Access to and use of infertility services in the United States: framing the challenges

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An overview of access to and use of general infertility and assisted reproductive technology (ART) services in the United States (U.S.) shows a declining trend for the ever-use of infertility services. Moreover, the use of ART services lags relative to other member nations of the Organization for Economic Co-operation and Development (OECD). Access to and use of general infertility and ART services is primarily undermined by a severely constrained underwriting universe dominated by self-insured employers and by a finite number of state infertility insurance mandates. The contribution of traditional public and private payers to the underwriting of ART is limited. As compared with OECD member nations wherein the access to and underwriting of general infertility and ART services is universal, the current status quo in the U.S. can only be characterized as dismal. Further, the current state of affairs is socially unjust in that the right to build a family in the face of infertility appears to have become a function of economic prowess. Given the dominance of the self-insured employers as underwriters of general infertility and ART services, advocacy directed at this interest group is likely to prove most productive. Improving the state of underwriting of general infertility and ART services in the U.S. must be embraced as a central moral imperative and as an unwavering strategic goal of the professional societies entrusted with the reproductive health of women and men. (Fertil Steril® 2016;105:1113–8. ©2016 by American Society for Reproductive Medicine.)

Key Words: Access to care, ART, barriers, infertility, underwriting

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The right to procreate, and by extension the right to infertility services in general and assisted reproductive technology (ART) in particular, is rooted in the notion of procreative liberty which rests on firm moral grounds. Viewed from a legal perspective, the right to procreate remains handicapped by a limited body of international conventions and laws as well as by an evolving body of American jurisprudence (1–6). International conventions are limited to the designation of "Infertility as a Disability" by the World Health Organization and the recognition that access to infertility services constitutes a protectable right "under the Convention on the Rights of Persons with Disability" (1, 2). Extant international law is limited to the case of *Murillo v. Costa Rica* wherein the Inter-American Court of Human Rights reaffirmed the right to procreate as a fundamental human right (3).

In the United States (U.S.), jurisprudence has not addressed itself directly to the matter of infertility. However, in keeping with the libertarian nature of the U.S. Constitution, a negative right such as the right to procreate is uncoupled from a positive entitlement for its effectuation. In keeping with multiple rulings of the U.S. Supreme Court (4–6), it is the responsibility of the state to protect individual rights but not necessarily to provide for them. This legal construct gives rise to a circumstance wherein the right to procreate is severed from state-sponsored underwriting of general infertility and ART services. It follows that the less economically fortunate are left to negotiate financial access barriers that can only be addressed by employers in the private sector and by Congress and the individual states in its public counterpart. To add insult to injury, precious little underwriting of general infertility and ART services is presently being furnished by the federal government. Although the precise reasons underlying the current state of affairs cannot be fully ascertained, contributing factors may include the perception that infertility care is costly, the notion that infertility does not constitute a disease, and the absence of truly vigorous well-funded advocacy efforts.

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STATE OF ACCESS TO AND USE OF GENERAL INFERTILITY AND ART SERVICES

The task of assessing the state of access to general infertility and ART services relies by its very nature on "measures of use" that are quantifiable, time trackable, and benchmarked. In this context, heavy reliance can be placed upon the National Survey of Family Growth (NSFG), which is being maintained and curated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC) (7). In its latest iteration, the NSFG makes note of the fact that the ever-use of infertility services by women aged 15–44 years and 25–44 years has decreased from 1995 to 2010 by 23% and 16%, respectively (8). The NSFG further notes that the ever-use of infertility services by nulliparous women aged 25–44 years with current, presumably primary infertility has decreased by 8% and 18% since 1995 and 1982, respectively (8). All told, these data suggest a declining trend for the ever-use of infertility services. The precise nature of the forces involved remains to be determined. However, consideration might be given to underwriting insufficiency, individual economic constraints, and delayed childbearing to name a few possibilities.

Efforts to ascertain the use of ART services must draw on the National Assisted Reproductive Technology Surveillance System (NASS) and on the VitalStats databases of the CDC (9, 10). Additional information is invariably afforded by the all-important U.S. Census Bureau. Informed by this body of data, it is readily ascertainable that the number of annual ART cycle starts in the U.S. has been growing steadily from 1997 through 2013 (Fig. 1), which is the last year for which reliable data are available (11). As such, this upward trend in the number of annual ART cycle starts appears to have been proceeding at an approximate rate of 5% per year (see Fig. 1). The number of ART cycle starts in 2013 (190,773) further suggests that the use of ART services is poised to break the 200,000 ART cycle starts barrier as early as 2014 (see Fig. 1). Additional analysis reveals the growth trend of annual ART cycle starts to hold steady when adjusted per 10^6 population, thereby suggesting that the use of ART services is keeping pace with the expanding U.S. census.

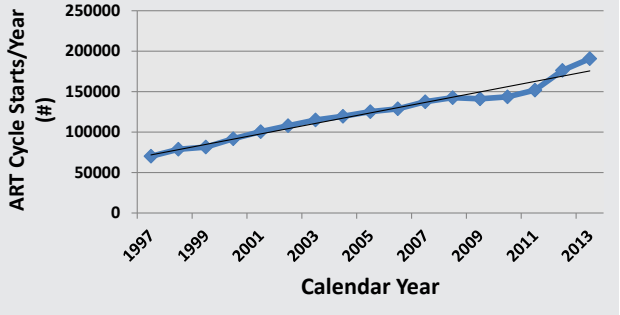
Less flattering conclusions are arrived at upon assessing the ART "supply" data of the U.S. against the "demand" benchmark for ART as estimated by the European Society of Human Reproduction and Embryology (ESHRE) (12, 13). Measuring the ART supply data of the U.S. against the ESHRE-estimated ART "demand" figure of $\geq$1,500 cycles/10^6 population/year reveals that as recently as 2013 the U.S. ART supply has met only 40% of the presumptive pent up national ART cycle start demand (Fig. 2). The corresponding figures for the United Kingdom, Scandinavia, and Australia are 62%, $\geq$100%, and $\geq$100%, respectively (12, 13). Subject to the accuracy of the ESHRE demand estimate, the unmet ART demand in 2013 alone would have amounted to a startling 475,000 annual cycle starts. Finally, note must be made of the fact that ART-attributable births, expressed as a percentage of the total live births in the U.S., has been growing steadily from 2009 through 2013 from 1.4% to 1.6%.

Taken together, these observations indicate that the U.S. is lagging in the use of ART services relative to other member nations of the Organization for Economic Co-operation and Development (OECD) as gauged by the annual ART cycle start growth rate, the annual ART-attributable birth rate, and the ability to meet estimated ART demands (14, 15). The OECD, which was originally the administrator of the Marshall Plan, is presently an international economic organization composed of 34 developed nations intent on stimulating economic progress and world trade.

BARRIERS TO ACCESS TO AND USE OF GENERAL INFERTILITY AND ART SERVICES

First, in a manner reminiscent of other areas of medicine, sociocultural barriers to access to care appear to play a major role in compromising the availability of general infertility

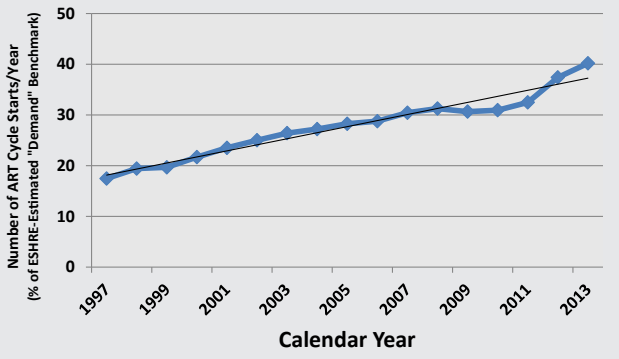
FIGURE 1



The number of ART cycle starts per year in the U.S. from 1997 through 2013 (9–12, and the U.S. Census Bureau). The *straight line* shown represents the best-fit linear trendline.

Adashi. Access to U.S. infertility care. Fertil Steril 2016.

FIGURE 2



The number of ART cycle starts per year in the U.S. from 1997 through 2013 as a percent function of the ESHRE-estimated demand benchmark (9–12, and the U.S. Census Bureau). The *straight line* shown represents the best-fit linear trendline.

Adashi. Access to U.S. infertility care. Fertil Steril 2016.

and ART services (16). Apart and distinct from the all-important social determinants of health, populations from culturally diverse communities are coping with language hurdles, preconceptions about health care, elements of communication, notions of privacy, and real and perceived stigmas (16). The prospect of conscious or subconscious provider bias must also be taken into account (16).

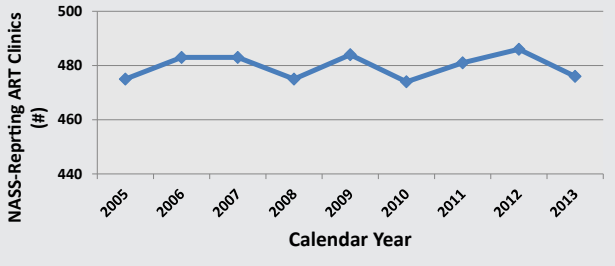
Second, equal consideration must be given to emotional barriers to access to general infertility and ART services. A thorough treatise of this challenge is being provided in this issue of *Fertility and Sterility* by Alice D. Domar, Ph.D.

Third, attention must be paid to infrastructural barriers to access to general infertility and ART services such as the availability of ART clinics. Analysis of the availability of ART clinics over the 2005 to 2013 interval (Fig. 3) reveals the number of NASS-reporting ART clinics to reliably hover around a mean of approximately 480 (9). However, normalization of this variable per 10^6 population reveals the 2005 ART clinics to population ratio (1.6) to display a modest if progressive decline compared with its 2013 counterpart (1.5). Whether the aforementioned downward trend in the ART clinics to population ratio constitutes a harbinger of future shortages in the availability of ART clinics remains to be seen. Viewed in aggregate, these observations suggest that the U.S. is broadly on par with other developed nations such as Denmark, Australia, and Israel wherein the ART clinics to population ratio varies from as low as 1 to ≥ 3.

Fourth, the existence of a geographic barrier to access to general infertility and ART services would hardly be unexpected in that it is emblematic of the entire U.S. healthcare system (17). At its core, this challenge is attributable to the maldistribution of medical services, which gives rise to medically disenfranchised regions. As recently as 2013, the distribution of ART clinics was such that it favored the Northeast, the Southwest, and, to a degree, the Southeast (17). Most importantly, the maldistribution of ART clinics gives rise to a circumstance that favors mandated states, high median income states, and urban over rural locales (18, 19). In addition, the mandated states are home to more ART clinics per 10^6 population as compared with non-mandated counterparts (unpublished data). Taken together, these observations are in keeping with the existence of a geographic barrier to access to general infertility and ART services. These data are also consistent with the view that the distribution of ART services is highly dependent on the state of underwriting and the median disposable income of the locales in question.

Finally, and some would say most importantly, access to general infertility and ART services is very much in the crosshairs of an economic barrier. This reality has been most poignantly articulated by the NSFG with the observation that "the ever use of infertility services was highest among women with higher levels of household income" (8). As it stands, the state of underwriting of general infertility and ART services in the U.S. is characterized by high underinsurance and uninsurance rates and high out-of-pocket expenditures. The underwriting of the ART component for its part is dominated by self-insured employers and by several state infertility insurance mandates. The contribution of traditional public and private payers to ART underwriters is limited. As compared with other OECD member nations, this state of affairs can only be described as dismal. Moreover, it is socially unjust in that the right to build a family in the face of infertility appears to have become a function of economic prowess.

FIGURE 3



The number of ART clinics reporting to the National Assisted Reproductive Technology Surveillance System (NASS) in the U.S. from 2005 through 2013 (9).

Adashi. Access to U.S. infertility care. Fertil Steril 2016.

THE ART UNDERWRITING UNIVERSE

State Infertility Insurance Mandates

Among the few bright lights in the underwriting universe of general infertility and ART services in the U.S. is the enactment of a total of 15 state infertility insurance mandates (20). A tribute to patient grassroots power, the statutes in question vary in the scope of general infertility and ART services covered. A total of 6 of the 15 state infertility insurance mandates ensure meaningful if variable access to ART services (20). Most mandated states display higher ART use rates, thereby reaffirming the connection between the state of underwriting and usage (12, 21). In so doing, the mandated states are leading the way in pointing out that improved access can and must include an expanded underwriting universe.

Some state infertility insurance mandates have given rise to modified patterns of practice. For example, in Massachusetts underwriters have promoted a direct path to in vitro fertilization (IVF) that bypasses superovulation and intrauterine insemination and emphasizes elective single-embryo transfers (22). The aforementioned notwithstanding, more work remains to be done. Existing state infertility insurance mandates are in need of redress of inequities such as the exclusion of same-sex couples [now reversed in Maryland (23)] and the exercise of age discrimination [now reversed in Connecticut (24)]. Looking ahead, newly enacted infertility insurance state mandates appear unlikely in the wake of the Affordable Care Act of 2010 in that the responsibility for such new expenditures would have to be borne by state governments rather than by resident private underwriters (25).

Public Underwriters

Although the ART underwriting universe in the U.S. is dominated by private underwriters, it is not devoid of public counterparts. Examples of the latter include TRICARE, home to 9.5 million active-duty beneficiaries of the Department of Defense. At present, TRICARE subsidizes ART services for all its beneficiaries (26), thereby giving rise to 1,200 ART cycle starts in 2013 (11) at an approximate out-of-pocket cost of $\leq$$7,000 per cycle. In addition, TRICARE fully covers ART services for a limited number of severely injured service members ("wounded warriors") whose reproductive function has been irreversibly compromised (27).

Yet another potential public ART underwriter, the Veterans Health Administration (VHA), home to 10 million veteran beneficiaries, many of whom are women, is precluded from offering infertility services by the Veterans Health Care Act of 1992 (28). As per the latter statute, "the Secretary of Veterans Affairs may provide to women the following health care services…not including…infertility services" (27). Over the last 3 years, the aforementioned VHA ban on general infertility and ART services has been the subject of several attempts at congressional repeal albeit without success. The last such effort [The Women Veterans and Families Health Services Act of 2015 (S. 469)], which was mounted by Senator Pat Murray (D-WA), failed as recently as July 2015 (28). The above notwithstanding, the VHA has elected to authorize and underwrite a limited series of general infertility and ART services (29). Included under these guidelines are diagnostic tests, surgical procedures (e.g., tubal reanastomosis), ovulation induction (e.g., clomiphene), superovulation and intrauterine insemination (e.g., gonadotropins), and select cases of cryopreservation (29).

Note must also be made of the Federal Employees Health Benefits (FEHB) Program, which is administered by the Office of Personnel Management. Home to 8 million federally employed beneficiaries, the FEHB contracts with $\geq$250 private payers to underwrite a large array of health insurance policies. As such, the FEHB does not require nor deny the provision of coverage for ART. At present, ART benefits are underwritten by a minority of the participating underwriters in a total of seven mandated states, one non-mandated state (Virginia), and the non-mandated District of Columbia. Viewed from a historical perspective, the notion of expanding FEHB ART coverage has been on the mind of Congress for nearly 30 years albeit without success. The first relevant bill, the Federal Employee Family-Building Act of 1987 (H.R. 2852), was sponsored by Representative Patricia Schroeder (D-CO) (30). A succession of bills followed sponsored by members of the House and the Senate. None were enacted. The last effort to expand FEHB ART coverage was led by Representative Anthony Weiner (D-NY) and Senator Kirsten Gillibrand (D-NY); the Family Building Act of 2009 (H.R. 697/S. 1258) never made it out of committee (31).

Finally, the Medicaid program, a federal/state partnership, has never underwritten ART services. Surveys of state Medicaid coverage of infertility services reported in 2001 and 2009 reveal that some states elect to cover non-ART general infertility services (32, 33). Thus, in the absence of a federal mandate, the decision to cover basic (or advanced) infertility services remains the domain of the states.

Self-insured Employers

The private ART underwriter universe is dominated by the self-insured employers who act as their own insurance companies and assume the risk for the actuarial costs involved. As such, self-insured employers, home to 60% of private-sector enrollees, constitute the leading purchasers of health care in the U.S. (34). This segment of the industry was surveyed most recently in early 2015 for its underwriting practices of general infertility and ART services by the Society for Human Resource Management, in which a total of 462 mostly large (>76%), mostly private (89%) employers from multiple industries participated (35). In aggregate, 27% of the employers surveyed reported including ART services in their benefits package. The corresponding figure for non-ART services was 29%. Prior surveys revealed similar rates of coverage going back to 2011.

Targets of Advocacy

Given the dominance of the self-insured employers as underwriters of general infertility and ART services, the imperative of advocating with this interest group would appear self-evident. Self-insured employers are represented most vigorously by the National Business Group on Health (NBGH), a Washington, D.C.-based organization (https://www.businessgrouphealth.org). The National Association of Health Underwriters (https://www.nahu.org/) and the Business Roundtable (http://businessroundtable.org) play a smaller, if still important, role in this context.

In each and every case, advocates would do well to provide the engaged party with relevant informational materials such as "An Employer Guide on Fertility Benefits" (36) or perhaps "Fast Facts for Employers on the Treatment of Infertility" (36). Consideration might also be given to the sharing of published peer-reviewed case studies that detail the infertility coverage experience of Fortune 500 companies such as Southwest Airlines (37).

Most importantly, the message conveyed to self-insured employers must not be limited to the notion that the inclusion of general infertility and ART services in the benefits package is the right thing to do. Instead, emphasis must be placed on the reality that the inclusion of general infertility and ART services in the benefits package is the smart thing to do. Indeed, doing so attracts and retains valuable employees, promotes a family-friendly environment and brand, and reduces health-care costs through the curtailment of plural births. Furthermore, the inclusion of general infertility and ART services in the benefits package increases premiums by <$4 per member per month and constitutes <1.5% of the total health care benefits costs (38, 39).

Above and beyond the preceding considerations, one would also do well to advocate with private national underwriters (the health insurance companies). Unlike the self-insured (large group) employers, health insurance underwriters are mostly focused on the fully insured small group

and individual markets. This segment of the industry is represented by the America's Health Insurance Plans (AHIP) association and by the Blue Cross and Blue Shield Association. One would also do well to approach some of the individual national underwriters, given that the industry is going through a remarkable phase of consolidation that is giving rise to colossi the likes of which have never before been seen. Examples include Anthem, soon to become home to Cigna (40), and Aetna, which is seeking to acquire Humana (41). Finally, it appears central that one continue to press the case with Congress with an eye toward expanding TRICARE ART coverage, repealing the VHA infertility ban, and expanding the FEHB ART coverage. Persistence appears especially well advised in that where public underwriters go, so go their private counterparts.

CONCLUSION

In our review of the state of access to general infertility and ART services in the U.S., we found that access to general infertility and ART services is compromised by severely constrained underwriting. This has given rise to high underinsurance and uninsurance rates and high out-of-pocket expenditures. This state of affairs is socially unjust: the right to build a family in the face of infertility is now tied to economic prowess. Improving the state of underwriting of general infertility and ART services must be embraced as a central moral imperative and as an unwavering strategic goal of the professional societies entrusted with the reproductive health of women and men in the U.S.

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