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The CHR Voice. The Rapidly Changing World of Infertility Practice: Where will it lead to?
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Editorials

The Rapidly Changing World of Infertility Practice: Where will it lead to?

The CHR Voice[1] [a]

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This article describes the radical changes in business models driving infertility care since the inception of IVF, which created the impetus for establishment of a separate sub-specialty of Reproductive Endocrinology and Infertility (REI). We here describe how this small new sub-specialty area of gynecology over 45 years grew into a highly influential subspecialty and, ultimately, into a true "industry," supported by ever-larger numbers of provider clinics and, in parallel, an equally quickly growing full-service support industry. With the finance-world for several good reasons discovering fertility as a growth industry, the world has especially over the last decade witnessed an acceleration in the pace of change, the largest likely being that only a minority of individual IVF clinic sites in the U.S. are still physician-owned. Throughout the country, but especially in larger cities, it appears that Wall Street has taken over, with large national chains of IVF clinics, mostly owned by private equity, buying up physician-owned clinics at record pace to compete among themselves for market share. How these developments have already greatly affected the provision of fertility services, and where they will lead, is the topic of this article, with, of course, particular attention to the New York Tristate area.

Modern infertility practice is only 45 years old. It started with the birth of Louise Brown on July 25, 1978, in Oldham, a town in northwestern England, - known as the world's first "test-tube baby," as in vitro fertilization (IVF) births in those days were called.[1] Up to that point, the treatment of infertility was still widely in the hands of general obstetrician-gynecologists because the handful of gynecologists presenting themselves to the public as "fertility experts," did not have many different treatments options to offer than general gynecologists: Female infertility was treated either with surgery, ovulation induction, and/or intrauterine inseminations (IUIs), and male infertility with IUIs and/or third-party donor sperm inseminations.

That IVF may become possible was rumored at the time; but even by those considering themselves fertility specialists, was not really taken seriously. Partially because of fear that IVF might produce Frankenstein-like human "monsters, "[2] and partially based on religious consideration,[3] IVF in those days was still widely perceived as unethical, - even among fertility specialists. A good example was what happened to **Landrum Shettles**, a very well-known scientist at *Columbia University* in NYC at the time, when he on September 12, 1973 - ca. 5 years before the birth of Louse Brown, at the request of a couple that had failed multiple tubal surgeries and IUIs, attempted IVF, using the female's egg and the husband's sperm. Becoming aware of this ongoing experiment, **Raymond Vande Wiele**, the Chair of the Obstetrics & Gynecology department at Columbia, himself an at the time widely-respected fertility specialists, is reported to have stormed into Shettles' laboratory, singlehandedly destroying the experiment.[4] When the couple later sued Vande Wiele and Columbia University, Vande Wiele is alleged to have defended his action based on the fear that the experiment may produce a monster.

The announcement of the first IVF birth, therefore, initially was received with considerable skepticism; but with other IVF pregnancies following rather quickly in Australia and elsewhere around the globe, it instantly downed on the gynecology field that a new gynecological subspecialty was evolving, requiring knowledge, practical expertise, and other qualifications that were distinct from what gynecologists, and even the small group of already existing fertility experts could offer. The subsequently very quick development of IVF, this time mostly driven by American IVF clinics spearheaded by the *Norfolk Clinic* at *Eastern Virginia Medical School*, Norfolk, VA, established by **Howard Wilbur Jones Jr.** and his wife **Georgeanna Jones**, after both retired from illustrious careers at John Hopkins University, led the way.

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Most of the pioneering first-generation IVF clinics in the country were hospital-based, - the CHR included (in those days, at *Mount Sinai Hospital* in Chicago, IL, and the first IVF clinic in the whole Midwest). This, however, changed rapidly after the CHR's investigators in 1983 reported in *The Lancet* in the format of a research letter (where in the same format several years earlier **Steptoe and Edwards** reported the first IVF baby) that eggs could be retrieved for IVF transvaginal under ultrasound control.[5] This meant that retrievals could be performed outside of operating rooms, where up to that point all retrievals had taken place, mostly under full anesthesia.

Vaginal egg retrievals very quickly became the world's standard retrieval method in IVF and, with it, IVF was no longer limited to the availability of operating rooms and, therefore, no longer dependent on being in hospitals. This led to the first explosive growth period for IVF in the U.S., as ambulatory IVF clinics were established all over the country, almost exclusively in private practice frameworks. This remained thereafter the dominant practice pattern in IVF for approximately 20 years, at which point private equity started to get interested in the fertility field, - interestingly initially in Australia and New Zealand, where within a few relatively short years three companies controlled a large part of the IVF market. In selected European countries, quickly growing physician-owned clinic chains, like IVI in Spain, evolved and became the example for the development of similar IVF clinic chains in the U.S.

In parallel, academic IVF centers, like Norfolk, Yale, John Hopkins, and others which in early years of IVF practice were the principal drivers of progress in the field in the U.S., progressively lost luster and leadership, often replaced in in this role by rapidly growing privately-owned regional clinic networks, mostly supported in their expansion by insurance mandates for IVF coverage a handful of states already passed in the late 1980s and early 1990s. Such mandates were state-wide and, therefore, encouraged the expansion from single center operations to regional clinic networks and led to the first multi-thousand IVF cycle operations, like *Boston IVF* in Boston and vicinity, *Shady Grove* in the Washington, DC, area and Virginia, and the CHR in Chicago (later replaced by the *Fertility Centers of Illinois (FCI*).

THE NEW YORK CITY (NYC) TRISTATE MARKET

Interestingly, while most larger cities very quickly developed dominant IVF centers (some, indeed, multiple), NYC lagged. While Boston, Maryland, and Chicago, for example, already had established above noted local provider networks, NYC offered IVF services at only a few small clinics and most NY patients who needed IVF still travelled to the *Yale* program in New Haven, CT. None of the major academic institutions in the city in these early days, indeed, offered IVF services worthwhile mentioning.

This changed radically when (what then was called) *Cornell*, hired **Zev Rosenwaks** away from *Norfolk*, (at that point, still, clearly the nation's leading IVF center). He at that time was the Jones's "young Turk" at the *Norfolk* program, just a few years out of fellowship training, brought to *Norfolk* as one of the program's first clinical hires. What, however, turned the new *Cornell* program instantly into the undisputed IVF leader in NYC and, indeed, replaced the *Norfolk* program in its national leadership, was the fact that Rosenwaks also succeeded in bringing with him *Norfolk's* founding IVF laboratory director, **Lucinda Veeks**, who at that point was clearly the nation's top-embryologist. *Cornell,* thus, in one masterful strategic move had gone from zero to becoming, likely, the country's most prominent IVF program, easily able to recruit other leading young voices in the field, like the clinician **Jamie A. Grifo** out of *Yale*, and the prominent European embryologist **Jacques Cohen**.

Observing Rosenwaks' enormous success at *Cornell* from afar, other major institutions also decided to enter the IVF market. Considering the still very small pool of IVF- qualified experts at that time, this was not a simple task. The best solution, therefore, was to copy *Cornell's* strategy of hiring away people from other programs with offers they could not refuse. As noted above, because of its prominence, *Cornell* had been able to accumulate many such people on the clinical as well as laboratory side of operations. Unsurprisingly, Cornell, therefore, saw happening to its program, what it previously had caused to the *Norfolk* program: *NYU* and, somewhat more surprisingly, *St. Barnabas* in New Jersey, instantly succeeded in establishing prominent IVF programs by, basically, partially dismantling Rosenwaks' program. Under the leadership of Grifo, a significant portion of *Cornell's* clinical program moved a few blocks south to *NYU,* while under the leadership of Cohen, mostly embryology staff from *Cornell* moved across the Hudson to New Jersey. Rosenwaks, however, must be given enormous credit for, in contrast to, for example, *Norfolk's* and *Yale's* programs, maintaining *Cornell's* position as a leading IVF center despite all of this upheaval.

Other institutions also made similar efforts in recruiting from other already successful academic programs like the *Yale* program. So, for example, *Mount Sinai* hired **Neri Laufer** from *Yale*, a temporary visitor from Israel (later to become Professor and Chair of the Obstetrics & Gynecology department at the famous *Hadassah Hospital* in Jerusalem) who basically ran Yale's program under the auspices of **Alan H. DeCherney**, than the division head of the REI division but more of a surgical than IVF expert at the time. Once Laufer returned to Israel, another *Yale* person of Israeli background, **Daniel Navot,** took over his position at the *Mount Sinai* program. *Columbia University*, in turn, hired **Mark Sauer** from the successful Los Angeles program at *USC*. By the mid- to late-1980s, all major medical schools in the tristate area had established IVF programs, - some more successful than others and, in parallel, by physician-owned smaller private independent IVF centers also had started to flourish.

As we previously described in *the VOICE* in more detail (and do not want to be repetitive about here), the CHR at that point was headquartered in Chicago and was at that time one of the largest IVF centers in the country with multiple clinical locations and two IVF laboratories in the larger Chicagoland area as well as a handful of IVF clin-

ics in other states. CHR entered the NYC market in 1988 in an initial contractual relationship with the *Columbia* and *Mount Sinai* programs to establish a combined program. *Mount Sinai* later withdrew from this contractual agreement, leaving the CHR only in a relationship with the *Columbia* program. After CHR-New York opened (in the space that now houses the *RMA-NY* program), this relationship under the stewardship of Sauer, however, only lasted for approximately one year, at which point CHR's current Medical Director and Chief Scientist, **Norbert Gleicher**, took over the reign (moving the CHR into its current quarters by 2001).

Though private IVF programs continued to proliferate, the Tristate marketplace, otherwise, remained more-less stable through ca. 2010, with *Cornell* and *NYU* remaining the two largest IVF programs in the city, *St, Barnabas* in New Jersey, initially featuring a highly successful program after **Richard T Scott Jr.** joined Jacques Cohen on the clinical side of the program's operations. The program, however, did not last after Scott decided to break off into his own private set-up, called *RMA-NJ* (after an initial short hook-up, unrelated to *RMA-NY*). *RMA-NJ* became a very successful multi-center chain of clinics (more about its interesting history later), while the *St. Barnabas* program significantly declined in size and especially scientific importance.

What, however, in the Tristate market happened since ca. 2010, can only be characterized as revolutionary; yet has remained mostly under the radar and, therefore, is really the principal motivation for this article.

THE MOST RECENT YEARS

Changes in the fertility field since 2010 have been dramatic, - both in how medicine is practiced and how medicine is structurally organized. This article has the purpose of pointing out the structural changes which, nationwide, have led to most IVF clinics in the nation (and in many other regions of the world) now being owned by investors rather than physicians. That this is also the case in the New York Tristate area, therefore, should not surprise. But what, still, may surprise is the fact that this also includes some well-known IVF centers still operating under the name of their former (not-for-profit) academic institutions. Moreover, even among privately owned IVF clinics, many have sold to equity-owned companies building still growing national networks of IVF clinics (see Table).

For example, *NYU Langone Health* in NYC describes itself as "one of the nation's premier academic medical centers devoted to patient care, education, and research and nobody can, indeed, argue with this description, considering the many accomplishments of this institution in recent years which clearly outcompeted other medical schools in the city. The *NYU Langone Fertility Center*, as its website suggests, is part of *NYU Langone Health*; but as its website suggests it is also part of a network of IVF clinics managed by a company with the name *Prelude Fertility Inc.*,[6] an equity-owned national network of IVF clinics (and other IVF-related businesses) claiming to be the largest such network in the U.S. Above noted James A Grifo is, indeed, Director of the *NYU Langone Fertility Center* in NYC and, at the same time, Prelude's Chief Medical Officer.[7]

Or take, for example *RMA of NY* (*Reproductive Medical Associates of New York*), which, as above noted, has its Manhattan main offices in the space originally built out for the CHR, on its website proudly announces itself to be "*the Department of Reproductive Endocrinology and Infertility for the Mount Sinai Health System*?"[8] It in 2023 equally proudly announced to have joined with all of its locations another national network of IVF clinics called *US Fertility*,[9] claiming to be the nation's largest physician-led fertility network.[10] This company arose out of above already noted local East coast network Shady Grove, which with help of equity investments has since expanded far beyond its original practice area. As the *VOICE* reported last October, its Manhattan location had lost its Medical Director, **Tomer Singer**, to *Northwell's* fertility program and, with the addition of *RMA-NY*, is scheduled to close as we learned.

Another good example for the upheaval in the IVF field is *RMA-NJ* (again, except for a very brief initial connection unrelated to *RMA-NY*). As noted, after separation from *St Barnabas*, a very successful and academically very productive regional IVF clinic network, *RMA-NJ* was in 2017 acquired by the *Valencia Fertility Institute (IVI)*, at the time one of the largest international chains of fertility centers, originally started in Spain, in the process creating *IVI-RMA Global*.[11] As also in detail previously reported in these pages, *IVI-RMA Global,* in turn, in 2022, in a record-breaking blockbuster deal was acquired by *KKR & Co* at an approximate enterprise value of $4 billion. But that is not the end of the story: As also already noted earlier, *Boston IVF* was one of the pioneering IVF clinic networks in the U.S. Starting in Boston, it in more recent years expanded into several other states, in the process becoming one of the largest clinic networks in the country. It was acquired in 2019 by *NMH Health PLC*, an Emirates-owned London Stock Exchange listed healthcare company that also owned Spain's second-biggest IVF clinic network, the *Eugin Group*., into which *Boston IVF* was integrated. By December 2020, *NMH* sold *Eugin* (with *Boston IVF*) to the German hospital network company *Fresenius Helios* for $525.7 million.[12]

But this saga does not even end here because in November of 2023, *KKR & Co*, which just the year before had acquired *IVI-RMA Worldwide*,[13] announced the acquisition of U.S. and Canadian operations of the *Eugin Group* (likely because of anti-trust concerns already expressed by the EU during the prior purchase, this acquisition did not include *Eugin's* Spanish and other European assets) for a rumored $600 million.

And then there is *CCRM* (the *Colorado Center for Reproductive Medicine*), which, founded by **William Schoolcraft** as a private infertility center, rose to significant academic prominence, not the least for promoting blastocyst-stage embryo transfer during Australia's **David K. Gardner's** tenure as the lead embryologist at the center.[14] After establishing one of the earliest national networks of IVF clinics, with growing presence in NYC, *CCRM* sold after sev-

Table. Tristate area's fertility centers and their ownership format (in alphabetic order)

Name	Ownership Format
Advanced Fertility Services	Private
Braverman IVF & Reproductive Immunology	Private
Center for Advanced Reproductive Medicine & Fertility	Private
CCRM Fertility -NY	Equity - national chain
CCRM - Institute for Reproductive Medicine	Equity – national chain
CCRM - Institute for Reproductive Medicine and Science	Equity – national chain
Chelsea Fertility NYC	Private
CHR	Private
Columbia University Fertility Center	Academic
Diamond Institute for Infertility & Menopause	Private
Extend Fertility*	Private
Fertility Institute of NJ & NY	Private
Generation Next Fertility	Private
Genesis Fertility & Reproductive Medicine	Private
Greenwich Fertility	Private
Island Reproductive Services	Private
IVI-RMA-NJ Worldwide	Equity – worldwide chain
Kindbody	Equity – national chain
Kofinas Fertility Group	Private
Legacy IVF	Private
Morgan Fertility and Reproductive Medicine	Private
New Hope Fertility Center	Private
Neway Fertility	Private
Northwell Health Fertility	Academic
NYU Langone Fertility Center	Equity – national chain
Offices for Fertility and Reproductive Medicine	Private
Rejuvenating Fertility Center	Private
RMA-NY	Equity – national chain
Sher Fertility Solutions	Equity – national chain
Spring Fertility*	Equity – national chain
Stony Brook Medicine – Island Fertility	Academic
The New York Fertility Center	Private
Weill Cornell Medicine – Center for Reproductive Medicine	Academic

*Primarily provider of egg-freezing services

eral earlier investment trunks, in 2021 to private equity under the name *United Women's Healthcare* (*Unified*).[14]

New York, like much of the rest of the country, therefore, no longer is just a very competitive marketplace among private and academic fertility centers, as the field started out, but is increasingly dominated by large investor-owned and managed IVF clinic networks in, as above noted examples well demonstrate, a quite frantic competitive clash for market share, nowhere probably as obvious as in NYC. That these developments have major consequences on how fertility treatments are dispensed, therefore, cannot surprise and is the subject of the next section.

THE CONSEQUENCES OF THESE DEVELOPMENTS

As the Table demonstrates, the NYC Tristate area is currently served by approximately 33 separately identified fertility provider organizations, many – if not most – with more than one office location. Among those, are only 4 left with exclusively academic ownership, 9 are equity (investor) – owned and are parts of national or worldwide clinic IVF chains, and the remaining 20 are still privately owned by their physicians. What, however, also will be obvious is that the latter are all clearly smaller centers and, except for the CHR, have no significant national and/or international visibility and/or patient following and have little or no academic connection and/or scientific production.

Though still a majority, these private centers, even combined, likely therefore represent only a minority of IVF cycles performed in the region.

The current direction the field of infertility in the Tristate area, therefore, follows national and international trends toward fewer IVF cycles performed in academic and private IVF clinics and increasing numbers conducted by rapidly growing national and international clinic networks funded by outside, mostly equity investments. That such a trend has significant consequences of how clinical care is provided, quality of care, and costs will be obvious and has already been studies in other areas of medicine that have undergone similar consolidations financed by outside investments. Here are some areas of hope and concern:

AREAS OF HOPE

Professional management: That professional management improves efficiencies, capital utilization, and informatics is unquestionable. One of the original founders of *IVI* always notes that the company did not really become "successful" until they brought professional management on board (personal communication).

Availability of capital: Similarly, there can be no doubt that deep-pocketed equity-supported companies have significant growth as well as development advantages over companies who only can self-finance through bank loans and/or profits.

Cost effectiveness of size: Rapid growth and increase in size also bolsters the purchasing power of a company, lowering costs of purchases and, of course, improving the competitiveness of the company versus companies with higher purchasing costs.

Hiring advantages: Larger and better funded companies also have clear hiring advantages, - not only over privately owned clinics but also academically and hospital-owned enterprises[15]: Not only can they afford to pay higher salaries and offer better benefits (as recent history has well demonstrated), but they offer what candidates for employment perceive to be better job-safety. In addition, through purchases of academic IVF clinics, these companies have also "purchased" fellow ship training programs, thereby, often receiving first choice in hiring graduating REI fellows.

Improved access to fertility treatments: Finally, it is frequently claimed by proponents of industrialization of medical practice away from physician-ownership tha access to medical care is improved. We, however, have so-fat not seen any supportive evidence for such a claim and as further addressed below, current evidence that entry of equity investments into medical practice actually increase costs, would argue against such a conclusion.

AREAS OF CONCERN

While for the longest time only theoretical, they, based on several recent publications (repeatedly addressed in the *VOICE*) have come into more focus.

The profit motive: Equity investments in principle have one overwhelming motive, - to make money! And this does not only mean to be profitable, - but to be as profitable as possible as quickly as possible because equity investments' profits generally are expected to be realized within a time frame of 5-7 years. In practical terms this means that an equity investor in a company expects within ca. 5-7 years (there, of course, are exceptions on both ends) to improve the profitability of the company by so much that she/he will be able to sell the company with significant profit. In other words, equity investors have absolutely no interest in remaining long-term owners of a company. Their interests are exclusively short-term and this, of course, will be reflected in their business plan for the company. As even acknowledged, by the finance industry itself, "*concerns over how private equity affects healthcare access, quality, and cost in the U.S. has exploded in the past few years, reflecting the growing activity of private investors in health care markets.*"[16]

Pressure for revenue and profit generation: Since any future sale of the company will depend on the degree of the company's improved profitability, this in practical terms always means that professional management's principal goal will be the quick achievement of improving profitability which, in turn means, increasing revenue and reducing overhead costs. Consequences, therefore, should not surprise: A recent article in the *Harvard Business Review* suggested concerns about surprising billings of patients after purchases of hospitals by private equity, scaling back of support staff, including nurses, avoidance of low-margin services (primarily used by vulnerable populations) and, of course, promotion of high-margin services.[17]

It seems reasonable to assume that, if such concerns are warranted after hospital acquisitions by private equity, the same should apply after clinic acquisition and/or if private equity manages clinic networks. A recent study in *JAMA Health Forum* (and previously discussed in the *VOICE*) indeed, confirmed this suspicion.[18] Studying 578 private equity acquisitions of dermatology, gastroenterology, and ophthalmology physician practices, the study revealed that equity-owned practices increased costs (amount of allowed charges per claim) and utilization of services (volume of encounters, and volume of new patients seen). The study also suggested that further research was required regarding quality of care, patient satisfaction, and – not to be forgotten – physician, nursing, and other staff satisfaction in such a framework. Preliminary data from Germany suggested significant concerns, with arguments being that such frameworks restrict physician autonomy in treating their patients (a similar argument as also heard regarding insurance company interventions into treatment decisions of physicians), therefore an adverse impact on quality of care, as well as work-life balance considerations. Significant concern was also expressed about the lack of medical understanding by professional management.[19]

A most recent systematic review of the subject in the *BMJ* concluded that in the U.S. equity ownership across almost all healthcare setting (including medical practices) were often associated with harmful impacts on costs to patients or payors and with mixed to harmful impacts on quality of care.[20] Probably most disturbing, a very recent U.S. study published in *JAMA*, rather devastating evidence

about adverse effect of hospital inpatient outcomes after hospitals were acquired by private equity, Quoting the paper, "*private equity acquisition was associated with increased hospital-acquired adverse events, including falls and central line–associated bloodstream infections, along with a larger but less statistically precise increase in surgical site infections. Shifts in patient mix toward younger and fewer dually eligible beneficiaries admitted and increased transfers to other hospitals may explain the small decrease in in-hospital mortality at private equity hospitals relative to the control hospitals, which was no longer evident 30 days after discharge. These findings heighten concerns about the implications of private equity on health care delivery*."[21]

Specific studies on the subject in the practice are of REI are lacking. We, however, recently presented at the 2023 *ASRM* Congress in New Orleans, LA, in abstract format a study (currently submitted for publication and under peer review) which, based on U.S. national reporting data by IVF centers, which unequivocally demonstrated that equity and venture capital-owned IVF clinics utilized preimplantation genetic testing for aneuploidy (PGT-A) significantly more frequently than academic/hospital-owned and physician-owned clinics, even though the chance of live birth significantly declined with increasing utilization of PGT-A.[22] As one would expect, the REI field, therefore, appears to demonstrate similar behavior patterns as other medical specialty areas in medicine when taken over by private equity.

De-individualization of medical care: One of the main arguments of proponents of clinic networks in IVF is their ability to establish "best practices," thereby allegedly improving fertility treatments overall. Aside of the fact that above noted PGT-A utilization findings contradict this argument rather vehemently, it, of course, also appears obvious that clinic networks must standardize care if they want to achieve consistency, predictability, and cost efficiency. We, therefore, must conclude that they, by definition, simply in their existence, already contradict the concept of "precision medicine." Accepting this conclusion then allows for considerations of certain solutions for at least some of the above outlined shortcomings of large clinic networks, discussed in the final section of this article.

ARE THERE SOLUTIONS?

At the current time, regional, countrywide, and even international IVF clinic networks appear unstoppable. Encouraged by the incredible price *KKR&Co* was willing to pay for *IVI-RMA Global* and the American and Canadian assets of *Eugin* (including *Boston IVF*), the speed of clinic purchases and establishment of new clinics by network companies even appears to accelerate. In addition, some smaller clinic networks are already being swallowed-up by larger ones to become even larger.

Will it work?

That remains to be seen and, we acknowledge a degree of skepticism in the ability of even good management wringing out of those clinics enough profit over the next few years to warrant even more exorbitant purchase prices for the clinic networks who then will have to find new owners.

That our skepticism may be warranted is supported by the observation that, based on the behavior of management at several clinic chains the initial "good times" appear over: Investments are curtailed, costs are trimmed and, if staff is not laid off yet, their production quotas are raised. Concerns at those companies are further aggravated because national IVF cycle numbers have not increased at the rate that had been forecasted. As we previously discussed in these pages, we also do not consider the decision of *Morgan Stanley Capital Partners* to divest of all its IVF assets,[23]and of German *Fresenius Helios*[12] to do basically almost the same to have been accidental. Both owned their fertility-related assets just long enough to better understand their earnings potentials and decided to sell without usually expected profits.

We, therefore, foresee the industry entering a period of significant belt-tightening which, inevitably, will be followed by increasing staff dissatisfaction and, therefore, declining quality of care, in turn leading to increasing patient dissatisfaction and, therefore, to a vicious cycle of even more-disappointing growth in IVF cycle numbers. We, however, also see a possible solution how such a period of belt tightening can be successfully managed for a large majority of infertility patients without causing above pointed out self-fulfilling prophecy. Such a solution would require that the management of such clinic chains learns to understand that not all IVF patients are the same.

As the Center of Human Reproduction (CHR) demonstrated even in overall poor-prognosis patients, every patient population undergoing IVF can be stratified into good-prognosis patients (ca. 15-20%), average-prognosis (60-70%), and poor-prognosis patients (15-20%).[24] Good- and average-prognosis patients, representing ca. 80-85% of every patient population, with current IVF practice will achieve excellent pregnancy rates with relatively minimal diagnostic workups and basic standard IVF. Their IVF cycle, therefore, can be protocol-driven, utilizing simple protocols (no PGT-A, for example), using increasingly automated embryology laboratories, and in many instances may, indeed, use physician extenders to provide much of these protocol-driven services. Such IVF cycles, therefore, can be offered relatively inexpensively, - yet will still achieve satisfactory pregnancy and live birth rates.

What to a significant degree raises IVF costs in the U.S. to, at times, almost absurd levels, are in principle mostly only two so-far unaddressed causes: (i) Unnecessary treatments (I.e., again, for example, PGT-A); and (ii) poor-prognosis patients, representing only ca. 15-20% of all patients. A big part of this patient population are older women. Because IVF patient populations in the economically more developed world are getting quickly older, poor-prognosis patients are increasing in numbers and need much more specialized treatments (i.e. precision medicine). Currently, they, however, are part of the general population of IVF clinics, greatly contributing to overtreatment of good-prognosis patients (because of their large majority a very costly proposition) and to undertreatment of poor prognosis pa-

tients (even though only a small minority, still, a great expense because their undertreatment leads to treatment failures and the need for large number of unnecessary repeat IVF cycles).

During very early IVF days, good IVF clinics could be easily differentiated from poorer ones based on their clinical pregnancy rates, The main reason was that nobody could achieve pregnancies in either older women or, overall, more difficult cases. Among remaining more homogenous patient population, better centers did then better than poorer centers. Today, practically every reporting IVF center in the U.S. has the knowledge and technical skills to achieve pregnancy in most good- and average- prognosis patients. Most, however, do not have the required skills (and, frankly, time) to properly treat the so-called poor prognosis population with the required "precision medicine."

Our proposal, therefore, is that clinic chains, in principle, concentrate on the large majority of good- and average-prognosis patients, while referring poor-prognosis patients to specialized clinics within their networks. If they do not exist, such clinics can be set-up regionally or, if that is not possible, clinic networks could subcontract for such services in local markets where qualified providers exist. Such a discriminatory system based on prognostic status of patients would reduce average costs for IVF, - yet at the same time improve overall IVF outcomes which in the U.S. until 2010 steadily increased but, since, has seen declining.[25]

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