

NIH Consensus Statement

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Impotence

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This statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.

Abstract

The National Institutes of Health Consensus Development Conference on Impotence was convened to address (1) the prevalence and clinical, psychological, and social impact of erectile dysfunction; (2) the risk factors for erectile dysfunction and how they might be used in preventing its development; (3) the need for and appropriate diagnostic assessment and evaluation of patients with erectile dysfunction; (4) the efficacies and risks of behavioral, pharmacological, surgical, and other treatments for erectile dysfunction; (5) strategies for improving public and professional awareness and knowledge of erectile dysfunction; and (6) future directions for research in prevention, diagnosis, and management of erectile dysfunction. Following 2 days of presentations by experts and discussion by the audience, a consensus panel weighed the evidence and prepared their consensus statement.

Among their findings, the panel concluded that (1) the term “erectile dysfunction” should replace the term “impotence”; (2) the likelihood of erectile dysfunction increases with age but is not an inevitable consequence of aging; (3) embarrassment of patients and reluctance of both patients and health care providers to discuss sexual matters candidly contribute to underdiagnosis of erectile dysfunction; (4) many cases of erectile dysfunction can be successfully managed with appropriately selected therapy; (5) the diagnosis and treatment of erectile dysfunction must be specific and responsive to the individual patient’s needs and that compliance as well as the desires and expectations of both the patient and partner are important considerations in selecting appropriate therapy; (6) education of health care providers and the public on aspects of human sexuality, sexual dysfunction, and availability of successful treatments is essential; and (7) erectile dysfunction is an important public health problem deserving of increased support for basic science investigation and applied research.

The full text of the consensus panel’s statement follows.

Introduction

The term “impotence,” as applied to the title of this conference, has traditionally been used to signify the inability of the male to attain and maintain erection of the penis sufficient to permit satisfactory sexual intercourse. However, this use has often led to confusing and uninterpretable results in both clinical and basic science investigations. This, together with its pejorative implications, suggests that the more precise term “erectile dysfunction” be used instead to signify an inability of the male to achieve an erect penis as part of the overall multifaceted process of male sexual function.

This process comprises a variety of physical aspects with important psychological and behavioral overtones. In analyzing the material presented and discussed at this conference, this consensus statement addresses issues of male erectile dysfunction, as implied by the term “impotence.” However, it should be recognized that desire, orgasmic capability, and ejaculatory capacity may be intact even in the presence of erectile dysfunction or may be deficient to some extent and contribute to the sense of inadequate sexual function.

Erectile dysfunction affects millions of men. Although for some men erectile function may not be the best or most important measure of sexual satisfaction, for many men erectile dysfunction creates mental stress that affects their interactions with family and associates. Many advances have occurred in both diagnosis and treatment of erectile dysfunction. However, its various aspects remain poorly understood by the general population and by most health care professionals. Lack of a simple definition, failure to delineate precisely the problem being assessed, and the absence of guidelines and parameters to determine assessment and treatment outcome and long-term results, have contributed to this state of affairs by producing misunderstanding, confusion, and ongoing concern. That results have not been communicated effectively to the public has compounded this situation.

Cause-specific assessment and treatment of male sexual dysfunction will require recognition by the public and the medical community that erectile dysfunction is a part of overall male sexual dysfunction. The multifactorial nature of erectile

dysfunction, comprising both organic and psychologic aspects, may often require a multidisciplinary approach to its assessment and treatment. This consensus report addresses these issues, not only as isolated health problems but also in the context of societal and individual perceptions and expectations.

Erectile dysfunction is often assumed to be a natural concomitant of the aging process, to be tolerated along with other conditions associated with aging. This assumption may not be entirely correct. For the elderly and for others, erectile dysfunction may occur as a consequence of specific illnesses or of medical treatment for certain illnesses, resulting in fear, loss of image and self-confidence, and depression.

For example, many men with diabetes mellitus may develop erectile dysfunction during their young and middle adult years. Physicians, diabetes educators, and patients and their families are sometimes unaware of this potential complication. Whatever the causal factors, discomfort of patients and health care providers in discussing sexual issues becomes a barrier to pursuing treatment.

Erectile dysfunction can be effectively treated with a variety of methods. Many patients and health care providers are unaware of these treatments, and the dysfunction thus often remains untreated, compounded by its psychological impact. Concurrent with the increase in the availability of effective treatment methods has been increased availability of new diagnostic procedures that may help in the selection of an effective, cause-specific treatment. This conference was designed to explore these issues and to define the state of the art.

To examine what is known about the demographics, etiology, risk factors, pathophysiology, diagnostic assessment, treatments (both generic and cause-specific), and the understanding of their consequences by the public and the medical community, the National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Medical Applications of Research of the National Institutes of Health, in conjunction with the National Institute of Neurological Disorders and Stroke and the National Institute on Aging, convened a consensus

development conference on male impotence on December 7–9, 1992. After 1½ days of presentations by experts in the relevant fields involved with male sexual dysfunction and erectile impotence or dysfunction, a consensus panel comprised of representatives from urology, geriatrics, medicine, endocrinology, psychiatry, psychology, nursing, epidemiology, biostatistics, basic sciences, and the public considered the evidence and developed answers to the questions that follow.

What Are the Prevalence and Clinical, Psychological, and Social Impact of Impotence (Cultural, Geographical, National, Ethnic, Racial, Male/Female Perceptions and Influences)?

Prevalence and Association with Age

Estimates of the prevalence of impotence depend on the definition employed for this condition. For the purposes of this consensus development conference statement, impotence is defined as male erectile dysfunction, that is, the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. Erectile performance has been characterized by the degree of dysfunction, and estimates of prevalence (the number of men with the condition) vary depending on the definition of erectile dysfunction used.

Appallingly little is known about the prevalence of erectile dysfunction in the United States and how this prevalence varies according to individual characteristics (age, race, ethnicity, socioeconomic status, and concomitant diseases and conditions). Data on erectile dysfunction available from the 1940's applied to the present U.S. male population produce an estimate of erectile dysfunction prevalence of 7 million.

More recent estimates suggest that the number of U.S. men with erectile dysfunction may more likely be near 10–20 million. Inclusion of individuals with partial erectile dysfunction increases the estimate to about 30 million. The majority of these individuals will be older than 65 years of age. The prevalence of erectile dysfunction has been found to be associated with age. A prevalence of about 5 percent is observed at age 40, increasing to 15–25 percent at age 65 and older. One-third of older men receiving medical care at a Department of Veterans' Affairs ambulatory clinic admitted to problems with erectile function.

Causes contributing to erectile dysfunction can be broadly classified into two categories: organic and psychologic. In reality, while the majority of patients with erectile dysfunction are thought to demonstrate an organic component, psycho-

logical aspects of self-confidence, anxiety, and partner communication and conflict are often important contributing factors.

The 1985 National Ambulatory Medical Care Survey indicated that there were about 525,000 visits for erectile dysfunction, accounting for 0.2 percent of all male ambulatory care visits. Estimates of visits per 1,000 population increased from about 1.5 for the age group 25–34 to 15.0 for those age 65 and above. The 1985 National Hospital Discharge Survey estimated that more than 30,000 hospital admissions were for erectile dysfunction.

Clinical, Psychological, and Social Impact

Geographic, Racial, Ethnic, Socioeconomic, and Cultural Variation in Erectile Dysfunction

Very little is known about variations in prevalence of erectile dysfunction across geographic, racial, ethnic, socioeconomic, and cultural groups. Anecdotal evidence points to the existence of racial, ethnic, and other cultural diversity in the perceptions and expectation levels for satisfactory sexual functioning. These differences would be expected to be reflected in these groups' reaction to erectile dysfunction, although few data on this issue appear to exist.

One report from a recent community survey concluded that erectile failure was the leading complaint of males attending sex therapy clinics. Other studies have shown that erectile disorders are the primary concern of sex therapy patients in treatment. This is consistent with the view that erectile dysfunction may be associated with depression, loss of self-esteem, poor self-image, increased anxiety or tension with one's sexual partner, and/or fear and anxiety associated with contracting sexually transmitted diseases, including AIDS.

Male/Female Perceptions and Influences

The diagnosis of erectile dysfunction may be understood as the presence of a condition limiting choices for sexual interaction and possibly limiting opportunity for sexual satisfaction. The impact of this condition depends very much on the dynamics of the relationship of the individual and his sexual

partner and their expectation of performance. When changes in sexual function are perceived by the individual and his partner as a natural consequence of the aging process, they may modify their sexual behavior to accommodate the condition and maintain sexual satisfaction. Increasingly, men do not perceive erectile dysfunction as a normal part of aging and seek to identify means by which they may return to their previous level and range of sexual activities. Such levels and expectations and desires for future sexual interactions are important aspects of the evaluation of patients presenting with a chief complaint of erectile dysfunction.

In men of all ages, erectile failure may diminish willingness to initiate sexual relationships because of fear of inadequate sexual performance or rejection. Because males, especially older males, are particularly sensitive to the social support of intimate relationships, withdrawal from these relationships because of such fears may have a negative effect on their overall health.

What Are the Risk Factors Contributing to Impotence? Can These Be Utilized in Preventing Development of Impotence?

Physiology of Erection

The male erectile response is a vascular event initiated by neuronal action and maintained by a complex interplay between vascular and neurological events. In its most common form, it is initiated by a central nervous system event that integrates psychogenic stimuli (perception, desire, etc.) and controls the sympathetic and parasympathetic innervation of the penis. Sensory stimuli from the penis are important in continuing this process and in initiating a reflex arc that may cause erection under proper circumstances and may help to maintain erection during sexual activity.

Parasympathetic input allows erection by relaxation of trabecular smooth muscle and dilation of the helicine arteries of the penis. This leads to expansion of the lacunar spaces and entrapment of blood by compressing venules against the tunica albuginea, a process referred to as the corporal veno-occlusive mechanism. The tunica albuginea must have sufficient stiffness to compress the venules penetrating it so that venous outflow is blocked and sufficient tumescence and rigidity can occur.

Acetylcholine released by the parasympathetic nerves is thought to act primarily on endothelial cells to release a second nonadrenergic-noncholinergic carrier of the signal that relaxes the trabecular smooth muscle. Nitric oxide released by the endothelial cells, and possibly also of neural origin, is currently thought to be the leading of several candidates as this nonadrenergic-noncholinergic transmitter; but this has not yet been conclusively demonstrated to the exclusion of other potentially important substances (e.g., vasoactive intestinal polypeptide). The relaxing effect of nitric oxide on the trabecular smooth muscle may be mediated through its stimulation of guanylate cyclase and the production of cyclic guanosine monophosphate (cGMP), which would then function as a second messenger in this system.

Constriction of the trabecular smooth muscle and helicine arteries induced by sympathetic innervation makes the penis flaccid, with blood pressure in the cavernosal sinuses of the penis near venous pressure. Acetylcholine is thought to decrease sympathetic tone. This may be important in a permissive sense for adequate trabecular smooth muscle relaxation and consequent effective action of other mediators in achieving sufficient inflow of blood into the lacunar spaces. When the trabecular smooth muscle relaxes and helicine arteries dilate in response to parasympathetic stimulation and decreased sympathetic tone, increased blood flow fills the cavernous spaces, increasing the pressure within these spaces so that the penis becomes erect. As the venules are compressed against the tunica albuginea, penile pressure approaches arterial pressure, causing rigidity. Once this state is achieved, arterial inflow is reduced to a level that matches venous outflow.

Erectile Dysfunction

Because adequate arterial supply is critical for erection, any disorder that impairs blood flow may be implicated in the etiology of erectile failure. Most of the medical disorders associated with erectile dysfunction appear to affect the arterial system. Some disorders may interfere with the corporal veno-occlusive mechanism and result in failure to trap blood within the penis, or produce leakage such that an erection cannot be maintained or is easily lost.

Damage to the autonomic pathways innervating the penis may eliminate “psychogenic” erection initiated by the central nervous system. Lesions of the somatic nervous pathways may impair reflexogenic erections and may interrupt tactile sensation needed to maintain psychogenic erections. Spinal cord lesions may produce varying degrees of erectile failure depending on the location and completeness of the lesions. Not only do traumatic lesions affect erectile ability, but disorders leading to peripheral neuropathy may impair neuronal innervation of the penis or of the sensory afferents. The endocrine system itself, particularly the production of androgens, appears to play a role in regulating sexual interest, and may also play a role in erectile function.

Psychological processes such as depression, anxiety, and relationship problems can impair erectile functioning by reducing erotic focus or otherwise reducing awareness of sensory experience. This may lead to inability to initiate or maintain an erection. Etiologic factors for erectile disorders may be categorized as neurogenic, vasculogenic, or psychogenic, but they most commonly appear to derive from problems in all three areas acting in concert.

Risk Factors

Little is known about the natural history of erectile dysfunction. This includes information on the age of onset, incidence rates stratified by age, progression of the condition, and frequency of spontaneous recovery. There also are very limited data on associated morbidity and functional impairment. To date, the data are predominantly available for whites, with other racial and ethnic populations represented only in smaller numbers that do not permit analysis of these issues as a function of race or ethnicity.

Erectile dysfunction is clearly a symptom of many conditions, and certain risk factors have been identified, some of which may be amenable to prevention strategies. Diabetes mellitus, hypogonadism in association with a number of endocrinologic conditions, hypertension, vascular disease, high levels of blood cholesterol, low levels of high density lipoprotein, drugs, neurogenic disorders, Peyronie's disease, priapism, depression, alcohol ingestion, lack of sexual knowledge, poor sexual techniques, inadequate interpersonal relationships or their deterioration, and many chronic diseases, especially renal failure and dialysis, have been demonstrated as risk factors. Vascular surgery is also often a risk factor. Age appears to be a strong indirect risk factor in that it is associated with an increased likelihood of direct risk factors. Other factors require more extensive study. Smoking has an adverse effect on erectile function by accentuating the effects of other risk factors such as vascular disease or hypertension. To date, vasectomy has not been associated with an increased risk of erectile dysfunction other than causing an occasional psychological reaction that could then have a psychogenic influence. Accurate risk factor identification and characterization are

essential for concerted efforts at prevention of erectile dysfunction.

Prevention

Although erectile dysfunction increases progressively with age, it is not an inevitable consequence of aging. Knowledge of the risk factors can guide prevention strategies. Specific antihypertensive, antidepressant, and antipsychotic drugs can be chosen to lessen the risk of erectile failure. Published lists of prescription drugs that may impair erectile functioning often are based on reports implicating a drug without systematic study. Such studies are needed to confirm the validity of these suggested associations. In the individual patient, the physician can modify the regimen in an effort to resolve the erectile problem.

It is important that physicians and other health care providers treating patients for chronic conditions periodically inquire into the sexual functioning of their patients and be prepared to offer counsel for those who experience erectile difficulties. Lack of sexual knowledge and anxiety about sexual performance are common contributing factors to erectile dysfunction. Education and reassurance may be helpful in preventing the cascade into serious erectile failure in individuals who experience minor erectile difficulty due to medications or common changes in erectile functioning associated with chronic illnesses or with aging.

What Diagnostic Information Should Be Obtained in Assessment of the Impotent Patient? What Criteria Should Be Employed To Determine Which Tests Are Indicated for a Particular Patient?

The appropriate evaluation of all men with erectile dysfunction should include a medical and detailed sexual history (including practices and techniques), a physical examination, a psychosocial evaluation, and basic laboratory studies. When available, a multidisciplinary approach to this evaluation may be desirable. In selected patients, further physiologic or invasive studies may be indicated. A sensitive sexual history, including expectations and motivations, should be obtained from the patient (and sexual partner whenever possible) in an interview conducted by an interested physician or another specially trained professional. A written patient questionnaire may be helpful but is not a substitute for the interview. The sexual history is needed to accurately define the patient's specific complaint and to distinguish between true erectile dysfunction, changes in sexual desire, and orgasmic or ejaculatory disturbances. The patient should be asked specifically about perceptions of his erectile dysfunction, including the nature of onset, frequency, quality, and duration of erections; the presence of nocturnal or morning erections; and his ability to achieve sexual satisfaction. Psychosocial factors related to erectile dysfunction should be probed, including specific situational circumstances, performance anxiety, the nature of sexual relationships, details of current sexual techniques, expectations, motivation for treatment, and the presence of specific discord in the patient's relationship with his sexual partner. The sexual partner's own expectations and perceptions should also be sought since they may have important bearing on diagnosis and treatment recommendations.

The general medical history is important in identifying specific risk factors that may account for or contribute to the patient's erectile dysfunction. These include vascular risk factors such as hypertension, diabetes, smoking, coronary artery disease, peripheral vascular disorders, pelvic trauma or surgery, and blood lipid abnormalities. Decreased sexual desire or history

suggesting a hypogonadal state could indicate a primary endocrine disorder. Neurologic causes may include a history of diabetes mellitus or alcoholism with associated peripheral neuropathy. Neurologic disorders such as multiple sclerosis, spinal injury, or cerebrovascular accidents are often obvious or well defined prior to presentation. It is essential to obtain a detailed medication and illicit drug history since an estimated 25 percent of cases of erectile dysfunction may be attributable to medications for other conditions. Past medical history can reveal important causes of erectile dysfunction, including radical pelvic surgery, radiation therapy, Peyronie's disease, penile or pelvic trauma, prostatitis, priapism, or voiding dysfunction. Information regarding prior evaluation or treatment for "impotence" should be obtained. A detailed sexual history, including current sexual techniques, is important in the general history obtained. It is also important to determine if there have been previous psychiatric illnesses such as depression or neuroses.

Physical examination should include the assessment of male secondary sex characteristics, femoral and lower extremity pulses, and a focused neurologic examination including perianal sensation, anal sphincter tone, and bulbocavernosus reflex. More extensive neurologic tests, including dorsal nerve conduction latencies, evoked potential measurements, and corpora cavernosal electromyography lack normative (control) data and appear at this time to be of limited clinical value. Examination of the genitalia includes evaluation of testis size and consistency, palpation of the shaft of the penis to determine the presence of Peyronie's plaques, and a digital rectal examination of the prostate with assessment of anal sphincter tone.

Endocrine evaluation consisting of a morning serum testosterone is generally indicated. Measurement of serum prolactin may be indicated. A low testosterone level merits repeat measurement together with assessment of luteinizing hormone (LH), follicle-stimulating hormone (FSH), and prolactin levels. Other tests may be helpful in excluding unrecognized systemic disease and include a complete blood count, urinalysis, creatinine, lipid profile, fasting blood sugar, and thyroid function studies.

Although not indicated for routine use, nocturnal penile tumescence (NPT) testing may be useful in the patient who reports a complete absence of erections (exclusive of nocturnal “sleep” erections) or when a primary psychogenic etiology is suspected. Such testing should be performed by those with expertise and knowledge of its interpretation, pitfalls, and usefulness. Various methods and devices are available for the evaluation of nocturnal penile tumescence, but their clinical usefulness is restricted by limitations of diagnostic accuracy and availability of normative data. Further study regarding standardization of NPT testing and its general applicability is indicated.

After the history, physical examination, and laboratory testing, a clinical impression can be obtained of a primarily psychogenic, organic, or mixed etiology for erectile dysfunction. Patients with primary or associated psychogenic factors may be offered further psychologic evaluation, and patients with endocrine abnormalities may be referred to an endocrinologist to evaluate the possibility of a pituitary lesion or hypogonadism. Unless previously diagnosed, suspicion of neurologic deficit may be further assessed by complete neurologic evaluation. No further diagnostic tests appear necessary for those patients who favor noninvasive treatment (e.g., vacuum constrictive devices or pharmacologic injection therapy). Patients who do not respond satisfactorily to these noninvasive treatments may be candidates for penile implant surgery or further diagnostic testing for possible additional invasive therapies.

A rigid or nearly rigid erectile response to intracavernous injection of pharmacologic test doses of a vasodilating agent (see below) indicates adequate arterial and veno-occlusive function. This suggests that the patient may be a suitable candidate for a trial of penile injection therapy. Genital stimulation may be of use in increasing the erectile response in this setting. This diagnostic technique also may be used to differentiate a vascular from a primarily neuropathic or psychogenic etiology. Patients who have an inadequate response to intracavernous pharmacologic injection may be candidates for further vascular testing. It should be recognized, however, that failure to respond adequately may not indicate vascular

insufficiency but can be caused by patient anxiety or discomfort. The number of patients who may benefit from more extensive vascular testing is small, but includes young men with a history of significant perineal or pelvic trauma, who may have anatomic arterial blockage (either alone or with neurologic deficit) to account for erectile dysfunction.

Studies to further define vasculogenic disorders include pharmacologic duplex grey scale/color ultrasonography, pharmacologic dynamic infusion cavernosometry/cavernosography, and pharmacologic pelvic/penile angiography. Cavernosometry, duplex ultrasonography, and angiography performed either alone or in conjunction with intracavernous pharmacologic injection of vasodilator agents rely on complete arterial and cavernosal smooth muscle relaxation to evaluate arterial and veno-occlusive function. The clinical effectiveness of these invasive studies is severely limited by several factors, including the lack of normative data, operator dependence, variable interpretation of results, and poor predictability of therapeutic outcomes of arterial and venous surgery. At the present time these studies might best be done in referral centers with specific expertise and interest in investigation of the vascular aspects of erectile dysfunction. Further clinical research is necessary to standardize methodology and interpretation, to obtain control data on normals (as stratified according to age), and to define what constitutes normality in order to assess the value of these tests in their diagnostic accuracy and in their ability to predict treatment outcome in men with erectile dysfunction.

What Are the Efficacies and Risks of Behavioral, Pharmacological, Surgical, and Other Treatments for Impotence? What Sequences and/or Combination of These Interventions Are Appropriate? What Management Techniques Are Appropriate When Treatment Is Not Effective or Indicated?

General Considerations

Because of the difficulty in defining the clinical entity of erectile dysfunction, there have been a variety of entry criteria for patients in therapeutic trials. Similarly, the ability to assess efficacy of therapeutic interventions is impaired by the lack of clear and quantifiable criteria of erectile dysfunction. General considerations for treatment follow:

- Psychotherapy and/or behavioral therapy may be useful for some patients with erectile dysfunction without obvious organic cause, and for their partners. These may also be used as an adjunct to other therapies directed at the treatment of organic erectile dysfunction. Outcome data from such therapy, however, have not been well-documented or quantified, and additional studies along these lines are indicated.
- Efficacy of therapy may be best achieved by inclusion of both partners in treatment plans.
- Treatment should be individualized to the patient's desires and expectations.
- Even though there are several effective treatments currently available, long-term efficacy is in general relatively low. Moreover, there is a high rate of voluntary cessation of treatment for all currently popular forms of therapy for erectile dysfunction. Better understanding of the reasons for each of these phenomena is needed.

Psychotherapy and Behavioral Therapy

Psychosocial factors are important in all forms of erectile dysfunction. Careful attention to these issues and attempts to relieve sexual anxieties should be a part of the therapeutic intervention for all patients with erectile dysfunction. Psychotherapy and/or behavioral therapy alone may be helpful for some patients in whom no organic cause of erectile dysfunction is detected. Patients who refuse medical and surgical interventions also may be helped by such counseling. After appropriate evaluation to detect and treat coexistent problems such as issues related to the loss of a partner, dysfunctional relationships, psychotic disorders, or alcohol and drug abuse, psychological treatment focuses on decreasing performance anxiety and distractions and on increasing a couple's intimacy and ability to communicate about sex. Education concerning the factors that create normal sexual response and erectile dysfunction can help a couple cope with sexual difficulties. Working with the sexual partner is useful in improving the outcome of therapy. Psychotherapy and behavioral therapy have been reported to relieve depression and anxiety as well as to improve sexual function. However, outcome data of psychological and behavioral therapy have not been quantified, and evaluation of the success of specific techniques used in these treatments is poorly documented. Studies to validate their efficacy are therefore strongly indicated.

Medical Therapy

An initial approach to medical therapy should consider reversible medical problems that may contribute to erectile dysfunction. Included in this should be assessment of the possibility of medication-induced erectile dysfunction with consideration for reduction of polypharmacy and/or substitution of medications with lower probability of inducing erectile dysfunction.

For some patients with an established diagnosis of testicular failure (hypogonadism), androgen replacement therapy may sometimes be effective in improving erectile function. A trial of androgen replacement may be worthwhile in men with low serum testosterone levels if there are no other contraindications. In contrast, for men who have normal testosterone levels, androgen therapy is inappropriate and

may carry significant health risks, especially in the situation of unrecognized prostate cancer. If androgen therapy is indicated, it should be given in the form of intramuscular injections of testosterone enanthate or cypionate. Oral androgens, as currently available, are not indicated. For men with hyperprolactinemia, bromocriptine therapy often is effective in normalizing the prolactin level and improving sexual function. A wide variety of other substances taken either orally or topically have been suggested to be effective in treating erectile dysfunction. Most of these have not been subjected to rigorous clinical studies and are not approved for this use by the Food and Drug Administration (FDA). Their use should therefore be discouraged until further evidence in support of their efficacy and indicative of their safety is available.

Intracavernosal Injection Therapy

Injection of vasodilator substances into the corpora of the penis has provided a new therapeutic technique for a variety of causes of erectile dysfunction. The most effective and well-studied agents are papaverine, phentolamine, and prostaglandin E₁. These have been used either singly or in combination. Use of these agents occasionally causes priapism (inappropriately persistent erections). This appears to have been seen most commonly with papaverine. Priapism is treated with adrenergic agents, which can cause life-threatening hypertension in patients receiving monoamine oxidase inhibitors. Use of the penile vasodilators also can be problematic in patients who cannot tolerate transient hypotension, those with severe psychiatric disease, those with poor manual dexterity, those with poor vision, and those receiving anticoagulant therapy. Liver function tests should be obtained in those being treated with papaverine alone. Prostaglandin E₁ can be used together with papaverine and phentolamine to decrease the incidence of side effects such as pain, penile corporal fibrosis, fibrotic nodules, hypotension, and priapism. Further study of the efficacy of multitherapy versus monotherapy and of the relative complications and safety of each approach is indicated. Although these agents have not received FDA approval for this indication, they are in widespread clinical use. Patients treated with these agents should give full informed consent. There is a high rate of patient dropout, often early in the treatment.

Whether this is related to side effects, lack of spontaneity in sexual relations, or general loss of interest is unclear. Patient education and followup support might improve compliance and lessen the dropout rate. However, the reasons for the high dropout rate need to be determined and quantified.

Vacuum Constrictive Devices

Vacuum constriction devices may be effective at generating and maintaining erections in many patients with erectile dysfunction and these appear to have a low incidence of side effects. As with intracavernosal injection therapy, there is a significant rate of patient dropout with these devices, and the reasons for this phenomenon are unclear. The devices are difficult for some patients to use, and this is especially so in those with impaired manual dexterity. Also, these devices may impair ejaculation, which can then cause some discomfort. Patients and their partners sometimes are bothered by the lack of spontaneity in sexual relations that may occur with this procedure. The patient is sometimes also bothered by the general discomfort that can occur while using these devices. Partner involvement in training with these devices may be important for successful outcome, especially in regard to establishing a mutually satisfying level of sexual activity.

Vascular Surgery

Surgery of the penile venous system, generally involving venous ligation, has been reported to be effective in patients who have been demonstrated to have venous leakage. However, the tests necessary to establish this diagnosis have been incompletely validated; therefore, it is difficult to select patients who will have a predictably good outcome. Moreover, decreased effectiveness of this approach has been reported as longer term followups have been obtained. This has tempered enthusiasm for these procedures, which are probably therefore best done in an investigational setting in medical centers by surgeons experienced in these procedures and their evaluation.

Arterial revascularization procedures have a very limited role (e.g., in congenital or traumatic vascular abnormality) and probably should be restricted to the clinical investigation

setting in medical centers with experienced personnel. All patients who are considered for vascular surgical therapy need to have appropriate preoperative evaluation, which may include dynamic infusion pharmaco-cavernosometry and cavernosography (DICC), duplex ultrasonography, and possibly arteriography. The indications for and interpretations of these diagnostic procedures are incompletely standardized; therefore, difficulties persist with using these techniques to predict and assess the success of surgical therapy, and further investigation to clarify their value and role in this regard is indicated.

Penile Prosthesis

Three forms of penile prostheses are available for patients who fail with or refuse other forms of therapy: semirigid, malleable, and inflatable. The effectiveness, complications, and acceptability vary among the three types of prostheses, with the main problems being mechanical failure, infection, and erosions. Silicone particle shedding has been reported, including migration to regional lymph nodes; however, no clinically identifiable problems have been reported as a result of the silicone particles. There is a risk of the need for reoperation with all devices. Although the inflatable prostheses may yield a more physiologically natural appearance, they have had a higher rate of failure requiring reoperation. Men with diabetes mellitus, spinal cord injuries, or urinary tract infections have an increased risk of prosthesis-associated infection. This form of treatment may not be appropriate in patients with severe penile corporal fibrosis, or severe medical illness. Circumcision may be required for patients with phimosis and balanitis.

Staging of Treatment

The patient and partner must be well informed about all therapeutic options including their effectiveness, possible complications, and costs. As a general rule, the least invasive or dangerous procedures should be tried first. Psychotherapy and behavioral treatments and sexual counseling alone or in conjunction with other treatments may be used in all patients with erectile dysfunction who are willing to use this form of treatment. In patients in whom psychogenic erectile dysfunction

tion is suspected, sexual counseling should be offered first. Invasive therapy should not be the primary treatment of choice. If history, physical, and screening endocrine evaluations are normal and nonpsychogenic erectile dysfunction is suspected, either vacuum devices or intracavernosal injection therapy can be offered after discussion with the patient and his partner. These latter two therapies may also be useful when combined with psychotherapy in those with psychogenic erectile dysfunction in whom psychotherapy alone has failed. Since further diagnostic testing does not reliably establish specific diagnoses or predict outcomes of therapy, vacuum devices or intracavernosal injections often are applied to a broad spectrum of etiologies of male erectile dysfunction.

The motivation and expectations of the patient and his partner and education of both are critical in determining which therapy is chosen and in optimizing its outcome. If single therapy is ineffective, combining two or more forms of therapy may be useful. Penile prostheses should be placed only after patients have been carefully screened and informed. Vascular surgery should be undertaken only in the setting of clinical investigation and extensive clinical experience. With any form of therapy for erectile dysfunction, long-term followup by health professionals is required to assist the patient and his partner with adjustment to the therapeutic intervention. This is particularly true for intracavernosal injection and vacuum constriction therapies. Followup should include continued patient education and support in therapy, careful determination of reasons for cessation of therapy if this occurs, and provision of other options if earlier therapies are unsuccessful.

What Strategies Are Effective in Improving Public and Professional Knowledge About Impotence?

Despite the accumulation of a substantial body of scientific information about erectile dysfunction, large segments of the public—as well as the health professions—remain relatively uninformed, or—even worse—misinformed, about much of what is known. This lack of information, added to a pervasive reluctance of physicians to deal candidly with sexual matters, has resulted in patients being denied the benefits of treatment for their sexual concerns. Although they might wish doctors would ask them questions about their sexual lives, patients, for their part, are too often inhibited from initiating such discussions themselves. Improving both public and professional knowledge about erectile dysfunction will serve to remove those barriers and will foster more open communication and more effective treatment of this condition.

Strategies for Improving Public Knowledge

To a significant degree, the public, particularly older men, is conditioned to accept erectile dysfunction as a condition of progressive aging for which little can be done. In addition, there is considerable inaccurate public information regarding sexual function and dysfunction. Often, this is in the form of advertisements in which enticing promises are made, and patients then become even more demoralized when promised benefits fail to materialize. Accurate information on sexual function and the management of dysfunction must be provided to affected men and their partners. They also must be encouraged to seek professional help, and providers must be aware of the embarrassment and/or discouragement that may often be reasons why men with erectile dysfunction avoid seeking appropriate treatment.

To reach the largest audience, communications strategies should include informative and accurate newspaper and magazine articles, radio and television programs, as well as special educational programs in senior centers. Resources for accurate information regarding diagnosis and treatment options also should include doctors' offices, unions, fraternal

and service groups, voluntary health organizations, State and local health departments, and appropriate advocacy groups. Additionally, since sex education courses in schools uniformly address erectile function, the concept of erectile dysfunction can easily be communicated in these forums as well.

Strategies for Improving Professional Knowledge

- Provide wide distribution of this statement to physicians and other health professionals whose work involves patient contact.
- Define a balance between what specific information is needed by the medical and general public and what is available, and identify what treatments are available.
- Promote the introduction of courses in human sexuality into the curricula of graduate schools for all health care professionals. Because sexual well-being is an integral part of general health, emphasis should be placed on the importance of obtaining a detailed sexual history as part of every medical history.
- Encourage the inclusion of sessions on diagnosis and management of erectile dysfunction in continuing medical education courses.
- Emphasize the desirability for an interdisciplinary approach to the diagnosis and treatment of erectile dysfunction. An integrated medical and psychosocial effort with continuing contact with the patient and partner may enhance their motivation and compliance with treatment during the period of sexual rehabilitation.
- Encourage the inclusion of presentations on erectile dysfunction at scientific meetings of appropriate medical specialty associations, State and local medical societies, and similar organizations of other health professions.
- Distribute scientific information on erectile dysfunction to the news media (print, radio, and television) to support their efforts to disseminate accurate information on this subject and to counteract misleading news reports and false advertising claims.

- Promote public service announcements, lectures, and panel discussions on both commercial and public radio and television on the subject of erectile dysfunction.

What Are the Needs for Future Research?

This consensus development conference on male erectile dysfunction has provided an overview of current knowledge on the prevalence, etiology, pathophysiology, diagnosis, and management of this condition. The growing individual and societal awareness and open acknowledgment of the problem have led to increased interest and resultant explosion of knowledge in each of these areas. Research on this condition has produced many controversies, which also were expressed at this conference. Numerous questions were identified that may serve as foci for future research directions. These will depend on the development of precise agreement among investigators and clinicians in this field on the definition of what constitutes erectile dysfunction, and what factors in its multi-faceted nature contribute to its expression. In addition, further investigation of these issues will require collaborative efforts of basic science investigators and clinicians from the spectrum of relevant disciplines and the rigorous application of appropriate research principles in designing studies to obtain further knowledge and to promote understanding of the various aspects of this condition.

The needs and directions for future research can be considered as follows:

- Development of a symptom score sheet to aid in the standardization of patient assessment and treatment outcome.
- Development of a staging system that may permit quantitative and qualitative classification of erectile dysfunction.
- Studies on perceptions and expectations associated with racial, cultural, ethnic, and societal influences on what constitutes normal male erectile function and how these same factors may be responsible for the development and/or perception of male erectile dysfunction.
- Studies to define and characterize what is normal erectile function, possibly as stratified by age.
- Additional basic research on the physiological and biochemical mechanisms that may underlie the etiology,

pathogenesis, and response to treatment of the various forms of erectile dysfunction.

- Epidemiological studies directed at the prevalence of male erectile dysfunction and its medical and psychological correlates, particularly in the context of possible racial, ethnic, socioeconomic, and cultural variability.
- Additional studies of the mechanisms by which risk factors may produce erectile dysfunction.
- Studies of strategies to prevent male erectile dysfunction.
- Randomized clinical trials assessing the effectiveness of specific behavioral, mechanical, pharmacologic, and surgical treatments, either alone or in combination.
- Studies on the specific effects of hormones (especially androgens) on male sexual function; determination of the frequency of endocrine causes of erectile dysfunction (e.g., hypogonadism and hyperprolactinemia) and the rates of success of appropriate hormonal therapy.
- Longitudinal studies in well-specified populations; evaluation of alternative approaches for the systematic assessment of men with erectile dysfunction; cost-effectiveness studies of diagnostic and therapeutic approaches; formal outcomes research of the various approaches to the assessment and treatment of this condition.
- Social/psychological studies of the impact of erectile dysfunction on subjects, their partners, and their interactions, and factors associated with seeking care.
- Development of new therapies, including pharmacologic agents, and with emphasis on oral agents, that may address the cause of male erectile dysfunction with greater specificity.
- Long-term followup studies to assess treatment effects, patient compliance, and late adverse effects.
- Studies to characterize the significance of erectile function and dysfunction in women.

Conclusions

- The term “erectile dysfunction” should replace the term “impotence” to characterize the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance.
- The likelihood of erectile dysfunction increases progressively with age but is not an inevitable consequence of aging. Other age-related conditions increase the likelihood of its occurrence.
- Erectile dysfunction may be a consequence of medications taken for other problems or a result of drug abuse.
- Embarrassment of patients and the reluctance of both patients and health care providers to discuss sexual matters candidly contribute to underdiagnosis of erectile dysfunction.
- Contrary to present public and professional opinion, many cases of erectile dysfunction can be successfully managed with appropriately selected therapy.
- Men with erectile dysfunction require diagnostic evaluations and treatments specific and responsive to their circumstances. Patient compliance as well as patient and partner desires and expectations are important considerations in the choice of a particular treatment approach. A multidisciplinary approach may be of great benefit in defining the problem and arriving at a solution.
- The development of methods to quantify the degree of erectile dysfunction objectively would be extremely useful in the assessment both of the problem and of treatment outcomes.
- Education of physicians and other health professionals in aspects of human sexuality is currently inadequate, and curriculum development is urgently needed.
- Education of the public on aspects of sexual dysfunction and the availability of successful treatments is essential; media involvement in this effort is an important component. This should be combined with information designed to

expose “quack remedies” and protect men and their partners from economic and emotional losses.

- Important information on many aspects of erectile dysfunction is lacking; major research efforts are essential to the improvement of our understanding of the appropriate diagnostic assessments and treatments of this condition.
- Erectile dysfunction is an important public health problem deserving of increased support for basic science investigation and applied research.

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Speakers

Stanley E. Althof, Ph.D.
“Choosing Among Contemporary
Alternatives: Self-Injection
Versus Vacuum Pump
Therapy”

Alan H. Bennett, M.D.
“When to Perform Venous Studies
in the Impotent Patient”

Gregory Broderick, M.D.
“Drug-Induced Male Sexual
Dysfunction”

Irwin Goldstein, M.D.
“The Effect of Age-Related
Diseases on the Development
of Impotence”
“The Venous System in the
Diagnosis of Erectile Impo-
tence”
“Intracavernosal Therapy for
Erectile Impotence”

Helen Singer Kaplan, Ph.D.
“The Psychological Evaluation of
the Impotent Male”

Stanley G. Korenman, M.D.
“The Relationship Between
Impotence and Aging”

Ronald W. Lewis, M.D.
“Penile Prosthesis”

Tom F. Lue, M.D.
“Anatomy and Physiology of
Normal and Abnormal
Erection”
“The Diagnosis of Arterial-
Related Impotence”
“Peyronie’s Disease”

William H. Masters, M.D.
“Introduction: A History of the
Diagnosis and Treatment of
Impotence”

John B. McKinlay, Ph.D.
“The Prevalence and Demo-
graphics of Impotence”

Arnold Melman, M.D.
“The Argument Against the
Utilization of Arterial Studies in
the Diagnosis of Impotence”

Drogo K. Montague, M.D.
“General Diagnostic Procedures
Employed in the Diagnosis of
Erectile Impotence”

Alvaro Morales, M.D., F.R.C.S.(C)
“Hormonal Studies in the
Evaluation of the Impotent
Man”
“The Medical Management of
Impotence”

David Osborne, Ph.D.
“Behavioral Intervention in the
Treatment of Erectile Impo-
tence”

Jacob Rajfer, M.D.
“Nitric Oxide and Erections”

John Rowe, M.D.
“The Prevention of Erectile
Impotence—The Need for
Education”

Iñigo Saenz de Tejada, M.D.
“Vascular Physiology of Erec-
tion”

Michael H.H. Sohn, M.D.
“Vascular Procedures for the
Treatment of Erectile Impo-
tence”

William D. Steers, M.D.
“Neurophysiology of Penile
Erection”

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