Memorandum

To: United States Senate Committee on Health, Education, Labor, and Pensions
   Tom Harkin, Chairman
   Mike Enzi, Ranking Member

From: Dave Cooke.

Date: 02/18/2011

Re: Fertility Clinic Success Rate and Certificate Act and the future of reproductive legislation

Background

Assisted reproductive technology (ART) over the past thirty years has evolved from a medical miracle to a commonplace infertility treatment. In the United States alone, it has blossomed from a single “test tube baby” in 1981 to accounting for about one in every hundred births. In order to quell unscrupulous practices in the burgeoning ART industry, Congress passed the Fertility Clinic Success Rate and Certificate Act in 1992, hereafter referred to as the Wyden Act after its author. This act requires clinics to collect and make publically available the results of ART treatment.

The CDC National ART Surveillance System

Currently, implementation of the Wyden Act is conducted by the Centers for Disease Control (CDC) under the Division of Reproductive Health. Each year, the CDC compiles data collected from each clinic and discloses it in an ART Surveillance Summary. This data includes in vitro fertilization (IVF) and egg donation statistics, but it excludes a common ART, intrauterine insemination (IUI).

While the CDC was given the responsibility of implementing the Wyden Act, it was not provided with any additional funding to do so and rely upon data submitted by the clinics without verification. Furthermore, because there are not serious penalties for noncompliance, the program is relying entirely on market pressure, though as of 2005 91% of the country’s ART programs were deemed in compliance.

Because of the unfunded mandate, the CDC are unable to verify the clinics’ data, instead relying upon the ethical guidelines established by the American Medical Association (AMA) and American Society for Reproductive Medicine (ASRM) to coerce responsible reporting. The Federal Trade Commission (FTC) has punitive programs in place for misrepresentation of success rates and has issued a handful of cease-and-desist orders for false advertising, and Offices of the Attorney General have similarly filed motions against fertility clinics for deception, but there are a number of ways in which the success rate can be manipulated that are not as clear-cut as lying.

Manipulating the success rate

The simplest way to control the reported success rate is to control the statistical population. At the onset of treatment, a doctor can determine a patient’s likely chance of pregnancy due to certain risk factors and choose to push the patients with a lower chance of success into treatment plans that might not be in the best interest of the patient but are not included in the IVF data reported by the CDC such as IUI or donor egg therapy⁵. A doctor might also choose to reclassify the patient as a “research patient”, which means that s/he is not required to report the statistics to the CDC. Once treatment is started, it is also possible to reclassify or cancel a failing treatment cycle⁶. Each qualifies as a “loophole” in reporting, thus artificially boosting the success rate with a simple sleight of hand.

After embryos are formed, a popular technique for ensuring success is to implant a larger number of embryos in the patient. This is commonly practiced despite medical data suggesting that the additional risks are disproportionate to the additional likelihood of conception⁷,⁸. A doctor might suggest to the patient a higher number based on her age, or he might simply discourage cryopreservation to justify the larger transfer of embryos⁵. Furthermore, by the time a patient is receiving IVF, she has likely gone through multiple rounds of IUI or other fertility treatment, making her more vulnerable to the pressure of ensuring a pregnancy through multi-embryonic transfer.

Multiple-gestation pregnancies

Since the first multi-embryonic transfers, there has been a concern over multiple-gestation pregnancies. The numbers today are staggering – while the normal rate of multiple births is just 3% overall in the United States, the rate of multiple births in ART-assisted pregnancies is 35%⁹. These twins and triplets come at extreme risk as well – 60% of twins are born prematurely, increasing their chances of neonatal death, mental retardation, and learning disabilities¹⁰.

The multi-gestation problem is compounded by the high costs associated with IVF – most states do not mandate that insurance cover IVF, resulting in the majority of the approximately $15,000 per treatment borne by the patient. At such high costs, this puts additional pressure on the patient to ensure success as well as the doctor.

Policy Recommendations

Tighten existing standards of reporting

Currently, patients are beset with statistics that do not always adequately convey the real measures of success for various clinics. By increasing the available data, it is possible to give the consumer a greater understanding of ART standards and norms and how a particular clinic may be able to address her particular needs.

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⁵ While egg donation is included in the statistics, it is not broken out by age group.
⁸ Mullin, Christine M., Fino, M. Elizabeth, Talebian, Sheeva, Krey, Lewis C., Licciardi, Frederick, and Grifo, Jamie A. “Comparison of pregnancy outcomes in elective single blastocyst transfer versus double blastocyst transfer stratified by age.” Fertility and Sterility 93, 1837 (2010).
⁹ Grunfeld, Lawrence, Luna, Martha, Mukherjee, Tanmoy, Sandler, Sandler, Benjamin, Nagashima, Yui, and Copperman, Alan B. “Redefining in vitro fertilization success: should triplets be considered failures?” Fertility and Sterility 90, 1064 (2008).
Include number of patients

Currently, the focus on cycles places a disconnect between the number of patients and number of successful live births. As such, it is impossible to know how well a clinic’s practices effect pregnancy in its patients. This data would be helpful not just to the consumer but also to policymakers and physicians.

Include IUIs

Approximately twice as many IUI cycles are performed on a yearly basis than ART procedures\textsuperscript{11}, but there is no way for a patient to currently compare different clinics’ success rates. Because the ART report excludes IUIs, an avenue is left open for fertility specialists to push high-risk patients to this treatment, particularly in cases where mild IVF may be more appropriate, because it will not be reported to the public. By reporting IUIs by number of cycles and number of patients, this limits the incentive to shuffle high-risk patients into this treatment based on reasons other than merit.

Exclude multiple pregnancies from success rate

In order to reduce the incentives for implanting more embryos than necessary, it has been suggested to remove multiple births from success rates\textsuperscript{12,13,14}. By redefining success in this manner, it was shown that the rankings of clinics with abnormally high levels of multi-embryonic transfers decrease significantly while the rankings for those clinics with a high fraction of single embryo transfers increased\textsuperscript{12}. Presumably, this effect would push doctors towards more conservative methods as the rankings would more heavily favor single-embryo transfers (SETs).

Include risk assessment

Currently, the CDC’s statistics for IVF are broken down by age group; however, age is not the only relevant predictor for a patient’s success rate. Another factor is the number of previous ART procedures\textsuperscript{15}. The CDC already collects information about ART patients’ prior attempts to conceive using assisted reproduction. Making this data publically available would help inform patients’ available options. Moreover, it would help physicians and policymakers better correlate the success of different treatment options on more specific populations. One example of what this modified report could look like is shown in a simplified form in Table I.

\textsuperscript{12} Grunfeld, Lawrence, Luna, Martha, Mukherjee, Tanmoy, Sandler, Benjamin, Nagashima, Yui, and Copperman, Alan B. “Redefining in vitro fertilization success: should triplets be considered failures?” \textit{Fertility and Sterility} 90, 1064 (2008)
\textsuperscript{13} Stillman, Robert J. “The Suleman octuplets: What can an aberration teach us?” \textit{Fertility and Sterility} 93, 341 (2010).
\textsuperscript{14} Min, Jason K., Breheny, Sue A., MacLachlan, Vivien, and Healy, David L. “What is the most relevant standard of success in assisted reproduction? The singleton, term gestation, live birth rate per cycle initiated: the BESST endpoint for assisted reproduction.” \textit{Human Reproduction} 19, 3 (2004).
Table I. Outcome Based Reporting System (OBRS). This datasheet represents an alternative metric for reporting of ART data including information not just about the patients’ age but also information about clinical history and treatment.

Increase compliance with ASRM/SART guidelines

The American Society for Reproductive Medicine (ASRM) has already acknowledged that “high-order multiple pregnancy is an undesirable consequence (outcome) of assisted reproductive technologies.” In order to combat this challenge, their guidelines for care must continue to evolve. Most recently, they have

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17 The Practice Committee of the ASRM and the Practice Committee of the SART. “Guidelines on number of embryos transferred.” *Fertility and Sterility* 92, 1518 (2009).

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### Table I

<table>
<thead>
<tr>
<th>Age of Patient</th>
<th>-35</th>
<th>35 - 37</th>
<th>38 - 40</th>
<th>41 - 42</th>
<th>OD</th>
<th>FET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age</td>
<td>30</td>
<td>35</td>
<td>39</td>
<td>41</td>
<td>NA</td>
<td>35</td>
</tr>
</tbody>
</table>

**Category of Complexity**
- A: 16 cycles
- B: 208 cycles
- C: 95 cycles
- D: 107 cycles

**Total Cycles**
- 269 cycles
- 208 cycles
- 95 cycles
- 107 cycles

**Clinical Pregnancy [%]**
- 53 cycles
- 21 cycles
- 46 cycles
- 14 cycles

**Average [%]**
- 36 cycles
- 37 cycles
- 22 cycles
- 17 cycles

**Ongoing Pregnancy [%]**
- 44 cycles
- 16 cycles
- 31 cycles
- 13 cycles

**Average [%]**
- 30 cycles
- 31 cycles
- 14 cycles
- 14 cycles

**Multiple Pregnancies [%]**
- 50 cycles
- 32 cycles
- 43 cycles
- 14 cycles

**Average [%]**
- 43 cycles
- 33 cycles
- 32 cycles
- 3 cycles

**Miscarriage [%]**
- 16 cycles
- 22 cycles
- 15 cycles
- 12 cycles

**Average [%]**
- 17 cycles
- 16 cycles
- 34 cycles
- 17 cycles

**Ectopic [%]**
- 0 cycles
- 6 cycles
- 0 cycles
- 0 cycles

**Medically Cancelled [#]**
- 10 cycles
- 3 cycles
- 3 cycles
- 6 cycles

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*Category of Complexity Legend:*
- **A**: Less than 2 failed IVF cycles
- **B**: 2 or more failed IVF cycles
- **C**: Less than 2 failed IVF cycles
- **D**: 2 or more failed IVF cycles

Table notes:
1. Calculations based on embryo transfers
2. Greater than 10 weeks gestation with fetal heartbeat
recommended limits on embryos to transfer based on age and technique. However, this is simply a suggestion to ART practitioners, and there are currently no penalties for not adhering to the guideline. While it is true that voluntary adoption of these practices has yielded an overall lower rate of multiple-gestation pregnancies, the reduction has been very slow, dropping from 37% to 32% over the span of a decade. More must be done to encourage ASRM members to adhere to these guidelines. Under the Wyden Act, embryo laboratories may apply for certification, but currently this voluntary program is not utilized by the states or the ASRM.

Increase funding for compliance with the Wyden Act

As outlined above, voluntary contribution of data and statistics from clinics without verification can lead to widespread malfeasance. It is in the best interest of the public to verify that clinics are complying with the standards of the Wyden Act in a consistent manner. However, it is necessary for this increased oversight to be paid for by the government and not passed on to the individual patients.

An increase in funding could help unify the practices of the ART community. The Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom is a model for more stringent, centralized oversight. Its program requires similar reporting data from clinics, but it verifies the clinical data. Furthermore, it is responsible for licensure, so failure to comply with the HFEA’s standards carries severe penalties. With this authority, it is able to mandate stronger standards. Finally, because it is more highly funded, it has the resources to publish more patient-friendly reports in addition to its large database of clinical statistics, which would help alleviate some of the reliance upon unreliable success rate data.

Improve health insurance coverage for IVF

At the center of the misrepresentation of data and the incentive for patients to elect for a larger number of embryos is the cost of the procedures. If instead the costs were picked up partially or entirely by insurance providers, this would reduce the incentives for success in the first cycle for both the doctor and patient. Indeed, while the data is not conclusive, research on the effects of insurance coverage on IVF seem to indicate that states with mandated coverage have a markedly lower average number of implanted embryos per transfer, resulting in a statistically lower percentage of multiple-gestation pregnancies. This is consistent with anecdotal evidence from countries such as Australia, which has the highest rate of SETs in the world (62%) – while the average cost for each average cycle is $7117, Medicare reimburses 80-90% of the cost and private health insurance 70-90%.

It has been argued that health care costs and health insurance premiums would be greatly increased if IVF is covered. However, evidence in states that have implemented these programs has found this belief to be unfounded. A careful analysis of the state of Massachusetts showed that infertility services accounted for 0.41% of total expenditures in 1993, and examination of ART utilization found no evidence of abuses by

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patients with a low chance of success\textsuperscript{24}. Another study found that even if this decrease cost results in a threefold increase in utilization, premiums would only increase about $9 per employee per year\textsuperscript{25}. This suggests that not only is mandatory insurance coverage a viable means of reducing abuses by doctors and encouraging safe practices for patients, it should also help increase access by reducing overall costs to the patients. While insurance decisions are made largely by each state, the federal government maintains control over the Employee Retirement Income Security Act (ERISA), which regulates the benefits of approximately 40\% of all Americans. An act such as the Family Building Act of 2005 (H.R. 735), which would have amended ERISA to require insurance companies to cover the costs of infertility treatments, would go a long way towards alleviating many of the current issues with IVF treatment.

**Conclusions**

Because IVF treatment is largely unregulated, the competitive marketplace has resulted in a number of loopholes, despite the intents of the Wyden Act. Congress has many avenues by which to attack the problem, from tightening the types of reporting to more comprehensive initiatives aimed at the practice of IVF treatment itself. And above all else, the focus needs to be on the health of the family and access to effective treatment.

\textsuperscript{24} Griffin, Martha and Panak, William F. “The economic cost of infertility-related services: an examination of the Massachusetts infertility insurance mandate.” *Fertility and Sterility* **70**, 22 (1998).