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Editor's Note

Consensus or position papers are important to publish as rapidly as possible and to be discussed as broadly as possible. This procedure definitely brings openness and transparency for the peer group and makes it possible to develop one's own thoughts for the individual.

Furthermore as the therapeutic possibilities within the field of erectile dysfunction rapidly have changed into non-invasive procedures, new and for the moment, more-or-less unprepared primary care physicians are faced with a sexual symptom complex that needs professional handling.

This position paper facilitates the understanding of the road which could be followed. A group of eleven US-specialists within male sexual dysfuction has produced the recommendations based on the fact of the new pharmacological approaches, which only seems to be the beginning of an explosive new era.

Members of the editorial board of the *International Journal of Impotence Research* (from outside the US) have provided some comments in order to emphasize that traditions, ethical and social conditions are to be incorporated in our understanding of a goal-oriented approach.

Whenever a group of highly selected, knowledgeable specialists is gathered to work on a specific medical approach to treatment the traditional questions have to be asked: Who selected, who participated, who sponsored? An eternal dilemma for those who have the energy and take the initiatives. Although the questions are relevant, the key issue is that disclosure, transparency and open debate follow.

Soon to appear is the 1st International Consultation on Erectile Dysfunction which comprises the work of 18 committees. An extensive presentation by the committees, followed by open discussion before a set of recommendations are formulated, will take place in Paris, July 1–3, 1999.

With the present Position Paper as a forerunner, a major international group should be able to work out a complete set of contemporary professional points of view in relation to erectile dysfunction.

Human sexuality has come out in the open in an hitherto unheard way just before the new Millennium and the professionals have to hurry up in order to be able to tackle the new patient's demands in a proper way.

Gorm Wagner

Editorial Comments

The recent emergence of effective oral treatments for male sexual dysfunction has greatly increased the number of patients seeking help and has changed the approach towards them. Following an era of a small scale specialised monodisciplinary and aetiology-directed approach in the 1980s, to date the approach of male sexual dysfunction has become multidisciplinary and goal-directed, centred around the primary-care physician. The choice of treatment is decided on factors such as ease of administration, reversibility, invasiveness, costs and last but not least the patient's and partner's choice.

This change of culture, in the literature characterised in terms of 'medicalisation of male sexuality' or 'male sexual emancipation' was boosted by the fact that the oral treatments are beneficial irrespective of aetiology, the increase of

sexological knowledge amongst physicians, public awareness and the availability of sexological diagnostic tools, such as questionnaires.

The new situation made evidence-based standards and guidelines for diagnosis and treatment mandatory. The multidisciplinary US panel has recognised this need and professionally employed a valid methodology to develop consensus on definitions and classifications, rational utilisation of diagnostic and therapeutic options and clinical guidelines in a primary care setting. Strong emphasis is placed on the need for a multidisciplinary approach and the value of specialist consultation in well-defined situations. This initiative is appreciated greatly and I'm convinced that it will serve as a solid template for the creation of multiple local culture-adjusted guidelines.

E Meuleman
Nijmegen

in July, 1995 and I used it in China. In April 1996, in the morning, a couple visited the clinic and I gave my suggestion of PGE1 20 μg for intracavernosal injection— and the wife refused: 'Doctor it does not work, do not do more harm to it!' After that I made the decision to use 20 μg for the first visit hoping to get success in obtaining an erection: 'The first impression is the best impression'!

Third-line therapy, according to the Model, consists of penile prosthetic surgery. Both AMS and MENTOR developed a 3-piece inflatable prosthesis which I used selectively for organic patients from 1987; because of the high cost of the devices both doctors and patients shy away at the sight of these nice devices. Still I should do my best to provide emotional support and empathy to the ED patients in my country.

Feng Yi-ping
Guangzhou

The process of Care Model for Evaluation and Treatment of Erectile Dysfunction Panelists have contributed a significant article to the art and science of how to concern the patients suffering from male erectile dysfunction (ED). Six core positions and a new management algorithm for these patients were formulated by means of a three-stage process and six core positions in meticulous detail. I should say that the panelists defined the state of their art in the compound and complex field of erectile dysfunction area. It is a novel idea developed by the panelists in the United States. I read it several times and compared it with the National Institute of Health in December 1992. That was a landmark event and a significant advance. Now the panelists have reviewed articles concerning physiology, pathophysiology, definition, classification, diagnosis and treatment. It is a guide book for the doctors working in these fields.

ED is defined as being of at least three months duration. Is it too long? Because the penis is a terminal vascular organ and for 23 hours is flaccid and in tumescence for only one hour during sleeping. So the penis is a vital organ and has its special activities. Because of moral ethics in China there are still many ED patients who are too shy to tell their history in the Impotence Clinic. They were very eager to get ancient secret recipes, herbs, animal genital organ mixtures, extracts and powders. Their only aim is to make them shine fresh with vigour and rejuvenation again. I reviewed the ancient acupuncture books; no needle points in the penis! The FDA approved the PGE1(CAVERJECT)

The Process of Care Model for Erectile Dysfunction represents an outstanding contribution to the management by primary care physicians of erectile dysfunction (ED). The role of sildenafil in the tremendous changes that have occurred in this field must be once again emphasized. Epidemiological data are likely incomplete because we don't know among men who are suffering from ED who will ask for treatment. The degree of severity might not be related to the search for any medication. One of the most important contributions which is still lacking in the current debate is from the cardiologists. In order to increase the quality of our practice we have to remind ourselves that ED is often associated with sexual disorders, that is ejaculatory and/or orgasmic disorders and/or decrease in sexual desire in both males and females. Accordingly the next challenge for researchers in the field of ED is to promote an integrative approach of human sexuality on a physiological basis. That would lead to consideration that penile mechanisms of erection are centrally driven and that there is a single process from the brain *via* the spinal cord to the erectile tissue. Pathophysiology of ED is also located in the central nervous system and the so-called psychogenic ED has a biological support that is currently completely unknown. There is a unique opportunity for urologists and other experts to bridge the gap between central nervous system and peripheral genital functions. Modulation of sexual functions including penile erection by androgens deserves more attention in the near future. Androgens *per se* are very rarely

indicated in the treatment of ED. Conversely it might be very interesting in ageing males to test the combination of androgenotherapy with proerectile drugs acting peripherally and/or centrally. In conclusion, what are the vast majority of men consulting for ED seeking? I would answer— the fountain of youth as much as sexual performance. Therefore the emerging sexual medicine will have to deal with psychoneurobiology as well as with all the consequences of ageing.

F Giuliano
Paris

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S Glina
São Paulo

The availability of safe and effective oral drug therapy for erectile dysfunction (ED) brought a new scenario to the field of erectile dysfunction. Before the commercial releasing of Sildenafil urologists were responsible for 86% of the prescriptions to treat ED; now this figure has dropped to 54% in Brazil.

However, in Brazil, and probably in all South America, specialists (psychologists and/or urologists) still see most of the ED patients first and I cannot see any change in the near future in this situation, mainly because of our reimbursement system. Thus, all efforts should be made to educate those specialists in the field of ED.

The authors recommend those standards to make the management of ED more rational and cost-effective. Thus, I do not agree that serum prolactin determination should be obtained for every patient, since the incidence of hyperprolactinemia is very low. [1] This dosage should be done only when patient complains of low libido. As well as serum TSH dosage; hyper or hypothyroidism is a very rare etiology of ED, [1] it should be done only when there are specific symptoms.

I agree with the goal-oriented approach to treatment of ED. But I prefer to classify therapies as curative or palliative. The first are those which definitively restore the ability to have a satisfactory sexual performance: psychotherapy, penile implant, hormonal replacement and vascular repair. The palliative therapies are those which patients have to use every time they intend to have sexual intercourse. And here we can classify them as first line therapy (oral treatment), second line therapy (vacuum device and intraurethral medications) and third line therapy (intracavernous vaso-active drugs).

Management of every disease should respect local and cultural backgrounds. Because of all the taboos and myths related to sexual function, for ED this is truer than ever.

This paper should be understood as a 'Position paper' and not as anything else. It should be pointed out that guidelines based on the principles of evidence based medicine (EBM) can not be drawn from this publication. An international consensus panel, the 1st International Consultation on Erectile Dysfunction, has just been constituted, which is co-sponsored by the World Health Organization (WHO). This consensus panel is expected to fulfil exactly the task to define standards of care and guidelines for diagnosis and treatment of erectile dysfunction. The results will be discussed and published in July 1999.

In an era of extreme cost restrictions by public health insurances and government, it will be of the utmost importance which treatment modalities will be recommended as effective and indicated. The International Society of Impotence Research should refrain from recommendation resulting from *national* consensus panels in such a situation, especially if such a consensus panel is sponsored by the leading pharmaceutical company in this field.

The content of this 'position paper' is elaborate and based on actual knowledge and scientific literature. Nevertheless many details remain to be discussed: what constitutes a standard laboratory work-up in suspected hormonal insufficiency? What is the role of microvascular surgery in the future? It is simply not correct that the long-term success-rate ranges from 60–70%. Will intracavernosal injection therapy really be a 'second-line' treatment in erectile dysfunction? Would this be the conclusion if other pharmaceutical companies had sponsored this Care Consensus Panel?

Michael HH Sohn
Frankfurt

This position paper, prepared exclusively by US-experts, does not include any foreign cultural

aspects, which is a major shortcoming of this position paper.

Although many aspects of this paper may have also validity outside the USA there are nevertheless considerable cultural diffences among African, Asian or European nations concerning the diagnostic and therapeutic approach to erectile dysfunction. So, differently from the USA, European people encounter Viagra® with considerable more sceptisism than in the USA which is reflected not by a non-acceptance, but rather by an absence of the Viagra®–euphory—and the boom as seen in the USA.

Erectile dysfunction represents a world-wide and not an exclusive USA-affair. Considering this aspect the position paper has some not neglegible limitations. I guess that the intended consensus panel of the WHO, including scientific work, opinions and feelings of experts coming from all nations and continents, will provide a much more valuable position paper than this national one.

If we restrict our diagnostic efforts to laboratory examinations and physical examination, afterwards resulting in a Viagra®-test at home, no statement on the etiology of erectile dysfunction and therefore no counselling of the couple is possible in terms of vascular risk factor. A positive Viagra®-test at home does not provide any evidence on the etiology of erectile dysfunction as males with psychogenic, neurogenic, arteriogenic or dysfuncitonal veno-occlusive mechanism may respond to Viagra®.

The only reliable and valid method in vascular assessment and disclosure of severe arteriogenic impotence represents duplex-sonography in combination with an i.c. injection test with PGE1 (Caverject® or Edex®). [1] According to my personal and the experience of others,[2] males with arteriogenic impotence proven by duplex-sonography are at a 10–20% risk of severe obstruction in the coronary arteries with many of them not showing any clinical symptoms. If these males, who were frequently unable to perform sexual intercourse for a couple of years, are provided with the Viagra®-pill at home without any counselling and further vascular assessment you will also in the future see a plethora of sudden heart attacks during sexual activities in conjunction with the Viagra®-intake as it was repeatedly reported in the USA mass media. A more reasonable approach is to perform a thorough vascular assessment, as described above and as we have done in a well-tried manner before the Viagra®-era and afterwards to counsel the couple about the risk-factors and refer those males with severe penile arterial obstructions to further vascular work-up prior to the prescription of the Viagra®-pill.

This approach enables us to discuss the underlying etiology with the couples and to reduce the Viagra®-life-risk in endangered patients. The USA consensus panel should think about this issue and perhaps we will see fewer severe 'Viagra®-complications' in the future, especially in the USA.

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Harmut Porst
Hamburg

This process of care consensual panel gives the physician a very complete and accurate vision of the management of male erectile dysfunction (MED). I did appreciate the third line therapies according to the recent progress in oral medications and the discussion of cost benefit ratio, as well as 'the partner preferences' for therapy decision.

In Europe, vacuum constriction devices are not as popular as in the USA. However, elastic constriction band at the base of the penis is often proposed and used in cases of venous incompetence. Psychological therapy can be of help to reduce some sexual disorders and improve sexual performance. We need more clinical trials to appreciate its effectiveness. I do not know why intracavernosal injections (ICI) are considered as second line therapy. Patients who have no significant decrease in desire can take advantage of such treatment. ICI entails a very low risk of side effects and the cost is comparable to Sildenafil. Penile prostheses especially in the USA have been thoughtlessly implanted with some disappointing partner opinions.

I have not read anything about microrevascularization. I think is a greater forgetfulness for some traumatic or vascular erectile dysfunction. In specific cases vascular surgery has to be proposed before prosthesis implants.

Because erectile dysfunction is a more and more frequent symptom, physicians and specialists need a consensus model for diagnosis assessment and treatment. Finally the international index of erectile function (IIEF) appears to be a mandatory scale of high sensitivity and specificity, in the detection of treatment related changes in patient suffering ED.

JP Sarramon
Toulouse

In this paper the authors propose a care model for erectile dysfunction.

I think most of us can subscribe the proposals! The consensus on definition, classification, rational utilization of diagnostic and therapeutic options and guidelines for the management of erectile dysfunction is certainly welcome. It is evident that a comprehensive medical and psychosocial history is the cornerstone for initial evaluation. This will permit the classification according to onset, severity and, eventually, probable etiology.

This will be completed by a physical examination, followed by selective laboratory testing. Whether the latter should be performed in all circumstances, when for example the etiology is evident, is debatable, but in the absence of an evident organic cause, a prolactin determination is certainly indicated. Although rarely the primary cause of sexual dysfunction, except in the relatively rare cases of primary hypogonadism consulting primarily for erectile dysfunction, it is evident that an adequate testosterone level is required for satisfactory sexual function. It is generally accepted that the biological active fraction of testosterone is more important than total testosterone and therefore either free testosterone or bioavailable testosterone should be measured. When subnormal levels are found, the cause of these low levels should be investigated, as psychogenic factors such as depression, anxiety or stress as well as several medications or drugs may affect Leydig cell function, besides affecting eventually directly erectile function. Also atherosclerosis may affect testicular perfusion and hence Leydig cell function.

We doubt whether in the absence of signs or symptoms of thyroid dysfunction, measurement of TSE is meaningful for the exploration of erectile dysfunction. If thyroid dysfunction is suspected, then free testosterone should be measured, as thyroid function affects the protein-binding of testosterone. The same can be said concerning PSA, the determination of which is only indicated when testosterone substitution is planned.

Modification of reversible causes of erectile dysfunction prior to or in conjunction with specific therapeutic interventions is self evident. Most effective will be the elimination, whenever possible, of drugs that may adversely affect sexual function, and their substitution by other medication.

The stepwise treatment approach for erectile dysfunction will certainly find general approval. Oral erectogenic drugs are certainly first line therapies, although new oral drugs, causing less side effects and hence with a broader indication field (and less expensive) are eagerly awaited.

Vacuum constriction devices, a rather unesthetic procedure are less popular in our country.

Psychosexual therapy, preferentially of the couple, should complement the oral treatment when necessary. Intra-urethral and intracavernosal prostaglandin E are nowadays second line therapies, whereas surgical implantation of penile prosthesis remains limited to selected cases, the more that the cost of this procedure is not negligible. Futher research on the role and mechanism of aging and disease related factors in the etiology of erectile dysfunction is certainly required and will, hopefully, allow a more etiologic approach to the treatment.

A Vermeulen
Gent

The need to provide guidance to primary care physicians for the management of erectile dysfunction is desirable now that effective oral therapy is available. I have no difficulty in supporting this document but unfortunately I think that it will fail in its objectives as although it is written by an eminent panel it lacks the focus and dogmatism that I believe to be necessary. This would seem to have occurred because of their commendable wish to educate and emphasise the need for holistic care.

I will focus on the minimum requirements for investigation as this is a much debated issue. The primary care physician needs clear guidance as to what is necessary and what is optional. The ESIR guide for physicians suggested that it was essential to exclude diabetes and have a testosterone level. One set of guidelines in the United Kingdom does not consider that it is necessary to have the testosterone estimation in all patients. The current guide would seem to suggest a testosterone and a prolactin level. What is the need to perform standard chemistries, a complete blood count, lipid profile, thyroid stimulating hormone and a PSA in selected patients with erectile dysfunciton? Are these screening tests to be performed whenever there is a doctor patient interaction, and, if not, when should they be performed? To say that they may be performed is to state the obvious and surely unnecessary.

Given the educational need of the guide it might well have been reasonable to include some indication of the outcomes expected from different treatments.

John P Pryor
London