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"Online" and "at-home" versus traditional models of health care: enhancing access or impeding optimal therapeutics?

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Disclaimer: Authors for "fertile battles" are chosen to represent the full breadth of opinions. Individual authors, even within one side of the debate, do not necessarily agree with all viewpoints expressed.

PRO: "Online" and "at home" health care enhances access to optimal therapeutics

Pro 1. Raul Clavijo, M.D.

CON: "Online" and "at home" health care impedes access to optimal therapeutics

Con 1. Alexis Melnick, M.D.

Online Procurement of Pharmacologic Agents for the Treatment of Reproductive and Sexual Health Conditions

Before the advent of telehealth, prescription medication was available to patients only through a physical encounter in a hospital or clinic with a physician. Currently, in the United States, policies exist allowing the prescription of a wide range of medications after a telehealth visit (1). Our first instinct is to be skeptical of virtual efforts to treat reproductive and sexual health conditions because of our ingrained notion that a physical examination is essential in formally evaluating all medical conditions, and therefore assessing risk-benefit profiles for medications. However, this skepticism is best imparted individually in our field, based on the diagnosis and potential therapeutic options, separating sexual health from infertility diagnoses. First, it is important to understand that

Online Procurement of Pharmacologic Agents for the Treatment of Reproductive and Sexual Health Conditions

In recent years, we have seen an upswing in the number of direct-to-consumer telehealth companies offering prescription medications. This trend has now reached the reproductive and sexual health spheres, with companies such as Roman and Hims garnering the most attention for treating men with ED. More recently, we have seen the emergence of at-home in vitro fertilization kits, which provide patients with a protocol of oral ovulation induction drugs and a nasal GnRH antagonist after an initial telehealth visit. The patient is first seen in person at the time of their retrieval, after monitoring for ovulation at home with urine luteinizing hormone test strips. Although these approaches seemingly allow for increased convenience and privacy, they pose sig-

Received July 13, 2020; accepted July 13, 2020.
You can discuss this article with its authors and other readers at https://www.fertstertdialog.com/posts/30977
R.C. has nothing to disclose. R.R. has nothing to disclose. J.H. has nothing to disclose. A.M. has nothing to disclose. J.S. has nothing to disclose. Z.R. has nothing to disclose. R.B. has nothing to disclose.
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https://doi.org/10.1016/j.fertnstert.2020.07.017

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stigma is more likely stigma associated with a patient seeking advice for sexual concerns compared with infertility (2). One study showed that <25% of patients with sexual dysfunction sought care with a physician in comparison with another study revealing that 56% of couples with infertility sought professional care (3, 4). Thus, owing to the lack of physical exposure to clinical settings, it is likely that our patients with sexual dysfunction, with or without infertility, who stand to benefit the most from our taking a potential risk of prescribing medications after virtual care. This being taken into account, medications approved by the U.S. Food and Drug Administration for sexual dysfunction are more likely to be considered in a virtual care setting than is the off-label use of medications (5). Diagnosing and treating erectile dysfunction (ED) with phosphodiesterase type 5 inhibitors such as sildenafil is a prime example of how sexual health prescription medications can be prescribed online safely. The safety profile in a patient can be mostly derived from history taking and careful chart review, focusing on medications such as nitrates that can lead to potentially fatal conditions. It is rare that a physical examination finding alone would deter a physician from prescribing phosphodiesterase type 5 inhibitors. However, if there is a need to move on to second-line options such as penile injections or vacuum erection devices, a physical examination is useful to assess for conditions such as buried penis that would limit the efficacy of those options. At least, by this point, patients have a baseline physician relationship established, likely facilitating their choice to present at a physical clinic. Similar to the reliance on history to diagnose ED, certain sexual dysfunction diagnoses such as hypoactive sexual desire disorder in premenopausal women do not strictly require a physical examination (6). However, prescribing medications such as flibanserin, despite being approved by the Food and Drug Administration, becomes problematic in the minds of many, mostly owing to a lack of overwhelming safety data and side effect profiles, such as that available for phosphodiesterase type 5 inhibitors. In fact, this difference is obvious in a comparison of the menu of treatment options available through widely advertised digital health companies. Men are offered treatment for conditions such as ED and premature ejaculation, whereas the menu for women has no mention of conditions such as hypoactive sexual desire disorder or dyspareunia. The makers of flibanserin, nevertheless, do offer telemedicine options advertising the ability to avoid physical clinical encounters. Along these lines, reproductive medications such as clomiphene citrate are relatively more appropriate for online procurement in men. For example, in men with oligospermia and low testosterone, both of which can technically be determined with at-home testing, it is conceivable that clomiphene can be prescribed empirically without a formal physical examination because contraindications such as thrombotic coagulopathies can be derived from a history. The risk in this situation would be missing a testicular tumor because no physical examination is available. For women, empiric treatment with clomiphene after an isolated virtual encounter becomes problematic because most practitioners

CON: "Online" and "at home" health care impedes access to optimal therapeutics *(continued)*

nificant risks to patient health while likely providing suboptimal care.

The greatest limitation of these modalities is the inability to conduct a complete physical examination at the time of the telehealth encounter. This is particularly concerning for ED patients. ED has been shown across several studies to be a proxy of overall health and a sentinel marker for cardiovascular disease, diabetes mellitus, and metabolic syndrome, particularly in men under 40 years old—the demographic most likely to use direct-to-consumer services (35). For this reason, the American Urological Association guidelines recommend a complete physical examination and selective laboratory testing in all men presenting with ED, which cannot be achieved with even the most comprehensive screening questionnaire and telehealth visit (36). Consequently, for many men using direct-to-consumer platforms, life-threatening comorbidities will not be identified.

The lack of an in-person encounter also restricts the ability to screen for contraindications before prescribing medications. Self-administered checklists may be effective for most patients but not all. A 2008 study of women screening for contraindications to the use of oral contraceptive pills revealed underreporting of hypertension (37). Therefore, simply relying on a patient's report of a recent blood pressure measurement, as Hims and Roman do, is insufficient. The remote screening for women using at-home in vitro fertilization kits will similarly fail to adequately identify contraindicated conditions for ovulation induction and/or pregnancy, such as hypertension, thyroid disease, and ovarian cysts. Furthermore, not all risk factors for ovarian hyperstimulation syndrome can be assessed remotely. Although the incidence of ovarian hyperstimulation syndrome from clomiphene and letrozole is low, it is not zero. Given the potential for severe disease in women with ovarian hyperstimulation syndrome, it is prudent to identify upfront those patients at risk.

Last, and perhaps most importantly, the direct-to-consumer approach to sexual and reproductive health allows patients to circumvent their general medical care. A 2019 report from Accenture found that only 55% of generation Z patients have a primary care physician, in contrast to 84% for prior generations (38). Whereas online health platforms clearly state that they are not a substitute for a primary care physician, by allowing for a "quick fix" they discourage a visit to the doctor in which a discussion of chief complaint will be followed by a thorough health history, a comprehensive physical examination, and a conversation about preventive care. It is often a problem-focused visit that leads to the establishment of a long-term doctor–patient relationship. The direct-to-consumer approach may therefore cause more harm than good, both within the domains it is aiming to treat and to the overall health of its consumers.

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advocate for a baseline pelvic ultrasound and hysterosalpingogram before a clomid cycle is attempted, both of which require physical interaction with a clinic. Overall, the availability of prescription medications with well-defined risk profiles to patients through virtual sources is only likely to enhance the access to care for sexual and reproductive health conditions by easing the pain of embarrassment some patients may experience. Furthermore, the ability to provide prescription medications virtually will increase the relevance of virtual health visits because "something was done to treat my condition" in the minds of patients.

Pro 2. Ranjith Ramasamy, M.D.

"At Home" Reproductive Diagnostic Assays for Men and Women

Given the current circumstances of the COVID-19 pandemic, where both patient-centered care and social distancing are important issues, home-based testing for fertility is becoming increasingly important. Semen analysis (SA) evaluation with manual microscopic analysis and computer-assisted SA are labor intensive, time limited, and expensive (1). Furthermore, many men are reluctant to seek conventional clinical testing because of embarrassment, long wait times, inconvenience, and social stigma. Men may be more willing to use home-based SA kits that can provide point-of-care fertility diagnostic analysis (7). A valid critique of the existing home SA kits includes that they lack adequate quality control, they are vulnerable to false-negative results by the provision of rudimentary quantitative or qualitative results, and they are prone to sample handling errors (8–10). However, new approaches to home SA testing are overcoming the challenges of current technology by including paper-based diagnosis (7), smartphone-based computer-assisted SA system (11), digital holography (12), and microfluidic channels (13).

With the development of the Y0 smartphone-based computer-assisted SA system, which uses the smartphone's camera and light source to measure motile sperm concentration, there's great potential to support home testing and evaluate fecundity in a young generation familiar with information technology without formal training (14). Both the Y0 device

CON: "Online" and "at home" health care impedes access to optimal therapeutics *(continued)*

Con 2. Joshua Stewart, M.D.

"At Home" Reproductive Diagnostic Assays for Men and Women

In addition to the increased availability of direct-to-consumer prescription medications, we have also witnessed a dramatic shift in the number of patients using at-home fertility testing. What was once only available through the physician's office is now easily accessible through the internet or in grocery store aisles. After home collection of a finger prick blood sample, patients can send away for anti-Müllerian hormone, follicle-stimulating hormone, and thyroid hormone levels. Additionally, at-home testing is also available for SA and genetic carrier screening. Ancestry and 23andMe, just two of the many commercial companies branded as "health and ancestry services," offer direct-to-consumer home DNA kits. At-home testing within the reproductive health space presents unique implications for both patients and healthcare providers, particularly as it relates to counseling, reliability, and privacy.

Commercial companies are not mandated to provide pretest and posttest counseling for the testing they offer, and when it is provided, it often requires the patient to take the initiative. In many situations, the individuals undergoing testing are not aware of the possible implications of the results on themselves, their families, and society as a whole. For example, at-home ovarian reserve testing is often marketed to individuals with amenorrhea or suspected polycystic ovary syndrome. After receiving the results, the consumer is left to interpret them on her own, which may result in false reassurance or the opposite—unnecessary anxiety. Real harm may be encountered if in-

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and paper-based devices claim to show 97.8% and 100% agreement with the results of computer-assisted SA, respectively (7, 9). Currently, less than a quarter of cancer patients bank sperm, and the most common reason for not doing so is lack of access to facilities (15). Timely cryopreservation is critical for cancer patients because in some cases, >1 visit will be required to cryopreserve a sufficient amount of sperm, or there's an urgent need to start anticancer therapy (16). Hence, home-based cryopreservation kits will be a valuable alternative. Home sperm-testing kits can be used to evaluate azoospermia after vasectomy. However, Goldstein et al. (17) observed that home SA kits failed to significantly improve compliance and suggested that there be partner involvement.

Home-based ovulation predictor kits have the potential to increase autonomy and empowerment to women who face barriers to enacting decisions in relation to their sexuality and reproduction. Ovulation predictor kits aid women in fertility awareness with regard to when ovulation should occur during their menstrual cycle and identify anovulatory cycles, which may prompt them to seek medical assistance earlier. During artificial reproduction treatment, patients need to be monitored by serial endovaginal ultrasound, which entails economic, logistic, emotional, and potential environmental cost and also reduces practitioners' time for more complex tasks. Self-operated endovaginal telemonitoring was specifically designed for this use and proved noninferior to traditional two-dimensional transvaginal sonographic monitoring (18). Despite physical separation and asynchronous communication, couples stated a better doctor-patient relationship when home-based diagnostic tests were used (19). In light of the current situation of the COVID pandemic along with the boom of telemedicine, physicians should consider incorporating home-based kits for both male and female fertility testing with the caveats that even though we may not get accurate data all the time, data from these kits can be used to guide care.

Pro 3. Joshua Halpern, M.D.

Telemedicine

The coronavirus pandemic has quickly catapulted telemedicine to the forefront of healthcare delivery (20). The value of telemedicine during the pandemic is clear—the ability to treat patients without the risk of exposure to and spread of the highly infectious COVID-19 virus is paramount. But

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dividuals substitute at-home testing for a thorough medical evaluation and counseling regarding the overall health and fertility implications of certain conditions. Furthermore, diagnosis of genetic carrier status and risk of associated health conditions, such as with *BRCA* testing, requires thoughtful interpretation regarding the implications for individuals and families. This testing and concurrent counseling should be conducted in conjunction with an experienced genetic counselor and physician.

The reliability of test results is another major issue with at-home testing, even with one of the most widely used tests, urinary ovulation predictor kits. While luteinizing hormone–based ovulation tests have demonstrated accurate and superior ovulation detection when compared with basal body temperature charting, calendar calculation, or observation of cervical discharge changes, errors can still occur (39). Furthermore, these kits have not been consistently associated with increased pregnancy rates when used alone. In one prospective cohort study in a population that conceived via donor insemination using either home monitoring with urinary luteinizing hormone kits compared with laboratory serum luteinizing hormone testing, pregnancy rates were significantly reduced in those performing home testing: 3.4% per cycle versus 12.7% over the same time period ($P<.005$, 95% CI 6.5–18.9) (40). With all forms of at-home testing, there is significant variability in the sensitivity and reproducibility of various tests, as well as user error, which may account for these differences in outcome.

Last, issues of data privacy and confidentiality must be considered with at-home fertility testing. Commercial testing allows significant data mining, often without consumers' consent or knowledge. Testing results may become part of large databases that incorporate demographic and genetic information, which may have unintended negative consequences for consumers.

Con 3. Zev Rosenwaks, M.D.

Telemedicine

At the time of this publication, the COVID-19 pandemic has fundamentally changed the way we deliver care to our pa-

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telemedicine offers advantages that will persist beyond the pandemic, such as increased access, cost savings, and patient and physician satisfaction.

Access to care is among the greatest barriers to delivering quality healthcare in reproductive medicine. The American Society for Reproductive Medicine recognizes the responsibility of providers and policy makers to address disparities in access to reproductive medicine, including the need to reach underserved populations and geographic areas (21). Nangia et al. (22, 23) found substantial geographic disparities in access to both artificial reproduction treatment and male reproductive specialists, and Harris et al. (24) estimated that approximately 18.2 million women of reproductive age lived in an area without an artificial reproduction treatment clinic. Women and men seeking fertility care who are geographically distant or cannot present for in-person visits can establish care through telemedicine. Although physical examination and in-office diagnostics are paramount for the evaluation of both female and male fertility, an initial telehealth visit can uncover pertinent history, identify risk factors, and establish the physician–patient relationship. A telemedicine visit not only provides the couple with initial counseling and a sense of progress but also can initiate a diagnostic cascade, most of which can be performed locally such as serum hormone and sperm analyses, and possibly formulate treatment approaches. Hernandez et al. (25) found that implementation of an electronic telehealth intervention for women presenting for fertility evaluation resulted in shorter time to diagnostic testing and artificial reproduction treatment. Telemedicine is also useful for couples seeking a second opinion because telehealth democratizes access to national experts, enabling couples to seek consultation beyond their typical geographic boundaries. Last, Zwingerman et al. (26) demonstrated that telemedicine can improve access to fertility preservation services among women presenting with cancer at geographically remote satellite centers, offering an expedient solution for a time-sensitive problem.

Implementation of telehealth can be seamless with rapid integration in just a few days (27). And whereas the initial investments in training and infrastructure for telemedicine may be costly, there is a long-term savings potential. Telehealth decreases the use of on-site resources, reducing the need for and optimizing the use of clinical space. Zholudev et al. (28) found that urologic telemedicine visits were $124 cheaper and more efficient than face-to-face encounters. The wide availability of telemedicine through free interfaces such as Doximity or even a simple phone call has democratized access for both physicians and patients alike.

There are already robust data to suggest that patients prefer telemedicine. Reed et al. (20) found 93% patient satisfaction with telemedicine across specialties within a large healthcare system, and others have shown high patient satisfaction within urology specifically (29–31). Although data regarding physicians' perspectives are limited, the potential

CON: "Online" and "at home" health care impedes access to optimal therapeutics *(continued)*

tients. One significant change has been an increased use of telehealth services. Certainly, even before the current health crisis, patients were increasingly using social media and fertility tracking applications on their electronic devices to obtain and engage with reproductive health information (41). Although these technological advances may offer some benefits, it is critical to ensure the safe delivery of the highest quality care and the dissemination of accurate information.

The greatest limitation to telehealth is the lack of an in-person physical examination. Unlike other areas of medicine that may be amenable to video consultation, many topics and diagnoses within sexual and reproductive health cannot be easily diagnosed and discussed. Subjective aspects of the physician–patient interaction, such as body language, are often lost during telehealth encounters, making patients feel less at ease, especially when discussing sensitive topics. Without the face-to-face interaction, the physician's ability to make an accurate diagnosis can be limited, with the potential for greater patient loss to follow-up.

Technical issues such as slow internet speed and poor audio or video quality can further complicate these encounters. Many telehealth applications require patients to set up and log into third-party portals, which often are not patient friendly and can be overly burdensome. This has been shown to lead to lower use of telehealth services by men and women of lower socioeconomic status, further accentuating health disparities in the delivery of care (42). To effectively deliver reproductive health care through telehealth, we need to first improve user-centered design to optimize patient engagement.

Additional concerns with telehealth involve privacy, physician liability, and reimbursement (43). Currently, standardized guidelines are not available to support appropriate safeguards and regulatory oversight, such as ensuring that these telehealth applications are compliant with the Health Insurance Portability and Accountability Act. Furthermore, delivery of reproductive medicine services via telehealth may present unique quality and safety risks for patients and may increase physician liability. For instance, given that as telehealth allows the delivery of care across state lines, physicians and practices are confronted with the complex issue of conflicting state licensure requirements. Last, current reimbursement structures present a major barrier to the adaptability of this technology. The Current Procedural Terminology codes have been insufficiently updated to facilitate reimbursement in both fee-for-service and value-based models of care delivery, and additional research is required to determine the effect of alternative payment models that use bundled telehealth services. All in all, physicians and patients should recognize that these emerging technologies require further refinement and may not always adequately substitute for previously accepted, traditional approaches to medical care.

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for increased flexibility in hours and practice location has great upside for physicians and could even have a significant impact in reduction of burnout, which also confers clear long-term cost savings.

Detractors may point to potential hurdles to the implementation of telemedicine for reproductive health, but they are easily overcome. Data have already shown equivalent outcomes for obstetric and fertility care provided via telemedicine (25, 32). The lack of physical examinations could result in missing critical diagnoses such as testicular masses, but telemedicine is intended not to supplant but to augment in-person examination (33). Others have raised concerns regarding the regulatory burden, reimbursement, and medical-legal liability of practicing telemedicine, particularly across state lines. However, Fogel and Kvedar (34) found no cases of medical malpractice pertaining to telemedicine. If physicians and institutions familiarize themselves with federal, state, and payer requirements, telemedicine can be practiced safely and with optimal physician reimbursement.

As providers, payers, regulators, and professional societies scramble to determine a roadmap for the implementation of telemedicine, one thing is clear: telemedicine is here to stay. The American Society for Reproductive Medicine has task forces and guidelines in place to usher our specialties into the era of telemedicine. While we look forward to future studies examining efficacy across a variety of metrics we should continue to proceed with telemedicine integration, albeit with caution, given the many potential benefits of this novel platform.

CON: "Online" and "at home" health care impedes access to optimal therapeutics *(continued)*

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