

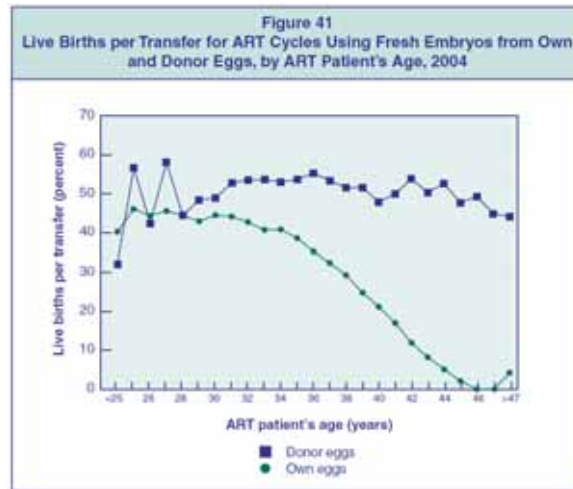
The Effect of Economic Access to ART on Availability, Pregnancy Success and
Multiple Pregnancy
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Not unexpectedly, medical practice in Reproductive Medicine involving Advanced Assisted Reproduction Technology (ART usually means in vitro fertilization/IVF) is affected by the social and legal environment (even excluding malpractice). It affects access, it affects practice, and so, it affects outcome, both good and bad.

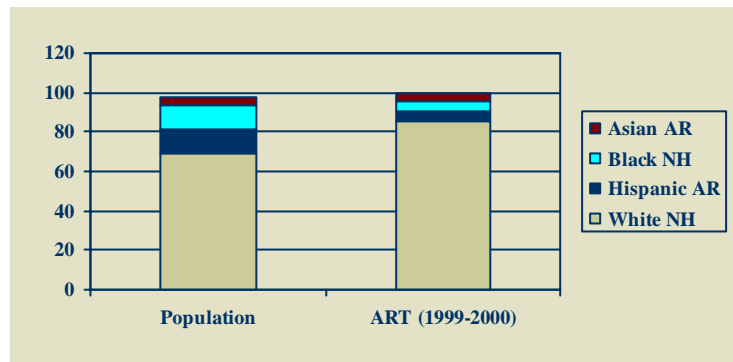
ART practice varies across the US varies from state to state. For the purpose of this discussion, we will divide this not between RED and BLUE states (well, maybe), but between states that make ART accessible by state law mandating that employers and insurance providers offer ART coverage as part of their employee health plans, or do not. There is a middle ground where some states 'mandate' the option, i.e. companies must offer the option that the employees as a group can elect to have ART coverage. But, this is not much of an option since at any one time only 15% of a population would be infertile, the majority votes to not include it because of the concern that it will raise the overall cost of their health insurance. Fewer than 10 states have some form of IVF coverage. It is difficult for patient groups to get state legislators to mandate IVF coverage as opposition groups such as the insurance industry, who realizes that they are hard to love, sends in representatives from the small business community who declare that if an IVF mandate is added to the existing ones, they will drop all of their health insurance coverage for their employees. This has a chilling effect on legislators since the result is to add to the state's cost of providing care for the uninsured. RESOLVE: The National Fertility Association a national organization commissioned a study of employers providing infertility coverage for their employees. Of the more than 600 employers that responded, 91% acknowledged that the impact of providing infertility coverage on their medical care costs was insignificant. More that 75% stated that this coverage aided their employee recruitment and retention by giving them a 'family friendly' image.

ART is performed by administering costly medication to stimulate the growth and maturation of a dozen or more eggs rather than the single egg normally released in a menstrual cycle. This is done because only a fraction of eggs released are genetically capable of initiating a pregnancy. This process must be monitored by ultrasounds and blood estrogen levels. The eggs must be surgically removed (OR techs, Anesthesia, Surgeon, Recovery Room), identified (culture lab, embryologist), cultured (incubators, culture media, technicians) and placed in the uterus at the time of embryo transfer (OR, recovery, Surgeon, Nurses). There are multiple pieces to the puzzle which add up financially. A routine IVF case is ~\$10-12K. While it is less expensive than many simple operative procedures such as an appendectomy, it is expensive to patients because there is not insurance coverage for the majority of couples going through IVF. (There can be partial coverage where health coverage will pay for a portion of the ultrasound testing, etc.). One effect of this in addition to limiting those who can afford ART procedures is that many couples are in their mid-30s before they can afford the disposable

resources to pursue IVF. The first effect of this is to lower the success of the procedure as age is one of the most important variables in predicting success of ART.



A demonstration of the effect of limited access is that the IVF volume per capita is three times higher in mandated states than non-mandated states. This suggests that financial aspects to care are restricting access/utilization. What about access as defined by ethnicity? In work performed by Dr. David Grainger and colleagues looking at data from ART in 1999/2000, only 4.6% of cycles were performed in Black couples versus 5.6% in Hispanic couples and 85% in white couples. The figure shown below from their presentation shows the relative contribution of different ethnic groups to the population and their relative utilization of ART. While Asians and Whites are well represented, the Hispanic and Black groups are under-represented.



While not specific to infertility coverage, there are gender discrepancies as well. The National Women’s Law Center in April of 2007 issued a Brief on “Women and Health Coverage: The Affordability Gap”. In this document they report, “Women have greater difficulty affording health care services even once they are insured. Women have lower incomes than men, and therefore greater difficulty paying premiums, they are less likely to have coverage through their employer, have higher out-of-pocket health care expenses, and use more health care services than men.”

To reduce the costs of IVF, some clinics offer patients the opportunity to ‘split’ cycles. This means that couples who could not afford an IVF cycle (the wife would be young with a good prognosis for pregnancy) would agree to undergo an IVF stimulation and retrieval for which they would get to use 4 of their eggs while agreeing to give the rest of the eggs to another couple (with ovarian failure) who paid 75% of the costs of the cycle. This has brought criticism to the clinics. The problem is access for which this is a partial solution. Would these couples agree to give up their eggs if they could afford an IVF cycle? The usual response is no.

How else does access affect medical practice? Earlier it was mentioned that only a fraction of eggs are capable in producing a live birth and this declines with age. In the 3rd decade of life only one egg in three is genetically normal. This begins to decline by the age of 32 so that only one egg in five is normal at age 35, one in nine or ten by age 40, and one in fifteen by the age of 45. So, if possible, many eggs are harvested to improve the likelihood of obtaining an egg with normal genetic potential, and currently, putting back two or three embryos is routine in the US with fewer transferred in younger women and more in older women. We put more than one back because we can’t tell precisely which embryo will produce a child.

There are useful parameters to help select the embryos to transfer, i.e. embryos continuing to grow and divide, being ‘pretty’ (symmetrical cell sizes and little fragmentation), reaching a certain size by a certain time in culture are all favorable factors for embryos with greater likelihood of producing a live birth. But, there is nearly always a higher pregnancy rate from putting more than one embryo back. [For women < 35 y/o, putting two embryos back results in a higher pregnancy rate than one. Whereas, putting three back does not increase the overall pregnancy rate, just increases the multiple pregnancy rate.]

The effect of putting more embryos back is an increased rate of multiple pregnancy. Even twins have twice the developmental problems of singleton pregnancies. Through the decade of the 1990’s, embryo culture efficiency improved resulting in more pregnancies. By 1998 only 8% of pregnancies involving quadruplets or more occurred naturally. Over the past decade we have steadily revised the embryo transfer guidelines and put back at embryo transfer fewer and fewer embryos based on age and other parameters. The rate of triplets or more has been cut by more than 2/3rds.

With thousands of dollars of their own money involved, couples rarely choose to only put one embryo back. In addition, most couples are delighted with the prospect of having twins. This affects the multiple pregnancy rates which have an effect on the health of the children produced due to prematurity and other causes.

Does increased access to insurance coverage help affect practices that affect multiple pregnancy number? In states in which there is insurance coverage for ART, the average number of embryos transferred is less than non-mandated states. Surveys comparing

patients in mandated states indicate their higher acceptance of reducing the number of embryos transferred. The European ART community which has a lower multiple pregnancy rate (and lower pregnancy rate in general) is often critical of the higher US multiple rates. Some of the Scandinavian countries offer their populations six IVF cycles if they agree to limit the number of embryos transferred. They have determined that the reduction in the costs of care of preterm babies in an intensive care unit more than covers the costs of IVF policies that limit multiple births. This coupling of costs and expenses has not occurred in the US. Further, this increased access results in a lower average age within the population undergoing the procedure which has a higher chance of pregnancy and a greater opportunity of success from fewer embryos transferred. The mean age of the US population seeking IVF care is over the age of 35 y/o. Some of this relates to the inability to afford IVF at an earlier age. Some countries, including Britain, by law limit the number of embryos that can be transferred. This is, supposedly, balanced by availability through the National Health Service. However, the limitations vary by region and may include: being within certain ages, being childless, etc. Further, recent concerns have been raised by patient groups that the health 'Trusts' within the different regions for IVF care have not been funded resulting in few or no ART cycles have been performed in some areas.

In conclusion, access to care issues involving infertile couples and IVF can be seen to limit utilization with more limitations seen for some ethnic groups, increase the mean age of those who do seek ART resulting in lower pregnancy efficiency, and drive risk-taking decision making which results in increased morbidity among offspring.