



## UK management guidelines for erectile dysfunction

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# Education and debate

## UK management guidelines for erectile dysfunction

David Ralph, Tom McNicholas for the Erectile Dysfunction Alliance

In 1998, a working party of experts in different aspects of erectile dysfunction was drawn together to develop guidelines for managing the condition, with the support of other experts and professional bodies.<sup>1</sup> Throughout the period of the development of these guidelines, input from the professional community was invited at every opportunity possible. This article covers the main points and recommendations of the guidelines.

### Chairman's introduction

Erectile dysfunction is a major healthcare issue and acts as a marker for other common major diseases. It therefore deserves attention, consideration, proper investigation, and appropriate treatment. These guidelines should help in facilitating proper management and avoiding unnecessary expense and inconvenience. We have set out minimum standards for the investigation and management of erectile dysfunction, with comments on what should be added to the barest acceptable minimum to achieve a better standard of management. The guidelines are evidence based, as far as possible.

### Methods

Information came from peer reviewed articles, meetings, and presentations. Articles were chosen by electronically searching the Cochrane Library, Excerpta Medica, Medline, and Embase for randomised controlled trials on erectile dysfunction and related topics. The abstracts of all resulting references were reviewed, and original papers concerning large numbers of subjects or addressing important or contentious issues were analysed. We handsearched journals for articles on impotence and testosterone and hypogonadism, and the past three years' volumes of the *International Journal of Impotence Research*. Where contentious issues were identified or when opinion or customary practice varied, chosen members of the working party critically appraised the relevant literature to assess the evidence base and to report back to the working party so that consensus could be reached. Information also came from a presentation given at the meeting of the European Society for Impotence Research, Madrid (1998); meetings held by the British Association of Urological Surgeons (1998 and 1999) and the American Urological Association (1998); and various meetings on sildenafil (1996-8).

### Summary points

Erectile dysfunction is common and is easily assessed and treated

A detailed history is most important, and for many patients examination can be limited to blood pressure and examination of the genitalia

Patients should be informed about the advantages and disadvantages of each treatment and given advice on treatment outcome as well as ease of use

Patients should be advised on what to do and who to contact if there are problems or complications due to treatment

Follow up should be tailored to goals established at the start of treatment

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For each of the guidelines' recommendations, we have graded the quality of the available evidence according to the system proposed by the US Agency for Health Care Policy and Research for defining types of evidence and grading recommendations (see box, p 500).<sup>2</sup>

### Assessment

It is important to appreciate that consultations will take more time than the average general practice consultation or outpatient appointment. Interviews and treatment should take place in comfortable surroundings, with privacy assured. Assessment of the patient can be carried out by any professional competent to achieve the reasonable minimum standards for history taking and examination as indicated in the relevant sections of this document. Where specialist nurses undertake initial assessment, they should be working within protocols signed by medical professionals, according to the guidelines of the UK Central Council.<sup>3</sup>

The assessing individual should be fully informed of local facilities and routes and protocols for referral, including those for psychosexual therapy. If referral to a specialist is made from general practice, the referring doctor should be prepared to cooperate in management according to shared care guidelines, and fund

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**Grading of quality of available evidence**

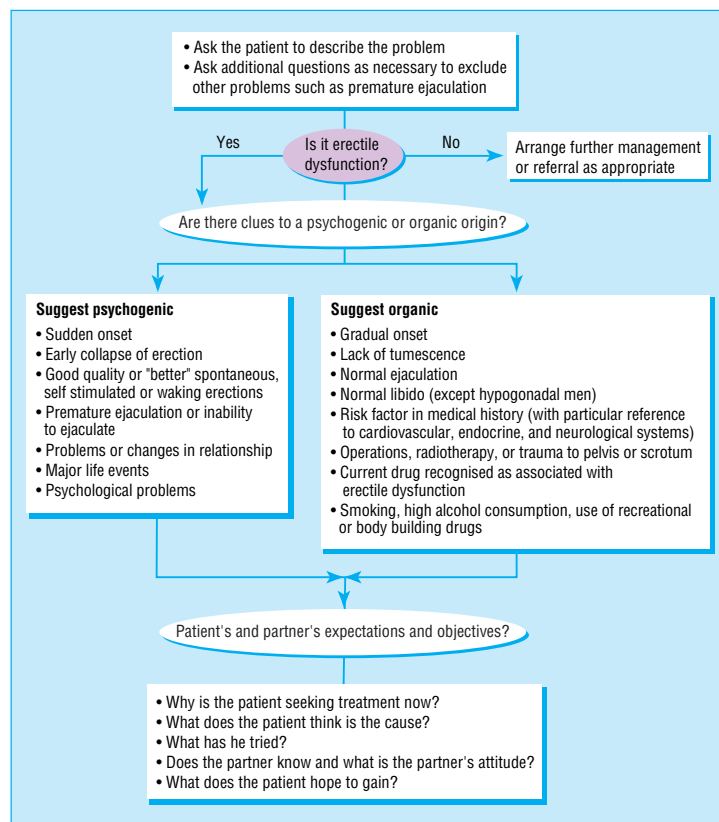
**Category of evidence**  
 Ia—meta-analysis of randomised controlled trials  
 Ib—at least one randomised controlled trial  
 IIa—at least one controlled study without randomisation  
 IIb—at least one other type of quasiexperimental study  
 III—non-experimental, descriptive studies, such as comparative studies, correlation studies, and case studies  
 IV—expert committee reports or the opinions or clinical experience of respected authorities, or both

**Strength of recommendation**  
*Grade A (levels Ia and Ib)*—at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing specific recommendations  
*Grade B (levels IIa, IIb, and III)*—availability of well conducted clinical studies, but no randomised clinical trials on the topic of recommendation  
*Grade C (level IV)*—evidence obtained from expert committee reports or the opinions or clinical experience of respected authorities, or both. Indicates absence of directly applicable clinical studies of good quality

continuing treatment according to local agreements (Grade C, level IV.)

**History**

A detailed history is the most important aspect of a patient's assessment (fig 1). If the initial assessment



**Fig 1** History taking in erectile dysfunction

indicates the possibility of an important psychiatric problem, this should be addressed before treatment for erectile dysfunction. (Grade C, level IV.)

Psychiatric problems to which the assessor needs to be alert include generalised anxiety states, depressive illness, psychosis, body dysmorphic disorder, gender identity problems, and alcoholism. It should be borne in mind that erectile dysfunction is associated with many types of drugs (table 1).

**Examination**

For most patients, examination should be limited to the basic minimum—that is, blood pressure and examination of genitalia (to include checking for abnormalities in testicular size, fibrosis in shaft of penis, and retractable foreskin). Further examination or referral may be appropriate where indicated by age or findings in the history—especially regarding cardiovascular, neurological, endocrine, and urinary systems. (Grade C, level IV.)

**Investigations**

Precise investigations indicated for any individual will depend on the history and examination findings. Patients who warrant investigations beyond those in table 2 should be referred for specialist assessment. These will include young patients who have always had erectile difficulty, patients with a history of trauma, patients in whom an abnormality of the testes or penis is found on examination, and patients in whom the initial screening tests have indicated an important abnormality.

Measurement of prostate specific antigen concentration and a rectal examination should be performed as a baseline on any patients who are to receive hormone replacement therapy. (Grade C, level IV.) If the history or examination suggest possible hypogonadism, free testosterone or androgen index assessment is preferred.<sup>4</sup>

**Treatment**

**Principles of treatment**

For most patients, the final selection of treatment will be according to their choice. The role of the professional is to inform the patient and help him to make a reasoned choice. Most erectile dysfunction is multifactorial; organic and psychological elements may both need to be addressed.

The professional discussing treatment options (fig 2) with the patient should ensure that

- Unbiased information is offered on all suitable treatment options, their merits, and known significant risks, in a form that the patient (and partner) can assimilate and from which it is sufficient for them to evaluate the options
- The final choice of treatment is tailored to the needs and preferences of the patient; although partners are encouraged to take part in discussions and the choice of treatment, no patient should be denied treatment because of the absence of a current partner
- Agreed treatment goals are established at the start of treatment

**Table 1** Drugs associated with erectile dysfunction

Type of drug	Examples	Alternative drugs with lower risk of erectile dysfunction
Antihypertensives	$\beta$ blockers (for example, propranolol, atenolol); thiazide diuretics (for example, cyclopenthiiazide, chlorothiazide); hydralazine	$\alpha$ Adrenergic blockers; angiotensin converting enzyme inhibitors; calcium channel blockers
Diuretics	Thiazide diuretics (as above); potassium sparing diuretics (for example, spironolactone, triamterene); carbonic anhydrase inhibitor (for example, acetazolamide)	Loop diuretics (for example, frusemide, bumetanide)
Antidepressants	Selective serotonin reuptake inhibitors (for example, fluoxetine, fluvoxamine, paroxetine, sertraline); tricyclics (for example, amitriptyline, imipramine); monoamine oxidase inhibitors (for example, phenelzine, isocarboxazid, tranylcypromine)	Newer agents may have lower risk but there is little experience to confirm this. Specialist opinion may be required before changing treatment
Antipsychotics	Phenothiazines (for example, chlorpromazine, thioridazine, fluphenazine); carbamazepine; risperidone	Newer agents may have lower risk, but there is little experience to confirm this. Specialist opinion may be required before changing treatment
Hormonal agents	Cyproterone acetate; luteinising hormone-releasing hormone analogues; oestrogens	Dependent on diagnosis and options available
Lipid regulators	Gemfibrozil; clofibrate	Statins (for example, simvastatin, pravastatin)
Anticonvulsants	Phenytoin; carbamazepine	Need neurologist's opinion—depends on condition control
AntiParkinson's drugs	Levodopa	Need neurologist's opinion—depends on condition control
Dyspepsia and ulcer healing drugs	H <sub>2</sub> antagonists (for example, cimetidine, famotidine, nizatidine, ranitidine)	Proton pump inhibitors (for example, omeprazole)
Miscellaneous	Allopurinol Indomethacin Disulfiram Phenothiazine antihistamines (for example, promethazine) Phenothiazine antiemetics (for example, prochlorperazine)	Cyclizine

Grade C, evidence level IV.

- Appropriate information is given on management of the chosen treatment, including advice on what to do and who to contact in case of problems and complications. (Grade C, level IV.)

### Psychosexual therapy

The success of psychosexual therapy depends on the motivation of the patient, because it will require him to work with the therapist to find an understanding of what prevents him from experiencing normal sexual arousal. A review of all outcome studies in psychosexual therapy published since 1970 showed successful outcomes in 50-80% of patients.<sup>5</sup> Psychosexual therapy may be used in conjunction with physical therapies. (Grade C, level IV.)

### Oral sildenafil

Oral sildenafil (Viagra, Pfizer, Sandwich) has been shown to be an effective treatment for erectile dysfunction. Improvement in erectile response has been

reported by 50-88% of patients.<sup>6, 7</sup> Clinical safety has been evaluated in more than 3700 patients.<sup>8</sup> (Grade A, level Ib.)

### Intracavernosal prostaglandin (alprostadil) injections

A choice of alprostadil preparations (for example, Caverject, Pharmacia and Upjohn, Milton Keynes; Viridal Duo, Schwarz Pharma, Chesham) offering different injection systems is available for administering by the intracavernosal route. Ease of use affects patient's and partner's satisfaction and therefore compliance; this is an important consideration in selecting the preparation.

### Transurethral alprostadil

Alprostadil given transurethrally (medicated urethral system for erection (MUSE, AstraZeneca, Kings Langley)) has proved efficacy in providing erections adequate for intercourse. In patients with erectile

**Table 2** Investigations in the management of erectile dysfunction

Investigation	Indication	Justification
<b>Common</b>		
Testosterone	If history or examination suggest possible hypogonadism or if required to reassure patient	Free testosterone or androgen index is preferred and will prevent unnecessary endocrine investigation in up to 50% of men found to have low total testosterone concentrations. <sup>4</sup> However, the working party only consider measurement mandatory if there is evidence of hypogonadism. Where there is clinical uncertainty, a morning measurement of testosterone concentration will help to identify pituitary adenoma or occult hypogonadism
<b>If indicated</b>		
Luteinising hormone	Only if testosterone low	
Prolactin	If testosterone low or loss of libido, <sup>4</sup> or both	
Dipstick urine analysis	If renal impairment or liver disorder suspected	To detect abnormalities of renal and liver function
Creatinine and electrolytes	If renal impairment suspected	To confirm or exclude renal problems
Haemoglobinopathy screen	AfroCaribbean patients	To exclude sickling disorder
Liver function tests	If liver disorder suspected	Abnormal liver function is linked with erectile dysfunction

Basic investigation in all patients is test to exclude diabetes—for example, measurement of plasma glucose concentration; the British Diabetic Association currently recommends measurement of fasting venous plasma glucose. NHS recommended guidelines developed by the British Diabetic Association are available for further guidance.

### Advantages and disadvantages of psychosexual therapy for treating erectile dysfunction

#### Advantages

Physically non-invasive, can involve partner, can lead to sustained improvement in sexual function and satisfaction, can improve couple's communication, can address partner's problems

#### Disadvantages

NHS services not available in every locality, patient or partner may be reluctant to attend, time consuming, variable reports of success rates

dysfunction from organic causes, 65.9% achieved erections that were sufficient for intercourse during testing at a clinic and 64.9% of a subgroup of these responders were able to achieve intercourse at least once during the three months that they treated themselves at home.<sup>9</sup> (Grade A, level Ib.)

### Vacuum devices

A vacuum device consists of an external cylinder fitted over the penis to allow air to be pumped out, resulting in engorgement of the penis with blood. A constriction ring is then fitted to the base of the penis to maintain this "erect" state. Vacuum therapy is suitable for a wide range of patients with chronic or occasional erectile dysfunction, whatever the cause. One study quoted an overall clinical success rate of around 90%, with more than 80% of patients continuing with the device, but in another study only 23% of patients asked for a prescription after a two week trial and only 53% of these reported complete or reasonable satisfaction.<sup>16 17</sup> (Grade A, level Ib.)

### Penile prostheses

Penile prostheses are semi-rigid, malleable or inflatable implants, which can be surgically inserted into the penis to allow an erect state. Prostheses should be considered in patients whose impotence has an organic cause and who are unwilling to consider, fail to respond to, or are unable to continue with medical treatment or external devices. (Grade B, level III.)

### Management of priapism

Any centre initiating medical treatment for erectile dysfunction must ensure that appropriate treatment for priapism will be available whenever needed and

### Advantages and disadvantages of drugs used to treat erectile dysfunction

#### Oral sildenafil (Viagra)

##### Advantages

Effective,<sup>6 7</sup> side effects predominantly transient and mild,<sup>8</sup> non-invasive

##### Disadvantages

Facilitator rather than initiator of erections  
Not suitable for all patients (contraindicated in patients taking nitrates and those with severe hepatic impairment, hypotension, hereditary degenerative retinal disorders, and recent stroke or myocardial infarction)  
Slower onset of action than injected or transurethral alprostadil

#### Intracavernosal prostaglandin (alprostadil) injections (Caverject, Viridal Duo)

##### Advantages

Proved efficacy in providing erections adequate for intercourse (66% of patients self injecting at home<sup>10</sup> and after 94% of such injections<sup>11</sup>); suitable for a wide range of patients owing to few contraindications or interactions; high rates (80-90%) of patient and partner satisfaction reported,<sup>10 11</sup> rapidly effective, recovery of spontaneous erections in a proportion of patients

##### Disadvantages

Penile pain on injection is a common complication but is usually mild<sup>11</sup>; penile fibrosis is a recognised complication, with reported incidence ranging from <1% to more than 20%<sup>12</sup>; low incidence of prolonged erections (for example, 5% in one study<sup>12</sup>) and priapism (1% in same study); invasive; patients need tuition on use and reasonable manual dexterity and eyesight (Grade A, level Ib)

#### Transurethral alprostadil (MUSE)

##### Advantages

Proved efficacy in providing erections adequate for intercourse, lower risk of priapism than with intracavernosal injections,<sup>9</sup> suitable for a wide range of patients, including those who are needle phobic

##### Disadvantages

Long term efficacy and side effects uncertain; studies show lower efficacy and higher side effects than with intracavernosal injection,<sup>15</sup> with more patients preferring to continue intracavernosal injection than transurethral use<sup>15</sup>; mild penile pain (10%-29% of patients) is most common side effect<sup>9 15</sup>; may cause discomfort in pre-existing lower limb varicosities; causes penile urethral discomfort and possible vaginal discomfort for partner; requires manual dexterity, good eyesight, and insertion after micturition; slower acting than injections (Grade A, level Ib)

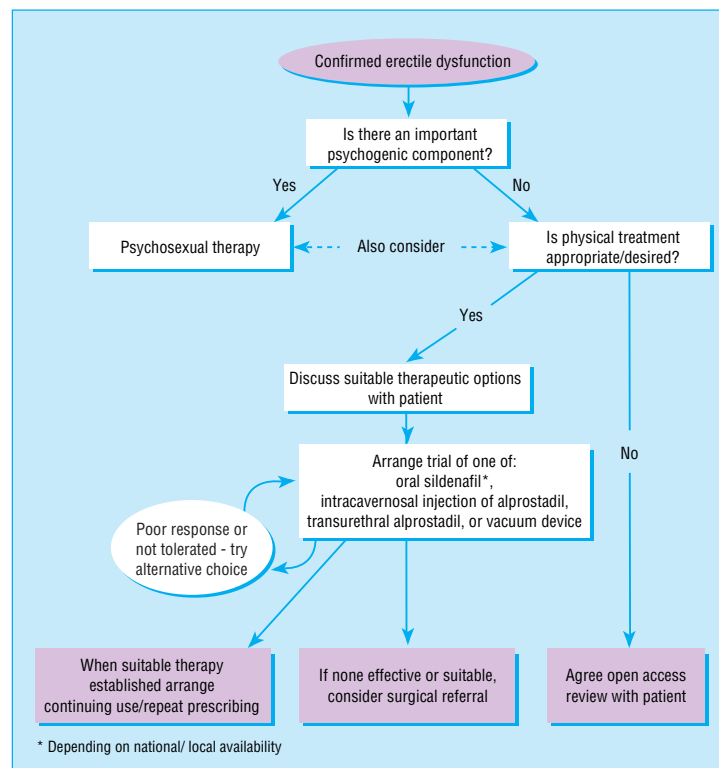


Fig 2 Suggested plan for treatment of erectile dysfunction

### Advantages and disadvantages of devices used to treat erectile dysfunction

#### Vacuum devices

##### Advantages

Low incidence of side effects; suitable for long term use; suitable for a wide range of patients, including those who have failed other therapy

##### Disadvantages

Contraindicated in patients with bleeding disorders, lack of spontaneity and cumbersome, erections can be uncomfortable and ejaculation may be impaired, pivoting at base of penis, "cold penis" for partner, cross over study showed ability to attain orgasm and overall satisfaction of patient and partner lower than with injection therapy<sup>18</sup>

#### Penile prostheses

##### Advantages

Technical success rates are high—for example, a revision rate of 2.5% and a removal rate of 4.4% were reported in a two year follow up study<sup>19</sup>; patient and partner satisfaction in confidence and device rigidity reported as 80%<sup>19</sup>; long term result; use independent of injections or tablet taking; particularly valuable approach in patients with penile fibrosis; cost of replacement prosthesis covered by lifetime guarantee

##### Disadvantages

Invasive, operative procedure; sepsis the most common complication, with rates quoted from 2-16% (other complications such as erosion, migration, and penile necrosis are rare<sup>19</sup>); cosmetic, as the semi-rigid and malleable devices protrude; mechanical problems with device but reported rates are  $\leq 5\%$ <sup>19</sup>; perineal pain can persist for 1-2 months; initial cost is high

that patients and their doctors know how to access this treatment. (Grade C, level IV)

### Follow up

Follow up is important for optimum management and patient satisfaction and contributes to audit of outcomes. A review between four weeks and six months allows for change or cessation of treatment. No single follow up protocol will, however, be suitable for all patients and all types of treatment. For those patients receiving injection therapy, longer term follow up to detect penile fibrosis may be advisable, although adequately informed patients may be equally able to detect this themselves and seek advice if necessary.

Follow up should be individually tailored and related to the treatment goals agreed at the start of treatment—the plan for follow up should be discussed and agreed with the patient when a specific treatment is initiated. In primary care, locally agreed protocols for repeat prescribing should be followed. (Grade C, level IV)

### Provision of care

It is now widely accepted that the ideal service provision for the management of erectile dysfunction in secondary care is multidisciplinary. The exact structure of the multidisciplinary team will vary.

#### Specialist nurses

Specialist nurses may play a key role in informing the patient and in initiating and monitoring therapy. This

role may amount to total patient management within protocols agreed with medical professionals (as is current recommended nursing practice<sup>3</sup>). Such protocols should include clear lines of responsibility and communication and also arrangements for prescribing and consent to drugs. Specialist nurses working within this role must receive appropriate training.

#### Pharmacists

Pharmacists have a role in discussions and decisions about purchasing, including those made by local prescribing committees, and in reviewing comparative costs. In an area in which patients may be reluctant to seek appropriate assistance, community pharmacists may be key figures in guiding patients towards appropriate care.

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