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The Impact of State Mandated Financial Coverage for Donor Egg In Vitro Fertilization (IVF) Cycles on Choosing Fresh Eggs from Infertile Donor vs. Paid Donors vs. Frozen Egg Banks

Laura Zalles¹, Kyle Le¹, Jerome H. Check^{2,3*}, Carrie Wilson³, Donna Summers³ and Jung K. Choe^{2,3}

¹Cooper University Hospital, Camden, New Jersey.

²Cooper Medical School of Rowan University, Dept. Ob/Gyn, Div. Reproductive Endocrinology and Infertility, Camden, New Jersey.

³Cooper Institute for Reproductive Hormonal Disorders, P.C., Mt. Laurel, New Jersey.

*Correspondence:

Jerome H. Check, M.D., Ph.D., 7447 Old York Road, Melrose Park, PA 19027, New Jersey, Tel: 215-635-4400, Fax: 215-635-2304.

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ABSTRACT

We sought to determine if using infertile oocyte donors donating only half of the eggs collected to recipients, had comparable live delivery rates following fresh and frozen embryo transfer (ET) when compared to oocytes obtained from compensated donors with a single recipient, compensated donors split between two recipients, or an oocyte bank. A retrospective review of 1,361 in vitro fertilization-embryo transfer (IVF-ET) cycles comparing live delivery rates after fresh ET and live delivery rates per retrieval by donor oocyte source was performed. Live delivery rates per fresh ET showed no significant difference between the four-oocyte sources. However, using an infertile donor had a statistically significant increase in live delivery rate per retrieval when compared to using a compensated donor split between two recipients or an oocyte bank. There was a 15% decrease in live delivery rate per retrieval when using an infertile donor compared to a compensated donor with a single recipient. Financial burden of infertility services has been a long-standing barrier to infertility treatment access. Sharing oocytes with an infertile donor can have financial advantage without significant sacrifice of success rates. It is especially cost saving for recipients in mandated states who actually are financially reimbursed for the majority of the cost of the IVF cycle.

Keywords

Infertility, Mandated fertility coverage, Oocyte sharing, Source of donor oocytes.

Introduction

A significant barrier to infertility care in the United States is the cost. In 2018, the Access to Infertility Treatment and Care Act (House Bill 5965 and Senate Bill 2920) was introduced to Congress by Senator Cory Booker (D-NJ) and Representative Rosa DeLauro (D-CT) in an attempt to make infertility services more accessible [1,2]. The bill was not passed, but this instance was the first attempt at a federal level to provide access to care for patients suffering with infertility [3]. As of March 2021, nineteen states have passed some version of mandated fertility insurance coverage laws. Of those nineteen states, thirteen of them have laws regarding *in vitro* fertilization (IVF) coverage and ten of them have laws regarding fertility preservation. However, coverage differs from state-to-state [4]. For example, Connecticut has specific numbers of cycles they will cover for patients such as two cycles of IVF and/or three cycles of intrauterine insemination (IUI) [5]. In contrast, Texas requires insurers to cover IVF only after the patients have experienced infertility for a continuous five years or have certain specific diagnoses such as endometriosis, tubal occlusion or low sperm count [5].

According to the New Jersey mandate, after a period of two years for women under the age of 35 and one year for women over the age of 35, *in vitro* fertilization-embryo transfer (IVF-ET) will be covered. If, however, there are infertility factors, e.g., tubal occlusion or significant sperm abnormalities, the waiting time is waived [5]. In general, a woman is financially compensated for four lifetime IVF cycles, although there are some variations according to specific insurance companies. One cycle includes not only the fresh ET that was performed, but also all subsequent frozen ETs derived from the initial cycle of IVF.

The New Jersey mandate also provides remuneration for donor oocyte cycles in egg recipients up to 46 years of age. This generally includes cost of medication to stimulate the donor to make multiple follicles, the cost of oocyte retrieval, and the cost of oocyte fertilization, the cost of the recipient's embryo transfer, anesthesia, and follicular monitoring [4]. However, any remuneration paid to the fresh oocyte donor or payment for frozen eggs from a commercial egg bank is not covered. Generally, compensated donors are paid between \$5,000 to \$8,000 and frozen eggs from a commercial bank cost the recipient around \$15,000.

When recipients with mandated financial coverage consult our group for consideration of the use of donor oocytes, we explain four options for obtaining donated oocytes. Option one: one-half of the oocytes retrieved by an infertile woman undergoing IVF will be donated to the recipient. The insurance will pay for the IVF cycle in the donor; however, insurance will not pay for the infertile donor's embryo transfer. This cost will be charged to the donor or the recipient according to decision made by the specific IVF center. At our center, the recipient of the oocytes pays the fee for the egg donor's embryo transfer. Option two: all the oocytes from a compensated donor will be given to the recipient. Under the New Jersey mandate, the donor's compensation is completely provided by the recipient. Option three: the recipient will receive only half of the oocytes from a compensated donor. The other half will be given to another recipient. In this scenario, a given recipient pays only half of the egg donor's fee. Option four: the recipient obtains frozen donated eggs from a commercial egg bank. The recipient pays the commercial egg bank for the frozen donated eggs at a cost determined by the egg bank. However, the fertilization of these eggs and the transfer of embryos into the recipient is paid by the insurance. Of these four, the least expensive option under the New Jersey mandate is selecting an infertile donor. Even with payment for the donor's embryo transfer, at least at our IVF center, the cost is 25-50% less than the cost of splitting retrieved oocytes from compensated donors between two recipients. The question is whether this is at the "cost" of a decreased chance of a live delivery.

A previous study done by our center showed that sharing oocytes from infertile versus compensated donors provides similar pregnancy and implantation rates [6]. A primary objective of this study was to determine, in a larger series, whether using an infertile donor provides comparable live delivery rates following fresh ET as compared to oocytes obtained from the three other donor sources. Logic would suggest that receiving all fresh oocytes from a paid donor without infertility would result in the best chance of a live delivery for the recipient. The question is how much higher is the success rate? For some patients looking to avoid the financial burden of donor oocytes, they may decide the difference in success using half of the retrieved oocytes, whether from an infertile donor or a compensated donor, is sufficient for the financial savings. This large retrospective study hoped to provide such data to allow the recipients to make an informed decision when choosing the right source of oocytes for their particular case.

Sharing oocytes between two recipients from a compensated egg donor would be the next most affordable option. Thus, another objective of this study was to compare pregnancy outcomes between the two scenarios: one where oocytes are received from an infertile donor versus one where half of the oocytes from a compensated donor are provided to the recipient.

As the New Jersey mandate defines one IVF cycle to include not just the initial fresh ET, but also all remaining frozen ETs resulting from that cycle, we sought to compare the live delivery rates from all subsequent frozen ET cycles, i.e., the odds of a successful live delivery without having to use another donor oocyte cycle. This is referred to as the live delivered pregnancy rate per retrieval.

Some recipients only want one child or perhaps, just one additional child; however, others may want several children. Commonly, the patient's preference is to have siblings with the same genetic background. Thus, another important question that we hoped to address in this study was the live delivery rate per retrieval following a successful live delivery.

Though commercial egg banks are the most expensive option for the mandated New Jersey recipient, the advantage of these banks is the availability of more donor choices that may better match the patient's desired phenotype. Generally, there are fewer oocytes provided. Furthermore, though oocyte freezing has made tremendous strides for improvement in recent years with the advent of vitrification, the question of how frozen oocytes compare to fresh oocytes in producing a live baby remains to be determined [7,8]. If there were a difference in live delivery rates per transfer or retrieval, the recipient would at least have more information to decide if the higher cost, and possibly lower chance of a second child with the same genetic background, is worth the gain of larger selection of donor characteristics.

Materials and Methods

Prospective donor oocyte recipients initially had a consult with one of the treating physicians along with the donor egg coordinator and the billing department. At this meeting they would be advised of the four different sources of oocytes: 1 - half of the retrieved oocytes from infertile donors, 2 - all of the retrieved oocytes from a financially compensated donor, 3 - half of the oocytes from a financially compensated donor, and 4 - frozen oocytes from a commercial donor egg facility. After meeting with each team member, the recipients would choose the source of oocytes that best fit their needs for characteristic matching and finances.

All donor oocyte cycles from January 1, 1997 to December 31,

2018 were included whether the recipient was financially compensated under the New Jersey mandate or not. Frozen donor oocytes from commercial egg banks were not started until October 13, 2015.

The recipients were treated with vaginal estradiol 2mg daily from day 1 of the donor's cycle with a graduated oral estradiol protocol so that the last 5 days would be 2mg vaginal estradiol and 6mg oral estradiol. Progesterone supplementation was provided using 400mg twice-daily progesterone vaginal suppositories or 90mg daily Crinone® vaginal cream or Endometrin® 100mg 2x/day plus 100mg intramuscular progesterone daily. Embryo transfer using day 3 embryos occurred on the fourth day of progesterone. For the sake of having similarity in the cycles day 5 blastocyst transfers were not included because they were used only in a minority of embryo transfers.

The percentage of day 3 embryo transfers according to donor oocyte groups was over 95% in all four groups. If for some reason a fresh ET was deferred in favor of freezing all embryos, and deferring the transfer to another time, that recipient cycle was excluded from the study.

Statistical analysis was completed using SPSS software, version 22 (IBM Corp, Armonk, NY). A z-test for independent proportions was used. Statistical significance was defined as P < 0.05. Pregnancy outcomes, including implantation rates and live delivery rates in the recipients, were compared across the four groups of oocyte sources for the fresh ET cycles. We then compared the live delivery rates per oocyte retrieval. This statistic represents the chance of a live delivery without having to fertilize more donor oocytes. Thus, the pregnancy rate per retrieval would count as a successful pregnancy if it were accomplished from a subsequent frozen ET (if the fresh ET failed) as long as the frozen embryos were derived from the same group of oocytes collected from the oocyte retrieval cycle.

We then analyzed the live delivery rate per oocyte retrieval cycle

in women who had already had a live delivery from the donor oocyte source. All of these cycles for second pregnancies were from frozen ET cycles from the initial retrieval.

Results

1,361 cycles met inclusion criteria for our study. The ages of the four donor oocytes groups were 31.0, 29.5, 28.7, and 25.5 years, respectfully. Implantation and live delivered pregnancy rates for the fresh ET according to source of donated oocytes are seen in Table 1. The implantation rates were almost identical across all four-donor oocyte sources. The live delivered pregnancy rates per fresh ET transfer were almost identical in the 3 groups receiving fresh oocytes. Though the live delivered pregnancy rates with frozen oocytes chosen from a commercial oocyte bank was about 20% lower than the other three groups, this was not shown to be statistically different.

The live delivered pregnancy rates per oocyte retrieval by donor egg source are shown in Figure 1. When compared to using a donor egg bank, the live delivery rate per retrieval for all three other donor oocyte options was higher. This increase was statistically significant when utilizing a paid donor for a single recipient (46.2% vs. 85.2%, p < 0.0001) or an infertile donor (46.2% vs. 70%, p = 0.0149). Using an infertile donor also had a statistically significant increased live delivery rate per retrieval when compared to using a compensated donor split between 2 recipients (70% vs 55%, p < 0.0001), but a significant decreased live delivery rate per retrieval compared to using a compensated donor with a single recipient (70% vs. 85.2%, p < 0.0001). Using a compensated donor for a single recipient also had a statistically significant increase in live delivery rate per retrieval when compared to using a statistically significant increase in live delivery rate per retrieval when compared donor for a single recipient also had a statistically significant increase in live delivery rate per retrieval when compared to using a compensated donor for a single recipient also had a statistically significant increase in live delivery rate per retrieval when compared to using a compensated donor for a single recipient also had a statistically significant increase in live delivery rate per retrieval when compared to using a compensated donor for a single recipient also had a statistically significant increase in live delivery rate per retrieval when compared to using a compensated donor for a single recipient also had a statistically significant increase in live delivery rate per retrieval when compared to using a compensated donor split between two recipients (85.2% vs. 55%, p<0.0001).

Table 2 shows the women who had a successful live birth from one of the three-oocyte sources and evaluates the live delivery rate for a second live birth from the same oocyte source. There was no significant difference between using an infertile donor or

Table	1: Implantation	and Live Deliver	v rates according t	to 4 donor oocyte sources

	Infertile Donor	Compensated Donor, 1 Recipient	Compensated Donor, Split Between 2 Recipients	Thawed Frozen Oocytes from Bank
Age of Donor (yrs)	31	29.5	28.7	25.5
Number of Fresh Transfers	356	473	506	26
Number of Fresh and Frozen Transfers	614	979	892	41
% Implantation	32.20%	33.10%	33%	31.10%
% Live Delivered / Initial Fresh Transfer	47.5% (164/356)	47.4% (224/473)	48.2% (244/506)	38.5% (10/26)
% Live Delivered / Retrieval	70% (249/356)	85.2% (403/473)	55% (278/506)	46.2% (12/26)

Table 2: Live delivered pregnancy rates according to 3 donor oocyte sources in women who had 1 live delivery previously from that same oocyte source.

	Infertile Donor	Compensated Donor, 1 recipient	Compensated Donor, Split between 2 recipients
Age of Donor (yrs)	31	29.5	28.7
Number of Initial FET cycle	27	57	56
Number of all Subsequent FET cycles	35	88	68
% Live Delivered / 1st FET	40.7% (11/27)	43.9% (29/57)	35.7% (22/56)
% Live Delivered / all subsequent FET	51.8% (14/27)	70.5% (40/57)	46.4% (26/56)

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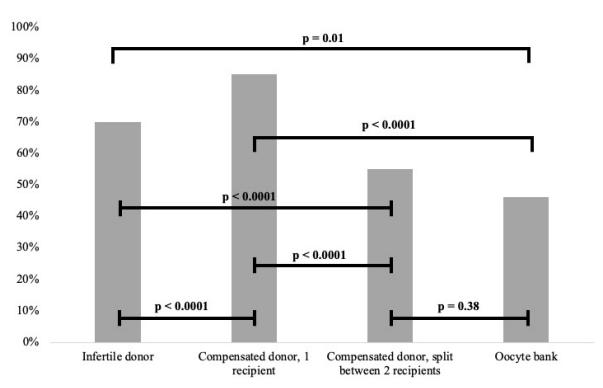


Figure 1: Statistical differences between live delivery rates per oocyte retrieval according to 4 donor oocyte sources.

a compensated donor split between two recipients. Using a paid donor for a single recipient had a statistically significant increased rate of a second live delivery when compared to recipients receiving oocytes from an infertile donor or half of the eggs from a compensated donor counting subsequent frozen ETs if the first one failed (70.5% vs. 48.2%, p = 0.01).

Discussion

With advancing technology, our options to treat patients with infertility are growing exponentially. Healthcare regulations have not yet caught up to our developing field, and this has exacerbated socioeconomic healthcare disparities in access to infertility services. A survey of childless women showed that finances was the fourth most common reason cited for permanently stopping fertility treatment [9]. As state legislation continues to adapt, with each state at different stages in the process, physicians should be aware of their state's legislation in order to understand what options can be offered to patients seeking affordable care.

A previous study by our group showed that donation of half of the collected oocytes from a compensated donor does not jeopardize the donor's live delivery rate [10]. In our state, mandated coverage has allowed us to offer patients the option of receiving one-half of the retrieved eggs from an infertile donor undergoing IVF, with no cost to the donor for fertilization of the donated eggs, or even the actual oocyte fertilization and subsequent ET.

However, if this option is going to be offered it should be with an understanding of outcomes for patients to make an informed decision regarding the best treatment protocol for them. There was no significant difference in implantation rates when comparing outcomes of fresh embryo transfers following donor oocyte from infertile donors, a paid donor with a single recipient, a paid donor with two recipients, and a donor oocyte bank. There was a significant increased live delivery rate per retrieval when using a paid donor with a single recipient versus an infertile donor. A couple receiving mandated coverage for donor egg cycles should be made aware of the 15% increased chance of a live delivery using all oocytes from a compensated donor and decide if that increase is worth the cost, compared to an infertile donor source with very little cost to the recipient.

Alternatively, there was also a statistically increased live delivery rate per retrieval when using an infertile donor rather than a compensated donor with the eggs split between two recipients. In this case, the more effective option of using an infertile donor is also more favorable financially. Finally, patients should consider whether they desire future pregnancies with the same oocyte source, as there was a statistically significant decreased second live delivery rate when using an infertile donor compared to a compensated donor with a single recipient.

The limitations of our study include the retrospective nature, as well as limited generalizability due to our office location in a mandated state. Mandated coverage is not yet applicable to every state, and even in those with infertility coverage, the application between states varies. However, our study does raise the idea that all infertility offices should be well versed in their state's infertility coverage and what options are available to patients. Though the frozen oocyte bank group was small, it was least likely to result in a live delivery before having to pay for another group of frozenthawed eggs, and thus was by far the most expensive option for couples with mandated coverage. Power analysis found that for the 40% increased live delivered pregnancy rate using fresh eggs to be significant the study would need to have 1.5x more patients and should therefore be repeated with a larger sample.

It should be noted that the shared process among infertile donors needing IVF allows the infertile donor to also obtain IVF services at very little cost without jeopardizing their own chances of success [10]. This allows more options for women with infertility, who are pursuing IVF, but do not have coverage by their insurance, and cannot afford IVF otherwise.

Financial burden of infertility services has been a long-standing barrier to patient access. For some patients, the decision to use donor oocytes comes later in their journey of battling infertility, at a time where this burden can seem even more daunting. The recipient may have already exhausted the IVF cycles covered by her insurance by attempting IVF with her own oocytes. Our study showed that with proper counseling, a safe option for donor oocyte source from infertile patients might give rise to cost-saving opportunities for patients in need of an oocyte donor.

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