

Health Economics and Sexual Dysfunction

Based on a presentation by Cyril F. Chang, PhD

Presentation Summary

Erectile dysfunction (ED) and the results of its treatment are two separate issues, centering on how outcomes of the disorder affect the economy and the impact its treatment has on quality of life. The treatment of ED has been an \$800-million-a-year business in the United States alone. The recent introduction of the drug sildenafil raises the possibility that revenues from its sale could reap

billions of dollars for the pharmaceutical industry, with much of that cost being borne by the managed care industry. The introduction of sildenafil raises new cost-effectiveness concerns about all available treatment options. Both the National Institutes of Health and the American Urological Association have identified the need for better studies whose outcomes could be used to analyze the problem of ED.

The outcomes of erectile dysfunction (ED) and the consequences of its treatment for men and their partners are separate issues, according to Cyril F. Chang, PhD. The consequent issues center on how the outcomes of ED affect the economy and how the treatment of ED influences quality of life.

Dr. Chang declined to address the consequences of ED on the national economy because of the lack of empirical evidence. He chose instead to focus on the costs of different treatment options. "I want to identify research that needs to be done so that credible, large-scale, cost-effectiveness analyses of ED can be narrowed

down and translated into a recommendation for a policy or practice guideline," he explained.

Evaluation of men with ED raises questions regarding the cost and cost effectiveness of various treatment options, Dr. Chang elaborated. "My search of the literature turned up more than 5000 articles on 'erectile dysfunction' and 'impotence' but only 15 when those terms were linked with the word 'cost effectiveness'," he said.

Costs of Treating ED

"Treating ED in America is an \$800 million business," Dr. Chang said, adding that "the remedies are harsh and range from a \$15 drug to a

\$20,000 penile implant." By contrast, he said, "one sildenafil tablet costs about \$9 and is swallowed 1 hour before intercourse, which accounts for its appeal, according to an article in *US News and World Report*." (Cohen W. Wall Street cheers new pill for impotence. *U.S. News and World Report* 1998;124(April 13):5.)

"The popularity of sildenafil is good news from the standpoint of a pharmaceutical firm," Dr. Chang noted, "because it means that if one in five men were to use sildenafil, its annual sales would be \$4 billion in the United States alone." (Stipp D. The selling of impotence. *Fortune* 1998;136:114-122.) However, from a managed care standpoint, if one company takes in that much revenue, it means managed care organizations will probably have to pay it," he added.

Available Treatment Options

Six types of treatment options are mentioned in the literature, according to Dr. Chang. These include removal of offending agents, counseling and sex therapy, constriction devices, oral pharmacotherapies, local pharmacotherapies, and surgical procedures. He went on to summarize each option in terms of its major outcomes, the direct cost of the intervention, and the indirect and hidden costs associated with each type of treatment.

"The number one offending agents are lifestyle products, such as tobacco, alcohol, and drugs that people take for other medical problems," Dr. Chang said, noting that "there is a direct cost that we can measure in identifying offending agents, but identifying the indirect cost is no less important. For example, suppose an agent is providing benefits to the patient, but when it is removed and replaced with an alternative, the alternative may not work as well. This leads to indirect costs that are also a cause for concern.

"The second treatment option," Dr. Chang continued, "is counseling and sex therapy, which some studies say

are effective. I don't know how cost effective they are, because there are no reliable estimates of direct and indirect costs."

The vacuum pump, a third option, is probably the least expensive way to treat ED, Dr. Chang, said, noting that it is quite effective as well as noninvasive. The cost of a vacuum pump ranges from \$200 to \$500, and it usually lasts a long time. (Cowley G. Is sex a necessity? *Newsweek* 1998;131(May 11):62-64.) "So, from a cost standpoint, the vacuum pump is a rather attractive option," he said, adding that some patients find it hard to use.

According to Dr. Chang, most oral agents have proved to be ineffective, except for sildenafil and three other investigative agents—phentolamine, L-arginine, and apomorphine—which are undergoing clinical trials.¹ The direct cost of sildenafil is between \$8 and \$10 a pill, depending on the frequency of use and whether or not the prescribing physician sees the patient. The indirect cost of sildenafil includes its side effects, which on the basis of current scientific results, are minimal.

Sildenafil Side Effects Worrisome

"The possibility of hidden adverse side effects to sildenafil is worrisome," Dr. Chang said. "Sildenafil has been on the market only since late March, so at this point we know its short-term side effects but not its long-term ones." However, he cautioned, "there can be identifiable, serious consequences. For instance, if the symptom of ED is smoothed over by this wonder drug, it may cause the physician to overlook the underlying problem. If that occurs, we will all pay a dear price for having prescribed sildenafil.

"Based on what I have learned from others involved in this presentation, I have changed my mind about sildenafil's indirect costs," Dr. Chang continued. "I realize that we have to be very vigilant in terms of knowing when to use it. Sometimes something

may be too good to be true, and this could be one of those times."

Another therapy for the treatment of ED is drug injections, of which there are several types. Dr Chang estimated the cost of these injections to be about \$18 for one-time use.² Over a 5-year period the cost of such an injection agent would be about \$3450, based on an average of 10 uses per month. The injections have some side effects, he noted, such as mild-to-moderate pain and fibrosis. Some of the agents might also cause a prolonged erection, which could have serious consequences.

The medicated urethral suppository for erection is another option, according to Dr. Chang. The effectiveness of this approach is in the 56% range, and it is moderately expensive. (Horvitz LA. Can better sex come with a pill? The nineties' impotence cure. *Insight on the News* 1997: 13:38-40.) Its side effects consist mainly of pain and moderate aching for both partners.

Surgery, the third line of defense, is the most invasive of the treatments for ED, both in terms of the procedure and its side effects. And such surgery is also "invasive" in terms of dollars and cents, costing \$10,000 to \$25,000, depending on where the procedure is performed and general medical costs in that locale. "Surgery is expensive, invasive, irreversible, and once it is performed it requires the subsequent use of a vacuum pump or injection therapy," Dr. Chang observed. "Little wonder it is considered to be the last line of defense!"

Research Funding Needed

There have been efforts to obtain funding from the National Institutes of Health for the treatment of ED, according to Dr. Chang. The American Urological Association has called for better research design studies and urged that outcomes be used for analysis.

Dr. Chang interpreted this to indicate that a comprehensive, well-

designed cost-effectiveness analysis of all viable treatment modalities for this medical condition is needed because currently, the best studies available are those based on cost identification.

"When doing economic evaluations of a medical intervention, there are several steps involved. First, you must identify the cost. Next, is to conduct a full-scale cost-and-benefit analysis that estimates the benefits as well as the costs of treatment to see whether the benefits exceed the costs by a substantial amount," Dr. Chang said. "Benefits relate to avoiding the consequences of inaction," he explained, noting that if a cost estimate can be assigned to the consequences of doing nothing, then avoiding problems becomes the main benefit of treating them.

Cost Benefit Versus Cost Effectiveness

When benefits are compared with the cost of treatment, the result is a cost-benefit analysis, but that is not usually the preferred approach to research in medical intervention, according to Dr. Chang.

With medical interventions, a cost-effectiveness analysis is done that starts with the assumption that an array of treatments can accomplish the same objective. Having such options is seen as being desirable.

"Such esoteric economic issues as discounting are also taken into consideration," Dr. Chang said, "because the cost of a one-shot approach is being compared with the cost of treatments that may go on for a lifetime. "If the cost for a one-time-only expense is compared with a long-term expense, inflation becomes a factor," he added.

"In addition to concerns about the identification of treatment costs and treatment outcomes, there is also a problem as to the quality of outcomes," Dr. Chang said. "No matter how accurately the costs and outcomes are defined, the latter must be clearly and appropriately defined for a

good cost-effectiveness analysis to result.

"But quality-adjusted outcome measures are not without their own problems," Dr. Chang warned. Sometimes such a measure rates outcomes satisfaction on a 100-point scale, he explained, adding that "once you define outcomes in that manner the results are not easy to translate into policy recommendations because they will be stated in terms of cost-per-satisfaction point. Such an approach makes very little sense to policy makers, managed care organizations, and practitioners."

"When we define ED," Dr. Chang continued, "we must be mindful of whether such an outcome measure will provide meaningful interpretations and how practical the policy is."

Dr. Chang cited a series of cost-effectiveness recommendations that were published in *The Journal of the American Medical Association* in

It is necessary to go beyond the clinical guideline of ED and come up with a well-designed cost-effectiveness analysis guideline for research on the problem that not only shows what works but what works in a cost effective manner.

—Cyril F. Chang, PhD

1997 as being the latest set of recommendations in terms of how to go about performing a cost-effectiveness analysis for medical interventions.³ "These results are very well written and are the result of 5 years' work," he noted.

"As to the details of such a cost-effectiveness analysis," Dr. Chang said, "it is necessary to go beyond the clinical guideline of ED and come up with a well-designed cost-effectiveness analysis guideline for research

on the problem that not only shows what works but what works in a cost-effective manner. Then and only then can the results of these cost-effectiveness analyses be translated into practical guidelines for practice and recommendations that managed care organizations can use so they not only practice effective medicine but also cost-effective medicine."

"Although I am an economist, I must emphasize that doctors should be allowed to be doctors and that medical decisions should be made primarily by doctors. The last thing we want to do is to turn doctors into MBAs," Dr. Chang concluded.

...DISCUSSION HIGHLIGHTS...

Dr. Chang: Before we begin this discussion, I suggest we separate it into two categories; one is theory, the other is evidence.

Economic Effects of ED

Dr. Leider: Do you mean determining if there is an economic impact to ED in terms of whether you treat it or not?

Dr. Jarow: Exactly, Dr. Leider. Let's take hypertension as an example. Theoretically, if you fail to treat it, you'll have heart attacks and strokes that will cost money down the road.

Dr. Parham: Erectile dysfunction certainly has an effect on emotional well-being.

Dr. Sadovsky: There may be no financial effect to mild arthritis, yet we treat it. Whether a symptom does or does not have economic consequences may or may not be germane to the final decisions at which we are trying to arrive. I just want us to keep that consideration in the background.

Dr. Basskin: The reason why managed care won't cover ED is pretty clear—it does not see economic ben-

efits that justify the cost. If employers went to managed care providers and said, "We have evidence that sexual dysfunction is costing us money, and we are prepared to pay more in premiums because we cannot afford to have employees absent from work," then maybe things would change.

Until somebody actually proves that quality of life is an outcome for which those who pay the premiums are willing to cover, I don't see managed care considering ED to be something that justifies treatment.

ED as a Lifestyle Issue

Dr. Parham: Dr. Basskin, some managed care plans already do cover treatment for ED.

Dr. Basskin: Yes, but sildenafil is an interesting drug. We know it works. This isn't theoretical—sildenafil works. I doubt there would be any problem about efficacy if you could find a number of surveys that demonstrated quality of life had improved for patients who now have erectile function. The issue is whether improved quality of life results in any economic benefits.

Dr. Leider: This is a lifestyle issue, Dr. Basskin, not an economic one. There are many disorders you could use as analogies to ED, where managed care is struggling to decide whether to cover them because of the lifestyle issue.

Think about infertility. It can cause depression, functional problems for couples, decreased productivity, days lost from work, and all sorts of things. We in managed care struggle to decide whether it is something we should cover—or is it a lifestyle issue? Psychotherapy for marital or family problems and cosmetic surgery are other analogous areas.

Consumer-Driven Response

Dr. Kloner: I think consumers are going to be the ones who eventually

drive managed care organizations to cover lifestyle services and treatments.

Dr. Parham: The question is whether in the 21st century consumers will say, "We want all the managed care we can get, and we are willing to share the costs of it."

Dr. Kloner: Dr. Leider, has anything been said about premiums or add-ons that consumers can choose to pay if they want managed care to cover a lifestyle service or treatment? Obviously, such coverage is going to increase their premiums.

Dr. Leider: Some plans, including ours, offer employers a rider, that is, additional coverage and cost if, for example, they want infertility treatment covered for their employees. So one paradigm would be that you could offer an enhanced or higher premium to employers and the government.

ED: Lifestyle or Medical Issue?

Dr. Jarow: We have all been using the term "lifestyle issue." Is there a general consensus that ED is just a lifestyle issue and not a medical one?

Dr. Leider: I think it is hard to separate the two. I can't clearly make that distinction.

Dr. Jarow: You wouldn't call diabetes a lifestyle issue, would you? Yet it is clearly impacted by lifestyle. What about heart disease?

Dr. Leider: Okay, I would say that ED is both a medical problem and a lifestyle issue.

Dr. Carson: It depends on your definition. You have to define your terms carefully when discussing a lifestyle issue. The arthritis you were talking about; that's a lifestyle issue. It makes a person uncomfortable to walk from

his or her car to his or her desk. Well, that person gets to his or her desk, but it hurts like hell getting there.

Dr. Sadovsky: I don't like the phrase "lifestyle issue." Unfortunately, it is being used both to defend and object to paying for things that affect lifestyle. There may be other, more appropriate terminology; not everything is either a lifestyle issue or a medical issue.

Dr. Basskin: I agree with Dr. Sadovsky. "Quality of life" is an appropriate term, but I don't like the term "lifestyle issue."

Dr. Rajfer: Then how do you define ED? What sort of guideline are you going to use? How do you decide what is medical and what is not?

Dr. Jarow: Regardless of coverage, is ED a medical problem or a quality-of-life problem?

Dr. Leider: I don't think managed care should make that distinction, Dr. Jarow, because it affects the person's life. I have not entirely bought into whether we should cover it or not, but I think it's pretty arbitrary to say to a man, "Well, if your ED is the result of a drug you're taking, we will cover it, but if it is caused by something else, we won't cover it."

Dr. Parham: I agree. Not only is it wrong to do that, it is simply administratively impossible. So the path most managed care plans have taken is that ED, regardless of its cause or who diagnosed it, is covered. The medical disorder versus lifestyle issue is just too difficult to administrate in an insurance environment, and even if you could, the expense of doing it would outweigh any benefit.

What Will Managed Care Cover?

Dr. Carson: But that's not what happens, Dr. Parham. All of us in urology have had patients for whom we write

a prescription for sildenafil and then we get a call from their managed care company saying we have to document the need for it.

Dr. Parham: True, but that doesn't mean we won't pay for it; it just means we require a certain level of documentation.

Dr. Carson: So it is back to the administrative thing. You are saying that managed care will pay for it if it is caused by XYZ, but will not pay for it if it is caused by ABC. You are asking the physician to indicate whether this is or is not a medical condition.

Dr. Chang: The central question is, how much is the patient entitled to under a managed care contract? How much care does a health plan owe a patient?

Insurance makes sense only for covering unpredictable events that involve large amounts of money. So when you pose the question of whether a certain treatment should be delivered, the answers you get from someone with insurance and someone without insurance will be very, very different.

Medical Savings Accounts

Dr. Carson: Dr. Chang, are you basically supporting medical savings accounts with crisis insurance on top of them?

Dr. Chang: I would go so far as to sever the relationship between employment and insurance so that employers can turn the amount they pay for employee medical insurance into take-home pay.

Dr. Basskin: According to urologists and family practitioners, ED is a medical problem no different from any other medical problem that they feel merits treatment and that cost is not an issue.

Dr. Sadovsky: Well, I don't know that any of us has directly said that

managed care should pay for sildenafil.

Dr. Basskin: Forget managed care, assume every patient pays for his or her own medication, and you don't even know whether the patient is insured. The question becomes, is there any medical problem in the area of sexual dysfunction that you think does not warrant treatment?

Dr. Leider: Yes, Dr. Basskin. I wouldn't treat problems experienced by patients whose ED does not bother them that much. They might only occasionally have a problem, and are able to have satisfactory sex most of the time.

Dr. Jarow: Going back to "lifestyle." I think "quality of life" is a better term.

Dr. Rowland: I agree, Dr. Jarow. I don't think any medical treatment exists that isn't improving quality of life in some way. That's the whole point of it.

Lifestyle is really a different issue. I believe each of us would agree that if a person wants to change his or her lifestyle, that's the person's responsibility. But quality of life is clearly an issue in situations involving ED. It is not simply a matter of how improved quality of life affects productivity or decreased quality of life worsens it; otherwise, anybody outside the work force would not deserve treatment.

We are really talking about how well a person functions in society, including in his interpersonal relationships. My point is that "functioning" applies to many aspects of a person's life; we should not limit its definition to productivity alone. We do not decide who gets medical treatment and who is going to pay for it on the basis of the person's productivity.

Dr. Leider: I feel everyone in our society has the right to aspire to whatever degree of quality of life he or

she wants. We don't have the right to say he or she doesn't deserve that quality of life.

Coverage as an Option

Dr. Chang: So it appears the solution for managed care organizations or insurance companies is to offer options to their basic plans. The trouble is when you offer those options to employers and add to that the com-

We are really talking about how well a person functions in society, including in his interpersonal relationships. My point is that "functioning" applies to many aspects of a person's life; we should not limit its definition to productivity alone.

—David L. Rowland, MD

petition you face from other companies that are offering the same thing, guess which plan the employer will buy for his or her employees? The employer will buy the one that simply promises to pay for everything that is medically necessary and at a very low cost.

Dr. Leider: The other point about the insurance issue concerns age. If we look at the age curves that were discussed earlier, the highest prevalence of ED is going to be in men older than age 65. In managed care, the government predetermines the reimbursement health plans receive if the patient is in a Medicare HMO. There is no negotiation, and there are no options you can offer the government. Depending on the county you're in, you receive a certain amount of money and are left to your own devices as to how to use it.

So even if we could create such a vehicle in the commercial market for

those younger than age 65, the government is not giving us the option of creating that sort of coverage for those 65 and older.

Dr. Jarow: Five years ago, Medicare and the Veterans Administration covered ED, so using that as a standard, it was a medical problem. Why is it that today, when sildenafil is available, coverage for treatment is viewed quite differently?

Dr. Parham: I'm sure there are any number of combinations of what managed care companies will and won't pay for.

Dr. Basskin: Realistically, many drugs are chosen by hospitals, health maintenance organizations, and managed care organizations on the basis of a combination of cost and efficacy, but if they can get a drug for free, they will use it.

One of the biggest examples is nitroglycerin patches, which are very expensive for patients, but drug companies give them away in hospitals. The hospitals then have a choice of buying nitro paste, which is messy and costly, or taking these free patches, which are quick and easy to use. But when the patient is discharged, he or she is hooked on the patches;

that's where the big expense comes in. The same thing happens with some asthma inhalers.

So when you devise your pathways and your algorithms, why do you omit a drug that we can get at no cost?

Dr. Parham: We don't omit it, we simply add it. Most managed care plans have tiers of coverage as opposed to no coverage. I think the managed care industry is moving away from the closed formulary concept, because it is very clear that when you try to include some things and exclude others it causes a lot of grief.

We have begun to include everything and fairly price it for those who are actually using the product or service. This puts the choice of which drug or procedure to use back on the individual who most benefits from it.

...REFERENCES...

1. Burnett AL. Erectile dysfunction: A practical approach for primary care. *Geriatrics* 1998;53:34-41.
2. Saunders CS. New treatment for erectile dysfunction. *Patient Care* 1998;32:30-40.
3. Skolnick A. Guidelines for treating erectile dysfunction issued. *JAMA* 1997;277:7-9.