



Increase in Direct-to-Consumer Telemedicine in Urology

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Abstract

Purpose of Review Direct-to-consumer telemedicine has vastly expanded in recent years, and urologic conditions are a common target for these companies. We aim to identify the urologic conditions being treated by direct-to-consumer telemedicine platforms and review the feasibility of adherence to evidence-based practice guidelines via this relatively new healthcare model.

Recent Findings Erectile dysfunction, premature ejaculation, testosterone deficiency, and male infertility are being treated with direct-to-consumer telemedicine. Such platforms treating erectile dysfunction perform modestly in practice guideline adherence. Guidelines-based treatment of other urologic conditions via telemedicine is feasible, however, the treatment of these conditions through popular direct-to-consumer telemedicine platforms is largely unstudied.

Summary The impact of direct-to-consumer telemedicine on the field of urology is vast and likely to continue to grow. Future studies should inspect direct-to-consumer telemedicine companies' practice patterns and treatment outcomes to ensure the field's standards of care are being met. Guidelines specific to the treatment of various urologic conditions via telemedicine are needed.

Keywords Direct-to-Consumer Telemedicine · Men's Health · Erectile Dysfunction · Premature Ejaculation · Testosterone Deficiency · Male Infertility

Introduction

A direct-to-consumer (DTC) business strategy aims to eliminate intermediaries, resulting in more efficient sales, higher profit margins, and an opportunity to create a highly curated business brand [1]. US pharmaceutical companies began to employ a DTC marketing strategy in the 1980s, termed direct-to-consumer advertising (DTCA). Advances in telecommunication technology and a population well-adapted to consuming online services have now allowed for a new type of DTC strategy in healthcare: direct-to-consumer telemedicine (DTCT). DTCT platforms offer highly branded, patient-initiated treatment by healthcare providers via telemedicine. To achieve this, a DTCT company connects the patient-consumer

with a healthcare provider outside of the patient's typical medical home, who performs a medical assessment and provides a recommendation virtually, often resulting in the prescription of a medication [2]. Many DTCT companies then partner with a specialty or delivery pharmacy through which the medication is sold and delivered directly to the patient. The result is an extremely profitable system that delivers highly accessible healthcare by cutting out several modern-day "middle-men" between the patient and prescription, such as large healthcare institutions, physician referrals, insurance companies, and even geographic or social stigma barriers.

Early DTCT platforms largely consisted of primary care initiatives aimed at offering around-the-clock virtual treatment of acute issues, such as upper respiratory tract or urinary tract infections [3]. However, DTCT platforms are now offering pharmaceutical management of long-term or complex urologic conditions, such as erectile dysfunction, testosterone deficiency, and male infertility. DTCT expansion undoubtedly offers several benefits to patients, such as increased convenience, privacy, and access to self-initiated specialty care. However, it is important for urologists to understand and evaluate the type and quality of services

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being offered, as to ensure the field's standards of care are being met via these virtual services. The aim of this review is therefore to identify which urologic conditions are being treated by DTCT platforms and review the feasibility of adherence to evidence-based practice guidelines via this relatively new healthcare model.

History of Direct-to-Consumer Advertising

The patient's right movement of the 1970s and the rise of "patient centered medicine" in the 1980s fostered a new type of patient-doctor relationship, in which the patient increasingly participated in their own healthcare decisions [4]. With consideration that patients could be more active in their care and thus, possibly more active in prescribing decisions, pharmaceutical marketers shifted their targeted audience from doctors to patients, who were now more active consumers in the healthcare market. Thus, the first direct-to-consumer advertising campaigns were launched in the 1980s [5]. Physicians, for the first time, began prescribing medication based on patient demand. The success of these early campaigns solidified DTCA as an effective strategy for marketers. However, several physician's organizations, such as the American Medical Association (AMA), took positions opposing this type of drug advertising, concerned that it threatened the doctor-patient relationship and facilitated medical decision making by patients, who may not be able to appropriately evaluate the risks and benefits of various medications [6]. Other critics note that advertisements as a source of information can seem biased and mislead consumers to believe that they would benefit from costly medications prior to an evaluation by a physician. Proponents, however, viewed DTCA as a vessel for spreading information about disease and treatment options to patients, and thus empowering patients.

Contemporary use of DTCA has had influence on the field of urology. Endo Pharmaceuticals launched a massive DTCA campaign in 2016 to increase awareness of Peyronie's disease (PD) [7]. The company's annual report noted the success of the campaign as marked by a significant bump in sales of their intralesional treatment, Xiaflex. Through increasing disease awareness and reducing stigma of seeking care, such campaigns are expected to expand PD care and increase reported prevalence rates of PD with time [8]. In another example, exposure to DTCA campaigns in the early 2000s on testosterone deficiency (TD) and treatment with testosterone therapy (TTh) was associated with increased testosterone testing, new initiation, and in some cases, initiation without proper laboratory evaluations [9]. Thus, it is conceivable how increased patient awareness and demand could potentially lead to overtreatment, when not kept in check by adherence to high-quality, evidence-based care

models. This becomes a particularly important consideration with the expansion of DTCT, as the effects on patient awareness and demand may be coupled with increased ease of access to prescription medications.

Expansion of Direct-to-Consumer Telemedicine.

In 2015, an estimated 1.25 million DTCT patient encounters occurred [10]. Just four years later, in 2019, over 4.9 million visits to DTCT websites offering treatment of erectile dysfunction alone were recorded [11•]. Expansion of this industry continues, as global DTCT services market size is projected to increase from \$292.9 million in 2020 to \$442.3 million by 2027 [12]. The COVID-19 pandemic has undoubtedly had a massive impact on the DTCT industry's expansion. Day-to-day virtual interactions became commonplace, and telemedicine became a crucial aspect of healthcare delivery for many. Telemedicine access was dramatically expanded via implementation of emergency legislation which allowed for Medicare reimbursement for telehealth [13]. At the state level, regulations that previously hindered the widespread application of telemedicine, like interstate licensure requirements and primary in-person physical examination mandates, were suspended by many state governments [14]. It is unclear which changes will remain in place as the pandemic evolves, however, growth of the telemedicine industry will unquestionably continue. As such, DTCT practices continue to warrant close observation, especially as they expand to offer more and more specialized care.

Methods

In order to assess the current DTCT landscape in urology, a Google search was performed to identify various DTCT platforms offering urologic services. Key search terms included combinations of "online", "telemedicine", "men's health", "erectile dysfunction", "premature ejaculation", "testosterone", "Peyronie's disease", "benign prostatic hypertrophy", "male infertility", and other related terms. A full list of search terms is available upon request. For each search performed, the websites on the first Google page were reviewed. Any website offering telemedicine services within the scope of urology was included and reviewed for information on the healthcare service provided.

A literature search was then performed using PubMed and Google Scholar to identify articles pertaining to direct-to-consumer telemedicine in urology. Keywords used included "direct-to-consumer", "telemedicine", "Men's health", "erectile dysfunction", "premature ejaculation", "testosterone deficiency", "Peyronie's disease", "benign prostatic

hypertrophy", and "infertility". Detailed search parameters are available upon request. Focus was applied toward articles that critically reviewed DTCT platform practices for adherence to evidence-based guidelines. Additional articles were identified using the bibliographies of the reviewed articles. For urologic conditions being treated via DTCT that have not been studied in a peer-reviewed fashion, we considered the feasibility of applying evidence-based practice guidelines to a telemedicine-only healthcare model.

Erectile Dysfunction

Erectile dysfunction (ED) is one of the early men's health conditions targeted by DTCT companies. For the patient-consumer in search of ED treatment, there are several advantages to using DTCT. The sensitive nature of ED may discourage some from discussing it with their physicians, and men often delay care due to fears of breached privacy, embarrassment, or a worry that a physician may dismiss their concern and not offer treatment [15–17]. An online service offering to evaluate for and treat ED from the comfort of a patient's home eliminates or minimizes each of these barriers. A study examining online traffic patterns to DTCT sites offering ED treatment revealed a 1,688% increase in quarterly visits between 2017 and 2019 despite relatively stable internet searches for "erectile dysfunction" over this time [11•]. Two dominant DTCT services offering ED treatment are Roman and Hims, which have paved the way to 'normalize' treatment of ED online.

DTCT Practice Details

DTCT companies offering for treatment for ED typically employ a "store-and-forward" methodology, where information is collected from the patient online and a healthcare provider asynchronously reviews the information [18]. Online questionnaires screen for past medical history, current medications, and current sexual health and related symptoms. Some measures like a self-reported blood pressure may also be obtained [19]. Laboratory analysis is typically not mandatory for prescription but may be offered to assess for underlying comorbid conditions [20, 21]. In this type of care model, a real-time telephone or video interaction between the patient and provider may be completely omitted, unless mandated by the state's telemedicine laws [21]. Most platforms prescribe both generic and brand name phosphodiesterase type 5 inhibitors (PDE5i). One company, BlueChew, specifically markets a non-FDA-approved chewable formulation of tadalafil and sildenafil created in compound pharmacies [22]. Patients who meet criteria for prescription are then typically entered into a subscription

service that involves direct mail of medications to the patient in recurring intervals. Platforms may also offer access to ongoing consultations with a provider as needed; however, it is unclear how much treatment monitoring and follow-up is required by each platform to maintain the subscription service. Patient costs vary but are likely to be higher than traditional pharmacy prices. For example, Roman advertises their lowest dose of sildenafil at \$2 per 20 mg tablet, and the price increases steeply for higher dosages, landing at \$10 per 100 mg tablet [23]. In comparison, these doses are currently less than \$1 per pill on GoodRx [24]. It is noted that the Frequently Asked Questions sections on many of these platforms' websites are generally detailed and offer counseling on several important points, such as treatment efficacy, risks, alternatives, and the possible association of ED with serious chronic comorbid conditions.

Adherence to Guidelines-Based Care

Hims and Roman have previously been evaluated for adherence to practice guidelines. Authors asked 10 board-certified urologists to evaluate the online screening questionnaires on the Hims and Roman websites and rate their adherence to 11 distinct American Urological Association (AUA) guidelines for the treatment of ED [25•]. On a Likert scale of 1 to 5, with 5 marking the best adherence, the average overall ratings were 2.4 and 2.2 for Roman and Hims, respectively. Notable concerns from the surveyed urologists included omission of a validated questionnaire, lack of physical exam, and questionable opportunity for longitudinal care. Other AUA-recommended practices omitted by these platforms include evaluating for testosterone deficiency with a morning serum total testosterone level and discussing non-PDE5i treatment options such as intracavernosal injections and penile implants. The platforms scored highest on following guidelines related to counseling for PDE5i treatment risks, benefits, contraindications, and dose titration. In a letter-to-the-editor response to this article, executives and physician leaders at Hims highlight an important study limitation: a lack of analysis of in-person visits by non-urology trained primary care practitioners to serve as a control [26]. They also note that the AUA guidelines are written without consideration for telemedicine and encourage the AUA and other organizations to consider creating telemedicine-specific guidelines.

While it is likely that store-and-forward telemedicine services can safely prescribe PDE5i [18], there is a concern that young men seeking DTCT treatment for ED may have significant comorbidities that are not addressed in this model. Indeed, ED may be the driving symptom that motivates young men to seek healthcare for the first time [27]. A retrospective review of 388 men aged 40 and under who

were evaluated for ED at an andrology clinic revealed high rates of medical comorbidities, such as dyslipidemia and prediabetes or diabetes [28]. In addition, several urologic issues such as subfertility and testosterone deficiency were identified and treated in this cohort. The authors argue that presentation for ED treatment to a DTCT platform would have resulted in a missed opportunity to identify and treat these comorbidities.

Evidence-based evaluation and management of ED is feasible in a DTCT model, however, several key practices should be undertaken. First, providers should ensure that patients have had a recent history and physical performed by a primary care provider. Laboratory analysis, such as screening for hypotestosteronemia, should be pursued as indicated and can be achieved using large chain laboratories. A store-and-forward technique may be used obtain a relevant medical history and should incorporate validated ED questionnaires to assess severity of symptoms and track treatment progress. Appropriate counseling is likely best achieved in a real-time virtual visit to ensure the risks and benefits of treatment are understood by the patient. All treatment options for ED should be discussed, and referral to an ED-specialist for more advanced treatment options should be offered when indicated. Finally, regular follow-up to evaluate for side effects and assess treatment success should be employed.

Premature Ejaculation

DTCT Practice Details

Premature ejaculation (PE) treatment is also commonly pursued by DTCT companies. A store-and-forward methodology is employed in a similar fashion to ED treatment, and information of past medical history, current medications, and current PE symptoms are obtained via online questionnaires. Real-time video consultations are offered in states that mandate this type of telemedicine interaction [29]. No laboratory analysis is typically performed. After a candidate is determined to be eligible for a prescription, treatment with serotonin reuptake inhibitors (SSRIs) and/or PDE5is may be offered. Over-the-counter topical lidocaine or benzocaine treatments in gel, wipe, and spray formulations and can be purchased through several platforms without a telemedicine consultation or prescription. Time to follow-up is not clearly delineated on many websites, however, the Lemonaid Health website does note that a follow-up video consultation is required after 90 days of treatment with sertraline, prior to refilling the prescription [29]. Costs of SSRIs are likely higher than through traditional pharmacies. Both Roman and Lemonaid advertise a price of \$0.80—\$1.00 per pill (dose unspecified) [23, 29], while

the lowest current prices for 100 mg tablets of sertraline on GoodRx are around \$0.20 per pill [30]. As similar with ED treatment, websites tend to offer much information on the risks and benefits of various treatments.

Feasibility of Guidelines-Based Care

DTCT practices and treatment outcomes have not been studied in a peer-reviewed fashion to our knowledge. However, we feel the treatment of PE is fairly well-adapted to a telemedicine format, as evaluation is largely based on a thorough medical, relationship, and sexual history. The most recent AUA/SMSNA guidelines on the treatment of PE do recommend performing a physical exam, however, they also acknowledge that an exam rarely impacts treatment and mostly serves to reassure the patient [31]. Acquired PE, classically marked by development of a shorter latency time later in life, has been associated with a higher rate of comorbidities such as hypertension and diabetes as compared to men with lifelong PE [32–34]. In this population, further assessment of hypothalamic-pituitary–testicular axis, thyroid function, glucose metabolism may be indicated and should be employed in a DTCT model. Patients pursuing treatment for acquired PE via DTCT models that do not offer adjective testing, may risk a lost opportunity to identify these comorbidities, similarly to treatment for ED.

Interestingly, DTCT treatment of PE with second-line pharmacologic options, such as on-demand tramadol or alpha-adrenergic antagonists is not commonly advertised. Tramadol is a Drug Enforcement Administration (DEA) schedule IV-controlled substance [35], and telemedicine companies may choose to avoid its use due to medico-legal concerns. However, it is notable that restrictions on prescribing controlled substances have relaxed since the onset of the COVID-19 pandemic. Currently, virtual prescription of these medications is allowable by the DEA if the telemedicine visit is in real-time with a two-way interactive system [36]. Therefore, achievement of guidelines-based and high-quality treatment of PE is most likely to be achieved by a DTCT model that employs real-time virtual visits, uses laboratory assessment as indicated, assesses for treatment effectiveness and side effects regularly, and offers second-line pharmaceutical treatment or referrals to a specialist as indicated.

Testosterone Deficiency

Prescription testosterone use has demonstrated an impressive increase over the last two decades, felt to be in part due to successful DTCA campaigns [9, 37]. Use among men less than age 45 is rising most rapidly and saw a fourfold increase from 2003 to 2013 [38]. Mirroring this increase is a rise in public internet searches for various types of testosterone

therapy seen in the last decade [39]. This young, internet-savvy population is the prime audience for DTCT, and as such, many DTCT companies have taken on this market.

DTCT Practice Details

Many of the DTCT companies offering testosterone therapy utilize an online intake form or communication with an employed non-provider to collect information such as past medical history, medication use, and symptom severity. Serum studies such as total testosterone, hematocrit, and PSA are performed using either large chain laboratories or an at-home blood test kit delivered to the patient [40]. An initial telemedicine consultation is then typically performed with a healthcare provider who interprets the laboratory findings and considers the patient for treatment. Patients who are deemed eligible for treatment are typically entered into a subscription package that may include delivery of testosterone to their home, regular laboratory work for treatment monitoring, and telemedicine checkups. Intramuscular, transdermal, oral, and trans-nasal formulations may be offered. Several platforms also offer non-testosterone pharmaceutical treatments, such as clomiphene, HCG, and anastrozole. Patient costs vary widely. Many sites advertise a monthly subscription fee which varies in the inclusion of different services like sale and delivery of medication, follow-up consultations, and laboratory work.

Feasibility of Guidelines-Based Care

The AUA created clear and specific guidelines for the evaluation and treatment of TD in 2018 [41]. While adherence to these guidelines by DTCT companies offering TTh has not been studied to our knowledge, a workflow for the initiation and management of TTh via telemedicine was recently proposed [42••]. The authors recommend an initial in-person visit be performed by the prescribing provider to allow for a physical exam or a recent visit by a primary care provider can be confirmed. A complete bloodwork evaluation can then be performed, and shared decision making should be implemented for consideration of testosterone therapy. After TTh initiation, regular follow-up with laboratory evaluation and assessment of treatment effect or side effects are imperative and can be achieved using a telemedicine format.

Interestingly, a physical examination is not specifically mandated in the AUA guidelines [41]. Thus, the argument can be made that AUA guidelines-based evaluation and management of TD is feasible in a completely virtual, DTCT model. Historically, a digital rectal examination has been considered a cornerstone for prostate cancer screening prior to initiation of TTh [43]. However, recent evidence supports that a digital rectal examination should not be utilized as a primary screening modality, which is the main goal

to achieve prior to initiating TTh [44]. Instead, the AUA guidelines call for prostate cancer screening with a serum PSA level to be performed in men over the age of 40 being evaluated for TTh. We must acknowledge, however, that the guidelines were written before widespread adaptation of DTCT to virtual TTh prescription, and therefore may not be directly applicable to this context. It is also noted that a lack of physical examination does preclude the ability to assess for physical signs of comorbid conditions, which may be of increased consequence in this patient population, as men with TD may have a high burden of cardiovascular and other comorbid diseases [43].

The prescription of testosterone online also raises concern for contribution to anabolic steroid abuse, a major public health issue [45]. In addition, the potential for omission of vital patient counseling through DTCT raises concern for some [46]. For example, failure to discuss the effects of exogenous testosterone on a patient's fertility can have serious implications. The extent of counseling offered on these platforms is unclear. Outcomes associated with the evaluation, treatment, and long-term management of TTh via DTCT warrant further investigation.

Male Infertility

Advancements in at-home and mail-in semen analysis technology have allowed DTCT companies to move into the male infertility space. Several at-home semen tests utilizing microfluidics, colorimetric tests, or small microscopes attached to a smartphone camera are now FDA-approved and have been previously described [47, 48]. These tests typically measure only one or two semen parameters and are felt to have a place in screening for males who should pursue formal infertility evaluation [49]. One such example, the Yo Home Sperm Test utilizes a smartphone camera and a miniature microscope to capture video of moving sperm. A proprietary algorithm is then applied to analyze light fluctuations caused by moving sperm to determine a motile sperm concentration, which is reported as normal (above 6 million/mL) or low (below 6 million/mL) [50]. The accuracy of the test in dichotomizing samples as either normal or low was compared to a computer-assisted sperm analyzer (the SQA-Vision) in a double-blinded study and found to have positive and negative agreement above 94% [51]. Several other at-home tests with varying mechanisms have also been shown to produce high accuracy in assessing sperm concentration [52], motility [52, 53], and progressive motile sperm concentration [54].

Novel mail-in semen analysis technology has also been developed. This involves the use of a sperm media that preserves the sample for extended periods to allow for shipment back to a Clinical Laboratory Improvement Amendments (CLIA)-approved laboratory and performance of a complete

semen analysis. This same technology also allows for collection and shipment of specimens for sperm cryopreservation. A study examining the efficacy of such a media compared 104 ejaculates from normospermic men within a CLIA laboratory at one hour and then four more times with up to 52 h of observation after sperm media application [55]. Authors found that sperm concentration remained stable, motility decreased by 0.39% per hour, and normal morphology decreased by 0.1% per hour over this time period, concluding that this delayed analysis may be sufficient for clinical application in fertility evaluation.

While the accuracy of alternative semen analysis technology appears encouraging, the role of these tests from both the patient and provider perspective is largely yet to be determined. A 2021 survey study of 634 men aged 18 and older without children revealed that more men would initiate a fertility evaluation with a semen analysis if it was a home-test in comparison to a traditional laboratory or clinic test, indicating that such tests are relevant to this population's needs [56]. However, a study examining the opinions of men who had used a home semen test called OVIEW-M found that only 43% of respondents felt the results were reliable while 18% did not [57]. Providers appear to be encouraged by the potential ability of home testing to reduce barriers related to comfort and cost, however, a concern lies in the possibility of promoting self-initiated over-testing, which could create a false sense of security and possibly delay appropriate medical evaluation [58].

DTCT Practice Details

Patient-consumers interested in a male fertility evaluation begin by purchasing a semen testing kit. Some DTCT companies may employ an at-home test, such as myLabBox, which sells the YO Home Sperm Test [50]. Motile sperm concentration results are reported as normal (above 6 million/mL) or low (below 6 million/mL). If a consumer receives an abnormal result (i.e., "low"), myLabBox then offers a free telemedicine consultation with a physician to review further.

Other DTCT companies offer telemedicine consultations following mail-in semen analyses. Consumers start by purchasing a package that includes a semen analysis only or a semen analysis in combination with sperm cryopreservation. Other packages specifically marketed for use following vasectomy assess for sperm count only. The patient is mailed a sample collection kit and is instructed how to collect a semen sample. A sperm media is applied to the sample, and it is then mailed to a CLIA-certified laboratory for full analysis. A full semen analysis report is given to the patient-consumer and a telemedicine consultation with a healthcare provider is offered to assist with result interpretation. Additional testing with sperm DNA fragmentation may be offered [59].

Feasibility of Guideline-Based Care

According to the AUA/American Society for Reproductive Medicine guidelines for the diagnosis and treatment of infertility in males, an infertility evaluation is indicated for failure to conceive after one full year of trying, or six months of trying if the female partner is 35 years or older [60]. The initial male infertility evaluation involves one or more semen analyses, and men with one or more abnormal semen parameters are recommended to undergo a full history and physical evaluation by a male reproductive expert. Therefore, DTCT platforms offering validated mail-in semen analyses have the potential for high-quality initial infertility *screening* from the comfort of the patient's home. Any abnormality should result in a referral for an in-person visit by a male reproductive specialist for full evaluation.

Despite the recommendation for couples seeking infertility care to undergo simultaneous evaluation of the male and female, an estimated 18–27% of male counterparts do not undergo an infertility evaluation [61]. DTCT models may increase access by addressing several barriers that limit the availability of fertility care for men such as geographic limitations, insurance coverage, or patient fear or discomfort of seeking an evaluation in person [62]. However, there are some patients who may not benefit from DTCT evaluation. For example, the male counterpart of a couple with recurrent pregnancy loss or a couple already pursuing assisted reproductive technologies requires an in-depth evaluation by a male infertility specialist, which is likely to include additional testing, such as hormone evaluation, karyotype, DNA fragmentation, or Cystic-Fibrosis Transmembrane Conductance Regulator mutation screening [63]. While it is likely that such patients undergoing DTCT evaluation would be referred to an in-person specialist, this DTCT care may add additional patient cost and delay specialized care.

Another consideration is that DTCT models in this space are often marketed as *fertility* assessments, or a way to check a consumer's baseline fertility status out of pure curiosity. The utility of the semen analysis in this context is unclear, as the sensitivity of semen analysis is predicting infertility is low, and up to 30% of men with normal semen parameters still have difficulty fathering a child [64]. In addition, DTCT platforms may encourage frequent, repeated use of the semen testing. For example, myLabBox consumers are encouraged to test their sperm concentration monthly to assess for changes in sperm parameters after implementing lifestyle changes [50]. Indeed, infertile males are known to have higher rates of co-morbid disease and counseling on disease risk and lifestyle changes is an important aspect of the infertility consultation [60, 64]. However, the use of monthly semen analyses to track the progress of lifestyle changes has not been validated, and this practice may simply incur a high, unnecessary expense for the patient-consumer.

The impact of DTCT fertility testing has been studied in the female infertility space. A 2018 observational study examined 21 women pursuing fertility testing through DTC companies [65]. Participants felt empowered by self-initiating fertility testing in this format, but they had varying degrees of certainty about test result interpretation or how to use these results to take the next steps in fertility preservation. The author argues that DTC testing can act as a unique tool to increase awareness and exposure of fertility care to broader, more diverse populations. The term “the new (in)fertility pipeline” was coined to describe this phenomenon. DTCT platforms offering male fertility assessments, when coupled with appropriate counseling and referral to male reproductive specialists, may also be able to act as an “(in)fertility pipeline” and ultimately decrease stigma, increase awareness, and increase access to infertility care for men. Further investigation as to the impact of male fertility DTCT technology is warranted.

Conclusion

Treatment of urologic conditions via DTCT is here to stay and is likely to continue to expand. Guidelines-based treatment of urologic conditions is feasible via DTCT in many cases, but future studies are needed to inspect these platforms’ practice patterns and treatment outcomes and ensure the field’s standards of care are being met. Guidelines specific to the treatment of various urologic conditions via telemedicine are needed. With innumerable potential benefits telemedicine has to offer patients, the urologic community should embrace our own use of telemedicine and work to expand its safe application to the field.

Declarations

Conflict of Interest The authors declare no competing interests.

References

Papers of particular interest, published recently, have been highlighted as:

- Of importance
- Of major importance

1. Direct-to-consumer: how this new business model can impact digitization - MJV [Internet]. MJV Technology & Innovation. 2022 [cited 2022Mar16]. Available from: <https://www.mjvinnovation.com/blog/direct-to-consumer/>
2. Bollmeier SG, Stevenson E, Finnegan P, Griggs SK. direct to consumer telemedicine: is healthcare from home best? *Mo Med*. 2020;117(4):303–9.
3. Martinez KA, Rood M, Jhangiani N, et al. Patterns of use and correlates of patient satisfaction with a large

4. Kassirer JP. Adding insult to injury. Usurping patients’ prerogatives. *N Engl J Med*. 1983;308(15):898–901. <https://doi.org/10.1056/NEJM198304143081511>.
5. Donohue J. A history of drug advertising: the evolving roles of consumers and consumer protection. *Milbank Q*. 2006;84(4):659–99. <https://doi.org/10.1111/j.1468-0009.2006.00464.x>.
6. American Medical Association (AMA), House of Delegates. Chicago: AMA Policy Compendium: current policies of the AMA House of Delegates through the 1989 Interim Meeting / AMA Council on Long Range Planning and Development in Cooperation with the AMA Division of Health Policy Development and the Division of Library and Information Management. June.
7. Bulik BS. Endo, building on DTC success, ramps up awareness campaign for Peyronie’s disease [Internet]. Fierce Pharma. 2018 [cited 2022Mar16]. Available from: <https://www.fiercepharma.com/pharma/building-dtc-success-endo-ramps-up-awareness-campaign-for-peyronie-s-disease>
8. Swislocki ALM, Eisenberg ML. Peyronie disease as a marker of inflammation-is there hope on the horizon? *Am J Med*. 2021;134(10):1218–23. <https://doi.org/10.1016/j.amjmed.2021.06.015>.
9. Kim Y, Alexander GC, Emery SL. Association between direct-to-consumer advertising and testosterone testing and initiation in the United States, 2009–2013. *JAMA*. 2017;317:1159–66.
10. Huff C. Telemedicine: medical doctors address health symptoms online [Internet]. AARP. 2015 [cited 2022Mar16]. Available from: <http://www.aarp.org/health/conditions-treatments/info-2015/telemedicine-health-symptoms-diagnosis.html>.
- 11.● Wackerbarth JJ, Fantus RJ, Darves-Bornoz A, et al. Examining online traffic patterns to popular direct-to-consumer websites for evaluation and treatment of erectile dysfunction. *Sex Med*. 2021;9(1): 100289. <https://doi.org/10.1016/j.esxm.2020.100289>. **Identifies a sharp and significant increase in recent online traffic patterns to DTC sites treating erectile dysfunction.**
12. Valuates Reports [Internet]. Global direct to consumer telehealth services market size, status and forecast 2021–2027. [cited 2022Mar16]. Available from: <https://reports.valuates.com/market-reports/QYRE-Auto-4I2436/global-direct-to-consumer-telehealth-services>
13. Telehealth policy changes after the COVID-19 public health emergency. Telehealth.HHS.gov. 2022. <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency/>. Accessed 18 July 2022.
14. U.S. states and territories modifying requirements for U.S. states and territories modifying requirements for telehealth in response to COVID-19 [Internet]. [cited 2022Mar16]. Available from: <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>
15. Althof SE, Rosen RC, Perelman MA. Standard operating procedures for taking a sexual history. *J Sex Med*. 2013;10:26–35.
16. Laumann EO, Glasser DB, Neves RCS. GSSAB Investigators’ Group A population-based survey of sexual activity, sexual problems and associated help-seeking behavior patterns in mature adults in the United States of America. *Int J Impot Res*. 2009;21:171–8.
17. Marwick C. Survey says patients expect little physician help on sex. *JAMA*. 1999;281(23):2173–4. <https://doi.org/10.1001/jama.281.23.2173>.
18. Broffman L, Barnes M, Stern K, Westergren A. Evaluating the quality of asynchronous versus synchronous virtual care

- in patients with erectile dysfunction: retrospective cohort study. *JMIR Form Res.* 2022;6(1):e32126. Published 2022 Jan 13. <https://doi.org/10.2196/32126>
19. Hims. Under the hood: How the hims & hers Telehealth platforms enable quality care [Internet]. Medium. hims & hers; 2019 [cited 2022Mar16]. Available from: <https://medium.com/hims-hers-under-the-hood-how-the-hims-hers-telehealth-platforms-enable-quality-care-873bcfd7d7f6>
 20. FAQ [Internet]. Roman. 2022 [cited 2022Mar16]. Available from: <https://www.getroman.com/faq/#Erectile-dysfunction>
 21. FAQ [Internet]. Lemonaid Health - FAQs. [cited 2022Mar16]. Available from: https://www.lemonaidhealth.com/faq#erectile_dysfunction
 22. Now you can buy chewable sildenafil & tadalafil ed treatment online (same active ingredients as in viagra or cialis) [Internet]. BLUECHEW. [cited 2022Mar16]. Available from: <https://bluechew.com/>
 23. Pricing [Internet]. Roman. 2022 [cited 2022Mar16]. Available from: <https://www.getroman.com/pricing/>.
 24. Sildenafil prices, Coupons & savings tips [Internet]. GoodRx. [cited 2022Mar16]. Available from: <https://www.goodrx.com/sildenafil>
 25. ● Hsiang WR, Honig S, Leapman MS. Evaluation of online telehealth platforms for treatment of erectile dysfunction. *J Urol.* 2021;205(2):330–2. <https://doi.org/10.1097/JU.0000000000001378>. **Identifies only modest performance of adherence to guidelines-based practice for popular DTC sites treating erectile dysfunction.**
 26. Stahl PJ, Millheiser L, Carroll P. Evaluation of online telehealth platforms for treatment of erectile dysfunction. *Letter J Urol.* 2022;207(1):246–7. <https://doi.org/10.1097/JU.0000000000001681>.
 27. Cohen SD. The challenge of erectile dysfunction management in the young man. *Curr Urol Rep.* 2015;16:84.
 28. Shahinyan RH, Amighi A, Carey AN, et al. Direct-to-consumer internet prescription platforms overlook crucial pathology found during traditional office evaluation of young men with erectile dysfunction. *Urology.* 2020;143:165–72. <https://doi.org/10.1016/j.urology.2020.03.067>.
 29. FAQ [Internet]. Lemonaid Health - FAQs. [cited 2022Mar16]. Available from: https://www.lemonaidhealth.com/faq#premature_ejaculation
 30. Sertraline prices, Coupons & savings tips [Internet]. GoodRx. [cited 2022Mar16]. Available from: <https://www.goodrx.com/sertraline>
 31. Shindel AW, Althof SE, Carrier S, et al. Disorders of ejaculation: an AUA/SMSNA guideline. *J Urol.* 2022;207(3):504–12. <https://doi.org/10.1097/JU.0000000000002392>.
 32. Serefoglu EC, Yaman O, Cayan S, et al. Prevalence of the complaint of ejaculating prematurely and the four premature ejaculation syndromes: results from the turkish society of andrology sexual health survey. *J Sex Med.* 2011;8:540.
 33. Zhang X, Gao J, Liu J, et al. Distribution and factors associated with four premature ejaculation syndromes in outpatients complaining of ejaculating prematurely. *J Sex Med.* 2013;10:1603.
 34. Gao J, Zhang X, Su P, et al. Prevalence and factors associated with the complaint of premature ejaculation and the four premature ejaculation syndromes: a large observational study in china. *J Sex Med.* 2013;10:1874.
 35. Controlled substance schedules. [cited 2022Mar16]. Available from: <https://www.deadiversion.usdoj.gov/schedules/>
 36. The future of Telehealth & Ryan Haight Act Post-pandemic: NABP Blog [Internet]. National Association of Boards of Pharmacy. 2021 [cited 2022Mar16]. Available from: <https://nabp.pharmacy/news/blog/the-future-of-telehealth-and-the-ryan-haight-act-post-pandemic/>
 37. Baillargeon J, Urban RJ, Ottenbacher KJ, Pierson KS, Goodwin JS. Trends in androgen prescribing in the United States, 2001 to 2011. *JAMA Intern Med.* 2013;173(15):1465–6. <https://doi.org/10.1001/jamainternmed.2013.6895>.
 38. Rao PK, Boulet SL, Mehta A, et al. Trends in testosterone replacement therapy use from 2003 to 2013 among reproductive-age men in the United States. *J Urol.* 2017;197(4):1121–6. <https://doi.org/10.1016/j.juro.2016.10.063>.
 39. Muncey W, Omil-Lima D, Jesse E, et al. Assessment of public interest and current trends in testosterone replacement therapy [published online ahead of print, 2021 May 18]. *Int J Impot Res.* 2021; <https://doi.org/10.1038/s41443-021-00445-4> <https://doi.org/10.1038/s41443-021-00445-4>
 40. Hone health - how it all works. [cited 2022Mar16]. Available from: <https://honehealth.com/how-it-works>
 41. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. *J Urol.* 2018;200:423.
 42. ● Dubin JM, Fantus RJ, Halpern JA. Testosterone replacement therapy in the era of telemedicine [published online ahead of print, 2021 Nov 19]. *Int J Impot Res.* 2021;1–6. <https://doi.org/10.1038/s41443-021-00498-5>. **Proposes a contemporary workflow for the evaluation and management of testosterone deficiency via telemedicine.**
 43. Zhou CK, Advani S, Chaloux M, et al. Trends and patterns of testosterone therapy among U.S. male medicare beneficiaries 1999 to 2014. *J Urol.* 2020;203(6):1184–90. <https://doi.org/10.1097/JU.0000000000000744>.
 44. Halpern JA, Oromendia C, Shoag JE, et al. Use of digital rectal examination as an adjunct to prostate specific antigen in the detection of clinically significant prostate cancer. *J Urol.* 2018;199(4):947–53. <https://doi.org/10.1016/j.juro.2017.10.021>.
 45. Esposito M, Salerno M, Calvano G, et al. Impact of anabolic androgenic steroids on male sexual and reproductive function: a systematic review [published online ahead of print, 2022 Feb 11]. *Panminerva Med.* 2022; <https://doi.org/10.23736/S0031-0808.22.04677-8>. <https://doi.org/10.23736/S0031-0808.22.04677-8>
 46. New Online Men's Health Sites Divide Opinion [Internet]. *Urology Times.* [cited 2022Mar16]. Available from: <https://www.urologytimes.com/view/new-online-mens-health-sites-divide-opinion>
 47. Yu S, Rubin M, Geevarughese S, Pino JS, Rodriguez HF, Asghar W. Emerging technologies for home-based semen analysis. *Andrology.* 2018;6:10–9.
 48. Kobori Y. Home testing for male factor infertility: a review of current options. *Fertil Steril.* 2019;111(5):864–70. <https://doi.org/10.1016/j.fertnstert.2019.01.032>.
 49. Masterson TA, Patel P. Clinical implications of home-based sperm testing. *Fertil Steril.* 2021;115(4):882. <https://doi.org/10.1016/j.fertnstert.2021.01.054>.
 50. At Home Male Fertility Test: Mylab box™ [Internet]. myLAB Box™ - At home wellness tests & at home health testing. 2022 [cited 2022Mar16]. Available from: <https://www.mylabbox.com/product/at-home-male-fertility-test/>
 51. Agarwal A, Panner Selvam MK, Sharma R, et al. Home sperm testing device versus laboratory sperm quality analyzer: comparison of motile sperm concentration. *Fertil Steril.* 2018;110(7):1277–84. <https://doi.org/10.1016/j.fertnstert.2018.08.049>.
 52. Nosrati R, Gong MM, San Gabriel MC, Pedraza CE, Zini A, Sinton D. Paper-based quantification of male fertility potential. *Clin Chem.* 2016;62(3):458–65. <https://doi.org/10.1373/clinchem.2015.250282>.

53. Kanakasabapathy MK, Sadasivam M, Singh A, et al. An automated smartphone-based diagnostic assay for point-of-care semen analysis. *Sci Transl Med*. 2017;9(382):7863. <https://doi.org/10.1126/scitranslmed.aai7863>.
54. Björndahl L, Kirkman-Brown J, Hart G, Rattle S, Barratt CL. Development of a novel home sperm test. *Hum Reprod*. 2006;21(1):145–9. <https://doi.org/10.1093/humrep/dei330>.
55. ● Samplaski MK, Falk O, Honig S, Shin D, Matthews W, Smith JF. Development and validation of a novel mail-in semen analysis system and the correlation between one hour and delayed semen analysis testing. *Fertil Steril*. 2021;115(4):922–9. <https://doi.org/10.1016/j.fertnstert.2020.10.047>. **Validates a novel mail-in semen analysis system, thus increasing opportunities for DTC male infertility evaluation.**
56. Hudnall MT, Greene LI, Pham MN, et al. Perceptions of infertility and semen analysis testing among American men without children. *Urology*. 2021;158:95–101. <https://doi.org/10.1016/j.urology.2021.07.045>.
57. Kim KS, Kim JH, Roh JH, Kim D, Kim HM, Jo JK. Ability and accuracy of the smartphone-based O'VIEW-M® sperm test: useful tool in the era of Covid-19. *PLoS One*. 2022;17(6):e0269894. Published 2022 Jun 16. <https://doi.org/10.1371/journal.pone.0269894>
58. Ambar RF, Parekh N, Agarwal A. Recent advances and controversies in diagnosing and treating male infertility. *Fac Rev*. 2020;9:22. Published 2020 Dec 10. <https://doi.org/10.12703/r/22>
59. Sperm testing - at-home semen analysis & male fertility testing [Internet]. Legacy. [cited 2022Mar16]. Available from: <https://www.givelegacy.com/sperm-analysis/>
60. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and treatment of infertility in men: AUA/ASRM guideline part I. *Fertil Steril*. 2021;115(1):54–61. <https://doi.org/10.1016/j.fertnstert.2020.11.015>.
61. Eisenberg ML, Lathi RB, Baker VL, Westphal LM, Milki AA, Nangia. Frequency of the male infertility evaluation: data from the national survey of family growth. *AKJ Urol*. 2013;189(3):1030–4.
62. Mehta A, Nangia AK, Dupree JM, Smith JF. Limitations and barriers in access to care for male factor infertility. *Fertil Steril*. 2016;105(5):1128–37.
63. Esteves SC. Clinical relevance of routine semen analysis and controversies surrounding the 2010 World Health Organization criteria for semen examination. *Int Braz J Urol*. 2014;40(4):443–53. <https://doi.org/10.1590/S1677-5538.IBJU.2014.04.02>.
64. Glazer CH, Bonde JP, Eisenberg ML, et al. Male infertility and risk of nonmalignant chronic diseases: a systematic review of the epidemiological evidence. *Semin Reprod Med*. 2017;35:282.
65. Kyweluk MA. Quantifying fertility? Direct-to-consumer ovarian reserve testing and the new (in)fertility pipeline. *Soc Sci Med*. 2020;245: 112697. <https://doi.org/10.1016/j.socscimed.2019.112697>.

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