Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

The Economics of Viagra Revisited: The Price Is Right

The coronavirus disease 2019 (COVID-19) pandemic caused dramatic reductions in clinically indicated care, but also cut services that produced little or no benefit to patients. As we establish a value-based "new normal" post-COVID-19, the clinical community should leverage this opportunity to enhance the efficiency of the delivery system by investing more resources in those services that improve patient-centered outcomes, while deterring a resurgence of low-value care.[1] This reset provides an opportunity to reassess and reprioritize services that were previously determined as high and low value.

A fresh look at the clinical and economic implications of the management of erectile dysfunction (ED) can serve as an intriguing example of how we might attain a more value-driven system. While certainly not at the forefront of the pandemic, the long-term clinical consequences of COVID-19-related illness will likely extend to men's sexual health.[2] There is growing evidence to support that COVID-19 targets endothelium.[3,4] Erectile dysfunction often results from endothelial dysfunction—early data suggest that COVID-19 remains present in penile tissue long after infection with COVID-19 and widespread endothelial dysfunction may be a major contributing factor to ED in COVID-19 survivors.[2,5,6] A potential increase in ED incidence,[5] coupled with the spectacular (>8000%) growth of telemedicine, is likely to create a 'perfect storm' of new demand for ED care. Although highly effective ED treatments exist, a lack of coverage for ED medications by public and private payers' limits utilization.[7-9] In a 2000 *Health Affairs* commentary, "The Economics of Viagra," Alison Keith explained that the main rationale used by US payers to avoid coverage was that Viagra was not a "medical treatment," but rather a "lifestyle enhancement" outside the realm of insurance contract.[10] Given the increased clinical knowledge of ED which supports its' use as a medical treatment and an improved value proposition ushered by a substantial decrease in ED drug pricing, a reassessment of coverage for ED medications and sexual medicine specialist consultations is warranted by health plans and public payers. The primary objective of this reassessment of coverage would be to enhance access to this high-value service and reduce the fragmented delivery of care provided by independent vendors that disrupts continuity of care.

The rising costs of branded and specialty prescription drugs are a top policy concern in the United States. Despite the widespread attention to a small number of extremely expensive medications, little consideration is paid to situations when drug prices decrease. Over the last decade, sildenafil, a first-line ED treatment, experienced a drastic price reduction from a peak of $88.45 per pill for the branded version (Viagra 100 mg),[11,12] to $1-$4 a pill for a generic version. A 2000 article in *Annals of Internal Medicine* reported that branded Viagra was cost-effective compared to other commonly used clinical interventions.[13] There is little doubt therefore, that the lower cost, higher value, generic version of Viagra represents an even more cost-effective intervention. ED services are of high value by virtue of their effectiveness, population-wide health impact, low price, and cost-effectiveness.[14,15]

Higher value, lower priced ED drugs couples well with the COVID-19 driven growth of telemedicine. Unlike many clinical conditions that require in-person evaluation, many ED patients are not required to have a physical presence at a clinician's office. This feature was a driving force behind the growth of independent, online men's health companies, which typically sell generic sildenafil at exorbitant prices. This current 'carved out' model of ED management disrupts continuity of care, the deterioration of which has been demonstrated to worsen patient satisfaction and clinical outcomes. Individuals with ED have an increased risk of cardiovascular disease, coronary heart disease, stroke, and all-cause mortality.[16] In addition to physical health, treatment of ED has been associated with improved psychological health (eg, anxiety, depression), which was especially notable during the period of COVID-19 lockdown.[17] Online men's health companies who offer ED treatment often provide limited evaluations and lack continuity of care; the fragmentation of care is a missed opportunity for a healthcare provider to evaluate a patients' overall health and evaluate for life-threatening comorbidities.[18] Diagnosis and treatment of ED and appropriate early optimization of other cardiovascular risk factors can improve overall health and life expectancy.[19] In addition, treatment of ED may promote overall general health and avoidance of risky behaviors through consultation with a provider or sexual medicine specialist who would promote a healthy lifestyle and harm reduction.[20] In the current system, the lack of coverage for sildenafil and other phosphodiesterase-5 inhibitors (eg, tadalafil) may effectively deter patients from engaging in routine doctor visits; this may have longstanding detrimental effects. With the recent rapid adoption of telehealth into routine practice, primary care and specialty providers can now offer the same convenience/discretion as online men's health vendors to patients as independent vendors. The added benefit is a relationship with a healthcare provider and continuity of care. Moreover, telehealth has been shown to be effective for patients with ED.[21]

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Though previously perceived by many payers as a low-value commodity, the decrease in sildenafil pricing (and correlated over 10-fold increase in value) presents an opportunity for public and private payers to reassess coverage decisions. This is of particular importance to Medicare and Employer-Sponsored prescription drug plans, many of which currently do not cover generic sildenafil.[22-25] This transition would lead to an improved care delivery model with substantial benefits, including a significant 'spillover effect' of increased continuity of care. A stable clinician-patient relationship would better facilitate the management of hypertension, diabetes, cardiovascular disease, and cerebrovascular disease, all closely associated with ED. In addition, reducing fragmentation will likely lead to a reduction in drug to drug interactions (often seen in the Direct To Consumer (DTC) setting),[26] decreased counterfeit distribution, enhanced preventive care utilization, and increased patient satisfaction. Counterfeit distribution of phosphodiesterase-5 inhibitors, which may have contaminants and is often done without consultation with a physician or sexual medicine specialist—this may seriously endanger patients.[27]

The enhanced availability of generic drugs can produce important incremental long-term benefits to the population at large. During the COVID-19 pandemic, generic medicines, most notably the steroid drugs that have significantly reduced the risk of death in COVID-19 patients, have proven themselves to truly be the bridge to a vaccine. Sildenafil provides a similar example. Viagra was developed after participants in an early trial assessing sildenafil's potential as an antihypertensive, experienced potent erections as a side effect. Its widespread use for ED led to its development as an effective agent for pulmonary hypertension. Restricted access may deter additional opportunities for discovery and innovation. If not for the widespread coverage of low-cost dexamethasone for multiple indications, its lifesaving potential in COVID-19 patients may not been realized.

As we strive to create a new normal post COVID-19, the reassessment of previously considered low-value services provides an appealing framework of how we might reallocate medical care spending to optimize population health. While ED may not be considered a high priority chronic condition, the negative impact on the quality of life of men and their partners will likely become more prevalent due to COVID-19. Given recent dramatic price reductions for generic formulations, the well-established clinical benefits of ED treatments should be reconsidered by payers. The resultant improvements in patient-centered outcomes from better access to these high-value services will be heightened further by the integration of telemedicine, positive impact on continuity of care, and the potential for future innovation.

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