Valuing Viagra: What Is Restoring Potency Worth?

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CONTEXT. The use of Viagra (sildenafil) (Pfizer, New York, New York) for treating impotence has increased dramatically. However, the cost of the drug and philosophical questions about what defines a medical condition have sparked controversy over whether insurance policies should cover impotence treatment.

COUNT. The utility of life with impotence at which Viagra meets the conventional criterion for cost-effectiveness (i.e., <$50,000 per quality-adjusted life-year [QALY]).

CALCULATION. We solved the following equation for utility of life with impotence:

$$\text{Cost-effectiveness} = \frac{(\text{Cost of Viagra} - \text{Cost of no Viagra})}{(\text{QALY potent} - \text{QALY impotent})}$$

$$\text{where QALY} = \text{years} \times \text{utility for health state}$$

RESULTS. Assuming that Viagra is used twice a week and that it costs $10 per pill, the utility of life with impotence would have to be less than 0.98 (compared with quality of life without impotence) for Viagra to meet the conventional criterion for cost-effectiveness. For patients using Viagra once or three times per week, the corresponding threshold utilities for impotence were 0.99 and 0.97, respectively.

CONCLUSIONS. For men whose quality of life is sufficiently diminished by impotence, Viagra would be considered cost-effective relative to other commonly used health interventions.

Impotence is a common disorder that affects approximately 10 million American men, including 25% of men older than age 65.[1] For a substantial proportion of men, Viagra can restore potency. In one randomized trial, 69% of Viagra users became potent, as compared with 22% of placebo users.[2] As a result of its efficacy, ease of use, and limited side effect profile, Viagra has enjoyed widespread popularity since its initial marketing in early 1998. Ongoing treatment with Viagra, however, is expensive (approximately $10 per pill). Three months after its introduction, prescriptions for Viagra totaled 2.9 million and sales were estimated at $260 million.[3]

Citing the cost of the drug and the "life-enhancing" nature of its effect, several large health plans and insurance companies decided not to cover Viagra or instituted restrictive coverage (e.g., covering only 10 or 12 pills a month).[4] These policies have stimulated a philosophical discussion about what constitutes a medical problem and whether we should distinguish between life-enhancing drugs and drugs that affect morbidity and mortality. To date, no formal assessments of the extent to which men feel their quality of life is diminished by impotence (i.e., utility; *see* **Primer**) have been done.

Cost-effectiveness analysis is a way to formally assess the relation among cost, efficacy, and patient values. An intervention's marginal cost-effectiveness ratio is determined by dividing its net cost by its net benefit, which is often expressed in terms of quality-adjusted life-years (QALYs).[5] Although the specific threshold at which an intervention becomes cost-effective is controversial, interventions with marginal cost-effectiveness ratios less than $50,000 per QALY saved are generally accepted as reasonable expenditures.[6] We used a simple cost-effectiveness model and

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Primer on Utilities

Utilities are numerical expressions of patient preferences for a particular state of health. Although utilities and measures of functional status both reflect quality of life, utilities describe how patients feel about or value living with a given clinical condition, and measures of functional status generally reflect the limitations experienced by patients with a clinical condition (e.g., New York Heart Association class for congestive heart failure). Utilities are typically assessed on a scale from 0 (death or worst health imaginable) to 1 (best health).

Patient utilities may be measured by using a variety of techniques (Figure). With the simplest approach, the visual analogue scale, patients simply mark an "X" on a continuous scale between 0 and 1. More commonly, utilities are elicited by asking patients to make a series of choices to identify at what point they are indifferent about the choice between two options. There are two commonly used iterative approaches to assessing utilities. With the time trade-off method, for example, patients might be asked whether they would prefer to live 10 years in good health or 20 years with a disabling stroke. If they chose the latter, the choice might be modified to 15 years in good health or 20 years living with a disabling stroke. This iterative process would continue until a patient was indifferent about the choice between the two options—for example, that living 12 years in good health was equivalent to living 20 years with a disabling stroke. In this case, the utility for stroke is the ratio of the two values: 12/20 = 0.6 (Figure). With the standard gamble method, a patient is instead asked to choose between life with a specific condition and a gamble with variable probabilities of life without the condition and death.

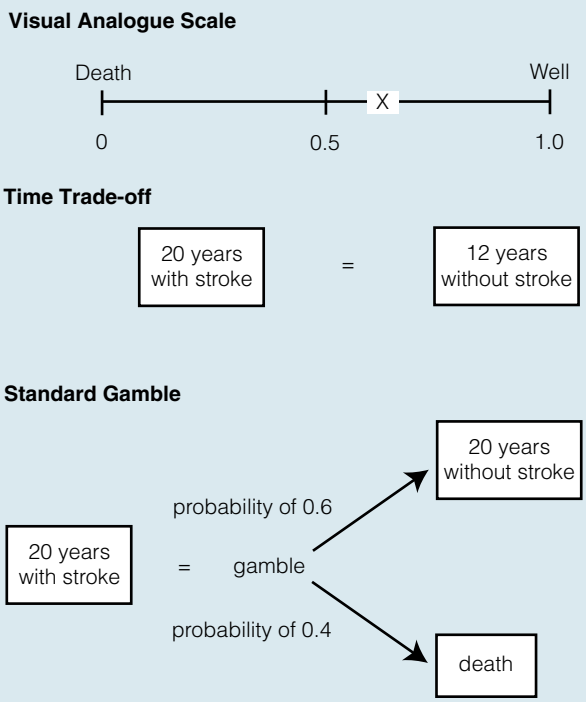

FIGURE. Three ways to measure or express a utility of 0.6 for disabling stroke.

Average utilities for a wide variety of clinical conditions or symptoms may be obtained from the literature. One often-used catalogue is the Beaver Dam study.[1] This population-based study describes utilities (obtained by two different methods) for patients with a variety of common clinical conditions, such as severe back pain (0.87), insulin-dependent diabetes (0.72), and cataract (0.94).

One familiar application of utilities is the quality-adjusted life-year (QALY). To calculate QALYs, time spent in a particular outcome state is multiplied by the utility for life in that state. For example, 10 years after a disabling stroke (utility of 0.6) is equivalent to 6.0 QALYs (10 x 0.6 = 6.0 QALYs). This aggregate measure is frequently used in decision analysis and cost-effectiveness analysis to compare the relative value of clinical interventions.

Reference

1. Fryback DG, Dasbach EJ, Klein R, et al. The Beaver Dam Health Outcomes Study: initial catalog of health-state quality factors. Med Decis Making. 1993;13:89-102.

sensitivity analysis to calculate the utility of life with impotence that would be necessary for Viagra to meet the conventional criterion for cost-effectiveness (i.e., <$50,000 per QALY).

Methods

Model

Figure 1 shows our back-of-the-envelope calculation. To calculate the threshold utility of life with impotence (that at which Viagra costs <$50,000 per QALY saved), we started with a basic equation for calculating marginal cost-effectiveness. We then specified each variable in greater detail, inserted values for known variables (utility of life without impotence = 1), and eliminated zero terms (cost of no treatment). Finally, the equation was rearranged, solving for the threshold utility of impotence. Note that both the numerator and the denominator of the cost-effectiveness ratio are directly proportional to the duration of treatment. Thus, our calculations of the threshold utility of impotence would not change regardless of whether they were based on a single year or remaining life expectancy. For similar reasons, our calculations would not be affected by discounting.

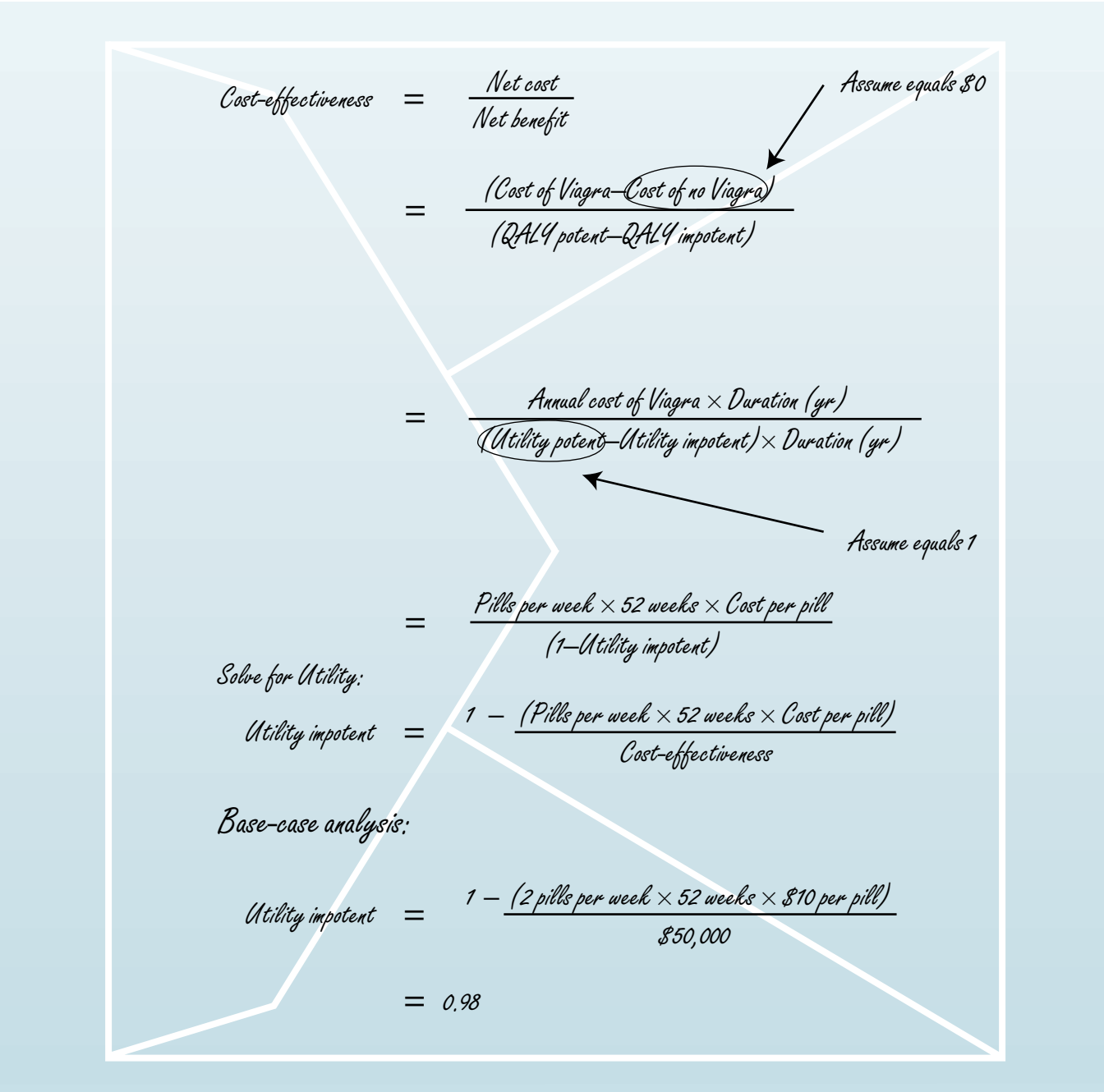

FIGURE 1. Back-of-the-envelope calculation for estimating the utility of impotence required for Viagra to be cost-effective (i.e., intervention costs less than $50,000 per quality-adjusted life-year [QALY]).

For our base-case analysis, we assumed that men would use Viagra two times a week at a cost of $10 per dose, or $1040 per year. We did not include costs for physician visits because men with erectile dysfunction are likely to see physicians for other health problems. Because the study of the efficacy of Viagra did not find significant adverse side effects, we assumed that it did not cause morbidity. Finally, we assumed that men for whom Viagra was ineffective would stop using it after a few attempts. Because their drug costs would be small compared with those for men who use Viagra regularly, we did not consider those patients in our analysis.

Benchmark Utilities

To provide benchmarks for the utilities generated in our analysis, we annotated **Figure 2** with utilities for other common health conditions. These utilities were measured in the Beaver Dam Health Outcomes Study.[8] Because the patients enrolled in this study often had multiple chronic diseases, the baseline utility of patients was less than 1.0 (the utility of life for people

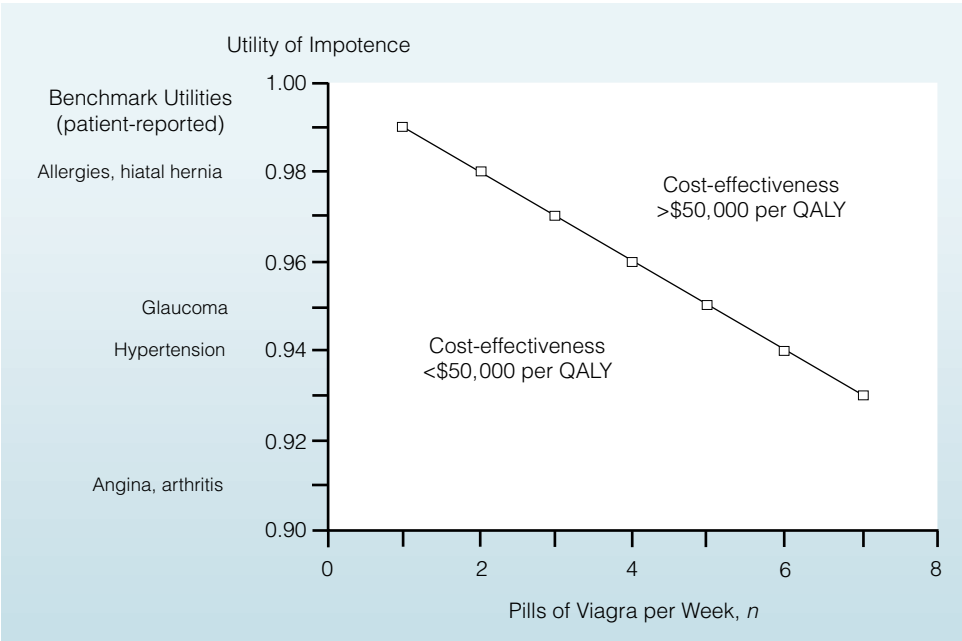

FIGURE 2. Sensitivity analysis of the utility of impotence by the number of pills per week. The y-axis is annotated with utilities reported by patients in the Beaver Dam study[8] to provide benchmarks for comparison (standardized to a baseline utility of 1). QALY = quality-adjusted life-year.

in perfect health). We adjusted for this by dividing the utility of persons with the condition by the utility of persons without the condition. For example, persons affected by hypertension had a utility of 0.83, whereas those without hypertension had a utility of 0.88. To find the decrement to quality of life from hypertension, we divided 0.83 by 0.88 to obtain an adjusted utility of 0.94.

Results

Figure 2 shows that, when used twice a week, Viagra is cost-effective for patients who rate the utility of life with impotence to be 0.98 or lower (relative to life without impotence). With less frequent use (and thus lower costs), the threshold utility is higher. However, with more frequent use (three or more times per week), Viagra is cost-effective only in patients with utilities for impotence of 0.97 and lower. **Figure 2** also shows that the threshold utility of 0.98 required for cost-effectiveness is identical to utilities measured in people with allergies and hiatal hernia and higher than those measured for chronic conditions like hypertension.

Discussion

By using a conventional benchmark of cost-effectiveness ($50,000 per QALY saved), Viagra is cost-effective for men who are sufficiently bothered by life with impotence. In our base-case analysis (based on twice-weekly use of the drug), the threshold utility for impotence was 0.98. In terms of the standard gamble[7] (*see* **Primer**), this number means that impotent men would have to accept a probability of death of 2% to undergo a procedure that would restore potency. In terms of the time trade-off method (*see* **Primer**), this means that impotent men would be willing to give up 2% of their life to live the remaining 98% as potent men. If their remaining life expectancy is 10 years, patients would have to be willing to trade 0.2 years for potency. Many common conditions are associated with adjusted utilities below 0.98.[8] For example, hypertension has an adjusted utility of 0.94. It is likely that many men consider impotence a larger detriment to quality of life than hypertension.

Because of the medication's cost, frequency of Viagra use has important implications on cost-effectiveness. In other words, as net cost increases, net benefit must also increase to maintain the same cost-effectiveness ratio. Because net benefit is simply the difference between utility for life potent and utility for life impotent, the latter must decrease. Specifically, with each additional time per week Viagra is used, the utility for life with impotence at which treatment is cost-effective decreases by 0.01. However, even people who use Viagra six times a week only need to have a decrement in quality of life equal to that of people with hypertension to make Viagra cost-effective. Furthermore, men who want to have intercourse more frequently are likely to value potency even more than men with less interest; consequently, such men probably experience a greater decrease in quality of life with impotence.

Our calculations have several limitations. First, because the only adverse effects noted were mild and included headache, flushing, and dyspepsia, we

assumed that the drug had minimal short-term effects on mortality and minimal effects on morbidity and therefore minimal effects on quality of life. However, patients with severe aortoiliac occlusive disease have concomitant coronary disease and receive nitroglycerin; these patients can have a precipitous decline in blood pressure and can have more severe effects with the drug.[8] Therefore, this calculation would not apply to patients with severe atherosclerotic disease. Second, the original Viagra trial was of relatively short duration (24-week follow-up for the dose-response study and 12-week follow-up for the dose-escalation study).[2] Therefore, long-term adverse effects or efficacy remains unknown. Third, we did not account for the cost of Viagra in men for whom it was not effective because this cost is likely to be a small proportion of the total cost. Fewer than 33% of men in the original trial found Viagra to be ineffective, and these men would probably use Viagra only a few times before stopping.

Our analysis assumes that payers and policymakers would evaluate Viagra in the same manner as they would more conventional clinical interventions that reduce morbidity and mortality. This may not be the case. The availability of treatments for lifestyle-limiting conditions that were previously left untreated (e.g., impotence, mild allergy disorders, male pattern baldness) is growing rapidly, and health plans are under increasing pressure to cover such treatments. Drawing a distinction between these treatments and other less controversial life-enhancing treatments (e.g., total hip replacement surgery) is obviously difficult. However, with the growing availability of life-enhancing treatments and their increasing demand, payers and policymakers may wonder how many "cost-effective" treatments they can ultimately afford.

Take-Home Points

- **The efficacy of Viagra in the treatment of impotence has been demonstrated in randomized clinical trials.**
- **Because Viagra is expensive (approximately $10 per pill), most health plans and insurance companies have placed restrictions on coverage.**
- **Viagra would be considered cost-effective (i.e., it costs less than $50,000 per QALY saved) in men who feel that impotence sufficiently diminishes their quality of life.**
- **Payers and policymakers may not choose to evaluate life-enhancing treatments (like Viagra) on the same scale as clinical interventions that reduce morbidity and mortality.**

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