# Changes to reproductive endocrinology and infertility practice, research, and training as investor mergers increase

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Private equity investment in fertility clinics has rapidly increased and is leading to unprecedented changes in the field of reproductive endocrinology and infertility (REI). The goal of this paper was to review private equity's current integration in REI and discuss both benefits and challenges of investor involvement. We found that at least 25% of fellowship programs and medical schools were affiliated with private practice fertility clinics, not free-standing academic clinics. Approximately half of medical schools and nearly all REI fellowship programs that were affiliated with private practices were also backed by private investors. Research participation remains robust in private equity-affiliated REI clinics. With the changing infrastructure, we discuss the potential influence on trainee experience and research while also acknowledging the unique advantages that investor involvement may offer. (Fertil Steril Rep® 2023;4:332–6. ©2023 by American Society for Reproductive Medicine.)

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dvances in in vitro fertilization (IVF) and assisted reproductive technology (ART) have transformed the field of reproductive endocrinology and infertility (REI). Innovation and medical education have traditionally been conducted by the REI clinics affiliated with universities. Recently, as private, outside capital has replaced owner-operator retained earnings as the primary source of growth capital within REI, the basic science, clinical research, and subspecialty training are bound to evolve as well (1). Here, we describe the integration of investor-backed fertility clinics, with a specific focus on trainee education, research, and clinical practice.

#### INVESTOR INVOLVEMENT IN FERTILITY CARE

From 2009–2019, there was a 126% increase in the number of IVF cycles reported in the United States (146,244 cycles in 2009 vs. 330,773 cycles in 2019) (2, 3). Recent reports document between 448 and 489 fertility clinics in the United States, with most clinics being private practices not affiliated with an academic center (1, 3). Physician-led ownership of fertility clinics has been inherent to the field of REI. Recently, however, the field has piqued the interest of nonphysician investors.

Thus far, most nonphysician investments in fertility clinics have been made by private equity. Private equity

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firms invest in companies that are privately owned and not publicly traded, and these investors seek businesses that have the potential for rapid growth in a short time span. Models of private equity's involvement in medical practices report a strategy of expansion, acquisitions of similar clinics, and/or mergers with a reputable clinic group (4). Ultimately, after several years of profit, the clinic enterprise is then sold to another investor (4). The involvement of private equity has been described in dermatology, ophthalmology, and orthopedics (5-7). As reported by Patel et al. (6), the specialties which have become of interest to private equity investors are typically performing outpatient procedures with high reimbursement.

Private equity acquisitions have increased in fertility clinics, and in 2018, 14.7% of clinics providing ART had private equity affiliation (8, 9). Interestingly, private capital in REI has been both domestic and international, as demonstrated by the acquisitions of Boston IVF by United Arab Emirates-based New Medical Centre (NMC) Health and HRC Fertility Management by Jinxin Fertility Group Ltd of China (1). Investments may be part of larger vertical and/or horizontal integration strategies. In horizontal integration, similar enterprises are purchased, consolidated, and rebranded. On the other hand, vertical integration strategies focus on creating supply chain efficiencies and synergies of ancillary services. In the case of fertility care, vertical integration strategies add related businesses, such as egg freezing, surrogacy, or sperm banking companies. An example of vertical integration can be seen in Prelude Fertility, which also owns MyEggBank and Vivere Clinics (10).

## REI FELLOWSHIP TRAINING REFLECTS CHANGES IN CLINICAL PRACTICE

Since 1972, when REI was officially recognized as a subspeciality of obstetrics and gynecology by the American Board of Obstetrics and Gynecology, REI fellowship programs have educating physicians through formalized training (11). Classically, REI fellowship includes clinical care at a university-owned or affiliated clinic as well as 30%–50% of dedicated research time. Mirroring the increasing demands and success rates of ART, there has been a notable focus on ART training during fellowship (11). As the field continues to incorporate investors, how will the standard and structure of REI fellowship be influenced?

#### PRIVATE INVESTMENT IN FELLOWSHIP TRAINING PROGRAMS

Recently, several university-based fertility clinics which host REI fellowship training have become affiliated with private investors. Concerns about the potential impact of investors on fellowship training have been introduced by Patrizio et al (1). We performed our own analysis to understand the degree to which private investments are occurring at clinics affiliated with fellowship training programs. In our analysis, the websites of each of the 48 accredited REI fellowship programs in March 2022 were explored, and clinical sites were recorded. To determine the location of clinical sites where not otherwise provided, we searched for the clinics affiliated with faculty members and also assessed the websites of major REI private practice clinics for university affiliations. Investment databases, press releases, and discussions with clinical faculty were used to ascertain the financial backing of clinics. If information was not available online, the clinic was directly contacted. Based on information available at the time of our analysis, we found that 12 (25%) out of 48 programs were affiliated with private clinics or large fertility networks.

The financial backing of each of the 12 fellowship programs affiliated with privately owned clinics or large fertility networks was explored via the aforementioned methods. Our search revealed that at least 10 fellowship programs (approximately 21% of all REI fellowship programs) were affiliated with private investor-backed clinics. For example, Shady Grove Fertility, which is a primary clinical site for the University of Colorado, the University of South Florida, and the National Institutes of Health, has a partnership with Amulet Capital Partners. Moreover, one program was affiliated with a free-standing clinic with physician ownership. The financial information of one clinic was unable to be determined.

Our results build on the information from a recent publication by Patrizio et al (1), which describes the business models of major private REI clinic networks in the United States. Notably, Patrizio et al. (1) reveal that all 8 major private REI clinic networks selected for analysis in their paper had involvement of private equity firms (1). Our findings demonstrate that these investor-backed clinic enterprises are now affiliated with 4 fellowship training programs.

## MEDICAL SCHOOL REI EXPERIENCE

Exposure to various subspecialties in medical school clerkships is important for future physicians' career decisions. Thus, REI rotations in medical school may positively foster medical student interest in REI or obstetrics and gynecology in general. We characterized REI clinical experiences of the 151 United States allopathic medical schools listed in the Liaison Committee on Medical Education directory as of March 2022 (12). Specifically, we searched each medical school's webpage for information on their REI services, Obstetrics and Gynecology Department, and/or clerkship information. If the REI faculty's clinical affiliation was not explicitly listed, another search was performed to determine their clinic's location. In situations when information was not available online, the medical school was contacted directly. Our analysis showed that 73 medical schools (48%) were associated with university/hospital-based clinics, and 38 medical schools (25%) were affiliated with private practice clinics. Four medical schools reported that their students did not have a REI rotation. One medical school had a mixed model of private and university clinics. In our analysis, we found that at least 18 (47%) of the privately owned clinics affiliated with medical school clinics had private investor funding. In total, this data demonstrates that at least approximately 12% of medical schools are affiliated with private investor-backed REI clinics.

Our profile of medical school's REI rotations is incomplete and limited by a lack of publicly available information and complete response to our outreach efforts. We were unable to determine primary REI clinical affiliations or experiences in 35 (23%) of the medical schools. Additionally, in 20 of the 38 private clinics associated with medical schools, no evidence of investor funding was found online, indicating either the clinics are physician owned or their investor information is not publicly disclosed.

# INVESTOR INFLUENCE ON TRAINEE EDUCATION

To date, there have not been any studies assessing REI trainees' perspectives on the involvement of private equity. In ophthalmology, where private equity has already taken hold, fellows expressed concern about ongoing acquisitions and their effect on future career opportunities. Ophthalmology fellows also desired formal research regarding the potential effects of private equity on their field (13).

Additionally, a survey of radiology residents, fellows, and radiologists early in their careers revealed similar concerns, and these physicians expressed a preference to work in independently-owned private practices and take part in the practice's leadership (14). Further, the survey revealed that training programs in radiology with private equity involvement were disproportionately affected by budget cuts and cancellation of lectures and other educational programs (14). Given the changing infrastructure, other specialties have called for formalized business education in medical training (15).

In the medical community, there is concern that private equity companies will not prioritize trainee education. This perspective is substantiated by events, such as the closing and declaration of bankruptcy of the Hahnemann Hospital shortly after a private equity firm gained ownership, a move that is speculated to have been driven by potential profit and left many trainees and patients abandoned (14, 16). We recognize that the degree of investor involvement in educational operations likely varies and recommend continued prioritization of trainee experience and education. This sentiment is reaffirmed by the American Medical Association, which recently instituted a policy to protect trainees in graduate medical education institutions with private equity ownership (17).

#### **INVESTOR-BACKED RESEARCH**

To continue progress in reproductive medicine, we must maintain a commitment to research. Discoveries in reproductive biology have commonly been translated into rapid advancements in fertility care. Thus, as scientific investigation is inherent to reproductive medicine, research has become an integral, well-established part of the major REI clinics. Scientific work can be performed in various settings. For example, Boston IVF, IVI-RMA, and Shady Grove Fertility all sponsor multiple clinical trials (Supplemental Table 1, available online). To further evaluate privately funded IVF clinics' engagement in research and innovation, we performed an analysis of funding for these clinics' research projects by reviewing the available information on www.clinicaltrials.gov. We found that most funding for clinical trials by major IVF clinics is provided by the clinic itself, affiliated universities/hospitals, or biotechnical, diagnostic, bio-pharmaceutical, and private research companies (Supplemental Table 1, available online).

Assuming the growing involvement of REI clinics by investors, how will innovation, research, and development be affected? It remains unclear if investors will regulate allocations of funding or if funding will favor discovery that can be patented and commercialized. There is currently a gap in the medical literature across sectors discussing the ownership and management of intellectual property developed in an investor-backed research setting. This is particularly relevant in reproductive medicine, where public funding from the National Institutes of Health has traditionally been scarce. In fields, including biotechnology for oncology and immunology, there is a well-established path on which government-funded basic science funding is leveraged by later-stage private product and service development, with the National Institutes of Health assuming the outcomes risk of the more difficult to handicap foundational science work. Without this early-stage funding, what is the motivation of any clinic, regardless of the source of capital, to undertake more demanding foundational research?

#### CLINICAL PRACTICE IN INVESTOR-BACKED MODELS

The role of private equity in women's health is starting to be examined in medical literature and other reflections (9, 18). A recent study has reassuringly revealed no significant differences in success rates of ART for patients receiving care at private equity-affiliated practices in 2018 (9, 18). Specifically, there were no significant differences between the rates of retrieval and transfer resulting in live births, the number of cycles for fertility preservation, or the percentage of transfers with at least one embryo created by intracytoplasmic sperm injection. Additionally, in comparison to nonprivate equity-affiliated clinics, practices with private equity involvement had similar rates of donor egg and embryo programs (9). Importantly, the same group found that significantly fewer male-factor fertility services and more preimplantation genetic testing were provided at private equity-affiliated clinics (9). As private investments in REI grow and financial connections to clinics shift the degree of operational control and allocation of resources within the practice, it is important to thoroughly assess how this directly impacts patient care.

Moreover, it is important to consider how investor involvement will intersect with current legal standards. In 1992, Stark Laws were enacted, which prohibit physician referrals to a service to which they or an immediate family member has a financial relation (19). With a private equitybased focus on the incorporation of ancillary services, it is important such integration is done in a manner that upholds Stark Laws (20). Additionally, although there are variations in legislation per state, the Corporate Practice of Medicine Doctrine prohibits firms from practicing medicine or commercially employing a physician to provide clinical care (4, 21). Private equity investors have bypassed these laws by forming management service organizations that provide nonclinical, administrative services for a fee or a portion of revenue (22). These investor-backed services may then offer equity in their services to physician leadership, which aligns the interests of investors and physicians (22). This relationship has been described in dermatology practice (22, 23); however, the exact nature of investor relations with REI clinics is not wellreported.

Furthermore, investor involvement in REI clinics may shift a practice toward the hiring of nonsubspecialist providers. In dermatology clinics, this has translated to increased hiring of physician assistants to increase profitability (24). In REI, such modifications may lead to staffing of REI clinics with generalist obstetrician-gynecologists as well as advanced practice providers.

#### **BENEFITS OF INVESTOR INVOLVEMENT**

We acknowledge and appreciate the benefits that private equity involvement affords the field of REI. The involvement of investors has likely increased overall access and availability to care and infertility treatments (1). Specifically, services may be more available through companies, such as Progyny Fertility, a publicly traded, venture capital-backed fertility benefits company that offers egg freezing and IVF coverage. Progyny now offers access to REI services to 1 million people, many of whom may otherwise not have coverage for services (25). The focus on business growth by private equity may ultimately increase access to care.

Moreover, private equity investments are suspected of facilitating the integration of technology in clinical care (4), which can better connect clinicians and patients and is relevant in the new era of telemedicine. Other efforts by private equity to maintain patient satisfaction may positively affect the overall patient experience. Additionally, private equity refinements improve outcomes for the patient population who have access to IVF services, as discussed in Summit: IVF (26). For example, if a small clinic is bought out by a larger, investor-backed conglomerate, the new affiliation with a larger clinic network increases the cycle data available to the clinic and provides access to well-established protocols.

#### CONCLUSION

The future of REI depends on a commitment to thorough training and mentorship, which takes significant time and resources. We found that private investors support at least 21% of REI fellowships and 12% of medical school clinical rotation sites. Investment models that profit on high efficiency and throughput may be incongruent with the current academic structures if the focus is on cost reduction alone; alternatively, the huge population of unserved patients, combined with new models of insurance discussed earlier, maybe a catalyst for more thorough clinical training, a greater focus on patient satisfaction and improved outcomes. Either way, we urge thoughtful consideration and protection of physician autonomy and trainee experiences during investment deals. Moreover, given that infertility remains "unexplained" in a significant proportion of patients, we need to continue to prioritize personalized medical care and continued scientific discovery. Although private equity-driven optimization has potential to streamline operations, it is important that this does not occur at the expense of research or expansion of care to underserved populations. We recognize that more information is needed to understand the ethical and practical implications of the evolution of IVF commercialization, particularly in an investor-driven model. In closing, investor involvement is rapidly changing the arena of REI, albeit with many accompanying advantages, and we recommend a thoughtful integration in a manner that upholds the highest standards of the field.

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