Testimony of Shady Grove Fertility Center before the Senate Finance Committee

Bill: SB 988 - Health Insurance - In Vitro Fertilization - Revisions

Hearing Date: February 26, 2020

Position: SUPPORT

Thank you for allowing me to speak on behalf of the men and women who will benefit from improved fertility coverage and in support of Senate Bill 988.

My name is Stephanie Beall and I am a physician at Shady Grove Fertility Center. Shady Grove Fertility Center is the largest fertility practice in Maryland. Our practice is comprised of 61 Reproductive Endocrinologists and 2 Urologists and we perform approximately 10,000 inseminations and over 8000 in vitro fertilization cycles a year. At Shady Grove Fertility, we help individuals and couples build families.

So what is infertility? The American College of Obstetricians and Gynecologists (ACOG) and the American Society for Reproductive Medicine (ASRM), define infertility as a disease characterized by the failure to achieve a clinical pregnancy after 12 months of regular unprotected sexual intercourse for women younger than 35 years of age or within 6 months in women older than 35 years of age. The diagnosis of infertility knows no boundaries. It affects individuals regardless of gender, race, sexual orientation or marital status. Female factors include age, ovulatory dysfunction, structural abnormalities such as blocked fallopian tubes or fibroids, and endometriosis. Male factors include low sperm counts, low sperm motility, and in 15% of men with infertility it is due to absent viable sperm in the ejaculate.

Given the anticipated age-related decline in fertility, and the increased incidence of pregnancy loss and having a child a child with a chromosomal abnormality, it is important not to delay fertility care for an individual or couple who have a clinical diagnosis of infertility. Delaying care from one year to two years of unprotected intercourse does not significantly increase the probability of a spontaneous pregnancy. In addition, continuing IUI cycles past the time in which there is a reasonable expectation of success, has a higher overall cost and delays access to more effective treatment options. Furthermore, the delay in access to care could significantly decrease the probability of success with treatment and increase the risk of age related pregnancy complications.

The probability of conceiving a clinical pregnancy decreases with increasing female age and increasing time trying to conceive. The Pregnancy Study Online (PRESTO)

is an ongoing prospective cohort study of North American couples attempting conception. For women 36 years of age and younger, 55-60% achieved a pregnancy

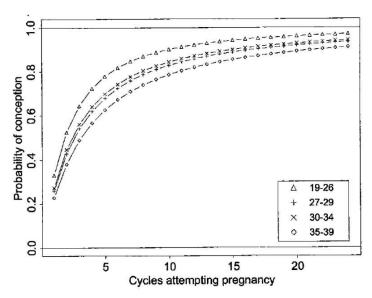


Figure 1: Clinical pregnancy decreases with increasing female age and time trying to conceive (Dunson 2004).

within 6 months and 70-80% of women achieved a clinical pregnancy within 12 months of unprotected intercourse. For women 37-39, the probability of pregnancy decreased to 46% within 6 months and 67% within 12 months. Between 40-45 years of age, the probability of pregnancy was 27% and 55% within 6 and 12 months respectably. For couples who do not conceive within 12 months, the probability of pregnancy each additional month attempting is low (Figure 1).²

Treatment for infertility includes ovulation induction, ovulation induction with intrauterine insemination (IUI), and in vitro fertilization (IVF). About 50% of treatment cycles performed at Shady Grove Fertility include ovulation induction and IUI. Ovulation induction involves using a medication to stimulate the ovary to mature and ovulate one or more eggs during a treatment cycle. IUI involves placing sperm inside a woman's uterus just prior to ovulation. IUI can be performed with or without ovulation induction.

In vitro fertilization is a procedure in which a physician will remove one or more eggs from the ovaries. The eggs are then fertilized by sperm in the embryology laboratory. The resulting embryos are maintained in culture and then transferred inside the woman's uterus. In vitro fertilization is the most successful treatment available for infertility. On average, 48% of women at Shady Grove Fertility conceive from an embryo transfer. Common indications for in vitro fertilization treatment include Fallopian tube damage or removal, endometriosis, low sperm count and low sperm motility.

Historically there has been the practice of starting treatment with IUI as long as there were no other complicating medical factors precluding its probability of success (i.e. blocked fallopian tubes). The per cycle success rate starts to decline

¹ Wesselink et al. Age and fecundability in North America preconception cohort study. Am J Obstet Gynecol. 2017 Dec: 217(6): 667.e1-667.e8.

² Dunson et al. Increased Infertility with Age in Men and Women. Obstet Gynecol 2004 Jun;103(1):51-6.

after 3 cycles, therefore there is a minimal increase in the cumulative success rate of IUI after 3-4 cycles (Figure 2). The FASTT trial, a randomized control trial designed

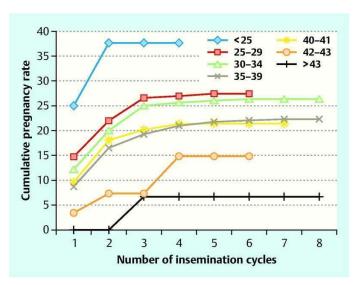


Figure 2: Cumulative pregnancy rates after each insemination cycle for the different age groups (Schorsch et al 2013).

to evaluate optimal treatment for unexplained infertility, demonstrated an increased pregnancy rate at a lower overall cost for the patients who underwent 3 cycles of IUI followed by IVF compared to 6 cycles of IUI followed by IVF. The observed incremental difference was a savings of \$2624 per couple and 0.06 more live births.³

The probability of pregnancy with fertility treatment also decreases progressively with increasing age. The percentage of IUI cycle starts that resulted

in a clinical pregnancy was 11.6% for women under 35 years of age, 8.84% for women 35-39, 9.01 for women 40-41, 6.25 for women 42-43, and 3.45% for women

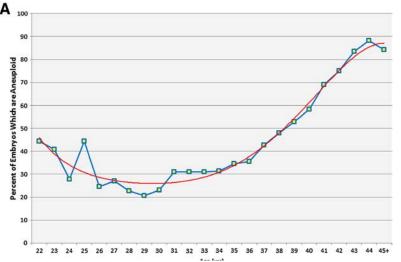


Figure 3: Increase in aneuploidy associated with increased female age (Franasiak et al 2004).

older than 43.4 A similar decline in treatment success is seen with IVF. Nationally, the percentage of IVF egg retrieval cycle starts that resulted in a live birth was 46.8% for women less than 35 years of age, 34.4% for women 35-37, 21% for women 38-40, 10.1% for women 41-42 and 3.1% for women older than 42 years of age.⁵

The age related decline in fertility reflects primarily a decrease in egg quality. With advancing female age there is an associated increase in rates of aneuploidy (embryos with an abnormal number of chromosomes) (Figure 3) which ultimately results in decreased fertility, an

³ Reindollar et al. A randomized clinical trial to evaluate optimal treatment for unexplained infertility: the fast track and standard treatment (FASTT) trial. Fertil Steril 2010 Aug; 94(3): 888-99.

⁴ Schorsch M et al. Success Rate of Inseminations Dependent on Maternal Age? An Analysis of 4246 Insemination Cycles. 2013. Geburt Frauen, 73(8) 808-811.

^{5 &}lt;u>www.sartcorsonline.com/rptCSR PublicMultYear.aspx?reportingYear=2017</u>

increased risk of having a child with a chromosomal abnormality and an increased risk of a miscarriage (Figure 4).⁶,⁷

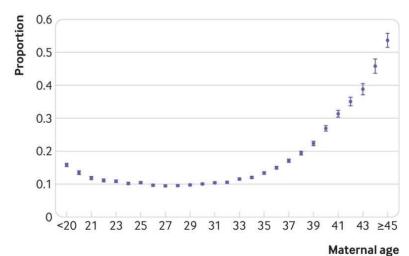


Figure 4: Miscarriage increases with increasing maternal age (Magnus et al 2019).

Thank you for the opportunity to speak with you today. I am happy to answer any questions on the medical aspects infertility care.

Stephanie Beall, M.D., Ph.D.

Shady Grove Fertility Center Dulaney Center II 901 Dulaney Valley Road, Suite 616 Towson, MD 21204 410-512-8300

⁶ Franasiak et al. The nature of aneuploidy with increasing age on the female partner: a review of 15,169 consecutive trophectoderm biopsies evaluated with comprehensive chromosomal screening. 2004 Fert Steril March 101(3): 656-663.

⁷ Magnus et al. Role of maternal age and pregnancy history in risk of miscarriage: prospective register based study. BMJ 2019; 364:1869.