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Male sexual health and dysfunction

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Direct-to-Consumer Telemedicine Practices in the Health and Fertility of Men: A Systematic Review of the Literature

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Purpose: Men are increasingly turning toward online direct-to-consumer (DTC) men's health platforms to fulfill their health needs. Research surrounding these platforms is lacking and the motivations and predictors underlying this online health-seeking behavior is largely unknown. This review scopes the existing literature concerning DTC men's health and identifies factors influencing engagement, as well as health outcomes of this platform.

Materials and Methods: A structured search was performed following PRISMA guidelines. CINAHL via EBSCO, Embase, MEDLINE via Ovid, PsycINFO, PubMed and Web of Science were searched.

Results: Peer-reviewed quantitative and qualitative studies with a focus on demographics and characteristics of those using DTC men's health platforms, as well as studies related to patient outcomes using such platforms, were included. Ten of the 3,003 studies identified met the inclusion and exclusion criteria. Four cross-sectional descriptive studies evaluated the motivations behind men's engagement with DTC platforms. Convenience, embarrassment and health motivation were identified as predominant factors associated with DTC platform use. The review identified a lack of qualitative studies, and major limitations were noted in the quantitative studies that impacted the accuracy of findings. Six further quantitative studies explored the quality of care provided by DTC platforms. DTC platforms were found to have a varying level of adherence to established clinical guidelines, but appeared to provide satisfactory patient outcomes with low levels of patient-reported side effects and adverse events.

Conclusions: There is a lack of research within the DTC men's health space given the infancy of the field. Important predictors and motivations underlying men's choices in accessing these platforms have been noted across several studies. However, further studies need to be conducted to investigate the psychosocial underpinnings of this behavior. Studies across a wider variety of male health conditions treated by these platforms will also help to provide insights to guide patient-centered care within the DTC landscape.

Keywords: Direct-to-consumer advertising; Erectile dysfunction; Men's health; Telemedicine

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INTRODUCTION

There has been a gradual shift toward direct-to-consumer (DTC) telemedicine as a model of care delivery over the last few decades [1]. The recent COVID-19 pandemic has amplified this modal shift. There are various models that DTC telemedicine assumes, each offering a different modality of healthcare delivery [2]. One of these models is private-sector DTC companies which sell custom branded prescription drugs and provide telemedicine visits in order to facilitate prescription and delivery of the medications. These companies have proliferated within the men's health space over the previous few years. Men's health conditions, herein defined as: erectile dysfunction (ED), premature ejaculation, hypogonadism, male infertility or male-pattern baldness, appear to not only be vulnerable to the DTC model, but also the most profitable [3,4]. Large sums of venture capital funding have poured into DTC pharmaceutical telemedicine companies, some now valued in the billions in USD [5,6]. Given the infancy of this emerging field, there is a need to understand the users of these platforms, as well as to determine the safety of using these platforms, in order to ensure that appropriate standards of care are being met by these services.

The aim of this review is therefore to: (i) assess the breadth of the literature surrounding this nascent field; (ii) investigate the predictors and motivations underlying men's choices in accessing online sexual health treatments via DTC telemedicine platforms; and (iii) the quality of consumer interaction, oversight and adherence to evidence-based healthcare within this space.

MATERIALS AND METHODS

A structured literature search was conducted according to the standards and guidelines established in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [7]. The protocol pertaining to this study was registed on Prospero (ID: CRD42023388833) before the study. A literature search was conducted for eligible studies on the following databases: CINAHL via EBSCO, Embase via Ovid, MEDLINE via Ovid, PsycINFO via Ovid, PubMed and Web of Science. The literature search and screening were performed by two reviewers independently (CL and WW). All titles and abstracts were screened for eligibility and discrepancies were resolved through discussion with a third reviewer (DJK). English-language studies published prior to August 2022 were identified. Titles, abstracts and methods were reviewed, and studies that met the inclusion criteria were retrieved in full. The reference list of all included sources of evidence was screened for additional studies that were not retrieved by the electronic search. Key terms incorporated in the search included 'direct to consumer', 'telemedicine', 'men's health', 'erectile dysfunction', 'testosterone replacement therapy', 'male infertility', 'alopecia', and 'premature ejaculation'.

Peer-reviewed studies, both quantitative and qualitative, were considered for inclusion. The focus population was men who have engaged with a DTC health platform, specifically for the following conditions: ED, premature ejaculation, testosterone deficiency, alopecia, and male infertility, based on a preliminary survey of common conditions treated by several prominent online DTC telemedicine platforms. Studies with outcome measures pertaining to the characteristics and motives of male DTC users were included, as well as those with a focus on diagnostic standards and outcomes associated with these platforms. The term "direct-to-consumer" was scrutinized, and studies which were related to other models of DTC services were excluded, including pharmaceutical advertising and nonprescription healthcare retail.

RESULTS

From the 3,035 articles screened, 32 articles were retrieved for further review and 10 met the eligibility criteria (Fig. 1). The methodologies and results of the included studies are summarized in Table 1, and the summary of relevant findings are provided in Table 2.

1. Demographics of male DTC platform users

Three cross-sectional descriptive studies evaluated the characteristics of men accessing DTC platforms across Germany and the United States between 2019 and 2020 [8-10]. The typical users appeared to be predominantly middle-aged men in a middle-income bracket. Rodler et al [8] characterized 11,456 male patients with ED who had obtained phosphodiesterase type 5 inhibitor (PDE5) inhibitor prescriptions through a German DTC service and found that the mean age was 49 years, and midrange earners were the largest subgroup

The World Journal of MEN's HEALTH

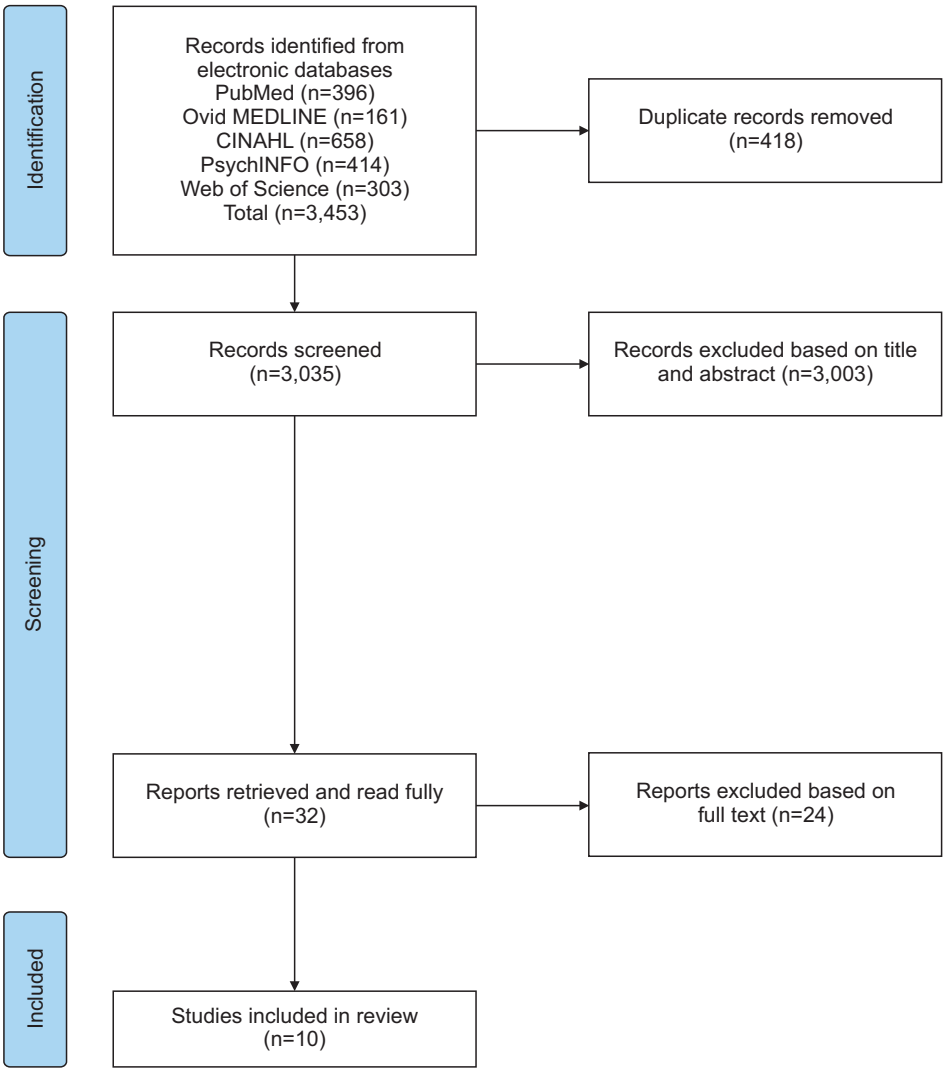

Fig. 1. PRISMA flowchart of study selection.

seeking help. This was consistent with Hudnall et al's study [9] which investigated DTC platforms for male infertility testing. In this cross-sectional survey of 634 participants, middle-aged men between 40 to 59 years were found to be three times more likely to utilize DTC infertility testing compared to millennial-generation men (OR=3.02, 95% CI: 1.16, 7.88; p=0.024). Hudnall et al [10] conducted another study of 1,276 men who had accessed DTC telemedicine services and reported that an age of less than 60 years was associated with the use of DTC men's health platforms, as was an income between $50K and $100K. This suggests that younger men in the middle-income bracket had higher odds of using online DTC men's health telemedicine services than older or wealthier men. The geographical location of users of DTC men's health platforms was also explored by Rodler et al [8], revealing that the majority (69%) of the investigated cohort lived in a rural area.

2. Rationale for uptake of DTC services

Four quantitative studies explored the motivations behind men's engagement with DTC platforms [8-11]. Convenience was consistently identified as a primary theme underlying this health-seeking behavior, along with a secondary psychological theme of embarrassment. Rodler et al [8] found that 48% of men engaged in DTC for its convenience (geographical and time-related), followed by shame (13%) and discretion (23%). In the Netherlands, Leusink and Aarts [11] investigated a cohort of 219 men using e-consultation on an internet ED website between March and December 2003 and found that most respondents indicated convenience as the chief reason for having resorted to a consultation via the internet. Embarrassment was also selected by

Table 1. Characteristics of included studies

Author	Participant profile[a]	Methodology[b]
Quantitative studies on characteristics and motivations of male DTC platform users		
Rodler et al [8], 2020 (Germany)	11,456 men/erectile dysfunction	Cross-sectional descriptive/Structured questionnaires
Hudnall et al [9], 2021 (United States)	1,276 men/infertility, low testosterone, semen analysis testing	Cross-sectional descriptive/online survey with 5-point Likert items assessing concern for low testosterone, infertility, and likelihood of conducting a semen analysis test without a physician recommendation
Leusink et al [11], 2006 (Netherlands)	219 men/erectile dysfunction	Cross-sectional descriptive/5-item version of the International Index of Erectile Dysfunction (IIEF-5)
Hudnall et al [10], 2021 (United States)	634 men/male infertility	Cross-sectional descriptive/structured questionnaires
Jesse et al [12], 2022 (United States)	Not applicable/testosterone replacement therapy	Cross-sectional descriptive/internet search and cost analysis of DTC telemedicine TRT platforms
Schneider et al [13], 2022 (United States)	Not applicable/erectile dysfunction	Cross-sectional descriptive/internet search and cost analysis of selected DTC companies and pharmacies for prices of 90-day regimens of common PDE5 inhibitors
Quanitative studies on diagnostic standards of DTC men's health platforms		
Hsiang et al [14], 2021 (United States)	Not applicable/erectile dysfunction	Cross-sectional descriptive/5-item Likert scale comparing DTC screening questionnaires to 2018 AUA guidelines
Shahinyan et al [15], 2020 (United States)	388 men/erectile dysfunction	Retrospective review/E-health records of men evaluated at an academic men's health clinic
Broffman et al [16], 2020 (United States)	10,000 men/erectile dysfunction	Retrospective review/analysis of patient records from DTC Telehealth platform
Broffman et al [17], 2022 (United States)	10,000 men/erectile dysfunction	Retrospective review/analysis of patient records from DTC Telehealth platform

DTC: direct-to-consumer.
[a]Numberof participants/condition sought or treated. [b]Study design/outcome measure.

these respondents as a secondary motive underlying their online health-seeking behavior.

Financial factors do not appear to be a major consideration driving DTC platform usage. Rodler et al [8] found that only a small percentage (4.6%) of men reported price as a primary reason driving them to seek treatment via DTC platforms. Jesse et al [12] conducted a cost analysis of three DTC testosterone replacement therapy (TRT) platforms in the United States, and found that while costs for an initial evaluation via a DTC platform were substantially lower than for patients at a tertiary center, costs for both intramuscular and transdermal TRT following the initial evaluation exponentially rose and surpassed those of a tertiary center. Schneider et al [13] also conducted a cost analysis of PDE5 inhibitor treatment using 2 prominent DTC men's health platforms in the United States, and similarly found that for a 90-day supply of medication, a physician visit or local pharmacy prescription was markedly more affordable than an online DTC platform despite higher initial costs.

Interestingly, health-tracking behavior seems to be an important predictor driving DTC telemedicine use. Hudnall et al [9] found that usage of a digital fitness tracker/wearable was associated with increased odds of self-initiating at-home semen testing via a DTC product (OR=1.95, 95% CI: 1.12, 3.39; p=0.018), compared to a traditional laboratory or clinic visit. In terms of specific health concerns, available research has emphasized low testosterone as a predominant issue for men using DTC platforms. Hudnall et al [10] found that the odds of men accessing DTC men's telemedicine services was three times higher in those with concerns of low testosterone (OR=3.16, 95% CI: 1.15, 8.69; p=0.026). This was consistent with a second study conducted by the same authors, where a multivariate analysis revealed that major factors associated with at-home semen testing via a DTC product were concerns of low testosterone and infertility [9].

Table 2. Summary of findings

Reference	Participant profile or methodology[a]	Relevant findings or themes identified
Demographics of male DTC users		
Rodler et al [8], 2020 (Germany)	11,456 men/erectile dysfunction	Mean age: 49 years Midrange earners Rural location
Hudnall et al [9], 2021 (United States)	1,276 men/infertility, low testosterone, semen analysis testing	Age <60 years Income between USD$50–100K
Hudnall et al [10], 2021 (United States)	634 men/male infertility	Mean age: 40–59 years
Rationale for usage of DTC platforms - Internal motivations		
Rodler et al [8], 2020 (Germany)	11,456 men/erectile dysfunction	Convenience Shame/discretion (embarrassment)
Leusink et al [11], 2006 (Netherlands)	219 men/erectile dysfunction	Convenience Embarrassment
Hudnall et al [9], 2021 (United States)	1,276 men/infertility, low testosterone, semen analysis testing	Usage of a digital fitness tracker Low testosterone
Hudnall et al [10], 2021 (United States)		Low testosterone & infertility
Rationale for usage of DTC platforms - Financial factors		
Rodler et al [8], 2020 (Germany)	11,456 men/erectile dysfunction	Small percentage (4.6%) of men reported price as a primary reason for usage
Jesse et al [12], 2022 (United States)	Internet search and cost analysis of DTC telemedicine testosterone replacement therapy (TRT) platforms	Low cost for initial evaluation Subsequent costs for TRT exponentially rose and surpassed those of a tertiary center
Schneider et al [13], 2022 (United States)	Internet search and cost analysis of DTC companies for prices of PDE5 inhibitors	DTC company had highest costs compared to traditional physician visit with local prescription fulfillment
Diagnostic standards of platforms		
Shahinyan et al [15], 2020 (United States)	388 men/erectile dysfunction	Multiple pathologies found during office evaluation would have been missed on a DTC platform Moderate adherence of screening questionnaires to guidelines
Hsiang et al [14], 2021 (United States)	Urologists used scale to compare DTC screening questionnaires to American Urological Association (AUA) guidelines	Absence of physical exam on DTC platforms Absence of validated questionnaires No opportunity for longitudinal care
Jesse et al [12], 2022 (United States)	Practice details of DTC companies compared to AUA guidelines	Initial evaluation and follow-up of patients on TRT were similar between DTC platforms and AUA practice guidelines
Patient outcomes of DTC platforms		
Leusink et al [11], 2006 (Netherlands)	219 men/erectile dysfunction	81% reported having better erections as a result of website treatment
Broffman et al [16] 2020 (United States)	100,00 men/erectile dysfunction Retrospective review	Distribution of the reported side effect types consistent with literature Incidence rates of reported side effects significantly lower than rates from clinical trials
Broffman et al [17] 2022 (United States)	100,00 men/erectile dysfunction Retrospective review	Lower but nonsignificant differences in the rates of reported PDE5i-related side effects

DTC: direct-to-consumer.
[a]Number of participants/condition sought or treated OR study design/methodology.

3. Diagnostic Standards of DTC men's health platforms

Diagnostic standards between DTC platforms and established American Urological Association (AUA) guidelines were compared in three quantitative studies. The studies evaluated guidelines for ED and TRT. Jesse et al [12] had a generally favorable evaluation, finding that initial evaluation and follow-up of patients on TRT were similar between DTC platforms and AUA practice guidelines. Another study, Hsiang et al (2020)

[14], was considerably more neutral in their evaluation, finding that some aspects of their diagnostic pathway for ED had high adherence to AUA guidelines while diverging significantly in other aspects, including the omission of validated questionnaires, physical exams, and the opportunity for longitudinal care. The final study conducted by Shahinyan et al [15] had a negative evaluation of the diagnostic standards of DTC men's health platforms. The authors performed a retrospective review on a population of 388 men under the age of 40 with a diagnosis of ED in order to identify underlying or concomitant conditions. The study highlighted multiple pathologies in men presenting with ED to an andrology lab between January 2016 and March 2019. These included high rates of obesity, prediabetes or diabetes, abnormal lipid levels, serum lab findings associated with subfertility, and a large incidence of varicoceles. These are all significant comorbidities that would have escaped identification by DTC platforms based on these platforms' existing screening and diagnostic procedures. Among the two DTC platforms evaluated, the study also revealed only moderate adherence of screening questionnaires to AUA guidelines for ED, with conditions such as premature ejaculation and lower urinary tract symptoms, as well as a physical exam and select laboratory testing, being omitted.

Patient outcomes can serve as a proxy of diagnostic quality of DTC platforms. Three quantitative studies examined patient outcomes of using DTC men's health platforms, evaluating both patient-reported side effects and self-reported satisfaction levels. Leusink and Aarts [11] found that a majority of respondents (81%) from the cohort surveyed replied in the affirmative to the question of whether their erections had improved as a result of the website ED treatment they had accessed. In the United States, Broffman et al [16] conducted a retrospective cohort study using 10,000 randomly sampled patient records from the DTC men's health company Romans, from 2018 to September 2019. Messages between patients and Romans-affiliated providers from initial treatment were reviewed to assess rates of patient-reported side effects from prescribed PDE5 inhibitors. The authors found that the distribution of the reported side effect types was consistent with the literature, and that incidence rates of reported side effects were significantly lower than rates from clinical trials. Most patients who initiated a conversation with the provider to report side-effects requested and received a change in medication or dose, indicating that treatment for ED via a DTC platform supports prompt and coordinated physician responses to requests for medication changes when side-effects do occur. A follow-up study from the same authors in 2022 further explored whether asynchronous care (the main modality of care offered by DTC platforms) led to worse patient outcomes compared to synchronous care (such as real time/face-to-face care) [17]. The authors utilized the same patient records as their 2020 study and reviewed the rates of medication-related side-effects from PDE5 inhibitors prescribed to patients on the platform. They noted that in the context of DTC treatment for ED, asynchronous care did not unduly prevent patients from reporting adverse events, nor did it result in any other notable differences in adverse events when compared to patients who had received face-to-face care.

DISCUSSION

This review has elucidated the demographics and motives of men utilizing DTC platforms for sexual health treatment. The identified studies were all quantitative in design, and a majority were conducted in the United States, where the DTC market is the largest and the most widespread in the world. Furthermore, it has revealed that an overwhelming majority of the studies focus specifically on TRT and ED treatments. There is a lack of research into other popular treatments offered on DTC platforms, such as premature ejaculation, male infertility and alopecia. Despite this, these findings can provide important insights into this developing industry that can guide future research.

The typical demographic of users engaging with DTC men's health platforms were predominantly middle-aged men. It has been well established that testosterone levels in men begin to decline after the age of 30 [18]. This may explain the increased access by this particular demographic, and is supported by the review's findings that concerns of low testosterone were an internal motivation for DTC use [9,10]. Further, living in a rural area was identified as a demographic factor associated with DTC use [8], suggesting that a DTC model may address geographical access barriers, increasing access of care for patients in rural areas lacking an availability of urological subspecialty care.

Psychological barriers, in particular perceived stigma, shame and embarrassment, as well as access barriers

such as convenience, have previously been identified as strong predictors of precluding factors to men accessing sexual health care and obtaining appropriate treatment [19-24]. The findings in this review have revealed that DTC platforms appear to be appropriately addressing these barriers faced by men, and suggest that these platforms have the potential to encourage presentation for conditions that men may not otherwise address. However, major limitations were noted in these studies that negatively impacted the accuracy of conclusions reported. In the study by Rodler et al [8], the survey in which participants were asked about their primary motivation was a voluntary, follow-up questionnaire, and the mean age of participants in the follow-up survey was significantly older than that of the initial cohort. This suggests that a sample bias was likely. Leusink and Aarts's study [11] investigating online ED treatment was conducted in 2006, which precedes the advent of modern online DTC men's health platform. The website was a very early version of a DTC platform that, although similar to modern iterations, may have differed in various aspects, and hence the study may not be translatable to present-day online platforms. Due to the lack of qualitative phenomenological studies within this field, little is known about the subjective experiences of men using these platforms and the broader reasons beyond the narrow scope encompassed in the surveys utilized in the above studies.

Fitness tracker use was also identified as another relevant internal motivation [9]. Fitness tracker use has been shown to be more prevalent in health-motivated individuals, particularly those involved in the "quantified self" movement, where individuals have an interest in tracking data about their own health. Together with the review's findings of concerns of low testosterone as a motivation for DTC use [9,10], this suggests that, in innately health-conscious men who have an interest in tracking their own health, DTC platforms may be a preferred option for self-investigation and/or treatment of sexual health.

Financial considerations have previously been identified as an access barrier preventing men from seeking sexual health treatment [19]. Two cost-analysis studies found that DTC platform usage was associated with higher total costs than a regular clinic visit in the domains of ED and TRT [12,13], while another found only a small minority reporting price as a relevant motivation in usage [8]. This implies that increased financial costs do not appear to be a barrier to DTC platform usage among the predominantly middle income users of these platforms. This could be attributed to a variety of reasons, including patients deeming privacy or other benefits of a virtual interaction worth the additional cost. However, it should be noted that both cost-analysis studies did not assess potential additional savings to patients using DTC platforms such as savings on public transportation or parking, and thus special considerations should be made for the unique socioeconomic situation of individual patients.

A common critique of DTC men's health platforms is non-adherence toward established AUA guidelines. The online nature of DTC platforms preclude a complete, hands-on physical examination for many of the treatments provided, which may operate in conflict with AUA guidelines and result in crucial diagnoses such as testicular masses being missed [15]. Other concerns have been raised regarding these platforms having incomplete or flawed screening procedures that culminate in comorbidities such as cardiovascular (CV) disease being missed [25], which is significant given that ED in young men is an early marker of symptomatic CV disease [26]. DTC platforms were found to have a varying level of adherence to established clinical guidelines. Both Shahinyan et al [15] and Hsiang et al [16] noted moderate to low adherence to established AUA guidelines. To this end, a recent review has suggested that several key practices should be undertaken, including DTC providers ensuring that patients have had a prior history and physical exam performed by a primary care provider, as well as the incorporation of validated questionnaires in the screening process of DTC platforms to assess the severity of symptoms and track treatment progress [27]. It is worth noting that established AUA guidelines have been written without any consideration for telemedicine, and its ability to assess the quality of telehealth care for male health conditions is therefore unclear.

Despite this, the studies in this review found that patient outcomes when using these platforms were considerably positive [13,16,17], suggesting that treatment via a DTC platform does not necessarily lead to unsafe outcomes for patients despite the lack of adherence to guidelines. However, major limitations were noted in these studies, as their findings each looked at single platforms and are thus unable to account for

individual provider variability that may exist between different platforms. Moreover, both studies conducted by Broffman et al [16,17] contain a large conflict of interest as the authors are employees and stakeholders in the DTC company from which the data used for analysis was retrieved. A reporting bias may also have been present in both studies as patients were not obligated to report side effects. However, the authors have noted that challenge is not unique to a telehealth setting.

1. Limitations

The literature search was limited to English-language only searches and included only peer-reviewed articles, and thus evidence relevant to this review may have been overlooked. Moreover, the search strategy limited the literature to specific male health conditions (that were identified as being the most commonly treated via DTC platforms), and therefore other evidence pertaining to other male health conditions may have been neglected. Of note, the included studies were mostly conducted within the domains of ED and TRT treatment. There was only one other study that was relevant to male infertility [9]. Furthermore, as a majority of these studies were conducted in the United States, the data may not be generalizable to other contexts.

CONCLUSIONS

This review has contributed to a better understanding of the current scope of DTC men's health platforms. Convenience, embarrassment and concerns of low testosterone were identified as key predictors for men choosing to use DTC online platforms. These predictors suggest that DTC platforms have the potential to bring stigmatized men's health topics out of the shadows, break down both psychological and physical barriers to access, and connect men to treatments for conditions that they might otherwise not address. Further, DTC services generally appear to provide satisfactory patient outcomes despite varying levels of adherence to established clinical guidelines across different service platforms. However, there are always inherent potential harms when receiving care from a source that is separated from an individual's usual health network or community. It is especially pivotal to establish evidence-based guidelines specific to the treatment of various urologic conditions via telemedicine, particularly in the early stages of this rapidly developing industry, in order to institute a foundation of appropriate care for men accessing these platforms for their sexual health needs. It is also vital for the medical community to gain a better understanding of the motivations of DTC users, as well the breadth of care provided by these platforms, in order to be able to provide contemporaneous care for these patients and enhance health outcomes. Further research in this area should be directed toward qualitative studies aiming to explore the subjective aspects of men's experiences using DTC platforms. Such research will provide a more comprehensive picture of this field for the medical community and a deeper appreciation of the psychosocial underpinnings of the predictors and motivations identified in this review.

Conflict of Interest

The authors have nothing to disclose.

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Author Contribution

Conceptualization: CL, DJK, WW. Data curation: CL. Formal analysis: CL. Investigation: CL. Methodology: CL. Supervision: DJK. Visualization: CL. Writing – original draft: CL. Writing – review & editing: WW, KMS, VC, GD, JL, DJK, DL.

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