# Meeting the demand for fertility services: the present and future of reproductive endocrinology and infertility in the United States

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The field of reproductive endocrinology and infertility (REI) is at a crossroads; there is a mismatch between demand for reproductive endocrinology, infertility and assisted reproductive technology (ART) services, and availability of care. This document's focus is to provide data justifying the critical need for increased provision of fertility services in the United States now and into the future, offer approaches to rectify the developing physician shortage problem, and suggest a framework for the discussion on how to meet that increase in demand. The Society of REI recommend the following:

1. Our field should aggressively explore and implement courses of action to increase the number of qualified, highly trained REI physicians trained annually. We recommend efforts to increase the number of REI fellowships and the size complement of existing fellowships be prioritized where possible. These courses of action include:

a. Increase the number of REI fellowship training programs.

Received August 17, 2023; accepted August 17, 2023; published online September 4, 2023. A report from "The Future of REI Taskforce," an ad hoc committee of the Society for Reproductive Endocrinology and Infertility. This consensus statement was commissioned by SREI and endorsed by SREI, SART, and ASRM. Correspondence: Ruben Alvero, Stanford Fertility and Reproductive Health, 1195 Fremont Avenue, Suite 1301 Sunnyvale, California 94087 (E-mail: ralvero@stanford.edu).

#### Fertility and Sterility® Vol. 120, No. 4, October 2023 0015-0282

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b. Increase the number of fellows trained at current REI fellowship programs.

c. The pros and cons of a 2-year focused clinical fellowship track for fellows interested primarily in ART practice were extensively explored. We do not recommend shortening the REI fellowship to 2 years at this time, because efforts should be focused on increasing the number of fellowship training slots (1a and b).

2. It is recommended that the field aggressively implements courses of action to increase the number of and appropriate usage of non-REI providers to increase clinical efficiency under appropriate board-certified REI physician supervision.

3. Automating processes through technologic improvements can free providers at all levels to practice at the top of their license. (Fertil Steril® 2023;120:755–66. ©2023 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.

Key Words: Infertility, reproductive endocrinology and infertility, assisted reproductive technology, access to care, fellowship

### THE SCOPE OF THE PROBLEM

The field of reproductive endocrinology and infertility (REI) is at a crossroads; there is a mismatch between demand for reproductive endocrinology, infertility and assisted reproductive technology (ART) services and availability of care. Specifically, this mismatch involves suboptimal numbers of properly trained physicians in the subspecialty of REI at the present time and in the foreseeable future; inadequate numbers of trained embryologists and other reproductive laboratory scientists; and geographic misdistribution and poor financial coverage of fertility services leading to major challenges involving access and equity. The goal of this document is not to provide analysis and solutions to all these fundamental problems, many of which are being concurrently addressed by other constituencies of the American Society for Reproductive Medicine (ASRM). This document's focus is to provide data justifying the critical need for increased provision of fertility services in the United States now and into the future, suggest approaches to rectify the developing physician shortage problem, and initiate a discussion on how to meet that increase in demand.

With the total number of children born using in vitro fertilization (IVF) approaching 10 million worldwide and 100,000 infants annually in the United States (1), reproductive endocrinologists should take pride in the important contributions that they have made to family building worldwide, in partnership with colleagues in embryology, nursing, mental health, healthcare administration, allied health fields, and genetic counseling. The growth of ART is largely attributable to improvements in the effectiveness and safety of IVF, along with the expansion of indications for its use. However, the field of REI is, in a sense, victim of its own success and now needs to address how it can provide access to treatment for any individuals or family that need it. This includes overcoming financial and geographic barriers to care, expanding access to genetic carrier screening and IVF for genetic disease prevention, defining and making available options for the LGBTO+ community, and offering proactive solutions for fertility preservation. In addition, it is a real possibility that the application of gene editing technologies to the germline treatment of devastating genetic diseases will be a reality in coming years. It needs to be recognized that only through adequate numbers of rigorously trained reproductive endocrinologists and a robust ART infrastructure could such technologies be safely and ethically applied.

To fulfill the true potential of assisted reproduction, the REI needs to move from an IVF ecosystem that helped conceive 10 million children over 4 decades to one that has the potential to help family building on the order of twice that number, per year. According to The United Nations Children's Fund, 140 million children were born worldwide in 2021. A 9% prevalence of infertility (2) suggests that another 12-13 million more families might have children if treatment were available to them. When considering a 1%-2% prevalence of recurrent miscarriage (3), a 6% rate of genetic and preventable birth defects (4), and a conservative estimate that LGBTQ families account for five percent of the population (5), the potential number of desired but currently unfulfilled births per year is likely to be close to 20 million-approximately 80-fold the number of worldwide IVF births today. This figure does not include fertility preservation or genetic indications for ART. In the United States, applying the same parameters to the approximately 3.7 million infants delivered in 2021 implies over 800,000 infants born annually from IVF, which represents approximately 10fold the current rate. Even with continued increases in the live birth rate per IVF cycle, this would require over 2 million annual IVF cycles in the United States.

To put that number in context, in the United States, there are approximately 1,500 board-certified REI subspecialists, with 1,250 in active practice (6–8). In 2020, Society for Assisted Reproductive Technology (SART) statistics show 291,484 cycles completed in the country, representing an average volume of 233 cycles per board-certified REI provider annually (9). To meet the theoretical demand, the average REI provider would need to oversee approximately 1,600 ART cycles per year.

The triumphs of IVF are evident in nearly every community, but not yet in every family in need. As REI subspecialists prepare to serve the increasing number of patients who need their services, it must be acknowledged that the IVF infrastructure developed over the last four decades is not adequate to handle the volume that the next four decades will bring. It is hoped that this document will serve to foster a conversation on how to scale the current model to accommodate the anticipated increase in demand for fertility services in the United States and, in parallel, provide a model that can be emulated worldwide.

#### **REI FELLOWSHIPS**

REI fellowship training is fundamental to solving the discrepancy between supply of physician subspecialists and the population's demand for fertility care, because REIs supervise fertility treatments, especially those using ART. Fellowships are rate-limiting in creating new board-certified subspecialists, all of whom derive from a limited pool of 50-60 annual REI fellowship graduates. Unlike the fellowships for other Obstetrics and Gynecology (OB/GYN) subspecialties, REI fellowship numbers have remained flat in the past several years. There are well-known financial and institutional barriers to creating new fellowships and additional fellowship slots. Furthermore, there has been limited backing by the medical community, government bodies, and insurance carriers for support of fertility services, because such services are often incorrectly viewed as elective, despite the fact that infertility has been defined as a disease by both the World Health Organization (WHO) (10) and more recently by The American Medical Association (11) and is highly prevalent in the general population. Despite the challenges these obstacles and misconceptions impose, increasing the number of graduating REI fellows remains essential to expanding access to highquality fertility care.

#### A Brief History of the REI Fellowship

REI was first recognized as a subspecialty by the American Board of Obstetrics and Gynecology (ABOG) in the early 1970s. Initially, fellowship training was 2 years in length and focused on reproductive endocrinology, medical and pediatric endocrinology, and evaluation and treatment of infertility, including male infertility. The 2-year fellowship period included 6-12 months of research (personal communication). In 1997, the fellowship officially lengthened to 3 years, eventually extending the research component to at least 18 months and with clinical focus centered largely on fertility treatment and procedures such as ovarian stimulation, oocyte retrieval, and embryo transfer as well as genetics. Throughout the history of the subspecialty, structured research has been a significant part of training and currently is a requisite for certification (12). It should be emphasized that research was and remains critical to appreciating the underpinnings of clinical practice and continual medical progress of the field and has been deemed integral to the development of life-long learning habits.

#### Fellowship Limitations in the Context of the Current Environment and Emerging Challenges

Current fellowship site requirements and practice standards are set by the Accreditation Council for Graduate Medical Education (ACGME) and programs are reviewed and accredited by the same body, with sites assessed every 10 years. ABOG certifies individual physicians. An ACGME-accredited academic institution must be one of the program sponsors and the fellowship must be an integral part of the institution's OB/GYN residency program. Trainees must have access to female and male infertility services, genetics, medical and pediatric endocrinology, full text medical literature, and structured educational activities outside of direct patient care. Fellowship directors and faculty must have academic productivity, and directors must have protected time for management of the fellowship. There must be a fellowship program coordinator with at least 0.3 FTE allotted. There must be a minimum of 12 months of dedicated time allocated to research. This requirement was recently reduced from a minimum of 18 months, and no longer needs to be contiguous (13). It should be mentioned that the substantial flexibility that now exists on time allocation for research is helpful to programs and individual fellows as there are substantial differences among the scheduling needs of bench vs. clinical vs. health services/public health research. Nevertheless, given the current guidelines and requirements, REI fellowship training is limited to academic-only divisions or academicprivate practice collaborations.

In the current environment, these requirements, especially the required affiliation with an OB/GYN residency training program, introduce challenges to the goal of expanding the number of graduating REI fellows. This obstacle is exacerbated by the significant migration of fertility care from academic institutions to private practices. This change in practice patterns stems from the challenges of providing high-tech, high overhead fertility treatments under the university umbrella that has been traditionally less efficient and less cost effective (14, 15).

Faculty need additional time for teaching and mentorship to provide a rich learning experience for each fellow and this may require decreasing clinical volume and/or impact on faculty personal time. Although opportunities to be involved in research may be available, funding may be limited and resources to support fellow research projects need to be considered when expanding fellowships. Furthermore, to comply with ACGME and ABOG reporting requirements, which demand documentation of fellow progress, feedback, and mentorship, additional fixed resources are needed. In addition to funding a 0.3 FTE Program Coordinator, Program Director must be funded at 0.2 FTE, in addition to the teaching time required of all program faculty.

#### **Fellowship Pool and Match**

An average of 67 US and foreign applicants (range, 60–75) have applied to REI fellowship over the past 5 years (2017–2022). There were no unfilled positions from 2019 to 2022 (16) and Program Directors indicated that it was not challenging to recruit highly qualified applicants. There are currently 48 accredited US REI fellowship programs (17). The mean candidate match rate over this time has been 71% (range, 63–88) with unmatched rates of 29% (range, 12–36). Unmatched candidates, representing a pool of candidates for additional REI training, have therefore been approximately 20 per year, and on the basis of the most recent 2016 fellowship directors survey, these unmatched applicants are generally highly qualified, potentially justifying an increase of up to 20 positions per year (18).

# Best Practices for Establishing or Expanding a Fellowship Program

Expansion of a fellowship program requires adequate clinical volume, adequate research mentorship, and research

opportunities for each fellow to have the breadth of experience and exposure to all aspects of REI as defined by the ABOG Blueprint (19). As stated above, the fellowship program must be affiliated with an ACGME-accredited institution and integrally involved with an OB/GYN residency program. There must be a minimum number of board-certified REI faculty members able to provide the graduated supervision and independence appropriate for a fellow level of experience. To consider adding fellow(s), all clinical rotations must be structured to accommodate an additional trainee without diluting the experience of any existing fellows or creating significantly different training experiences among fellows within the same program. ACGME requirements also state that adding additional fellows should not dilute the experience or training for residents who rotate through the REI division. In addition, non-OB/GYN departments, divisions, institutions, and/or ancillary faculty must be able to accommodate learners for additional clinical experience in pediatric endocrinology, medical endocrinology, medical genetics, and reproductive urology. Research opportunities for basic and/or clinical research must be available with appropriate research mentors. Programs with a dedicated research division and clinical research director have an advantage in the provision of adequate research oversight for REI fellows.

# Financial Considerations for Establishing or Expanding a Fellowship

There are multiple costs associated with expanding a fellowship. There is significant variation in the cost of training an REI fellow by institution and by region. When all US REI fellowship program directors were asked to complete an IRB-exempt survey/web form for the purposes of this report, 17 completed the form. Programs reported total costs ranging from \$76,856 to \$190,000 per fellow per year in 2022 dollars. These data may be biased because only 17 programs completed the survey, yet represent the best data we have on the cost of current REI fellowships. In addition to salary, benefits, and malpractice insurance, reported costs included parking, meal allowance, course fees/tuition (e.g., statistics, biomedical science, clinical research, continuing medical education), IT hardware, travel, conference fees, research funding, and licensing fees. Although the university/university hospital may support the fellowship in part, most respondents indicated that the largest share of costs are covered by the REI division itself, with several reporting a private practice affiliation covering a portion of the cost. In multiple instances, the private practice covered most or all the fellowship costs. University-based programs may rely on a general departmental pool of graduate medical education (GME) funding for varying amounts of the financial funding of their fellowship. Programs are effectively competing within OB/GYN subspecialties and all other surgical programs for institutional funding, contributing to the common practice of REI divisions and/or affiliate private practice providing REI fellowship funding in part or in full.

Some medical specialties, such as Gynecologic Oncology, have sought alternative sources of funding to expand fellowship programs to meet the need for services. For example, leaders in the Society for Gynecologic Oncology identified states that had no fellowships and/or had low numbers of practicing Gynecologic Oncologists. They presented these data to state legislatures and, in some cases, received full funding for a new fellowship, including funding for fellow, faculty, and research costs (personal communication). These successful programs now have annual funding completely independent of institutional monies, increasing both fellowship training slots and access to care in that state. One such example is the Georgia Medical College Gynecologic Oncology Fellowship, which became ACGME-accredited in 2017 for one fellow per year fully supported by the Georgia state legislature. New and established REI fellowship programs with the ability to add new fellows, but insufficient funding should explore alternate sources of funding such as these.

#### **Additional Challenges of REI Fellowships**

Market forces have made it increasingly difficult for some academic centers to recruit qualified REIs and to compete with private practices for patients, which has limited REI fellowship faculty (20). In recent years, many academic REI centers have faced financial hardship, providing further hurdles for increasing fellowship positions. Cumbersome institutional bureaucracies also pose challenges, and academic REI divisions have struggled to compete with offers made by private practices to hire academically inclined junior faculty. The increasing chasm in academic vs. private practice compensation, as well as increased clinical, teaching, and administrative demands on REIs in academic centers, has strained available resources for fellowship training. Furthermore, the switch to ACGME oversight of fellowships in 2016 has led to new documentation requirements that are timeconsuming, unfamiliar, and occasionally challenging for even long-time Programs Directors.

There have been newly approved REI fellowships in the past 3 years; however, more fellowships have closed than new ones opened over that time (three have formally closed whereas two have been approved by ACGME but have not yet begun training). Although financial factors have surely played a role in the closure of some REI fellowships and discouraged other institutions from applying for new REI fellowships, additional institutions that have applied to the ACGME for new fellowships have been declined. Although some aspiring institutions truly lack the resources to meet the current ACGME standards for modern REI fellowship, others may simply misunderstand the ACGME common program requirements, which are quite complex. To assist new program applications, societies with interest in REI fellowship education (i.e., ASRM and Society for Reproductive Endocrinology and Infertility [SREI]) could develop and implement tool kits and provide a mechanism for aspiring new programs to seek guidance from current program directors in crafting the initial application or in response to ACGME declination.

#### **Training Goals of REI Fellowships**

The goal of the current 3-year fellowship in REI is to train OB/ GYN physicians to be safe and effective, board-certified

subspecialists in the practice of REI. From a clinical perspective, the current basic REI "learning objectives" include a wide range of topics in broad areas such as reproductive endocrinology, ART/infertility, male infertility, genetics, and reproductive surgery. Of note, the ABOG REI "blueprint" no longer includes learning objectives related to statistics or study design. Although the submission of a fellowship thesis is still required for board certification, examiners no longer ask candidates questions specifically related to their research theses during the certifying examination (21). The benefit of the requirement that every fellow spends 12 months (recently reduced from 18 months) conducting research is debated. Its value is questioned by some, especially because most REI subspecialists go on to focus on the clinical practice of REI and the cost of such research training is considerable. That said, the decision by ABOG to remove principles of study design and statistics from the "blueprint" (and presumably from the oral examination itself) contrasts with ACGME's current 12-month research requirement and ABOG's own requirement for the submission and approval of a research thesis manuscript to sit for the examination. Data suggest that the field of infertility has greatly benefited from the impressive research productivity of SREI members and clearly the research training involved in REI fellowship training has advanced the field of reproductive medicine (22). Fellow research education is of paramount importance for training competent REI physicians and for advancing reproductive medicine.

Within the current "traditional" model of fellowship, there is variability among REI fellowship programs in the depth of training in the subcurricula, e.g., endocrinology, surgery, ultrasonography, genetics, ART, and research. The ACGME does not specify minimum numbers of surgical procedures that must be completed during REI fellowship (13) and the reported range of completed cases by fellows is wide (23). Given that Minimally Invasive Gynecology and Pediatric and Adolescent Gynecology practice areas overlap significantly with areas traditionally ascribed to REI, the very definition of what it means to be an REI continues to evolve.

In this environment, the role of sub-sub-specialty tracks within REI fellowships is increasingly being explored. For instance, the Society for Reproductive Surgeons (SRS) in collaboration with the SREI have established a multiprogram Surgical Scholars Track, a specialized pathway embedded within the traditional 3-year REI fellowship. There is a set curriculum and opportunities for interspecialty collaboration within this program (24). Some fellowships also offer the ability to obtain a master's degree (e.g., Master of Science in Clinical Epidemiology or in Clinical Investigation) during training, whereas a few also offer a combined fellowship in REI and Medical Genetics under a 4-year training program.

Recently graduated REI fellows (n = 58) were queried for the purposes of this report (personal communication). The goal of the survey was to understand the perspective of recent fellowship grads on specific training requirements, including on the number of different procedures required to achieve procedural proficiency as a clinically practicing REI. Twenty-seven responded, for a response rate of 47%. Most graduating fellows felt that they had performed many more procedures than were needed to master the skills queried (e.g., egg retrievals, embryo transfers, saline sonograms, follicular monitoring scans, and intrauterine inseminations). For example, although 48.2% of respondents performed >150 IUI procedures in fellowship, all but one respondent (96.3%) felt that they needed training with <100 IUI procedures to perform this independently. Similarly, although 66.7% of respondents performed >150 oocyte retrievals during fellowship, 96.3% of respondents felt that they needed <150 retrievals to perform this procedure independently. For comparison, OB/GYN residents need to complete a minimum of 85 hysterectomies to graduate, a procedure that is accepted to be much more technically challenging than an oocyte retrieval, for example (25).

When asked about strategies to improve REI fellowship, many respondents commented that they felt they could be proficient in the clinical aspects of REI after 12–24 months of training. Comments included concern about "too many procedures" such as hysterosalpingographies (HSGs) and ultrasounds, and not enough exposure to clinical counseling or surgical training. Given the heterogeneity in REI fellowships as it regards clinical volume and structure, further inquiry into this area is needed.

#### The Conflict Between Scientific Innovation and Maximizing Clinical Capacity

Although critical for the promotion of innovation within REI, enrichment pathways, such as advanced research, surgical, embryology, and genetics training, may be even more impacted by funding constraints. As alternative funding sources are explored, medical ethics must be strictly followed with care to avoid conflicts of interest. Nonetheless, evaluating new avenues for funding is needed as most centers have a narrow profit margin with which to fund these.

Postgraduate training is more readily available for research-motivated REIs. Funding for motivated early career physician-scientists exists, e.g., via the American Association of Obstetricians and Gynecologists Foundation (26), Reproductive Scientist Development Program (26), Building Interdisciplinary Research Careers in Women's Health (27), Women's Reproductive Health Research (28), and Clinical Reproductive Scientist Training (29) programs. These are exceedingly competitive programs, however, and fellowships and national institutions must be willing to devote resources, likely including extra time during training, to enhance the likelihood of acceptance for motivated and talented early career REI researchers.

### THE ROLE OF ADVANCED PRACTICE PROVIDERS AND OTHER REI EXTENDERS

There is a deficiency in the number of fellowship-trained REIs to meet population needs, especially if access to care is substantially improved and demand increases. It is therefore important to review the potential roles of team members that, safely mobilized, can help increase our ability to care for patients needing fertility services. To meet the current and anticipated demand, practices are encouraged to have non-REI providers perform clinical tasks consistent with their highest qualification and to explore approaches to minimize the burgeoning burden of nonclinical work that can be supported by administrative staff.

### **Advanced Practice Providers**

The titles for advanced practice providers (APPs) vary on the basis of training, and most include completion of a master'slevel program. Nurse practitioners and midwives are trained in women's health; physician assistants/associates are trained in general medicine and can specialize further after graduation. They are all licensed to prescribe medications. Because APPs have extensive training in patient management, they can play broad roles in the practice of clinical REI. In addition to planning care and cycle management (30), potential roles for APPs include (but are not limited to) performing gynecologic examination and first trimester obstetric ultrasounds, saline sonograms, hysterosalpingograms, IUIs, endometrial biopsies, urgent evaluations for pain/bleeding, and new patient consultations. For cases that may be more challenging, these tasks can be performed with an REI subspecialist available to assist. A new APP ASRM professional group has been formed and will help as the role of the APP evolves within reproductive medicine. A recent IRB-exempt survey was emailed to the ASRM APP interest group and their APP colleagues working in REI. A total of 191 responded of the 200 APPs to whom surveys were sent. Results showed that most APPs see new patient consults with the expectation that the APP will continue to oversee that patient's immediate ongoing care, with 31% acting independently in conducting new patient consults, and 35% conducting new patient consults in conjunction with or under the supervision of a physician. A smaller percentage (9%) reported seeing new patients for the new patient consult, then transferring care to a physician without continuing managing that patient's care plan. The remaining 26% reported that they do not routinely conduct new patient consults.

#### **Ultrasonographers**

Numerous practices already employ American Registry for Diagnostic Medical Sonographers-certified ultrasonographers, although their specific role(s) vary from clinic to clinic. Fully trained ultrasonographers may perform complete diagnostic pelvic ultrasound/antral follicle count, follicular stimulation monitoring ultrasound (limited pelvic ultrasound), transabdominal ultrasound guidance for embryo transfers, and early pregnancy obstetric ultrasound. Delegating routine ultrasounds to ultrasonographers is likely cost effective given that it enables other clinicians to consult with patients and perform procedures. At least one clinician should be readily available to assist the sonographer in case a time-sensitive clinical issue or question arises.

# **OB/GYN Specialists Trained in Reproductive Care**

Board-eligible or board-certified OB/GYN specialists who have an interest and training in basic infertility care can serve

as supplemental physician providers in an REI practice and provide certain aspects of care. The practice scope of OB/ GYN specialists participating in infertility care may resemble that of senior APPs with the addition of significant surgical skills. Per current REI practice accreditation and for an IVF clinic to qualify for active membership in the SART, the practice must have a board-certified REI as the Medical Director. We do not support non-REI physicians taking on the role of a subspecialty REI in planning and managing ART treatments. It is strongly recommended that only REIs perform oocyte retrievals or embryo transfers. REI physicians are the only professionals qualified to oversee an ART program.

Surgical support by board-certified OB/GYN specialists may further increase access to appropriate fertility evaluation and treatment. With the increasing demands for ART treatments, OB/GYN specialists with appropriate experience have the potential to reduce the time that REIs devote to routine, GYN diagnostic or therapeutic surgical procedures such as hysteroscopy, laparotomy, and laparoscopy for polyps, fibroids, endometriosis, and ectopic pregnancy, enabling the REI to care for more patients in need of more complex fertility treatments. Tubal anastomosis and advanced robotic surgery should be performed only by those with adequate training, because it is critical that complex reproductive surgery be performed by those with needed training, which involves expert consideration of future, postsurgical reproductive outcomes. It is recognized that some fellowship training programs are surgically focused and enable REI fellows to become experienced surgeons. These programs are encouraged to continue their efforts, to maintain the diversity of training opportunities and meet the needs of interested fellows.

#### Nursing Level (BSN, RN, LVNs, and MAs)

Practices rely heavily on nursing staff to carry out patient education and facilitate critical daily communication. They can create cycle calendars, provide medication teaching, troubleshoot urgent pharmacy matters, triage calls, and establish important touchpoints for patients throughout treatment. In addition, nursing staff have the most frequent and intimate involvement with the care of the fertility patient and, thus, are best positioned to develop wellness programs that may complement standard fertility treatment(s).

In a more hands-on role, registered nurses may be specifically trained and encouraged to perform intrauterine inseminations. Both registered nurses and medical assistants may assist with transabdominal ultrasound guidance for embryo transfers, because it has been shown that the ultrasonographer's level of experience does not significantly impact IVF pregnancy outcome (31).

# **TECHNOLOGY**

Even with maximization of existing workforce and an increase in the number of graduating REI fellows, our current system will likely still fall short of the fivefold anticipated growth in volume described above. To close the gap and further increase capacity, there is a need to embrace innovative workflows and leverage new technology to improve efficiency and outcomes. Examples include applications to help manage medications and streamline patient communication, software to streamline patient education and informed consent (32, 33) and artificial intelligence to improve ovarian stimulation and embryo selection (34, 35). Before the broad adoption of any new technology into clinical practice, rigorous validation should be undertaken, and effectiveness demonstrated (32, 36). Care must be taken to avoid the use of expensive but unproven add-ons.

#### SUMMARY RECOMMENDATIONS

As we aim to expand access to fertility services to all patients who need it, we should train more REI fellows; use non-REI clinicians to practice at the top of their clinical skillsets to support existing REIs; and maximize utility of wellvalidated technologies. In so doing, the utmost care must be exercised at every juncture.

Increasing access to care does not only mean expanding the capacity of the current ART system to care for more patients, but also to reduce cost and make the fertility evaluation and treatment process financially accessible to a larger portion of the population. Although the latter is not the specific focus of this article, it is believed that the presented recommendations will also help to expand access to patients who are currently not able to afford care, by reducing the unit costs of delivering fertility care.

With regard to the strategy proposed to expand the number of fellowship-trained REIs, special caution must be exercised to prioritize quality education and to avoid conflicts of interest which may result from the source and contingencies of funding. Furthermore, efforts should be undertaken to bolster research and innovation and to enable high-quality specialized training (e.g., in surgery, genetics, basic/translational/and epidemiologic research, and high complexity laboratory procedures) for trainees who desire it.

On the basis of the data provided in this report, this committee's preliminary recommendations to expand access pertain the following areas: changes to REI fellowship training (with the overall goal of training more fellows while holding paramount the quality of training and the expertise of the graduating REI subspecialist physician); appropriate incorporation of non-REIs into the administration of clinical fertility care; and optimal utilization of technology in the service of improving safety and efficiency:

(1) Fellowship changes

REI fellowship training could follow one of the following pathways/models, or a combination of the options. We recommend efforts to increase the number of REI fellow-ships and the size complement of existing fellowship.

Increase the number of US REI fellowship programs

 Societal-level exploration of alternative sources of
 funding, which are not dependent on the limited GME
 funds of private institutions and universities may enable
 the creation of de novo programs and the expansion of
 existing ones, particularly in underserved areas. These

funding sources might include government, endowments, grants, private equity, and industry funding among others, within the bounds of the ethical considerations described above.

- o Use the expertise of current fellowship directors to help advise new fellowship applications on ACGME requirements to increase the rate of new fellowship approval. ASRM, SREI, SRS, and SART will be essential to develop the toolkits needed.
- o Standardizing and regulating research time and the infrastructure required may allow medium to large size private fertility clinics to participate in fellowship training while partnering with OB/GYN training programs as per current requirements.
- Increase the number of fellowship slots in existing REI fellowship programs:
  - o Programs with significant clinical volume and adequate resources to achieve appropriate education in reproductive endocrine, genetics, and research as described above, would be strongly encouraged to increase their fellow complement by up to 50%.
  - o If local GME funds are unavailable for an additional fellowship slot per year in a program otherwise capable of training more fellows, we recommend alternative funding be explored, as per above.
- Two vs. 3-year REI fellowship training: we do not endorse a reduction in fellowship training. The importance of education in research design and statistics combined with the additional importance of genetics and embryology (among others) requires 3 years of training. This committee spent significant effort in consideration of shortening the fellowship, and therefore, the main points are discussed below.
- Although this is a path that might be considered in the future, the model only works to increase the number of competent REI physicians if the individual institutions redirect the cost-savings toward increasing the fellow complement OR if it allows new program who might not have previously considered developing a fellowship does so, inspired by lower costs inherent in a 2-year fellowship. How the model may increase fellow number if fully implemented is described in Table 1. In addition, any future considerations on this topic must consider the program's appropriate clinical volume to meet ACGME requirements to train additional fellows. These following items would need to be considered, if future discussions of 2-year REI fellowships should occur:
  - o One year of the fellowship would focus on ART/infertility and 1 year would primarily focus on research, including formal education in epidemiology, statistics, research methodology, and thesis development. Depending on the research project, the research time could be concurrent with clinical blocks throughout the fellowship. Some limited time in the research year would additionally be devoted to medical genetics, medical endocrinology, reproductive urology, and pediatric endocrinology. It should be acknowledged that reduced time in these allied fields cedes some REI participation in these fields, but this is a reality that has been occurring

# TABLE 1

#### Impact of a sample 2-year REI fellowship.

Hariton. Meeting the US demand for fertility services. Fertil Steril 2023.

	Focus	program
Year 1 Year 2	ART/fertility Reproductive endocrinology/ genetics/reproductive epidemiology and statistics/ research methodology/thesis	33% cost reduction for all programs per graduated fellow, which could serve to increase fellow complement by at least 1/3, if not more (depending on fellowship size)
	reproductive technology; REI = reproductive endocrinolog y 55 fellows currently graduating per year.	y and infertility.

Coot to followahim

No. of fellows in training over 5 y

Baseline<sup>a</sup> = 55 + 55 + 55Year 1 = 55 + 55 + 73Year 2 = 55 + 73 + 73Year 3 = 73 + 73 + 73Year 4 = 73 + 73 + 73Year 5 = 73 + 73 + 73329 total graduates (vs. 275 in current case state) 66 graduates per year (vs. 55 in current state) 73 graduates yearly after year 3

for some time.

- o The dedicated research time formal requirement could be standardized across fellowships and perhaps be modeled on the existing Clinical Reproductive Scientist Training curriculum (13, 29). Furthermore, we strongly recommend that study design and basic principles of statistics be reinstated in the ABOG "blueprint" and that fellows be examined on these principles, which are so important for improving life-long learning and practice, during the candidate's qualifying AND certifying examinations. Furthermore, we recommend maintaining the requirement to complete a research thesis over the course of the fellowship and that the thesis be submitted as a requirement for REI board certification.
- o Although a 2-year curriculum may produce graduates who are, overall, less experienced in research than those fellows who have graduated because the fellowship was extended to 3 years, fellows with an academic interest could pursue further research training following the formal fellowship graduation and depending on available research resources (funding, faculty time, etc.). Alternatively, and depending on the graduating fellow's prior education and research expertise, the fellow could go straight into a junior faculty position, possibly supported by mentored award such as NIH's K08, K23, K12 (Women's Reproductive Health Research, Building Interdisciplinary Research Careers in Women's Health, Reproductive Scientist Development Program) or American Association of Obstetricians and Gynecologists Foundation career development awards. This may ultimately enable concentration of funding and training resources to be directed toward REIs who are talented and highly motivated to follow a research-focused career. However, as has previously been highlighted, fellows and junior faculty so interested would need to have dedicated resources given them through the training process to allow them to successfully apply to these very competitive programs, and most will need extra time in training to be competitive for a training award.
- o Fellows with specific interests that are not covered in depth during fellowship, such as advanced reproductive surgery, gamete and developmental biology and embryology to qualify for Reproductive Laboratory Directorship, or reproductive genetics, could pursue additional training in these fields through programs such as the Surgical Scholars Track. We recognize that this will result in the tradeoff of a smaller proportion of fellows pursuing these sub-sub-specialty areas, but we must weigh the advantages of increased fellowship-trained REI physicians vs. a smaller proportion with the skills needed to push the field forward.
- Funding: given the need to significantly increase the number of graduating fellows and the high cost of fellowship training, additional funding sources must be identified.
  - o Although education in fellowship training must be held paramount over service, apprenticeship has long been the mainstay of clinical training, and conducting clinical care under supervision remains the centerpiece of clinical education. Therefore, fellowship programs, whether university or private practice based, should explore mechanism(s) to bill for visits and procedures conducted by fellows, particularly if the fellows' compensation is not covered by GME-designated federal funds AND within the confines of state and insurance requirements. Such potentially revenuegenerating mechanism(s) for fellows can help fund the proposed additional training slots. One option that has been successfully employed by some programs is to designate fellows 0.1 FTE faculty. This has enabled centers to bill for appropriate clinical activities as an OB/ GYN specialist would (office consultations, ultrasounds, HSGs, etc.). Such flexibility may not exist if GME federal dollars fund (even in part) the fellows' time. In addition, training costs include more than just salary and benefits, because they also include liability insurance that differs between trainees and faculty. Such considerations should be kept in mind because the accounting of revenue-generating options to fund fellows is being contemplated.

- o Alternative sources of funding, as modeled by other similar Societies, should be explored. Proven models include state funding, but many other options should also be explored.
- Improved educational efficiency: fellowship programs should consider having allied services (APPs, ultrasonographers, nurses, Mas, etc.) performing more routine procedures (e.g., HSGs, IUIs, ultrasounds, etc.), once fellows have demonstrated appropriate competency in these skills. The continuing improvement of adjunct training such as the Embryo Transfer Simulator and surgical simulation should create opportunities for fellows to advance their learning in a more efficient manner (8, 23). Fellowship programs could work together, either in networks or nationally, to develop educational materials and conferences (e.g., weekly lectures, journal clubs) that can improve standardization and reduce the cost and time of formal didactic education, to supplement the efforts of each individual program. A standardized core curriculum can be developed, in conjunction with SREI, ASRM, SRS, American College of Medical Genetics and Genomics, ACGME, ABOG, and Council on Resident Education in Obstetrics and Gynecology. Standardization would be particularly important in the creation of a 2-year curriculum, to ensure efficiency and quality of training. Indeed, in an era of virtual conferencing, many fellowship programs, including some in REI, have incorporated virtual and/or "hybrid" (virtual option offered) format for lectures. Creating a national curriculum for REI fellowship would draw on the significant expertise of leaders and educators in the field while ensuring access to all fellows nationally. This type of program was utilized by many specialties for resident and fellow didactics as a response to the coronavirus disease 2019 pandemic (37). This model, in a more limited format, is already in use as part of the SRS Surgical Scholars Track, in which all enrolled programs share a surgically focused didactic curriculum (24). Similarly, national programs, such as the Basic Training in Reproductive Medical Genetics, a virtual course for MFM and REI fellows, demonstrate the feasibility and efficacy of a national program to teach foundational concepts for REI fellows in training (38). This model could build on the significant resources already available to fellows and programs through ASRM, including online courses and the ASRM/SREI Grand Rounds (39). It should be noted that training fellows requires in-person teaching and training by engaged and expert faculty and such a national curriculum would be designed to complement and enhance rather than supplant such in-person efforts. A standardized curriculum should be viewed as a resource and should not preclude the individual programs from developing their own approaches to their particular needs.
- Maintenance of strict certification standards: to demonstrate competency as an REI, we recommend that physicians who complete a 2-year REI fellowship as described above complete and submit to ABOG a rigorous scientific project (thesis) as the primary investigator and pass subspe-

cialty qualifying (written) and certifying (oral) examinations, involving review of the candidate's postfellowship clinical practice patterns. ACGME and ABOG will need to be involved in establishing the specific requirements of the 2-year REI fellowship curriculum. To fully leverage collaborations between academic and private practices, toolkits will need to be developed to enhance these relationships, with the interest of fellow education and training held paramount and as the guiding principle. (2) Allied providers

For the utilization of APPs, ultrasonographers, and OB/ GYNs trained in reproductive care, we recommend the following:

- Per SART membership requirements, only a board-certified REI can oversee an ART clinic as Medical Director and a single REI can oversee no more than three practices. We recommend ideally that each Medical Director oversees only a single ART program.
- All ART clinics should follow the guidance documents from SART and ASRM on the appropriate training and supervision of ART personnel.
- REIs should be the providers performing transvaginal oocyte retrievals and embryo transfers, and this committee does not support the performing of these procedures by non-REI providers. However, we must acknowledge that non-REI providers are already engaged in carrying out these procedures in some settings and that this practice may serve to increase access to care. If these procedures are being performed by non-REIs providers, then the performing provider must in all cases be supervised by a board-certified REI.
- Providers must openly and actively disclose to patients what their training level and role in their care is. For example, we discourage the use of general terms such as fertility provider or doctor, and instead encourage the use of specific terms such as reproductive endocrinologist and infertility physician, OB/GYN specialist with training in reproductive care, or nurse practitioner/physician's assistant with training in reproductive care.
- APPs with the appropriate training in reproductive medicine and supervision should be utilized within an REI practice to streamline and increase practice productivity, including, but not limited to, gynecology pelvic and early pregnancy ultrasounds, saline sonograms, hysterosalpingograms, endometrial biopsies, IUIs, urgent evaluations for pain/bleeding, and new patient consultations.
- A certification process for APPs should be developed. For instance, we recommend that ASRM partner with the appropriate certifying nursing board to explore and facilitate development of a nursing reproductive subspecialty that will have the authority to certify Registered Reproductive Nurse Specialists.
- Fully trained ultrasonographers may perform the following ultrasounds: complete and limited pelvic ultrasounds for initial and baseline evaluations and AFC and ovarian

stimulation monitoring; transabdominal ultrasound guidance for embryo transfers; and early pregnancy monitoring.

- Board-eligible or board-certified OB/GYN specialists with the appropriate training in reproductive medicine and supervision can perform all tasks that an APP or ultrasonographer can perform. In addition, these physicians can perform surgical procedures (i.e., diagnostic or operative hysteroscopies and/or laparoscopies) for which they have undergone appropriate training.
- (3) Technology
- We welcome the evaluation and implementation of innovative technology in ART with the goal of improving outcomes and decreasing the cost of case. Utilizing artificial intelligence-based interventions has the capacity to achieve both objectives simultaneously. We caution that, before its widespread clinical implementation in patient care, these technologies must be evaluated through well-designed trials that test effectiveness, safety, and cost-effectiveness.
- We discourage the routine use of non-evidenced-based add-ons because these are costly both in time and financial resources.

# CONCLUSION

There is little doubt but that REI is at an inflection point. The field has matured, technology has vastly improved, worldwide exchange of knowledge is well established, and we are transitioning from a time of establishing "the basics" to a time where ethical and quality care and societal responsibility is the expectation. Despite this growth, there are many disappointing aspects, including and especially deep disparities in who can access this care. The WHO and American Medical Association have established that infertility care is a basic human right but unfortunately this remains aspirational for many if not most patients. There is now an opportunity to expand access to high-quality care by harnessing our knowledge and scaling it to meet the demand. However, along with this opportunity, there is also the risk that unmet demand could incentivize alternative care models that are neither well regulated nor emphasize the best outcomes.

Rather than allowing ourselves to be subject to the vagaries of these new forces, we can instead harness the strengths of our institutions (ASRM, SREI, SART, SRS, ACGME, and ABOG) to actively manage our futures. We believe that this manuscript fosters the kinds of discussion and action that are needed to keep us headed toward continued growth on behalf of our patients. If this conversation results in a grand council, a loya jirga, of the stake holders in our field, we will have achieved our goal.

**Declaration of interests:** G.D.A. reports consulting fees from LabCorp; Advisor, World Health Organization (WHO); Chair, International Committee for Monitoring Assisted Reproductive Technology (ICMART); Past Chair Member, International Federation of Gynecology and Obstetrics (FIGO) Committee on Reproductive Endocrinology and Infertility; President, World Endometriosis Research Foundation (WERF); Non-voting Board Observer, International Federation of Fertility Societies; Advanced Reproductive Care, Inc. (DBAARC Fertility): Founder and CEO outside the submitted work. C.C. reports funding from NICHD P50-HD068157 and NICHD K12-HD001256; travel support from Institutional (UPenn) professional-related account; American Gynecological and Obstetrical Society (Member of the Board and President 2022-23) outside the submitted work. L.B.C. reports funding from Ferring Pharmaceuticals site investigator, Presbyterian Health Foundation, and R01HD100305 Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH/NICHD: travel support from Ferring Pharmaceuticals; Patent application Methods and compositions for treating diseases and conditions associated with gonadotropin releasing hormone receptor; leadership roles - OU Health Partners Board of Directors, American Board of Obstetrics & Gynecology division of Reproductive Endocrinology and Infertility outside the submitted work. K.D. reports consulting fees from Bludiagnostics (Amazon-affiliated women's health product), Medscape, and Presagen; honoraria from ASRM, UCSD, and Medscape; travel support from ASRM, SART, and Granata Bio; SREI Research chair, SART Quality Assurance Chair outside the submitted work. E.H. reports stock options as medial advisor for Alife Health and Cercle AI outside the submitted work. M.J.H. reports Research Advisor for Thread Robotics outside the submitted work. S.P. is chair-elect for the ASRM Advanced Practice Provider Professional Group outside the submitted work. D.S. reports leadership role Hamilton Thorne Ltd and Celmatix Inc.; stock options Hamilton Thorne Ltd; manages investment funds that invest in the IVF industry, with ownership in Cooper Companies Inc., CryoPort Inc., Hamilton Thorne Ltd, INVO Bioscience Inc., Jinxin Fertility Group Ltd, Monash IVF Group Ltd, Progyny Inc., Virtus Health Ltd, Vitrolife AB, Celmatix Inc., MedAnswers, Oova, and TMRW Life Sciences outside the submitted work. K.T. reports Advisory Board: fee for travel and participation on advisory board form LabCorp; honoraria from Midwest Fertility Society; travel support ASRM Board of Directors: Data Safety Monitoring Board - Yale Center statistics Science is the Data Coordinating Center for the PREGnant and Friend Randomized trials; member ASRM Board of Directors; stockholder Pharmaceutical Contracting Alliance outside the submitted work. L.V. physician advisory board at ALife outside the submitted work. S.L.Y. reports licensed intellectual property to CiceroDX for the ReceptivaDx clinical test; author for an UpToDate chapter on endometriosis and infertility outside the submitted work. R.A. has nothing to disclose. J.E.M. has nothing to disclose. F.W. has nothing to disclose. P.H. has nothing to disclose. A.N.I. has nothing to disclose. E.B.J. has nothing to disclose. R.B.L. has nothing to disclose. P.C.L. has nothing to disclose. E.E.M. has nothing to disclose. M.M. has nothing to disclose. G.R-D. has nothing to disclose. L.W.R. has nothing to disclose. A.K.S. has nothing to disclose. R.S.W. has nothing to disclose.

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# Satisfacer la demanda estadounidense de servicios de fertilidad: el presente y el futuro de endocrinología reproductiva e infertilidad en los Estados Unidos

El campo de la endocrinología reproductiva y la infertilidad (ERI) se encuentra en una encrucijada; existe un desajuste entre la demanda de servicios reproductivos de endocrinología, infertilidad y tecnologías de reproducción asistida (ART), y disponibilidad de atención. El objetivo de este documento es proporcionar datos que justifiquen la necesidad crítica de una mayor prestación de servicios de fertilidad en los Estados Unidos ahora y en el futuro, enfoques que rectifiquen el creciente problema de escasez de médicos y sugerir un marco para el debate sobre cómo hacer frente a ese incremento en la demanda. La Sociedad de REI recomienda lo siguiente:

1. Nuestro campo debe explorar e implementar agresivamente cursos de acción para aumentar el número de médicos REI calificados y altamente capacitados anualmente. Recomendamos esfuerzos para aumentar el número de becas REI y el tamaño de las becas existentes, priorizándose donde sea posible. Estos cursos de acción incluyen:

A. Incrementar el número de programas de formación de becas REI.

B. Incrementar el número de becarios capacitados en los programas de becas REI actuales.

C. Se exploraron ampliamente los pros y los contras de una beca clínica de dos años para becarios interesados principalmente en la práctica de ART. No recomendamos acortar la beca REI a 2 años en este momento, porque los esfuerzos deben centrarse en aumentar el número de plazas de becas de formación (1a y b).

2. Se recomienda que el campo implemente agresivamente cursos de acción para aumentar el número y el uso apropiado de proveedores que no pertenecen a REI para aumentar la eficiencia clínica bajo la supervisión adecuada de un médico de REI certificado por la junta.

3. La automatización de procesos a través de mejoras tecnológicas puede liberar a los proveedores de todos los niveles para ejercer al máximo su licencia.