Sexual Medicine Reviews, 2025, **13**, 471–482
https://doi.org/10.1093/sxmrev/qeaf028
Advance access publication date 2 August 2025
Invited Review

The ethical and economic aspects of sexual medicine: recommendations from the Fifth International Consultation on Sexual Medicine (ICSM 2024)

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Abstract

Introduction: In recent years, the field of sexual medicine has undergone major transformations brought about by the internet and concern with genital performance and aesthetics. On the other hand, economic transformations have increased barriers to better care and sexual education.

Methods: Given the emerging knowledge of this topic, we conducted a narrative review of the extant literature through wide searches in PubMed and Google and on global websites relevant to this topic, such as the World Health Organization, the United Nations, and others. The content of this paper was reviewed by all the authors, discussed where disagreements occurred, or additional perspectives were needed, and further literature was incorporated.

Results: The Internet has made valuable contributions to the dissemination of sexual health education, but it has also promoted non-evidence-based information that can contribute to sexual dysfunctions and has contributed to sexual exploitation and cyberbullying. Of concern is the rise of an Internet-based industry that promotes and dispenses dietary supplements. Liberal, unfettered marketing has brought the dissemination of products that, at best, do not deliver the desired result, and at worst, are adulterated and become a threat to individual and public health. In the context of false advertising, men's anxiety about penis size has been exploited. Advertising of techniques that would produce penis enlargement preys on these anxieties without evidence to support efficacy of these techniques. Economic barriers have impeded men's ability to access sexual healthcare. The lack of coverage by health plans, the lack of trained professionals, and the costs of exams and treatments impede access to sexual healthcare in many parts of the world.

Conclusions: We recommend that doctors inform patients of the risks of non-evidence-based practices and that the International Society of Sexual Medicine produce evidence-based information accessible to the general public and seek to work toward finding solutions to existing economic barriers.

Keywords: internet; dietary supplements; penile enlargement; health economic; ethic; sexual health.

Received: February 23, 2025. **Revised:** May 1, 2025. **Accepted:** May 21, 2025

Recommendation statements

Recommendation statement	Strength of recommendation
The role of the Internet in sexual health	
1. Clinicians should inform patients about the potential benefits and harms of content exploration on the Internet.	Strong
2. The International Society of Sexual Medicine (ISSM) should work with clinicians and patient stakeholders to develop an ethical framework to evaluate information available on the Internet that is related to sexual medicine.	**Strong**
3. The ISSM, in collaboration with scientific societies, may establish a quality certification system to verify the accuracy and reliability of online information related to sexual medicine, based on the ethical framework.	Weak
4. The ISSM should support the global dissemination of evidence-based sexual medicine information.	Strong
Deceptive and/or dangerous practices in the dietary supplement industry	
5. Governmental agencies and/or institutions of higher learning should be invested with the responsibility to advise the public about the safety and efficacy of dietary and food supplements. The Committee believes that, despite infringement on personal freedom, there are precedents for governments to create laws that protect their citizens from harm. Examples are: (1) laws that regulate automobile driving, such as stop signs, traffic lights, and seat-belt requirements, and (2) laws that regulate air travel, such as security checkpoints. These regulations are accepted and desired by the public because they save lives, even though they infringe on personal freedoms. The Committee believes that the same concepts are valid for creating more stringent regulations for the dietary supplement (DS) industry.	Weak
6. The ISSM and other interested professional societies should commission a careful review of international publications and laws on fraudulent advertising and adulteration of DSs.	Strong
7. The ISSM and other interested professional societies should produce guidelines to assist consumers in making rational health choices about DSs.	Strong
8. The ISSM and other professional societies should join with governmental agencies and institutions of higher learning to advise the public about the safety and efficacy of DSs.	Weak
9. Governments should provide greater oversight of the manufacturing and marketing of DSs and should provide more stringent enforcement of regulatory laws that apply to the DS industry.	Weak
10. The ISSM and other interested professional societies should commission a thorough international review of the literature on fraudulent advertising and adulteration of dietary and food supplements. The goal of this review would be to produce guidelines to assist consumers in making rational health choices with regard to DSs.	Strong
11. Clinicians should inform themselves about quality and health surveillance in the supplements industry and inform their patients about the risks of using products without adequate control.	Strong
12. Clinicians should educate patients that there are very few meaningful clinical trials of DSs.	Strong
13. Clinicians should educate patients about the very sparse proof that DSs are beneficial to human health.	Strong
14. Clinicians should educate patients that adulterated DSs can be dangerous to their health and even fatal.	Strong
Marketing on genital cosmetic surgery	
15. Clinicians should approach all patients requesting penile enhancement with empathy and respect.	Strong
16. Clinicians should refer any patient requesting penile enhancement for a comprehensive psychological evaluation to rule out psychological issues, such as body dysmorphia.	Weak
17. Clinicians should educate any patient requesting penile enhancement about the risks and benefits of those procedures before they undergo treatment.	Strong
18. Clinicians should educate any patient requesting penile enhancement about healthy sexuality, since sex education and medical counseling are often adequate to dissuade the majority of men from undergoing augmentation procedures.	Strong
19. Clinicians should follow the recommendations of the European Society of Sexual Medicine (*ESSM*) and the Sexual Medicine Society of North America (*SMSNA*) regarding the setting in which penile enhancement procedures can be conducted, for example, in the context of a clinical trial.	Strong
20. The ISSM should provide public education about the status of development of the various penile enhancement procedures.	Weak
Economic aspects in sexual medicine: barriers in access and costs	
21. Physicians, particularly in low-income societies, should be mindful of the financial capability of patients to afford the recommended treatment in order to prevent non-compliance.	Strong
22. Advocacy efforts should focus on expanding insurance coverage to include sexual health evaluations, sexual aids, counseling, and other treatments, ensuring that individuals can access the care they need without significant financial strain.	Weak
23. The ISSM should amend guidelines to inform patients about low-cost treatments with a discussion of their effectiveness to minimize patients' economic burdens when seeking sexual healthcare. It is relevant that not only scientific evidence must be taken into account but also cost-effectiveness.	Weak
24. The ISSM should stimulate research in low- and middle-income countries (LMICs) to develop and disseminate locally relevant knowledge.	Strong

Introduction

In recent years, the field of sexual medicine has garnered increasing attention, both from medical professionals and the general public. As our understanding of human sexuality expands, so too does the complexity of the ethical and economic considerations that accompany it.

Since the last part of the 20th century, there has been a great liberation of customs, and sex began to be accepted as a way of seeking pleasure and not just for procreation. Also, the discovery of effective medications for the treatment of sexual dysfunctions, mainly phosphodiesterase type 5 inhibitors, has led many people to wrongly seek other medical or surgical treatments that they believe can allow "super" sexual performance. For many, the search for pleasure has been accompanied by the need to have larger or "prettier" genitals.[1]

Concomitantly, technological development creates new challenges and possibilities for the experience of sexuality. The internet has brought a "democratization" of knowledge and the dissemination of medical practices that are not always based on scientific evidence. On the other hand, the heterogeneity of economic and educational conditions around the world creates barriers, sometimes very difficult to overcome, that make access to sexual education and different types of treatment difficult.

Who has access to sexual healthcare services, and who is left underserved or marginalized? How do market forces and healthcare policies influence the availability and affordability of treatments, and what are the implications of these dynamics for individuals, healthcare systems, and society at large?

This paper aims to explore some of these ethical and economic challenges that surround the exercise of sexual medicine in recent and future years.

Methods

Understanding the ethical and economic aspects of sexual medicine is an emerging field of knowledge. In this paper, we conducted a narrative review of the extant literature. The authors conducted wide searches in PubMed and Google and on global websites relevant to this topic, such as the World Health Organization, the United Nations, and others. The content of this paper was reviewed by all the authors, discussed where disagreements occurred or additional perspectives were needed, and further literature was incorporated.

We report not only on the available research findings but also on perspectives on the issues in sexual medicine where opinions vary and are evolving as evidence becomes available. Recommendations were drafted by authors of each section, then modified by consensus among all authors, and finalized using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach to deriving recommendations.[2,3]

Results

The role of the Internet in sexual health

In the 1990s, public access to the World Wide Web brought about an information revolution, and its impact on the global field of sexual health has been profound—both positively and negatively. The World Wide Web, often simply referred to as the Internet, possesses qualities that make it an ideal platform for delivering sexual health promotion interventions. Among these attributes are anonymity, accessibility, affordability, privacy, and acceptability.[4] Moreover, it serves as a remarkable tool for the dissemination of research findings in the field of sexual health.

However, like any innovative technology, the use of the Internet in healthcare, particularly in the context of sexual health, raises many concerns. In this section, we aim to explore the potential benefits and harms associated with the Internet in the field of sexual health.

Potential benefits

The Internet has emerged as a powerful tool with the potential to address critical issues in the field of sexual health, particularly for marginalized and underserved communities. Online platforms have become a common go-to resource for individuals seeking information and guidance on sexual health matters.[5] In regions where access to sexual medicine providers is limited—for example, in rural areas or in middle- or low-income countries—or where specific communities face unique challenges in sexual health, the Internet serves as a bridge to essential information and support. These populations encompass a broad spectrum, including the LGBTQ+ community (an umbrella term for lesbian, gay, bisexual, transgender, queer [or questioning], and other identities that fall outside of the traditional heterosexual, cisgender norms), people with disabilities and chronic conditions, sex workers, refugees and migrants, low-income communities, incarcerated individuals, the homeless population, adolescents in conservative societies, the elderly population, and survivors of sexual assault.

Understanding the needs of these communities is the first step to being able to address them. Focus groups on preferences for an Internet-based sexual health empowerment curriculum involving 52 women in a minimum-security county jail revealed four themes that this curriculum should include: healthy sexual expression, how to access resources, educational modality in video form, and a non-judgmental approach.[6]

Furthermore, the Internet facilitates a space for individuals to explore their attitudes toward sexuality and navigate their own sexual identities while assuring anonymity. Recent studies among Chinese gay males have revealed the Internet's role in various aspects of identity development—including confirming, practicing, and coping with one's gay identity—demonstrating its significance in providing resources and support during what can often be a challenging time of self-discovery.[7]

The issue of stigma surrounding sexual health is pervasive and transcends cultural, social, and geographical boundaries, often leading to misinformation and a lack of open dialogue. The Internet's global reach breaks down geographical barriers, allowing individuals to engage with content and communities representing diverse cultural norms and values. Online support networks enable peer-to-peer knowledge sharing, offering valuable insights and experiences. Studies have shown the potential of online participatory interventions to promote sexual health among adolescents and young adults, emphasizing the opportunity for further research in this domain.[8] Also, the Internet has the advantage of customizing content to specific populations.[9]

Additionally, the Internet serves as a complementary tool for existing sexual health education efforts. Programs like the Health Education and Relationship Training demonstrate the

potential of web-based interventions to enhance knowledge, attitudes, and skills related to sexual health among high school students. Importantly, these interventions have been effective across various demographic groups, underlining their potential to benefit a diverse range of youth.[10] Moreover, social media platforms such as TikTok offer a unique space for addressing topics rarely discussed in standard sex-education programs, including female anatomy and sexual pleasure.[11]

Online education may also be helpful in educating researchers and healthcare providers. The Geneva Foundation for Medical Education and Research, in collaboration with the World Health Organization, developed an online postgraduate course on sexual and reproductive health research.[12] Course evaluation revealed that a majority of respondents (98%) applied the knowledge gained, with 47% publishing scientific papers as authors and 39% implementing their course research projects. A review of articles detailing sexual health training modules for healthcare providers from 1980 to 2015 was performed, excluding online modules. The study revealed 38 published training modules, with 58% designed for medical doctors and allied health professionals and 42% for nurses and midwives.[13] Ninety-seven percent were used in developed countries, with only 3% used in developing countries. The prevalence of online sexual health training modules is unknown. Increased accessibility to these training courses and modules via the Internet may improve access to training opportunities for health professionals, particularly in underserved areas.

The integration of artificial intelligence (AI) into the realm of sexual health is another promising development. AI applications can help detect diseases, provide health-related education, and offer mental health support. For instance, the Wysa app demonstrates how AI can act as an initial touchpoint and educational tool, offering evidence-based self-help practices to build emotional resilience skills.[14] AI also has the potential to assist in public health initiatives related to sexual health by analyzing Internet data to better understand stigmas and misinformation, especially concerning sexually transmitted infections.[15]

However, with the rise of disruptive technologies like AI in healthcare, proper education and awareness regarding its uses are crucial. Studies have shown that medical students have varying perceptions of AI, with many not only seeing it as an assistive technology but also expressing concerns about its impact on healthcare services and the medical profession. This highlights the need for comprehensive medical education that includes discussions on the risks and benefits of AI use.[16]

The Internet has emerged as a dynamic platform with the potential to address various aspects of sexual health. It offers accessibility to information, support for diverse populations, customization of content, and the integration of AI technologies. Recognizing international disparities, it also promotes cross-cultural collaboration and the sharing of best practices. As we navigate the evolving landscape of sexual health, harnessing the power of the Internet thoughtfully and ethically can greatly benefit both individuals and communities.

Potential harms

While the Internet offers immense potential for advancing sexual health education and awareness, it is important to recognize and address the significant barriers and potential harms associated with this digital landscape.

One of the foremost challenges is the overwhelming abundance of online sexual health content. Navigating through this vast sea of information can be a daunting task for individuals seeking reliable guidance. Limited awareness of specific, trusted sources, along with difficulty in filtering content, makes it challenging to discern credible information from misinformation.[17]

Social media platforms like Facebook, YouTube, Instagram, TikTok, and Twitter offer valuable knowledge-sharing opportunities. However, misinformation on these platforms—associated with the lack of quality control—turns them into an important source of disinformation. Studies have shown that the quality of health information can vary significantly, with content produced by healthcare professionals generally deemed more reliable but often lacking in user engagement.[18-21]

Privacy and confidentiality are paramount concerns, particularly due to the sensitive nature of sexual health. Ensuring the protection of personal information and maintaining client confidentiality in online outreach services is a complex ethical issue.[22]

Informed consent in the digital realm poses significant challenges. The accessibility of explicit sexual content on the Internet can expose individuals, including minors, to explicit material without their consent, potentially leading to adverse psychological consequences. Moreover, patients engaging in remote consultations for sexual health concerns may not fully grasp the implications of sharing sensitive information online, compromising their privacy and confidentiality. The variation in legal and ethical standards across jurisdictions on a global scale adds another layer of complexity to informed consent in the context of online sexual health services and research.[23] These multifaceted challenges underscore the urgent need for robust ethical frameworks and clear communication of risks and benefits to ensure informed consent in the digital landscape of sexual health.

Harmful content on the Internet, including explicit material, can contribute to an increased risk of sexual dysfunction. Problematic online pornography consumption has been associated with a higher likelihood of erectile dysfunction (ED), particularly among young men.[23] In addition to ED, pornography has been correlated with various aspects of sexual dysfunction, including orgasm difficulty, reduced libido, reduced enjoyment with sexual intimacy, reduced sexual and relationship satisfaction, and preference for Internet pornography over partnered sex.[24]

Sexual cyberbullying is another grave concern, with personality traits associated with the Dark Triad (psychopathy, Machiavellianism, and narcissism—traits associated with socially undesirable behaviors, manipulation, and a lack of empathy) and more recently the Dark Tetrad (which includes sadism), being linked to a greater likelihood of engaging in such behaviors. Creating policies and procedures to detect and deter cyberbullying is essential to foster a respectful online environment.[25]

The dark web, which constitutes an obscure segment of the Internet composed of a network of forums and websites that cannot be accessed using standard web browsers or search engines, presents a significant concern in the realm of sexual health on the Internet due to its clandestine and unregulated nature. Firstly, it serves as a hub for the illegal trade of explicit and often non-consensual sexual content, including child pornography, leading to the exploitation

and harm of vulnerable individuals. Child exploitation sites have been growing exponentially. According to data from the National Center for Missing and Exploited Children, there were nearly 32 million reports of suspected child abuse material in 2022.[26] There is also concern about the increasing demand for children to record themselves engaging in specific sex acts on video or livestreaming platforms, as well as aggressive blackmail of children for financial gain (termed sextortion). Secondly, the dark web offers a platform for the sale of counterfeit sexual health products, such as medications and supplements, posing serious risks to consumers who may unknowingly purchase ineffective or harmful substances. Thirdly, the anonymity provided by the dark web can facilitate the exchange of sensitive sexual health information without proper consent, potentially exposing individuals to privacy breaches and blackmail. Moreover, forums and communities on the dark web may promote harmful sexual behaviors, fetishize non-consensual acts, and spread dangerous ideologies related to sexual health. Healthcare records may also be exposed on the dark web following cyberattacks. Lastly, the clandestine nature of the dark web makes it challenging for authorities and regulatory bodies to monitor and combat these harms effectively, underscoring the urgent need for increased awareness, education, and law enforcement efforts to protect individuals from its dangers.

Conclusion

While the Internet offers tremendous opportunities for advancing sexual health and education, there are significant barriers and potential harms that must be addressed. The responsibility falls on sexual medicine specialists and stakeholders to work toward creating a more inclusive and responsible online environment for sexual health. Thoughtful collaboration, adherence to ethical standards, and an emphasis on quality control are essential to harness the Internet's potential for improving patient outcomes, providing comprehensive education, disseminating research findings, and expanding global access to sexual health resources. Scientific societies should consider the establishment of a quality certification system to verify the accuracy and reliability of online information related to sexual medicine.

Deceptive and/or dangerous practices in the DS industry

Between January 1, 2008, and May 26, 2008, 150 non-diabetic patients were admitted to hospitals in Singapore with severe hypoglycemia.[27] The hypoglycemic agent glyburide was found in 127 (85%) of these patients. Forty-five (30%) of these patients admitted that they had taken illegal sexual enhancement drugs just prior to the onset of hypoglycemia. Analysis of the drugs the patients had used, and drugs seized in police raids, revealed glyburide in doses of 13-100 mg per tablet. Typical doses of glyburide for the treatment of hyperglycemia are less than 20 mg daily. Whether the sexual enhancement product was accidentally or intentionally adulterated with glyburide is not known. Seven of the 150 non-diabetic patients were comatose due to severe neuroglycopenia, and four subsequently died. This tragedy in Singapore exemplifies how deceptive, misleading, or fraudulent marketing and/or illicit adulteration of DSs can cause serious morbidity and mortality.

Deceptive advertising and product adulteration can be found throughout the world of medicine. These practices appear to be more prevalent in sexual medicine and in urology than in other medical specialties because of widespread consumer demand for sexual enhancement and the ease of producing sildenafil and other phosphodiesterase type 5 (PDE5) inhibitors.[28,29] Deceptive advertising and adulteration of DSs are unethical and illegal, and they may be dangerous. They are, at the very least, responsible for the economic exploitation of patients seeking sexual healthcare.

Worldwide, many consumers of sexual healthcare products assume that businesses that market products for the treatment of sexual dysfunction are trustworthy. However, consumers' confidence in marketing in sexual medicine is often naïve. Many consumers do not have the ability to evaluate the accuracy of advertising claims for sexual healthcare products. The differences between pharmaceutical drugs, which are strictly regulated, and DSs, which are lightly regulated, are not understood by the average consumer. The public is prone to assume that sexual healthcare products that are publicly advertised or marketed must have been approved by a legitimate healthcare authority as being safe and/or efficacious. This assumption is almost always incorrect for DSs because pre-market clinical trials of sexual healthcare supplements and post-market testing of chemical content are not required by law and therefore are rarely done.

In the United States, the passage of a law[30] in 1994 defining DSs as foods rather than drugs accelerated the access of DSs to public markets. This accelerated access, and the subsequent advent of internet marketing, have resulted in enormous growth in the number of products available and in sales of these products. In 1994, there were about 4000 DSs of all types available on the US market, and consumers spent USD 4 billion on them that year.[31] In 2022, the number of DSs on the US market had increased to well over 75 000, and consumer spending had increased to USD 50 billion.[32]

Laws regulating DSs

Regulations regarding the production and sale of DSs vary around the world. In the United States, the federal law that regulates DSs is called the Dietary Supplement Health and Education Act (DSHEA) of 1994.[30] Because this law defines DSs as foods, not as drugs, manufacturers of DSs are not subject to the strict rules applied to the drug industry. DSHEA makes the path to market entrance for DSs far more lenient than the path for pharmaceutical agents.

Two federal agencies in the United States are invested with responsibility to apply and enforce the provisions in the DSHEA: the U.S. Food and Drug Administration (FDA), which oversees development, manufacturing, testing, and approval of drugs and foods, and the Federal Trade Commission (FTC), which oversees the marketing and advertising of drugs and foods in the United States.

The DSHEA contains certain consumer-protection provisions. It requires DS manufacturers to use Good Manufacturing Practices (GMPs) and prohibits DS marketers from claiming to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.[30] The DSHEA does not require pre-market approval of DSs as long as they contain only ingredients that were in common use prior to 1994, when the DSHEA became law. These older ingredients are called GRAS (Generally Recognized as Safe). The result of this law is that regulation of DSs occurs post-market, not pre-market.

If regulatory agencies discover that a DS has caused health-related problems, or that there is deceptive marketing or advertising of a DS, penalties—which may include heavy fines and/or incarceration—can be applied.

Since it became law in 1994, the DSHEA has been considered controversial by many public health experts because: (1) oversight by the FDA and/or FTC of manufacturing, marketing, and advertising is limited by budgetary constraints; (2) adulteration of DSs has proliferated markedly since the introduction of PDE5 inhibitors; and (3) manufacturers' scientific evidence of their products' safety and efficacy is sparse, nonexistent, and/or misleading.[33]

Many nations have laws that regulate dietary, food, and health supplements through government agencies that apply and enforce these laws.

The European Union (EU) and United Kingdom equivalent to the US term "dietary supplements" is "food supplements." Food supplements are regulated in the EU as foods under the European Food Safety Authority.[34] As in the United Kingdom and United States, pre-market approval of food supplements is not required, thus making enforcement a post-market practice.[34,35] According to the EU General Food Law Regulation (EC) No.178/2002,[35] the responsibility for the safety of food supplements lies with manufacturers, importers, suppliers, or distributors.

In China, the National Medical Products Administration[36] has regulatory authority over health foods. For domestic health foods produced and sold in China, registration is conducted with the State Administration for Market Regulation (SAMR) and the Provincial Administration for Market Regulation (PAMR). For imported health foods, registration and filing are done with the SAMR.[36] Certain tests are required for health food registration in China. These include safety and toxicology testing, animal and/or human function tests, stability testing, and several others.

In India, the Food Safety and Standards Act of 2006 provides the legal basis for regulation of health supplements.[37] The Food Safety and Standards Authority of India (FSSAI) is solely responsible for regulating health supplements and nutraceuticals. Under this 2006 Act, "solid scientific support" is required to back up all manufacturers' claims. If solid evidence is not available, the FSSAI can make a judgment based on "adequate scientific evidence." There is a complex set of standards and requirements that manufacturers of health supplements must satisfy, but how these standards are enforced is not clear.

Food supplements are regulated in the United Kingdom under the Food Supplements Regulation (2003).[38] Laws in the United Kingdom do not require pre-market approval of food supplements. The UK government Nutrition Legislation Information Sheet states, "There is no requirement to register food supplements in the UK . . . It is the responsibility of the manufacturer, importer or retailer to ensure that they comply with the law."[39]

In Canada, dietary, food, and health supplements are called natural health products (NHP). Manufacturers of NHPs must hold valid product and site licenses and must follow GMPs.[40] Clinical trials may be required if an NHP is being tested for a condition not on the product label; for new and unapproved NHPs for which additional efficacy and safety evidence is required; and for NHPs with no prior history of use in humans.[41]

Laws governing DSs or food supplements also exist in many, if not all, large nations. Many less populous nations have regulatory laws as well. A brief Internet search suggests that regulation of DSs may not exist in some low-income countries, but guidelines for health food regulation in these countries may be adopted from regional political organizations such as the African Union, Organization of American States, Association of Southeast Asian Nations, and others.[42]

It is critically important to understand that the existence of regulatory laws does not guarantee their effective enforcement. While laws in many countries describe regulatory requirements for development, registration, marketing, sales, and/or reporting in the dietary, food, and health supplement industry, some laws fail to explain clearly how these requirements are monitored and enforced. Application and enforcement of regulatory law may be inconsistent with the intent of the law because of local cultural conditions, historical practices, corruption, bribery, and/or governmental budget constraints.

Potential harms of fraudulent advertising and adulteration of DS

Misleading advertising in sexual medicine is found throughout the world. Although adulteration of DSs seems less common than misleading advertising, it is more threatening to public health. The prevalence and dangers of deceptive marketing and adulteration of DSs are poorly documented and poorly understood. Data about these practices are limited. Most of the data come from the United States, the world's largest healthcare market.[32]

It is not unusual for DS marketers to use either misleading language or suggestive product names to attract consumers. A small sampling of a few old and a few current names in the United States includes *Alpha Male*, *Rock Hard Weekend*, *Hard Steel*, *Viril X*, *Steel Libido*, and *Jungle Beast*. Despite the lack of statistical proof for the safety and efficacy of DSs for sexual health, naïve consumers may be enticed by suggestive names to try products that have unproven or no value. The risk of medical harm from unadulterated sexual health products is probably small, but financial harm occurs to consumers who buy products that are not effective.

Despite many advertising claims regarding the safety of supplements, DSs are not free of adverse events. A 2015 report calculated that there were slightly over 23 000 annual emergency department visits due to adverse events from DSs between 2004 and 2013. These visits resulted in over 2000 hospitalizations each year in the United States. The most common adverse events in this study were palpitations, chest pain, tachycardia, and swallowing problems.[43]

Some, if not many, DSs have minimal value, and some have no value. More worrisome is that some DSs are dangerous because they are illegally adulterated with pharmaceutical products.[29,40] Practical clinical experience informs medical professionals that most DSs are ineffective for the treatment of ED. This has led unethical DS manufacturers to clandestinely add PDE5 inhibitors to make their offerings effective and boost their sales.

The percentage of DSs that are contaminated with PDE5 inhibitors is unknown, but two studies suggest that the percentage is not insignificant.[29] Between 2007 and 2016, the FDA identified 776 adulterated DSd produced by 146

different companies.[29] Of these adulterated products, 45% were sold for sexual enhancement, 40.9% for weight loss, and 11.9% for muscle building. The most common adulterants were sildenafil (sometimes in therapeutic doses) in 47.0%; sibutramine—now a banned substance—for weight loss in 84.9%; and synthetic steroids for muscle building in 89.1% of these products.

In another study,[44] 91 samples of products sold as herbal supplements, all-natural supplements, or DSs for sexual enhancement were procured from convenience stores, filling stations, and US customs seizures. Seventy-four of these samples (81%) contained PDE5 inhibitor pharmaceutical ingredients. Of these 74, 18 (20% of the 91 samples) contained more than 110% of the highest approved dose strength of a PDE5 inhibitor. Significant concentration variability of contents in different samples of the same product suggests poor quality control and a lack of GMPs.

The potential danger of DSs adulterated with PDE5 inhibitors is that many patients with ED are older men who also have coronary artery disease and may be using organic nitrates for the treatment of chest pain. PDE5 inhibitors must *never* be used in combination with organic nitrates. Patients using a PDE5 inhibitor–adulterated DSs are unaware that they are ingesting a PDE5 inhibitor. It is impossible to know how many men with angina pectoris may have suffered life-threatening hypotension, acute myocardial infarction, or acute cardiac death following self-treatment—or unwitting treatment in an emergency room—with an organic nitrate, after unrecognized ingestion of an undeclared PDE5 inhibitor. It seems reasonable to expect that morbidity and mortality events under these conditions have occurred, but the frequency of these hidden events and the magnitude of the public health danger are impossible to calculate because patients are unaware that they have consumed a PDE5 inhibitor.

In summary, deceptive advertising in sexual medicine is common and easily visible in public media such as print, online, radio, and television advertising in the United States. The magnitude and dangers of DS adulteration are simply unknown. Morbidity and mortality due to adulteration of DSs may be infrequent, or they may be common and threatening to a nation's population. Greater enforcement of laws regulating manufacturing and marketing of DSs and much more frequent post-marketing testing of the chemical content of DS products are necessary to provide a better understanding of whether illegal practices in the DS industry are threatening to public health.

Ethics of regulating the DS industry

The laxity of laws concerning the manufacturing and marketing of DSs and the exploitation of consumers of sexual health products by dishonest manufacturers raise the following ethical questions:

- To protect the health and safety of their citizens, should governments provide greater oversight and regulation of healthcare products that do not require a prescription?
- Would greater government oversight and regulation of DSs infringe inappropriately or excessively on individual citizens' personal rights and freedoms?
- Should governments make efforts to educate their citizens about how to recognize DSs that are adulterated and those that are safe and/or effective?
- Given the large number of DSs and the universal demand for better health, are regulatory laws enforceable at a reasonable cost?

Conclusion

The prevalence of health, psychological, and financial harms caused by DSs is impossible to calculate without greater governmental oversight and data collection. The magnitude and severity of morbidity and mortality events caused by DSs are not known. Harm due to DSs may be minimal—or it may constitute an unrecognized threat to the public health of a nation.

Current practices in the DS industry raise the ethical question of whether protective government regulation should be more stringent or whether governments should let individuals make their own health decisions. Few citizens of any country possess sufficient scientific sophistication, statistical knowledge, or business understanding to enable them to make rational decisions concerning the efficacy and safety of DSs.

Marketing of genital cosmetic surgery

Historically, male genital size has been linked to a man's sense of virility, fertility, and sexual performance. Evidence of male supremacy and dominance, represented by phallic imagery, can be found across cultures and throughout history.[45] Nowadays, the "bigger is better" attitude is still reinforced by many forms of media, such as the pornographic industry, magazines, and websites. This scenario strengthens the association between size and masculinity and often portrays an exaggerated sexual response from the partner,[46] leading many men with normal-sized penises to seek ways to enlarge their sexual organs.

Over the years, many non-invasive and invasive procedures have been described for penile augmentation, and although evidence for their indication is still lacking, *there is* widespread advertising on the Internet and other media.[47] A Google search for "Penile/Penis enlargement" on May 26, 2024, retrieved nearly 114 million results—many of them advertisements for enhancement procedures and devices with suggestive titles, such as "Life is short. You don't have to be."

What is considered a normal penis?

A systematic review by Veale et al. included 15 521 men from 20 different studies and reported the following average measurements: flaccid length 9.16 cm (SD 1.57), stretched penile length (SPL) 13.24 cm (SD 1.89), erect length 13.12 cm (SD 1.66), flaccid circumference 9.31 cm (SD 0.90), and erect circumference 11.66 cm (SD 1.10).[48]

Furthermore, a true micropenis—defined as a stretched penile length of less than 2.5 standard deviations (SD) below the mean for age[49]—is rare (<1% of the overall population). Therefore, the vast majority of men seeking penile enhancement procedures actually have normal-sized penises.[49]

Accordingly, we can clearly see that unethical marketing of genital cosmetic surgery has the potential to reinforce misconceptions about penile size in men who, from a physical-anatomical standpoint, fall within normal parameters.

Online marketing of penile enhancement procedures

The marketing landscape surrounding penile enhancement procedures is often characterized by enticing advertisements

that prioritize appealing promises over comprehensive information about potential complications. Tennenbaum et al. conducted research outlining the imbalance in the presentation of risks and benefits in these advertisements.[50] Using Google and Google Trends, the researchers identified websites offering procedures ranging from synthetic injections to surgical interventions, primarily in the United States. Plastic surgeons, followed by urologists, were the most common subspecialists advertising these procedures, but the list also included dermatologists and other specialties. The findings revealed a significant disparity in the presentation of information, with only a minority of sites providing critical data alongside the advertised benefits. Notably, interventions offered outside the United States were more likely to disclose critical information than those within the country.[50]

These findings underscore the need for greater transparency and regulation in online marketing practices related to penile enhancement procedures. Furthermore, as outlined below, strong evidence for most of these procedures (if not all of them) is still lacking, which exacerbates the problematic nature of such advertisements.

Men's perceptions of penile size

Heterosexual men and men who have sex with men (MSM) appear to have similar perceptions of penile size, although published studies have not directly compared these two populations. In an Internet survey of 52 031 heterosexual men and women, 85% of women reported being fully satisfied with their partner's penis size, whereas only 55% of men were satisfied with their own.[51] A total of 46% of men who rated their penis as average still desired a larger one, and 14% of men who rated their penis as larger than average still wanted it to be bigger. Only 14% of women wanted their partner to have a larger penis.[51]

In a survey of MSM, 40.5% of participants with average-sized and 14.7% of men with above-average size wished for a larger penis.[52]

Psychological disorders associated with penis size

A negative perception of one's own penis size may underlie a somatoform disorder known as penile dysmorphic disorder (PDD), a recognized mental health condition. Although not a separate, independent diagnosis, PDD is considered a specific subtype of body dysmorphic disorder (BDD), according to the *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (DSM-5).[53] BDD affects 2.4% of adults in the United States and can be associated with depression, functional impairment in various aspects of life, and suicidal ideation.[54]

As there are many other men who are dissatisfied with their penis size but do not meet the criteria for BDD, the literature defines this condition as "small penis anxiety" (SPA). These patients generally experience less distress and functional impairment. Most of them likely have a normal penis size, yet worry excessively and overestimate the average penis size in other men.[55] It is important to understand that the same psychological reasons causing these patients to request surgery may also lead them to be dissatisfied even with a technically successful surgical outcome.[56]

The importance of counseling

A study evaluated 250 men who presented to a urologic clinic complaining of small penis size. Notably, only two of them had a true micropenis. After following a structured counseling protocol developed by the authors, *96.4%* of the patients reported resolution of their concerns and decided not to undergo any type of penile enhancement procedure.[57]

Another study that included 92 patients with similar complaints found that education about realistic expectations and accurate measurement of penile size resulted in *86%* of patients reporting resolution of their concerns. Thirteen men were referred for psychosexual assessment. After 3 months of therapy, *11 of the 13* no longer expressed interest in surgical intervention.[58]

Respect for self-determination is central to modern medical ethics. In that sense, the main objective of healthcare providers should be to foster patient autonomy in decision-making. However, clinical judgment should guide patient education and, when necessary, override a patient's wish in order to prevent negative clinical or psychological consequences.[59]

Current evidence for the efficacy of interventions

Until recently, there were no specific guidelines for patients with normal-sized penises who sought enlargement procedures,[47] mainly due to the very weak evidence supporting the efficacy of the proposed techniques.[59-61]

In March 2024, the SMSNA published a position statement on cosmetic enhancement procedures.[62] The panel first emphasized that it is not appropriate to perform augmentation procedures in men with uncontrolled psychological conditions. Severe disorders such as PDD must be ruled out before considering invasive treatments.

The SMSNA acknowledged that the main limitation in the cosmetic/augmentation field is the lack of high-quality studies. Therefore, the threshold for accepting complications and risks in men with normal-sized penises must be stricter. The SMSNA encourages clinicians performing penile girth enhancement with injectable hyaluronic acid and polylactic acid fillers to conduct safety and efficacy analyses under Institutional Review Board-approved research protocols.

Conversely, the panel strongly recommends against penile fillers using permanent materials (including paraffin and silicone). Regarding suspensory ligament division, the advisory panel recommends that the procedure may be reasonably offered by experienced surgeons to patients who are appropriately counseled about expectations and potential complications.

As for graft-and-flap procedures, sliding/slicing techniques, and silicone sleeve implants, the panel considers these methods investigational and recommends they be performed only under IRB supervision, pending the availability of long-term outcome data.[62]

Economic aspects in sexual medicine: barriers in access and costs

Sexual health is a fundamental component of overall well-being. However, numerous economic factors can create barriers to accessing sexual healthcare services and prevent individuals from receiving necessary treatment and support.

In recent years, healthcare systems around the world have faced enormous challenges. Population growth and the cost of new technologies are some of the factors that have made it difficult to facilitate universal access to healthcare.[63]

According to the 2023 World Bank report, inadequate financial protection is a significant obstacle that prevents approximately 1 billion people from obtaining healthcare services.[64] In 2019, out-of-pocket expenditures on health amounted to around 10% of household income, and 13.5% of the global population experienced devastating out-of-pocket healthcare payments. Additionally, in 2019, 4.4% of the global population slipped into extreme poverty due to out-of-pocket healthcare payments.[65]

In sexual health, this reality is no different; the most important economic barrier is the limited or nonexistent insurance coverage for treatment of sexual dysfunctions or sexual health counseling. Furthermore, poverty, income inequality, low levels of education, stigma, racism, sexism, and homophobia can make it more difficult for many communities to access sexual healthcare.[66]

Many individuals require aids such as ED medications, psychotherapy, lubricants, or sexual devices to improve their sexual health. This is particularly true for individuals who experience sexual difficulties due to chronic conditions such as diabetes, cancer, or heart disease. These conditions—or their treatments—often result in sexual dysfunction that is largely left unattended by clinicians. In addition, the cost of these products is often not covered by insurance plans, leaving individuals to bear the full financial burden themselves. Similarly, sexual health counseling services, which can address various concerns related to sexual dysfunction or relationship issues, may not be covered, making them financially inaccessible to those who need them. While there is limited coverage of certain treatments or services in some countries, in most LMICs, these treatments are generally paid out of pocket.[66] A recently published systematic review with meta-analysis showed that even in the United States, disparities exist; the prevalence of health insurance among transgender people is 75%, considerably lower compared with the general population (91.2%).[67]

The costs linked to the treatment of sexual health conditions can vary significantly depending on the specific condition and the chosen therapeutic strategy. Pharmacological agents, hormone therapy, surgical procedures, and other interventions may be required to address sexual dysfunction and related concerns. Counseling sessions may be needed short term or over a longer period, particularly when past relationship conflict or trauma is involved. Studies evaluating the socioeconomic barriers to consulting physicians for sexual dysfunction suggest that lower levels of education and younger age are factors associated with avoiding medical care.[68,69]

Kimani et al.[70] examined the barriers faced by Kenyan Somali women who have undergone female genital mutilation/cutting (FGM/C) when seeking healthcare for complications arising from the procedure. The authors gathered qualitative data from women aged 15-49, their partners, community leaders, and healthcare providers in Nairobi and Garissa Counties. Among other findings, they identified that high costs of care and long distances impeded access to healthcare.

Considering economic costs, the World Health Organization created an interactive data tool to estimate the current and future economic burden of health system costs and national budgets related to healthcare for women experiencing complications (from immediate effects to long-term gynecologic, obstetric, urological, mental, and sexual health consequences) across the life course due to FGM/C. In 27 of 30 FGM/C-practicing countries that provided data, this tool estimates that if FGM/C were abandoned in countries with prevalence rates greater than 10%, the associated savings in health costs would exceed 60% by 2050.[71] While FGM/C rates continue to decline globally, there is a need to quantify the impact of interventions on reducing harm and the cost of care. The FGM Cost Calculator may be a crucial tool in assessing these impacts.

Haire et al. conducted a study in Australia to understand the experiences of healthcare access among trans and gender-diverse individuals.[72] They found that participants faced multiple challenges, including managing complex health needs like gender-affirming care and mental health services, as well as economic hardship affecting appointment scheduling and co-payments. The study emphasizes the need for comprehensive, affordable services that incorporate peer support and address physical, mental, and social health for this population.

Tran et al. found that high-deductible health plans in the United States disproportionately affected access to care for sexual minority adults, especially for gay, lesbian, and bisexual individuals.[73] These plans, which require individuals to pay significant out-of-pocket costs before insurance coverage begins, create financial barriers. This research highlights disparities in healthcare access based on sexual orientation and economic status and underscores the need to address structural issues to ensure equal access to sexual and reproductive healthcare (SRH) services.

Hubach et al. investigated barriers to SRH care among adolescents living in the US–Mexico border region.[74] The identified barriers included transportation difficulties, lack of insurance, the financial burden associated with accessing services covertly, extreme financial hardship, and family disintegration.

Miyamoto et al. discussed the challenges of providing quality sexual assault care in rural areas, including healthcare delivery limitations, workforce shortages, and training gaps.[75]

The lack of adequate coverage of healthcare services—and the need for individuals to pay out of pocket for examinations and treatments—has led to the emergence of low-cost clinics around the world. However, these clinics do not always prescribe treatments and procedures based on scientific evidence for patients with sexual dysfunctions. In some cases, unethical practices occur, such as unnecessary investigations, treatments, or invasive procedures aimed at maximizing profit. Individuals seeking sexual healthcare must be cautious and consult reputable, evidence-based providers who prioritize patient well-being over financial gain. Invasive, expensive investigations should only be conducted if they are expected to change the management plan or improve the patient's overall well-being.[76] For similar reasons, drugs intended to improve sexual performance and physical appearance are among the most commonly counterfeited products in the world.[77]

Finally, according to a recent report,[76] sexual medicine clinicians in middle- and low-income countries face specific resource limitations, such as a lack of research training, which hinders their ability to conduct well-designed studies. As a result, international guidelines often favor therapies with the best available evidence, overlooking cheaper alternatives that lack sufficient research—making it difficult for clinicians to use more affordable options.

Overcoming barriers

According to a report from the Guttmacher Institute, investing in sexual and reproductive health in LMICs is essential for achieving universal health coverage.[65] Achieving this goal requires careful planning and budgeting. The authors studied the costs and impacts of providing such services in LMICs and found that while salaries for providers make up the largest cost component, investing in these providers can prevent the need for more expensive services later. These findings may assist policymakers and planners in budget allocation for universal health coverage and ensure that everyone—including marginalized populations—can access essential sexual and reproductive healthcare.[66]

Shah et al. recommend the inclusion of low-cost treatment options in therapeutic guidelines, the engagement of ISSM in promoting affordable alternatives, and academic support for clinician-researchers in LMICs so they can publish and disseminate local knowledge.[78]

Overcoming economic barriers to sexual healthcare requires creative and focused solutions. Substituting low-cost treatments helps alleviate financial strain. Group therapy, for instance, can be a cost-effective approach to treating psychogenic sexual dysfunction. The dissemination of sexual education through mobile technology and distance learning—already present in many low-income settings—can help clinicians provide care aligned with the highest standards.

Conclusion

Economic barriers significantly impact access to sexual healthcare. These include a lack of insurance coverage for sexual aids, counseling, and treatments. The costs of consultations, diagnostic exams, and therapy further exacerbate these barriers. Addressing the economic aspects of sexual medicine requires advocacy for comprehensive insurance coverage, accessible and affordable services, and regulation to prevent the spread of unethical "treatment mills." Reducing these economic barriers will ensure that individuals receive the support they need to improve their sexual well-being and overall quality of life.

Author contributions

Conceptualization: All. Content draft: Internet (A.P.), Dietary supplements (I.S.), genital cosmetic surgeries (P.C.E.Z.), Introduction, Methods, Discussion (D.W. and S.G.). Statistical analysis: NA. Scientific review and editing: All. Recommendations: All.

Funding

None declared.

Conflicts of interest

D.W. has a contract with Movember as a consultant.

A.P. is a Consultant for and received grant funding from Boston Scientific, is a member of the Advisory board Marius Pharmaceuticals and of the Advisory board The Coach: Men's Health App, is a Consultant to Endo Pharmaceuticals Advisory board, and FirmTech, is on the Advisory board of PhalloFill, a Consultant for MenMD, and an Investor in ByteMD.

The following authors have no disclosures or conflicts of interest: J.A., C.J.-A., I.S., N.S., H.G., S.G., P.C.E.Z., and K.P.

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Sexual Medicine Reviews, 2025, 13, 471–482
https://doi.org/10.1093/sxmrev/qeaf028
Invited Review