivelle patches in the morning.
3. All Minivelle patches are 0.1 mg each. Patches are changed every 48 hours except for first time.
4. Please schedule vaginal sonogram on cycle day 12, 13 or 14 to determine endometrial quality and to insure no ovarian follicular activity is present.

Cycle Day #	# of Minivelle patches for patient to wear	What to do
1	Place 1 Minivelle patch (1)	
2		
3		
4	Change Minivelle patch (1)	
5		
6	Change Minivelle patch, add 2 nd (2)	
7		
8	Change Minivelle patches (2)	
9		
10	Change Minivelle patches, add 3 rd and 4 th (4)	
11		
12	Change Minivelle patches (4)	
13		
14	Change Minivelle patches, decrease to 2 (2) and change patches (2) every 2 days until period starts or 10 weeks of pregnancy	Can stay in holding pattern here as long as needed
15	If ET* is satisfactory, this is corresponding day for egg retrieval, egg thaw and ICSI	Start Progesterone and continue until period starts or 10 weeks of pregnancy
16		
17		Start antibiotics for 2 days the day before and day of embryo transfer
18		
19		
20		

The World Egg Bank

4202 N. 32nd Street, Suite 1

Flowing, Arizona USA 85018

Tel: +1 602 678 0327

US: +1 602 678 1906

Fax: +1 602 678 0328

www.TheWorldEggBank.com



*Satisfactory endometrium is thickness > 6 mm and A or B pattern.

A pattern: Multilayer seen as triple line with hypoechoic gland area (3 layers).

B pattern: Well defined central line with endometrium and myometrium showing equal reflectivity

C pattern: Echogenic endometrium which obscures a central line.

Modified From: Queenan JT et al. Human Reproduction 1997;12:1176-80.

Remembering Stanley Leibo Ph.D.

We are saddened to report that MSAB board member Dr. Leibo died in March at the age of 77 after battling melanoma. Having developed a method to cryopreserve mouse oocytes with Whittingham and Mazur in 1972, he went on to develop methods of freezing many other types of mammalian cells and embryos, including human.

He was awarded the Pioneer Award from the International Embryo Transfer Society in 2009, and was described as "indisputably one of the best, and best known, cryobiologists."



Dr. Leibo, 2013. Photo courtesy of Jane Farley.

<http://www.uno.edu/news/2014/InMemoriamUNOProfessorStanleyLeibo.aspx>.

Dr. Masa Kuwayama attended his memorial service. Our condolences to his wife Beth and son Jonathan, as well as to his many collaborators and students.

The World Egg Bank

43022 N. 32nd Street, Suite 1

Phoenix, Arizona USA 85018

Toll Free +1 877 231 2422

USA +1 602 678 2906

Fax +1 602 678 0328

www.TheWorldEggBank.com