

Title Page

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Authors

Mrugesh Vaishnav¹, Arun V. Marwale², Amit Tak³, Shobit Garg⁴

Affiliations

¹ Mrugesh Vaishnav, MBBS, MD: Director, Samvedana Happiness Hospital, Ahmedabad; Director, Institute of Psychological & Sexual Research, Ahmedabad, Gujarat, India

² Arun V. Marwale, MBBS, DPM, DNB (Psychiatry), Professor and Head, Department of Psychiatry, CSMSS Medical College, Chatrapati Sambhajnagar, Maharashtra

³ Amit Tak, MBBS, MD, Assistant Professor, Department of Psychiatry, CSMSS Medical College, Chatrapati Sambhajnagar, Maharashtra

⁴ Shobit Garg, MBBS, DPM, MD: Professor, Department of Psychiatry, Shri Guru Ram Rai Institute of Medical and Health Sciences, Patel Nagar, Dehradun, Uttarakhand, India. ORCID: 0000-0001-5913-9021

Corresponding author

Dr Mrugesh Vaishnav, MBBS, MD

Director, Samvedana Happiness Hospital; Director, Institute of Psychological & Sexual Research

Samvedana Happiness Hospital, 3rd Floor, Satya One Complex, Opp. R3 Mall, Helmet Circle, Memnagar, Ahmedabad 380052, Gujarat, India

Mobile: +91 98257 67565

E-mail: mrugeshvaishnav@gmail.com

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To

The Editor

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Subject: Submission of the manuscript “Assessment and Management of Erectile Dysfunction” for the Indian Psychiatric Society Clinical Practice Guidelines for Psychosexual Health, Dysfunction and Disorders

Dear Editor,

On behalf of all the authors, I am pleased to submit our manuscript “Assessment and Management of Erectile Dysfunction”, prepared for the Indian Psychiatric Society Clinical Practice Guidelines for Psychosexual Health, Dysfunction and Disorders, for consideration for publication in the Indian Journal of Psychiatry.

The chapter sets out a psychiatry-led, resource-stratified approach to the assessment and management of erectile dysfunction. Because region-specific evidence, including Indian data, remains limited, the recommendations follow a universal approach anchored in international guidelines and the wider evidence base, and build on the Society’s earlier guidance on sexual dysfunction published in this journal.

The draft was reviewed by the Clinical Practice Guideline Sub-Committee of the Indian Psychiatric Society, and all the changes it advised have been incorporated, as summarised below.

No.	Change advised	How it was addressed
1	Number the tables in sequential order (1, 2, 3), without letter suffixes such as 1A or 1B.	All tables are numbered consecutively from Table 1 to Table 14 in the order of their first citation in the text, and every in-text citation, cross-reference within the tables and reference in Figure 1 has been updated.
2	Place the heading of each table above the table, and expand all abbreviations used in the table in a footnote.	Every table heading now appears above the table, and a footnote below each of the 14 tables expands every abbreviation used in it.
3	Provide Figure 1 at adequate quality and in an editable format.	Figure 1 has been redrawn and is supplied as a 300-dpi image and as a fully editable PowerPoint file; its abbreviations are expanded in the figure legend.
4	Editorial changes to the text.	Section numbering has been removed, the opening section retitled “Introduction”, and author–year labels removed from the guideline comparison table; cross-references that relied on section numbers now refer to section titles.

The manuscript has not been published previously and is not under consideration for publication elsewhere. All authors have read and approved the final manuscript and agree with its submission. The submission comprises the title page, the blinded manuscript (with the figure legend), the tables, Figure 1 (image and editable file) and this cover letter.

Thank you for considering our work.

Yours sincerely,

Dr Mrugesh Vaishnav, MBBS, MD

Corresponding author, on behalf of all authors

Director, Samvedana Happiness Hospital

Director, Institute of Psychological & Sexual Research

President, Indian Association of Private Psychiatry

Member, State Mental Health Authority (Gujarat State)

Past President, Indian Psychiatric Society (2019–20)

Member, Editorial Board, WPA E-Journal

International Distinguished Fellow, American Psychiatric Association

Samvedana Happiness Hospital, 3rd Floor, Satya One Complex, Opp. R3 Mall, Helmet Circle,

Memnagar, Ahmedabad 380052, Gujarat, India

Mobile: +91 98257 67565 | E-mail: mrugeshvaishnav@gmail.com

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Keywords: erectile dysfunction; psychosexual health; PDE5 inhibitors; performance anxiety; premature ejaculation; clinical practice guideline.

Introduction

Erectile dysfunction (ED) is defined as a persistent or recurrent inability to achieve and/or maintain an erection of sufficient rigidity for satisfactory sexual activity.¹ Most guidelines state that this should have been going on for about three to six months before the label is applied, unless something obvious precipitated it, trauma, pelvic surgery, a new medication, in which case the time frame is ignored.

It's really three things: trouble with an erection, trouble maintaining it until sex is over, and loss of rigidity.^{2,3} Any one of them will do, so long as it annoys the man or his partner.³ And ED is very common. Even in surveys of ordinary men, rather than men attending clinics, a sizeable minority report some form of sexual dysfunction and the complaints climb steadily from the fourth decade onwards, climbing further still in men with diabetes, hypertension or depression.⁴ A community-based study of adult men in rural Haryana showed erectile dysfunction in 5% and premature ejaculation in 4.6%. Notably, 81% reported at least one sexual health disorder when self-perceived defect in semen (64.4%), loss of libido (21%) and masturbation guilt (20.8%) were considered. Smoking, cannabis use, diabetes and hypertension all had an independent association with any sexual health disorder and not specifically with erectile dysfunction.⁴

And something most guidelines now say flat out: ED is not just a nuisance. Penile arteries are smaller than coronary arteries, so vascular disease often shows up there first, sometimes years before an anginal or cardiac event. In other words, a new case of ED in a middle-aged man is an invitation to evaluate his cardiovascular risk, not only to write a prescription.^{1,2}

There is a further reason for setting this out carefully. Few countries have a psychiatry-led clinical practice guideline on erectile dysfunction, and in many settings, India among them, practice borrows largely from the American Urological Association and the European Association of Urology, filtered through urology-society consensus statements and individual habit, so the same man may be worked up quite differently depending on which door he happens to walk through.^{1,2} The Indian Psychiatric Society's 2017 clinical practice guideline on the management of sexual dysfunction, and its subsequent guidance on psychosocial interventions for sexual dysfunction in addictive disorders, remain the closest psychiatric precedents, but ED sat within a much wider brief there, and a great deal has moved on since.^{23,45} In ICD-11 the diagnosis has been removed from the chapter on mental disorders; the evidence for the oral agents has matured; and new treatments have arrived, as have new patterns of misuse. Meanwhile, the aspects of the problem a psychiatrist is best placed to address, namely

performance anxiety, unrecognised depression, relationship strain, dysfunction emerging from the very drugs we prescribe, and culturally shaped beliefs about semen loss and vitality, receive comparatively little attention in urology-led documents. Advice written for a well-staffed specialist clinic is also often not implementable in a resource-limited setting. Because region-specific data, including Indian data, remain limited, this chapter adopts a universal approach: recommendations rest on the international evidence base and are stratified by the resources available rather than by geography, so that they apply equally in a tertiary sexual-medicine clinic and in a primary-care or district setting.

Primary versus Secondary Erectile Dysfunction

Guidelines classify ED along two axes. The first is timing, lifelong or primary ED, which is present from the very first sexual experience, versus acquired or secondary ED, which develops after a period of presumably normal function. The second is context, generalised (every partner, situation and type of stimulation) versus situational (related to specific circumstances).^{1,5}

Lifelong ED, the less common of the two, usually suggests a psychogenic, developmental or sometimes a congenital-anatomical etiology. A detailed developmental and psychosexual history is indicated before anyone reaches for pharmacotherapy. Acquired ED, the classic pattern observed in most clinic attenders, especially those past middle age, is typically organic or mixed. Vascular disease, nerve injury, hormonal changes, medication effects, or structural change (post-surgical, post-radiation, Peyronie's-disease-related) are superimposed on an aging vascular bed.^{1,2}

In practice, however, the distinction between organic and psychogenic is rarely clear-cut. The cases that a psychiatrist actually sees are mostly mixed: an organic substrate that is made worse by performance anxiety, relationship conflict, or an underlying depressive or anxiety disorder. The assessment approach set out below is designed to tease the two apart rather than assume one or the other from the outset.

Classification by underlying mechanism complements classification by timeline. ED can be organic (further subdivided into vasculogenic, neurogenic and endocrinologic subtypes), psychogenic, iatrogenic or mixed, set out in Table 1.⁶ Iatrogenic ED is usually kept as its own category rather than being folded into the other three, largely because the precipitant, a medication or a procedure, is identifiable and often reversible or substitutable once someone notices it. As with the lifelong/acquired split above, organic and psychogenic contributors coexist in most men who actually reach a clinic. This is why this guideline considers the two schemes as complementary lenses on the same patient, not competing diagnoses. Table 2 sets out each aetiological domain alongside its clinical pointers and its practical significance.

Performance anxiety is one of the psychogenic contributors, and deserves to be mentioned first, not at the end of a list. It is the most common psychological cause of erectile failure, and it accounts for somewhere between a tenth and a quarter of men. The loop that perpetuates this problem is easy to describe but difficult to break: one failure breeds anticipatory anxiety, the anxiety diverts attention away from erotic cues and towards self-monitoring, and the next attempt then fails for that reason alone.²⁶ Two other situational drivers are easy to miss in a routine consultation unless you specifically ask about them. The first is fear of an unplanned pregnancy or the lack or unreliability of contraceptive arrangements. The loss of an erection specifically related to condom use is well described and has a cycle of its own. Worrying about losing the erection while putting on or wearing a condom makes the loss more likely, which, in turn, undermines the motivation to continue using them.²⁷ The other is a mismatch between a man's sexual orientation and the sexual situation that he encounters. Sexual minority men do report worse erectile function than heterosexual men on average, but the difference largely disappears when the actual pattern of sexual practice is taken into account, and that is the clinically useful finding: sexual orientation is not itself a cause of erectile dysfunction and must never be treated as pathology.^{28,29} Situational ED can be due to context, a heterosexual marriage undertaken under coercion from family or society, concealment or the chronic pressure of minority stress, and that needs sensitive, non-judgemental history taking not a diagnosis.

Diagnostic Systems: ICD-10, ICD-11, DSM-5-TR and Non-Western Frameworks

The major diagnostic systems in current use do not fully agree on where ED belongs, or even how to define it, and that disagreement actually matters for how a psychiatrist frames the diagnosis for a patient in any cultural setting. Table 3 sets the systems side by side.

ICD-10

ICD-10 splits erectile dysfunction by presumed cause, which sounds tidy but rarely is in practice. F52.2, "Failure of genital response," sits in the mental and behavioural disorders chapter for cases judged non-organic, while N48.4, "Impotence of organic origin," sits instead in the genitourinary chapter.⁷ This has long been criticised as an artificial divide, since most real-world ED is mixed, and in practice clinicians often defaulted to whichever chapter matched their own specialty rather than the patient's actual pathophysiology.⁵

ICD-11

ICD-11 does away with that split entirely. Male erectile dysfunction is now coded HA01.1, within the block of Sexual Arousal Dysfunctions, itself part of a new stand-alone chapter, "Conditions Related to

Sexual Health,” deliberately moved out of the mental-disorders chapter to reduce stigma while keeping the diagnosis clinically usable.⁵ The core definition asks for an inability, or marked reduction in the ability, to attain or sustain a penile erection of sufficient duration or rigidity for sexual activity, occurring despite adequate desire and stimulation, present episodically or persistently over at least several months, and associated with clinically significant distress.⁵ Four sub-codes capture the lifelong/acquired and generalised/situational distinctions described earlier (HA01.10 lifelong generalised, HA01.11 lifelong situational, HA01.12 acquired generalised, HA01.13 acquired situational), and a separate qualifier axis, HA40, lets the clinician record aetiology, medical, psychological or behavioural, substance-related, or relational, without forcing everything into a single-cause label. Most ED does not fit neatly into one box anyway.⁵

DSM-5-TR

DSM-5-TR keeps Erectile Disorder (302.72/F52.21) inside the psychiatric manual's Sexual Dysfunctions chapter. To meet criteria, a man needs at least one of three symptoms, marked difficulty obtaining an erection, marked difficulty maintaining it until completion of the sexual activity, or a marked decrease in erectile rigidity, occurring on almost all or all occasions (roughly 75–100% of the time) for a minimum of six months, causing clinically significant distress, and not better explained by a non-sexual mental disorder, severe relationship distress or another significant stressor, a substance or medication, or another medical condition.⁸ Where the presentation is fully explained by a medical condition, it is coded as Erectile Dysfunction due to another medical condition rather than as a mental disorder. The lifelong/acquired, generalised/situational and severity specifiers track the ICD-11 structure closely, actually one of the few places the two systems were deliberately harmonised during the ICD-11 revision.^{5,8}

Non-Western and Integrative Frameworks

Across East and South-East Asia, formal diagnostic practice generally sits inside the same ICD-based biomedical framework used for drug licensing and guideline development, something reflected in the joint consensus work produced by regional sexual-medicine and men's-health societies.⁹ In much of mainland Chinese and Taiwanese practice, though, a Traditional Chinese Medicine syndrome differentiation, most often kidney-yang deficiency, liver-qi stagnation or damp-heat, still gets recorded alongside the biomedical diagnosis to guide adjunctive herbal or acupuncture treatment. It is integrative rather than alternative, two frameworks used together rather than one rivalling the other.

For a guideline intended for use across settings, the practical point is that idioms of distress around erectile failure, and beliefs about semen loss (Dhat) and vitality in particular, are described across

South Asia and in several other cultures and are not confined to any one region. ICD-11's shift toward a non-stigmatising, cause-neutral code may travel more comfortably across culturally diverse settings than either ICD-10 or DSM-5-TR manage to.

Is Erectile Dysfunction Recognised in Women?

“Erectile dysfunction” is, by convention, a male-specific term, but the clitoris is embryologically and physiologically the same kind of erectile tissue, engorging through the identical nitric-oxide/cyclic-GMP-mediated pathway that produces penile erection.¹⁰ ICD-11 reflects this structurally: Female Sexual Arousal Dysfunction (HA01.0) sits alongside Male Erectile Dysfunction (HA01.1) within the same Sexual Arousal Dysfunctions block, rather than in some unrelated category.⁵

Two further conditions push the parallel beyond a mere classification quirk. Clitoral priapism, a persistent and painful clitoral engorgement, usually drug-induced, is the direct analogue of penile priapism, and Persistent Genital Arousal Disorder (PGAD), uncontrolled genital arousal without any accompanying desire, is increasingly recognised as a distinct entity in its own right, occasionally traced to something as specific as a Tarlov cyst.¹¹ Cardiology literature, in particular, tends to discuss male ED and female sexual dysfunction together, as parallel markers of the same underlying vascular and endothelial process, especially in patients with cardiovascular disease or diabetes; PDE5 inhibitors have even been trialled, with mixed results, for female sexual arousal disorder itself.¹⁰

The practical takeaway here is straightforward: a woman's report of reduced arousal, lubrication or genital sensitivity, whether in the context of a partner's ED, a shared risk factor such as diabetes, or antidepressant use, deserves the same structured assessment the male partner's complaint would get, rather than being treated as incidental to it.

Assessment

The assessment should be contextual, not a one-size-fits-all script. It is neither necessary nor, in many resource-limited settings worldwide, even possible to run a full battery of tests on every man who walks in.^{1,2}

The difference between a flexible and an unsystematic assessment is that a flexible assessment will go through the same domains in the same order every time, and will simply address each to the depth allowed by the setting. Those domains, the ground each one needs to cover and what is realistic in a resource limited clinic vs a fuller specialist work-up are listed in Table 4, and the corresponding baseline investigations in Table 5.

Minimum Assessment in a Resource-Limited Setting

- A focused sexual and medical history: onset, course, whether the problem varies by situation, whether morning or nocturnal erections still occur, and how much alcohol, tobacco or recreational drugs are in the picture;
- A quick pass through medication and comorbidity history, diabetes, hypertension, cardiac disease, depression, and any prior pelvic, prostatic or spinal surgery;
- A brief physical examination: blood pressure, waist circumference rather than BMI alone (central obesity, defined as ≥ 94 cm in Caucasian men, with ethnic-specific cut-offs elsewhere, tracks ED severity and hypogonadism more closely than BMI does), peripheral pulses, and a genital examination for anything obvious, Peyronie's plaque, phimosis, testicular atrophy;⁶
- The five-item IIEF-5, also known as the Sexual Health Inventory for Men (SHIM), which takes under two minutes and grades severity reliably;¹²
- The IIEF-5 does not have to be administered in English. Linguistically validated Hindi, Urdu, Punjabi and Tamil versions were used to assess erectile function in a large primary-care study of South Asian and European men, which makes the instrument usable well beyond English-speaking clinic populations; Grover and Shouan's review of assessment scales for sexual disorders remains the practical reference for choosing between instruments, and for knowing which have been used in Indian samples.^{30,12}
- Fasting blood glucose or HbA1c and a basic lipid profile, where available, since both change management and flag cardiovascular risk that would otherwise go unnoticed.^{1,2}

Comprehensive Assessment

- A fuller physical examination than the minimum work-up calls for: secondary sexual characteristics, body hair distribution, gynaecomastia, muscle bulk, assessed alongside the genital exam, since reduced secondary sexual characteristics together with an increased waist circumference raise real suspicion for hypogonadism and should prompt actual metabolic and hormonal evaluation rather than a reflex prescription;⁶
- A detailed psychosexual history, ideally taken with the partner present or at least consulted, covering relationship quality, other sexual dysfunctions, and psychiatric comorbidity, depression, anxiety, psychosis, substance use;
- Morning total testosterone, repeated if low, with LH, FSH and prolactin added as indicated, in men with reduced libido, hypogonadal signs, or a poor response to first-line therapy;²
- Thyroid function and PSA in selected men, as ordinary good practice rather than something reflexively ordered in every case;¹
- Validated multi-domain instruments beyond the IIEF-5, the full 15-item IIEF, the Erection Hardness Scale, and the Sexual Encounter Profile, when a fuller picture, treatment-response

documentation, or research-grade records are actually needed. Grover and Shouan's review of assessment instruments for sexual disorders rates these among the strongest for validity, reliability and sensitivity to change in the arousal/erection domain, and Table 6 below draws directly on that review;¹²

- Specialised testing, nocturnal penile tumescence and rigidity testing, penile duplex Doppler ultrasonography, and, rarely, dynamic infusion cavernosometry or arteriography, kept for young men with a history of pelvic trauma, medico-legal evaluation, surgical or vascular-intervention candidates, or cases where the diagnosis still is not clear after standard work-up.^{1,2}

Screening for Co-occurring Premature Ejaculation

The thing most often missed in a man presenting with erectile dysfunction is premature ejaculation, because he doesn't volunteer it and the consultation does not ask. The two travel much more often than chance would dictate. In a community survey, PE was found in 19.5% of men with ED vs. 2.0% of those without, and ED in 76.3% of men with PE vs. 19.4% of those without, with odds of PE increasing markedly with increasing severity of ED.³² In a tertiary andrology cohort of 1258 men presenting with ED alone, one quarter had unreported concomitant PE once directly asked, and these men were younger and less comorbid than the ED only group.³³ Data from South Asia are similar: of 270 men attending a general health clinic in Southern India, PE was reported by 43.0% and ED by 47.8% and both were under-recognised by the treating physician relative to a structured research interview. In a linguistically matched primary-care study,³¹ South Asian men and women, with and without diabetes, reported PE significantly more frequently than did European men and women.³⁰ That gives rise to two things. Ejaculatory latency and control should be a routine part of the history in any man being evaluated for ED —an afterthought. Secondly, the importance of sequence: where the two co-exist erectile function generally needs to be addressed first, since restoring confidence in the erection often improves perceived control. Topical anaesthetics used for PE need caution in a man whose erection is already marginal.³⁴

When to Perform a Hormonal Assessment

Hormonal testing in ED: worth doing well, worth not doing reflexively. The Endocrine Society guidance is based on the concept that a diagnosis of hypogonadism requires symptoms and signs plus unequivocally and consistently low testosterone measured fasting in the morning on an accurate assay and confirmed on a repeat sample before any action is taken. Where total testosterone is near the lower limit, or where sex hormone-binding globulin is likely to be altered, free testosterone is required rather than a repeat total.³⁶ Timing of qualification for each test is presented in Table 7. There is one trigger that deserves particular attention of psychiatrists. Antipsychotic induced hyperprolactinaemia is a common, reversible and often missed cause of decreased libido and erectile difficulty in our patients.

When and to Whom to Refer

Knowing when to hand on, and to whom, is part of the pathway as much as knowing what to prescribe. Most men with ED can be assessed and started on treatment by a psychiatrist without any referral at all; the situations that genuinely need another pair of hands are reasonably well defined, and are listed in Table 8. Two worth flagging here. Where hypogonadism is confirmed rather than suspected, where prolactin is raised but no obvious drug cause, or where testosterone therapy is being considered in a man who also wants to have children, the two goals are diametrically opposed as testosterone suppresses spermatogenesis and endocrinology input is needed.^{2,35} When the problem unit is the couple and not the erection, referral to a sexual-medicine specialist or a trained psychosexual therapist is indicated; the clearest examples are unconsummated marriage and lifelong ED.

Management

Every source behind this chapter agrees on the same shape of treatment: start conservative, escalate only if you have to. Lifestyle change and an oral agent come first, then injectable or device options if that is not enough, surgery last. Psychological and couple-focused care is not a side-track added at the end; it runs through every step, which is what the pathway in Figure 1 is meant to show.^{1,2,3}

Pharmacological Management

First line. The four oral PDE5 inhibitors available, sildenafil, tadalafil, vardenafil and avanafil, sit at the top of the ladder, and for good reason: a large, consistent trial base, an acceptable safety margin, simple dosing.^{1,2,3,13} Which one gets picked usually comes down to half-life, whether food interferes with absorption, and cost, not any meaningful difference in how well they work (the kinetics and interactions are set out in Table 9). One newer point from the 2024 ICSM evidence review: in men with severe ED, or a poor response to a single agent, stacking two PDE5-inhibitor dosing strategies, or combining a PDE5 inhibitor with an intracavernosal or intraurethral vasoactive agent, is now an accepted next step rather than a jump straight to devices or surgery.^{3,13}

Dose stratification. Much of the safety of this class is in the starting dose and that dose should be tailored to the patient rather than standardized across the clinic. Age and organ dysfunction significantly modify sildenafil pharmacokinetics. Systemic exposure in men 65 years and older is approximately twice that of young men. Peak concentration is approximately 60-70% higher in men 65 years and older with systemic exposure approximately 2-fold higher in men 65 years and older than men less than 65 years of age. Severe renal impairment (creatinine clearance < 30 ml/min) further increases systemic exposure. Stable hepatic cirrhosis decreases oral clearance by about 46% and increases peak concentration by about 47%. Therefore, a dose of 25 mg is recommended with slower titration than usual in patients with severe impairment of renal or hepatic function.³⁶ The warnings

that accompany the oral agents are best kept together, not spread through the chapter. That is what Table 10 does. Absolute contraindication with nitrates and riociguat in any form. Longer nitrate-free interval after tadalafil than after the shorter-acting agents, owing to its half-life. Lowest effective dose with staggered timing in men already on an alpha-blocker. Dose reduction with strong CYP3A4 inhibitors.^{18,15,16} The corollary matters as much as the caution. Many apparent treatment failures reflect an inadequate trial rather than true non-response: in a series of 100 sildenafil non-responders, 45 had never used the highest recommended dose, and 31 responded once the dose was titrated and instructions on timing, food and sexual stimulation were corrected.⁴⁷ The on-demand dose should therefore be titrated to the highest tolerated licensed dose (sildenafil 100 mg, tadalafil 20 mg, vardenafil 20 mg, avanafil 200 mg), and a man should be considered a non-responder only after six to eight attempts at that dose with adequate sexual stimulation, as the earlier IPS guideline specified.^{23,47} In a dose-specific network meta-analysis of 83 placebo-controlled trials, the higher on-demand doses produced the larger effects (tadalafil 20 mg vs 10 mg, OR 7.13 vs 3.14; avanafil 200 mg vs 100 mg, OR 3.42 vs 1.75).⁴⁸ For tadalafil, the lowest effective dose depends on the regimen: 10 mg is the usual on-demand starting dose, titrated to 20 mg, whereas 2.5 mg is the lowest once-daily dose with randomised evidence of clinically important benefit, and 5 mg daily is the usual maintenance dose.^{46,49} Regulatory status varies between countries and should be confirmed locally; India illustrates the point. All four oral PDE5 inhibitors discussed in this chapter have been approved by the Central Drugs Standard Control Organisation (CDSCO) for erectile dysfunction. Vardenafil is available in 2.5, 5, 10 and 20 mg strengths (since 11 June 2018) and avanafil is available in 50, 100 and 200 mg strengths (since 26 February 2021). Sildenafil and tadalafil are well established, with tadalafil now available in additional dosage forms and as a fixed-dose combination with dapoxetine for concomitant ED and premature ejaculation.^{42,43,44} One CDSCO condition is of special emphasis in a psychiatry-led guideline. The Subject Expert Committee recommended avanafil be sold by retail only on the prescription of cardiologists, psychiatrists or urologists. This puts us explicitly among the recognised prescribers for this class rather than at its fringes. Alprostadil is also available in India by prescription only. What differs in practice then is not approval but stocking and out-of-pocket cost. Selection within the class should then still be from what is really obtainable and affordable for the man in front of you. The position is summarised in Table 11.

Second line. Intracavernosal injection (alprostadil alone, or bimix/trimix combinations with papaverine and phentolamine) and intraurethral or topical alprostadil remain the standard second-line options. They work in most men regardless of the underlying cause, but needle-related anxiety, priapism risk, and simple drop-out over time all limit how well they actually get used.^{3,13}

Hormonal therapy. Testosterone replacement belongs only in men with biochemically confirmed hypogonadism and compatible symptoms, never as an empirical add-on to ED treatment. The 2025 EAU update is explicit that correcting testosterone alone rarely restores erectile function in a man whose baseline level was normal to begin with.²

Combination and adjunctive pharmacotherapy. For men with only a partial response to a PDE5 inhibitor alone, a few add-ons genuinely help, modestly, but without adding much to the side-effect burden. Nitric-oxide precursors, L-arginine and L-citrulline, and the combination of propionyl-L-carnitine with acetyl-L-carnitine, enhance endothelial NO availability and have shown incremental benefit layered onto a PDE5 inhibitor; daily low-dose tadalafil added to on-demand sildenafil has similarly outperformed either drug alone in men with severe ED.¹⁴ Smaller studies also report gains from adding folic acid, a statin, metformin, or an ACE inhibitor to PDE5-inhibitor therapy, particularly in men with diabetes or metabolic syndrome, though the evidence here remains single-trial rather than a consistent body of replication.¹⁴ None of this replaces first-line therapy or the lifestyle measures described under Non-Pharmacological Management; it is best thought of as a low-risk second step worth trying before intracavernosal injection or a device, especially when the non-response looks partial rather than complete.

Non-Pharmacological Management

Modification of risk factors and lifestyle change. Weight loss, exercise, smoking cessation, reduced alcohol intake and tighter control of diabetes and hypertension belong alongside drug treatment and improve the efficacy of PDE5 inhibitors and of any later surgery.^{1,2,13} Exercise has its own true dose-response relationship: at least 18 metabolic-equivalent hours a week, about six hours of easy walking, 3.5 hours of brisk walking, or two hours of running, correlates with measurably better erectile function, an effect probably mediated by higher serum testosterone and by reducing obesity-related inflammation, in addition to the direct vascular benefit.¹⁴ Sedentary behaviour does the opposite, increasing ED risk in a dose-dependent manner, making “become more active” something other than vague advice, something tangible and measurable. Another first-contact option worth being aware of is topical therapy. Alprostadil cream and MED3000 (marketed as Eroxon) are the first topical agents to receive FDA approval and the latter is now available over the counter. Both produce an erection in about ten minutes in roughly half of users. The mechanism is thermal, nerve-stimulating rather than vascular. Adverse effects are generally mild and mainly local.¹⁴ Vacuum erection devices are suitable for men who prefer to avoid medication altogether, or who are unable to take a PDE5 inhibitor due to nitrate therapy or unstable angina.^{19,13}

The evidence for the device is better than its reputation would suggest. In a systematic review and meta-analysis of 18 studies with 1065 men with refractory ED in 2025, an overall efficacy of 0.80 (95% CI 0.76-0.84) for successful or satisfying intercourse was found, with subgroup rates of 82.9% for mixed-aetiology ED, 84.5% for post-radical prostatectomy, 73.0% for diabetes and 71.8% for spinal cord injury. Penile bruising was the most frequent adverse effect, pooled at 24.3% and even higher after spinal cord injury, and drop-out rather than lack of efficacy limits the device in practice.³⁷ Low-intensity extracorporeal shockwave therapy (LI-ESWT) has progressed from experimental to conditional for the treatment of mild-to-moderate vasculogenic ED, alone or in combination with a PDE5 inhibitor, in the AFU/SFMS 2024 guideline and in the position statement from the Asia-Pacific Society for Sexual Medicine. Both point out the heterogeneous treatment protocols and call for larger trials before this can replace established first-line treatment.^{13,20}

We have been able to group the energy-based therapies for grading. A 2025 meta-analysis of 32 randomised controlled trials and 1,986 men grouped low-intensity extracorporeal shockwave therapy, low-intensity pulsed ultrasound and electromagnetic-field treatment under the single heading of micro-energy treatment, and found erectile function significantly better than control at one, three, six and twelve months. No single energy source was clearly superior; vasculogenic ED responded better than neurogenic ED, twice-weekly sessions better than weekly sessions, courses longer than four weeks added no benefit, and micro-energy treatment combined with standard therapy outperformed either alone.³⁸ This provides Level 1 evidence for efficacy to these modalities, but the recommendation is conditional as the protocols are heterogeneous and the long-term durability is unproven and this is much where the AFU/SFMS and Asia-Pacific statements are positioned^{13,20}. In many settings, availability and out-of-pocket cost, rather than evidence, are the binding constraints, and neither should be permitted to displace a well-conducted trial of first line therapy.

Psychological and relationship care. Performance anxiety, relationship strain, and a comorbid depressive or anxiety disorder require direct attention along with any physical treatment, sometimes as the primary treatment when ED is predominantly psychogenic, more often as what actually makes drug treatment work in mixed and organic cases. This is where psychiatry has something to offer that urology alone does not.^{1,2}

This claim can be grounded on a base of evidence rather than left as professional advocacy. A Cochrane review of 11 randomised and quasi-randomised trials in 398 men showed group psychotherapy was more effective than no treatment in reducing persistence of ED (RR 0.40, 95% CI 0.17-0.98; NNT 1.61) and this benefit remained at six months (RR 0.43, 95% CI 0.26-0.72). Focused

sex-group therapy did even better (RR 0.13, 95% CI 0.04-0.43). Group therapy added to sildenafil was better than sildenafil alone (RR 0.46, 95% CI 0.24-0.88; NNT 3.57) and, as importantly as the efficacy numbers, men in the combination group were far less likely to drop out of treatment (RR 0.29, 95% CI 0.09-0.93).^{39,40} An umbrella review of 98 meta-analyses involving almost four million participants reached a consistent conclusion. The effects of psychological and behaviour change interventions were similar to drugs but the confidence intervals were wider because the trials were smaller and more heterogeneous.⁴¹ Table 12 gives the status of each non-pharmacological modality.

Surgical treatment. The outcome data are uniformly good wherever the procedure has been studied. Penile prosthesis insertion is reserved for men who fail, or cannot tolerate, medical and device options, or simply want a permanent solution. Penile revascularisation is a more limited option, reserved mainly for young men with isolated arteriogenic ED after pelvic trauma and without wider vascular disease.^{19,13} It is worth mentioning candidate screening separately from the surgery itself. Urologists have an acronym for a personality pattern that predicts post-operative dissatisfaction no matter how well the operation itself goes, and that is CURSED, for compulsive/obsessive, unrealistic, revision-seeking, surgeon-shopping, entitled, and psychiatric.¹⁴ This is the role of a psychiatric opinion in the surgical pathway, not to gatekeep the procedure but to identify men who need more extensive counselling, realistic expectation setting or treatment of an underlying condition before insertion of an irreversible device.

The Pharmacist's and Primary-Care Role

The extent to which ED management has moved to first-contact and self-care settings is usefully described in the 2025 handbook for pharmacists by the International Pharmaceutical Federation. This framework enables pharmacists to identify red-flag features that require referral, provide lifestyle advice, advice on the use of PDE5-inhibitors and to identify men with ED who may have undiagnosed cardiovascular disease or diabetes. This is particularly important wherever access to specialist sexual-medicine clinics is limited, as it is outside the major cities in many low- and middle-income countries.²¹ AGREE II independently examined published ED guidelines and found the methodological quality to be highly variable. Only five of the 17 guidelines that were reviewed – Cancer Care Ontario, EAU, AUA, American College of Physicians and the Japanese Society for Sexual Medicine – were considered to meet a high quality threshold. Independent funding for development made a quantifiable difference.²² It is worth remembering that the provenance of a guideline, or the society behind it, is not automatically evidence of rigour. Table 13 purposefully draws on sources with a transparent systematic review and grading process, not reputation.

Additional Clinical Considerations

Other Vascular Disorders and Heart Disease

Sexual activity is associated with a cardiovascular demand of similar magnitude as climbing two flights of stairs. The Second Princeton Consensus Conference developed a three-tier risk assessment approach that remains the standard for determining the safety of resuming sexual activity and using a PDE5 inhibitor in a man with cardiac disease (Table 14).¹⁸ Low risk men can be managed with first line ED treatment in primary care. Intermediate risk men require cardiology opinion before any decisions are made. High risk men should be deferred from sexual activity and PDE5 inhibitors withheld until cardiac status is stabilised and reassessed.¹⁸ The same rule applies to all risk categories that a PDE5 inhibitor should never be combined with a nitrate in any form and the time between the two depends on the PDE5 inhibitor used, with the longest time for tadalafil given its half-life.¹⁸ More generally, ED is now recognized as an early marker rather than a late complication of vascular disease other than coronary disease. ED often precedes a clinical cardiac event by 2 to 5 years, so a new complaint of ED, especially in a man younger than 60 years, should prompt evaluation of cardiovascular risk factors, even in the absence of other symptoms.¹⁰ The same endothelial mechanism applies to peripheral arterial disease, prior stroke, and poorly controlled hypertension, as does the same general caution about combining vasodilators. Hypertension alone is not a contraindication to PDE5 inhibitors, but the added antihypertensive load increases the risk of symptomatic hypotension, so the low-starting-dose approach in older adults (Table 10) applies here too.

Young men and adolescents

ED was previously believed to be rare in men prior to middle age. Recent surveys of men aged 18–40 tell a different story: ED symptoms in well over half of respondents, and prior use of ED medication in close to two in five, obtained more often from primary care than from a specialist, but with a real minority sourced through direct-to-consumer online platforms without any clinical assessment. The two most common reasons given by men for how they chose to get treatment were privacy concerns and cost.²⁵ In this age group, most ED is still psychogenic, performance anxiety, relationship difficulty or a mismatch between expectation and experience, but organic causes, undiagnosed diabetes or hypogonadism, pelvic or perineal trauma, medication effects and substance use including cannabis, still need to be actively excluded rather than dismissed simply because of the patient's age.²⁵ PDE5 inhibitors are not licensed for use in minors, and prescribing them off-label to an adolescent should be an exception made after careful assessment, not the default response to a presenting complaint. The psychiatrist's real contribution in this age group is treating performance anxiety and any underlying mood, anxiety or substance-use disorder as primary management, addressing pornography-related expectation and relationship factors directly, before or alongside any pharmacological trial, and keeping the threshold for excluding an organic cause low rather than assuming psychogenic ED by default.

Conclusion

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474 Erectile dysfunction is rarely a single-cause problem. Vascular, neurogenic, endocrine, iatrogenic and
475 psychogenic contributors overlap in most men who actually reach a clinic, and even the diagnostic
476 label shifts depending on which system is used, ICD-11 is the first to drop the organic/non-organic split
477 that ICD-10, and in its own way DSM-5-TR, still carries. None of that complexity needs to slow down
478 first contact, though: a focused history, a brief examination and the five-item IIEF-5 are enough to
479 start most men on treatment, with laboratory testing and specialised investigation reserved for the
480 cases that actually need them.

481 All the major guidelines discussed here follow the same stepped logic to management with lifestyle
482 change and an oral PDE5 inhibitor first, then injectable or device options, then surgery. Psychological
483 and couple-focused care is threaded through every step rather than confined to one. PDE5 inhibitors
484 remain the most effective, best-tolerated first step for most men, and the choice between agents is a
485 matter of pharmacokinetics and patient preference more than efficacy. The same pathway is adjusted
486 rather than abandoned where the clinical context demands it: lower starting doses for older men and
487 those with renal or hepatic impairment (Table 10), closer cardiovascular coordination for men with
488 cardiac or other vascular disease, and, in young men, a much lower threshold for treating the
489 psychological driver as the primary problem. In every case, an adequate trial means titration to the
490 highest tolerated dose before an agent is judged ineffective.

491 What this chapter has tried to hold onto throughout is that ED is a psychiatric concern as much as a
492 urological one. It is frequently the first visible sign of otherwise silent cardiovascular or metabolic
493 disease, it responds to psychological and couple-focused treatment in its own right, and it sits at
494 exactly the intersection of body and relationship that psychiatric practice is built to address. Few
495 settings yet have a unified, psychiatry-led guideline on ED. This chapter, prepared for the IPS Clinical
496 Practice Guidelines for Psychosexual Health, Dysfunction and Disorders, builds on the Society's earlier
497 guidance and follows a universal, resource-stratified approach so that it can serve clinicians wherever
498 they practise while the region-specific evidence base continues to grow.

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Table 1. *Etiopathogenesis-based classification of erectile dysfunction, drawn from Crocetto et al. and the wider literature cited in this chapter.*⁶

Category	Subtype	Typical mechanism	Representative examples
Organic – vasculogenic	Arteriogenic, veno-occlusive, or both	Inadequate arterial inflow and/or excessive venous leakage; the commonest organic form	Atherosclerosis, diabetes-related vascular disease, pelvic radiotherapy
Organic – neurogenic	Central or peripheral	Disruption of the neural pathways governing the erectile reflex	Spinal cord injury, pelvic/prostate surgery, diabetic or non-diabetic neuropathy, multiple sclerosis
Organic – endocrinologic	Hormonal	Hormonal imbalance affecting libido and/or erectile capacity	Hypogonadism, hyperprolactinaemia, thyroid dysfunction, adrenal insufficiency

Psychogenic	Generalised or situational	Performance anxiety, depressive or anxiety symptoms, relationship distress	New-relationship anxiety, depressive illness, unresolved conflict; often situational early on
Iatrogenic	Drug-induced or procedure-induced	An identifiable, often reversible or substitutable precipitant	Antihypertensives, antidepressants, antiandrogens; pelvic surgery or radiotherapy
Mixed*	Combination of the above	Organic substrate compounded by a psychological or iatrogenic contributor	Most presentations past midlife; the pattern this chapter's assessment pathway is built around

*Most men seen in clinic fall into the mixed category.

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Table 2. Comprehensive aetiological framework for erectile dysfunction, setting each domain alongside its clinical pointers and its relevance to clinical practice.

Aetiological domain	Representative causes	Clinical pointers	Why it matters in clinical practice
Vasculogenic	Atherosclerosis, hypertension, dyslipidaemia, diabetes, smoking, pelvic radiotherapy, veno-occlusive dysfunction	Gradual onset; loss of morning and nocturnal erections; coexisting cardiovascular risk factors	The commonest organic substrate past midlife, and often the first visible sign of silent vascular disease ^{1,2,6}
Neurogenic	Spinal cord injury, diabetic and non-diabetic neuropathy, multiple sclerosis, stroke, pelvic or prostatic surgery	Abrupt onset after injury, stroke or surgery; associated bladder or bowel symptoms	Post-stroke and post-surgical ED is common and rarely asked about ⁶
Endocrinologic	Hypogonadism, hyperprolactinaemia, thyroid dysfunction, poorly controlled diabetes, chronic kidney disease	Reduced libido, gynaecomastia, loss of body hair, small or soft testes	Warrants a structured hormonal work-up and, where confirmed, endocrinology input (Tables 7 and 8) ^{2,35}
Iatrogenic and substance-related	Antihypertensives, antidepressants and antipsychotics, antiandrogens, opioids; alcohol, tobacco and cannabis	Clear temporal link to a new drug, a dose change or a period of heavy use; often reversible or substitutable	Psychotropic-related ED is squarely a psychiatric responsibility; smoking, cannabis use, diabetes and hypertension each independently raise risk in community data ^{4,6}
Psychogenic	Performance anxiety; depressive and anxiety disorders; relationship conflict; fear of unplanned pregnancy or absent contraception; condom-associated erection loss; mismatch between orientation and sexual context; semen-loss (Dhat) and vitality beliefs	Situational or abrupt onset; morning erections preserved; difficulty confined to a particular partner, setting or method	The domain where psychiatry contributes most; semen loss through masturbation or nocturnal emission is among the commonest explanations men themselves put forward, particularly in South Asian settings ^{26,27,28,29,31}
Mixed	An organic substrate compounded by a psychological or iatrogenic contributor	The usual picture in men who actually reach a clinic	Assessment should assume a mixed aetiology unless the history clearly indicates otherwise ^{1,2}

Abbreviations: ED, erectile dysfunction.

659 **Table 3.** *Erectile dysfunction across the major diagnostic systems.*

System	Location / code	Core requirement	Distinctive feature
ICD-10	F52.2 (non-organic) or N48.4 (organic)	Failure of genital response / impotence of organic origin	Splits ED by presumed cause across two different chapters ⁷
ICD-11	HA01.1, in “Conditions Related to Sexual Health”	Marked reduction in ability to attain/sustain erection ≥ several months, with distress	Single cause-neutral code; moved out of mental-disorders chapter; separate aetiology qualifier (HA40) ⁵
DSM-5-TR	302.72 / F52.21, Erectile Disorder	≥ 1 of 3 symptoms, on 75–100% of occasions, ≥ 6 months, with distress	Remains in the psychiatric manual; excludes cases fully explained by another medical condition ⁸
Chinese integrative practice	Biomedical ICD code plus TCM syndrome (bianzheng)	Biomedical criteria for diagnosis; TCM pattern for adjunctive treatment	Two parallel frameworks used together, not a rival classification ⁹

660 *Abbreviations:* DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; ED,
661 erectile dysfunction; ICD, International Classification of Diseases; ICD-10, International Classification of Diseases,
662 10th Revision; ICD-11, International Classification of Diseases, 11th Revision; TCM, Traditional Chinese Medicine.

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Table 4. Domain-wise framework for the assessment of erectile dysfunction, showing what each setting can reasonably be expected to cover.

Domain	What to cover	Minimum (resource-limited)	Comprehensive assessment
Sexual history	Onset and course; situational versus generalised; morning and nocturnal erections; rigidity; frequency and circumstances of attempts; partner factors; contraceptive arrangements and any fear of unplanned pregnancy	Essential	Essential, with partner corroboration where consented
Psychiatric and psychosexual history	Performance anxiety; depression, anxiety, psychosis; substance use; relationship conflict; the context of the sexual relationship, including orientation where relevant; semen-loss and vitality beliefs	Essential	Essential; structured, with a partner interview where the patient consents
Medical and drug history	Diabetes, hypertension, cardiac, renal and hepatic disease; pelvic, prostatic or spinal surgery; every prescribed drug; alcohol, tobacco, cannabis and opioids	Essential	Essential, with formal medication reconciliation
Examination	Blood pressure, waist circumference, peripheral pulses, genital examination, secondary sexual characteristics	Focused examination	Full examination, including assessment for hypogonadal signs
Instruments	IIEF-5 / SHIM for severity; a validated premature-ejaculation screen; further domain measures where a fuller picture is needed	IIEF-5 alone	Full 15-item IIEF, Erection Hardness Scale, Sexual Encounter Profile, plus PE screening
Investigations	Cardiometabolic screening; hormonal panel where indicated; specialised testing in selected men	Glucose or HbA1c and lipids where available	As set out in Tables 5 and 7

Abbreviations: HbA1c, glycated haemoglobin; IIEF, International Index of Erectile Function; IIEF-5, five-item International Index of Erectile Function; PE, premature ejaculation; SHIM, Sexual Health Inventory for Men.

669 **Table 5.** Recommended baseline investigations in the assessment of erectile dysfunction, stratified by
670 setting.

Investigation	Minimum / resource-limited setting	Comprehensive assessment	Rationale
History and focused examination (BP, waist circumference, peripheral pulses, genital exam, secondary sexual characteristics)	Always	Always, plus corroborating partner interview	Identifies reversible contributors and red flags ^{1,2}
IIEF-5 / SHIM	Always	Always, plus full 15-item IIEF for a fuller domain profile	Grades severity and tracks treatment response ¹²
Fasting blood glucose or HbA1c	Yes, where available	Yes	Diabetes is a leading organic cause of ED ^{1,2}
Fasting lipid profile	Yes, where available	Yes	Shared vascular risk-factor profile with cardiovascular disease ^{1,2}
Morning total testosterone	Only if reduced libido or hypogonadal signs	Routine in comprehensive work-up; repeat if low, with LH, FSH and prolactin added as indicated	Detects treatable hypogonadism ²
Thyroid function, PSA	Not routine	Selected cases, per general age-based screening practice rather than reflexively	General good practice, not ED-specific ¹
Nocturnal penile tumescence testing, penile duplex Doppler ultrasound, cavernosometry/arteriography	Not indicated	Reserved for young men with pelvic trauma, surgical/vascular-intervention candidates, or medico-legal evaluation	Distinguishes organic subtype where the answer changes management ^{1,2}

671 *Abbreviations:* BP, blood pressure; ED, erectile dysfunction; FSH, follicle-stimulating hormone; HbA1c, glycated
672 haemoglobin; IIEF, International Index of Erectile Function; IIEF-5, five-item International Index of Erectile
673 Function; LH, luteinising hormone; PSA, prostate-specific antigen; SHIM, Sexual Health Inventory for Men.

Table 6. Validated instruments for the assessment of erectile function, condensed from Grover and Shouan's review of assessment scales for sexual disorders and restricted here to the arousal/erection domain.¹²

Instrument	What it captures	Where it fits
IIEF-5 / SHIM (5 items)	Overall erectile function severity, brief screen	Minimum assessment, every setting
IIEF (15 items, full scale)	Desire, erectile function, orgasm, satisfaction, overall satisfaction across five domains	Comprehensive assessment, treatment-response monitoring
Erection Hardness Scale (EHS)	Single-item, patient-rated erection hardness (grade 1–4)	Quick clinic or trial outcome measure
Sexual Encounter Profile (SEP)	Event-based diary of penetration and maintenance success per attempt	Treatment-response tracking over time

Abbreviations: EHS, Erection Hardness Scale; IIEF, International Index of Erectile Function; IIEF-5, five-item International Index of Erectile Function; SEP, Sexual Encounter Profile; SHIM, Sexual Health Inventory for Men.

Table 7. *When to perform hormonal assessment in erectile dysfunction, and what to do with the result.*

Test	When to order it	How to interpret and act
Fasting morning total testosterone	Reduced libido; hypogonadal signs (small testes, sparse body hair, gynaecomastia); poor response to a PDE5 inhibitor; chronic opioid use; type 2 diabetes or obesity; chronic kidney disease	Repeat on a second morning before acting; a single low value is not a diagnosis ³⁵
Free or calculated free testosterone	Total testosterone near the lower limit of normal, or any condition altering sex hormone-binding globulin (obesity, diabetes, thyroid or liver disease, ageing)	Equilibrium dialysis, or estimation using an accurate formula ³⁵
LH and FSH	Confirmed low testosterone, to separate primary from secondary hypogonadism	Distinguishes a testicular from a pituitary or hypothalamic cause and directs referral ^{2,35}
Serum prolactin	Low testosterone with low or normal LH; galactorrhoea; visual field symptoms; any antipsychotic or other dopamine-blocking drug	Antipsychotic-induced hyperprolactinaemia is common, reversible and frequently missed ²
Thyroid function	Clinical suspicion of thyroid disease; unexplained loss of libido	Good general practice, not a reflex test in every man with ED ¹
HbA1c or fasting glucose, and lipids	Every man presenting with new ED	Cardiometabolic screening rather than hormonal assessment as such ^{1,2}

Abbreviations: ED, erectile dysfunction; FSH, follicle-stimulating hormone; HbA1c, glycated haemoglobin; LH, luteinising hormone; PDE5, phosphodiesterase type 5.

Table 8. Referral pathway for erectile dysfunction: who to involve, when, and what each referral contributes.

Refer to	Trigger for referral	What the referral adds
Cardiology	Intermediate or high cardiovascular risk on Princeton stratification; new ED with multiple risk factors or with exertional symptoms	Restratifies risk before sexual activity and PDE5-inhibitor use are permitted ¹⁸
Endocrinology	Confirmed or persistently low testosterone; hyperprolactinaemia without an obvious drug cause; suspected pituitary lesion; poorly controlled diabetes; hypogonadism in a man wanting fertility	Cause-specific work-up and safe supervision of testosterone therapy ^{2,35}
Urology or andrology	Peyronie's disease, phimosis, penile or pelvic trauma; failure of oral and second-line therapy; candidacy for prosthesis or revascularisation; abnormal prostate findings	Specialised testing and the surgical options ^{1,2}
Sexual medicine, sexologist or trained psychosexual therapist	Unconsummated marriage; lifelong ED; prominent performance anxiety; couple conflict as the dominant issue; a mismatch between orientation and sexual context needing sensitive exploration	Structured sex therapy and couple work, which the trial evidence supports in its own right ^{39,40}
Nephrology	ED with advanced chronic kidney disease or on maintenance dialysis	Dose adjustment, and consideration of transplantation where feasible ²⁴
Back to psychiatry, from other specialties	Depression, anxiety or substance use driving the presentation; psychotropic-induced ED; a CURSED profile before prosthesis surgery	Treatment of the primary disorder, and realistic expectation-setting ¹⁴

Abbreviations: CURSED, compulsive/obsessive, unrealistic, revision-seeking, surgeon-shopping, entitled and psychiatric (a personality profile that predicts dissatisfaction after penile prosthesis surgery); ED, erectile dysfunction; PDE5, phosphodiesterase type 5.

691 **Table 9.** *Characteristics of the oral phosphodiesterase type 5 (PDE5) inhibitors licensed for erectile*
692 *dysfunction.*^{15,16,17}

Agent	Onset	Tmax	Half-life	Usual dose range	Food effect	Key adverse effects	Notable interactions
Sildenafil	≈30–60 min	≈60 min	≈4 h	25–100 mg, on demand (max once/day)	High-fat meal delays/reduces absorption	Headache, flushing, dyspepsia, nasal congestion, visual disturbance (blue tinge, photophobia via PDE6 cross-reactivity), rare NAION	Nitrates and riociguat (contraindicated); alpha-blockers; strong CYP3A4 inhibitors (ritonavir, ketoconazole, itraconazole) – reduce dose
Vardenafil	≈30 min (ODT formulation faster)	≈60 min	≈4–5 h	5–20 mg, on demand; ODT 10 mg	High-fat meal delays Tmax	Similar profile to sildenafil; caution with QT prolongation	As sildenafil; avoid with Class IA/III antiarrhythmics and other QT-prolonging drugs; strong CYP3A4 inhibitors
Tadalafil	≈30–60 min (full effect up to 2 h)	≈2 h	≈17.5 h (longest)	On demand: start 10 mg, titrate to 20 mg (maximum). Once daily: 2.5 mg (lowest effective dose) to 5 mg ^{46,48}	Unaffected by food	Headache, dyspepsia, flushing (less common), distinctive back pain/myalgia	Nitrates and riociguat (contraindicated – caution extends beyond dosing window given long half-life); alpha-blockers (doxazosin specifically flagged); strong CYP3A4 inhibitors
Avanafil	≈15 min (fastest)	≈30–45 min	≈5 h	50–200 mg, on demand	High-fat meal delays Tmax modestly	Headache, flushing, nasal congestion; lower rate of visual and	Nitrates and riociguat (contraindicated); alpha-blockers;

						myalgia effects (higher PDE5 selectivity)	strong CYP3A4 inhibitors
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Nitrates in any form, and riociguat, are absolutely contraindicated with every agent in this class regardless of dose or timing, because of the risk of severe, potentially fatal hypotension; alpha-blockers may be co-administered but require the lowest effective PDE5i dose and, where possible, staggered timing, for the same reason.¹⁸ *Abbreviations:* CYP3A4, cytochrome P450 3A4; h, hours; max, maximum; mg, milligrams; min, minutes; NAION, non-arteritic anterior ischaemic optic neuropathy; ODT, orally disintegrating tablet; PDE5, phosphodiesterase type 5; PDE5i, phosphodiesterase type 5 inhibitor; PDE6, phosphodiesterase type 6; QT, QT interval on the electrocardiogram; Tmax, time to peak plasma concentration.

Table 10. Risk-stratified prescribing of oral phosphodiesterase type 5 (PDE5) inhibitors, bringing the dose adjustments and precautions for sildenafil, tadalafil, vardenafil and avanafil into a single table.

Patient group	Starting dose and adjustment	Precautions
Healthy adult, no relevant comorbidity	Sildenafil 50 mg, tadalafil 10 mg, vardenafil 10 mg or avanafil 100 mg on demand; titrate by response and tolerability up to the maximum on-demand dose (sildenafil 100 mg, tadalafil 20 mg, vardenafil 20 mg, avanafil 200 mg) before declaring non-response ^{23,47}	Standard counselling on timing, food effect and the need for sexual stimulation ^{1,2}
Older adults (65 years and above)	Start at the lowest dose in the range, for example sildenafil 25 mg; titrate slowly	Roughly twofold higher exposure; review the whole drug list for hypotension-prone agents; watch for postural hypotension and falls ^{36,17}
Severe renal impairment (creatinine clearance under 30 ml/min) or on dialysis	Sildenafil 25 mg, with slower up-titration	Reduced clearance; monitor blood pressure closely; hormone replacement only where hypogonadism is biochemically confirmed ^{24,36}
Hepatic impairment (cirrhosis, Child-Pugh A or B)	Sildenafil 25 mg	Oral clearance falls by about 46%; avoid in severe hepatic failure ³⁶
On alpha-blocker therapy	Lowest effective PDE5-inhibitor dose; stagger the timing of the two drugs where possible; ensure the alpha-blocker is on a stable dose first	Symptomatic hypotension; doxazosin is specifically flagged with tadalafil ¹⁸
On strong CYP3A4 inhibitors (ritonavir, ketoconazole, itraconazole)	Reduce the dose and lengthen the dosing interval	Markedly raised PDE5-inhibitor concentrations ^{15,16}
On nitrates or riociguat, in any form	Absolutely contraindicated, at any dose	Risk of severe and potentially fatal hypotension; the nitrate-free interval is longest for tadalafil given its half-life ¹⁸
Intermediate or high cardiovascular risk	Defer the treatment decision until cardiology has restratified the patient	See Table 14 for the Princeton categories ¹⁸

Abbreviations: CYP3A4, cytochrome P450 3A4; mg, milligrams; ml/min, millilitres per minute; PDE5, phosphodiesterase type 5.

Table 11. *Illustrative national regulatory status: approval status in India of the agents, as recorded in Central Drugs Standard Control Organisation new-drug approval listings.*

Agent	CDSCO status	Approved strengths	Note for practice
Sildenafil	Long approved and widely marketed for erectile dysfunction	25, 50, 100 mg	The reference agent, and generally the least expensive
Tadalafil	Approved; additional dosage forms subsequently cleared (oral jelly 20 mg, 16.02.2024); fixed-dose combination with dapoxetine approved for co-existing ED and premature ejaculation ⁴⁴	2.5, 5, 10, 20 mg	Longest half-life; the dapoxetine combination is directly relevant where PE coexists (see Screening for Co-occurring Premature Ejaculation)
Vardenafil	Approved 11 June 2018, bulk and tablets, for erectile dysfunction in adult men ⁴²	2.5, 5, 10, 20 mg	Orally disintegrating formulation useful where a rapid, predictable onset is wanted
Avanafil	Approved 26 February 2021, bulk and tablets ⁴³	50, 100, 200 mg	CDSCO condition: retail sale only on the prescription of a cardiologist, psychiatrist or urologist ⁴³
Alprostadil	Marketed in India on prescription	Varies by preparation	Second-line; intracavernosal and intraurethral routes (see Pharmacological Management)
MED3000 (topical gel)	No CDSCO approval identified at the time of writing	Not applicable	Discussed under Non-Pharmacological Management as an international development rather than a currently available Indian option

Abbreviations: CDSCO, Central Drugs Standard Control Organisation; ED, erectile dysfunction; MED3000, topical gel formulation marketed as Eroxon; mg, milligrams; PE, premature ejaculation.

Table 12. Level of evidence for the non-pharmacological management of erectile dysfunction, covering psychological, mechanical and energy-based modalities; supporting sources are cited in the final column.

Modality	Strength of evidence	Practical note
Lifestyle and risk-factor modification	Strong	Belongs alongside every other treatment and improves cardiovascular risk at the same time ^{41,14}
Psychological and sex therapy, individual or group	Moderate; consistent direction, small trials	Effective alone and as an adjunct, and it improves adherence to PDE5 inhibitors ^{39,40}
Couple-based and partner-inclusive work	Moderate	Particularly relevant where relationship conflict or unconsummated marriage is central ^{3,39}
Vacuum erection device	Moderate to strong in refractory ED	Bruising in roughly a quarter; drop-out is the main practical limitation ³⁷
Micro-energy treatment (LI-ESWT, LIPUS, electromagnetic field)	Level 1 evidence for efficacy; conditional recommendation	Best in vasculogenic ED; twice weekly, four weeks or less; availability and cost limit use in many settings ^{38,13,20}
Topical agents (alprostadil cream, MED3000)	Emerging	Availability varies considerably between countries ¹⁴
Penile prosthesis	Strong in refractory cases	Screen for the CURSED personality profile before referral ^{14,19}

Abbreviations: CURSED, compulsive/obsessive, unrealistic, revision-seeking, surgeon-shopping, entitled and psychiatric (a personality profile that predicts dissatisfaction after penile prosthesis surgery); ED, erectile dysfunction; LI-ESWT, low-intensity extracorporeal shockwave therapy; LIPUS, low-intensity pulsed ultrasound; MED3000, topical gel formulation marketed as Eroxon; PDE5, phosphodiesterase type 5.

719 **Table 13.** First-line and second-line pharmacological recommendations across the major international
720 erectile dysfunction guidelines and professional bodies reviewed for this chapter, with each source's
721 distinguishing emphasis.^{1,2,3}

Guideline / body	First line	Second line	Distinguishing emphasis
AUA ¹	Oral PDE5 inhibitors	Intracavernosal injection, VED, intraurethral alprostadil	Frames ED explicitly as a cardiovascular risk marker, not just a nuisance symptom, and leans heavily on shared decision-making
EAU ²	Oral PDE5 inhibitors, lifestyle optimisation	ICI, VED, combination therapy	Builds a hypogonadism work-up directly into a systematic, personalised diagnostic pathway
ICSM 2024 ³	Oral PDE5 inhibitors	Combination PDE5i + ICI/intraurethral alprostadil	A global, GRADE-rated consensus that weighs partner and psychosocial outcomes alongside erectile function itself
CUA ¹⁹	Oral PDE5 inhibitors	VED, ICI	Uses a GRADE and evidence-to-decision framework, with an eye to access and cost in a public-insurance setting
AFU/SFMS ¹³	Oral PDE5 inhibitors (Grade A)	Alprostadil (ICI/intraurethral), combination therapy, LI-ESWT (mild-moderate ED)	Grades every recommendation A–C and goes furthest of any guideline here in endorsing LI-ESWT
Asia-Pacific / ASMHA–APSSM ^{9,20}	Oral PDE5 inhibitors	LI-ESWT, ICI	Written with regional resource variation and socio-cultural factors specifically in mind
FIP pharmacist handbook, 2025 ²¹	Lifestyle counselling, referral for PDE5i	Not applicable (referral-based)	A first-contact, community-pharmacy and self-care framing, built around recognising red flags for onward referral
Japanese Society for Sexual Medicine ²²	Oral PDE5 inhibitors	ICI, VED	One of the highest-quality ED guidelines worldwide on independent AGREE II appraisal, alongside AUA and EAU

IPS ²³	Oral PDE5 inhibitors; psychosexual therapy, alone or in combination	Intracavernosal or intraurethral vasoactive agents; penile prosthesis if both first- and second-line options fail	Psychiatry-led; places ED within the full range of sexual dysfunctions and defines PDE5-inhibitor non-response only after 6–8 attempts at the maximum dose with adequate sexual stimulation
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Abbreviations: AFU, Association Française d'Urologie; AGREE II, Appraisal of Guidelines for Research and Evaluation II; APSSM, Asia-Pacific Society for Sexual Medicine; ASMHA, Asian Society of Men's Health and Aging; AUA, American Urological Association; CUA, Canadian Urological Association; EAU, European Association of Urology; ED, erectile dysfunction; FIP, International Pharmaceutical Federation; GRADE, Grading of Recommendations Assessment, Development and Evaluation; ICI, intracavernosal injection; ICSM, International Consultation on Sexual Medicine; IPS, Indian Psychiatric Society; LI-ESWT, low-intensity extracorporeal shockwave therapy; PDE5, phosphodiesterase type 5; PDE5i, phosphodiesterase type 5 inhibitor; SFMS, Société Francophone de Médecine Sexuelle; VED, vacuum erection device.

Table 14. Cardiovascular risk stratification for sexual activity and phosphodiesterase type 5 (PDE5) inhibitor use, adapted from the Second Princeton Consensus Conference.¹⁸

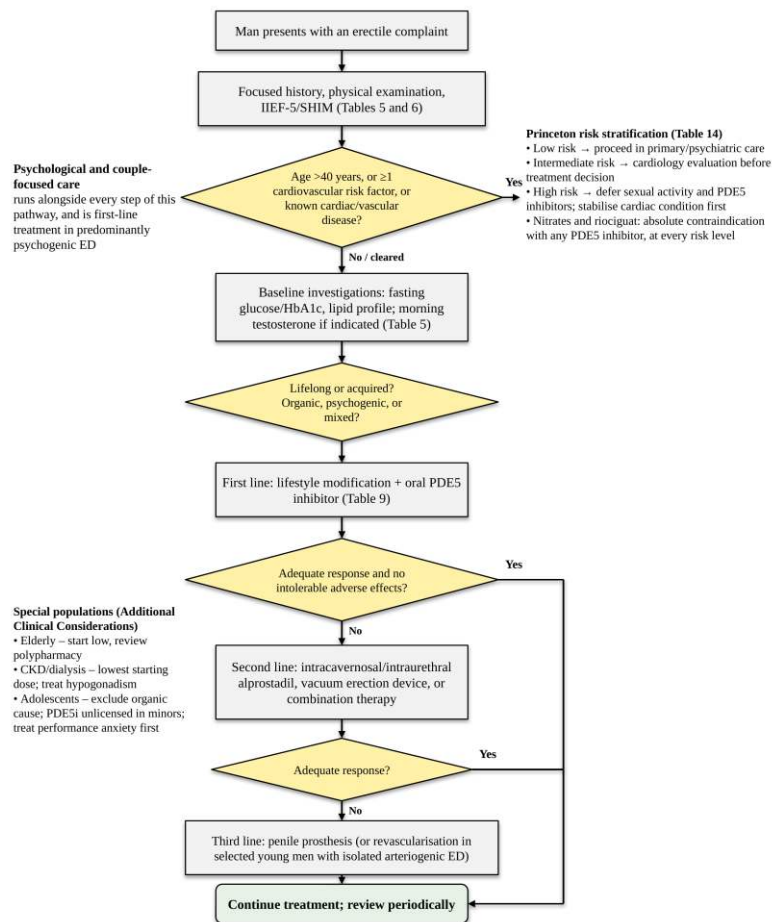
Risk category	Representative features	Management
Low risk	Asymptomatic, <3 cardiovascular risk factors; controlled hypertension; mild, stable angina; successfully revascularised; mild valvular disease; post-MI >6–8 weeks and asymptomatic	Sexual activity and first-line PDE5-inhibitor therapy can proceed in primary care/psychiatric practice
Intermediate / undetermined risk	≥3 cardiovascular risk factors; moderate, stable angina; recent MI or stroke (2–6 weeks); LVEF <40% or NYHA class II heart failure; non-cardiac atherosclerotic disease sequelae	Defer treatment decision until cardiology evaluation restratifies the patient into the low- or high-risk group
High risk	Unstable or refractory angina; uncontrolled hypertension; NYHA class III–IV heart failure; recent MI or stroke (<2 weeks); high-risk arrhythmia; hypertrophic obstructive cardiomyopathy; moderate-to-severe valvular disease	Defer sexual activity and withhold PDE5 inhibitors until the cardiac condition is stabilised and reassessed

Abbreviations: LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PDE5, phosphodiesterase type 5.

Figure Legend

Figure 1. Clinical approach to erectile dysfunction: assessment and management pathway.

Abbreviations: CKD, chronic kidney disease; ED, erectile dysfunction; HbA1c, glycated haemoglobin; IIEF-5, five-item International Index of Erectile Function; PDE5, phosphodiesterase type 5; PDE5i, phosphodiesterase type 5 inhibitor; SHIM, Sexual Health Inventory for Men.



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