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Editorial

The Inhibitory Impact of National IVF Registries on the Development of Gentle IVF Cycles in the United States

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Introduction

In 1992, the US Congress passed the Fertility Clinic Success Rate and Certification Act, which required that all ART clinics provide data to the CDC for the purpose of publishing results on an annual basis [1]. Subsequently, SART, a component of ASRM began collecting a slightly different version of the same data and publishing it separately [2]. The intention of these annual publications was to better inform the public. At the time of the enactment of this act, there were reportedly IVF clinics providing care for patients that had not been successful in achieving any deliveries [3]. The public might reasonably choose to avoid these programs.

Although ART success rates depend upon adequate laboratory support, they also depend on the underlying patient medical characteristics in the group treated, a clinic's entrance criteria to undertake treatment, and the protocols used to manage patients. SART has long recognized this in their advertising policy by stating that comparisons of success rates are not meaningful [4]. However, as long as numerical success rates are the primary information contained in these reports, comparing program success rates is the primary way that patients will use these reports [5]. Insurance companies and government agencies are also beginning to use the registry reports in that way [6,7]. As such, having a high published pregnancy rate in the national registries will remain important to a program's financial well being.

The competition for patients may lead some programs to manipulate data to enhance their success rate in these reports [8]. It may also cause programs to value interventions that enhance pregnancy rate over inventions with other benefits such as increased patient safety, decreased costs for patients, and improved simplicity of participating in the ART program. For example, a program could choose to freeze all embryos over several retrieval cycles in a poor prognosis patient in order to have more embryos to choose from and replace them in a better uterine environment prepared using estrogen outside of stimulation. The enhanced pregnancy rate per transfer would be a trade off for greater expense and more patient inconvenience.

Gentle IVF cycles are cycles employing a more limited ovulation induction than that used in conventional IVF. The ovulation induction component of these IVF cycles includes natural cycles, cycles using oral ovulation inducing agents, cycles in which in vitro maturation will or may be used, and cycles in which the objective of the ovulation induction is to produce only 1 to 2 mature follicles, 3 to 5 mature follicles, or less than 8 mature follicles [6,7]. ISMAAR, the International Society for Mild Approaches in Assisted Reproduction, has proposed terminology for some types of gentle forms of IVF, but innovations on this theme have made those definitions inadequate [8]. Gentle IVF cannot be defined simply by gonadotropin use since many PCOS patients require very low gonadotropin use in cycles that are clearly conventional IVF cycles.

Gentle IVF cycles have a lower pregnancy rate per cycle start and per cycle transfer than conventional IVF cycles [9,10]. They also cost at most half as much as a conventional IVF cycle [12,13]. Rather than as a replacement for conventional IVF cycles, gentle IVF should be viewed as an intermediate therapy between oral medications and intrauterine insemination (IUI) and conventional IVF. Recent randomized trials show relatively disappointing results with the use of gonadotropin IUI cycles (in addition to their increased risk of high order multiple gestations) [14,15]. Gentle IVF is a natural intermediate step in the hierarchy of invasive reproductive therapies.

Since gentle IVF incorporates many of the advantages of conventional IVF such as the ability to overcome tubal oocyte pickup problems or to ensure that sperm get to the oocyte, such cycles should be especially effective for good prognosis patients with simple well defined infertility problems. Patients who do not achieve pregnancy after a few gentle IVF cycles could then go on and undertake conventional IVF. Good prognosis patients likely do not require all of the power intrinsic to conventional IVF. With gentle IVF, patients will have less taxing experiences while both patients and the medical delivery systems will benefit financially. Fewer people would require conventional IVF. ART utilization would increase if costs were reduced [16].

Although there are many advocates in the medical literature for gentle IVF, because of its benefits for patients, providing gentle IVF to large numbers of patients in the United States is hazardous to a program's reputation as presented by the national registries. Since gentle IVF is an ART procedure, it must be reported as such. National reporting does not differentiate between gentle and conventional IVF cycles. Since gentle IVF is a procedure with an expected success rate between IUI and conventional IVF, the average pregnancy rate

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for such a program would be lower than if it did conventional IVF alone. Furthermore the information that would be published in the registry's reports would be misleading because average success rates presented in a setting where there are two distinct populations with different means are meaningless. An average success rate should not be reported in this situation since it obscures the content of the data. The appropriate analogy is that a man with one foot in a bucket of boiling water and one foot in a bucket of ice water. This man is experiencing a normal temperature (on average). In order for the data presented to be meaningful it must look at these two different populations separately.

Even if the data on gentle IVF and conventional IVF were separated in a program's report, data publication still may mislead the public if it is viewed as a measure of the competency of the program. It is likely that the pregnancy rate for conventional IVF in a program performing a significant number of gentle IVF cycles will be lower than if they did not provide gentle IVF since the best prognosis patients would have an even higher pregnancy rate with conventional IVF. However, in this situation the public could be more easily educated on how to interpret a more complex report that does not focus on a single number.

Some might argue that as ART has evolved, the registries have outlived their usefulness [5]. Furthermore, since they are so important for program promotion, they currently skew the direction of ART development. To the extent that this is true is a loss for patients, physicians, and the science of reproduction. One partial fix for this problem would be for the registry to become more complex in its reporting and publish more details about the different innovations that programs are using to help couples get pregnant. Avoiding publication of overall or average pregnancy rates will limit a program's ability to manipulate data for their benefit, but more importantly, it will help us better and more quickly understand the value of the many new innovations, like gentle IVF, that some programs are developing.

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