

# Increasing Access to Erectile Dysfunction Treatment via Pharmacies to Improve Healthcare Provider Visits and Quality of Life: Results from a Prospective Real-World Observational Study in the United Kingdom

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## Abstract

**Objectives:** The Medicines and Healthcare Products Regulatory Agency in the United Kingdom (UK) formally reclassified sildenafil citrate 50 mg tablets as a pharmacy medicine (sildenafil-P) in 2017 for adult men with erectile dysfunction (ED). A one-year prospective real-world observational study was conducted to track men's health behavior, particularly their healthcare resource utilization (HCRU) and quality-of-life (QoL) before and after the availability of sildenafil-P. **Methods:** Adult men with ED aged [?]18 years provided data at baseline (prior to launch of sildenafil-P) and every three months after the launch. Demographics, health characteristics, treatments at baseline and HCRU, including number of pharmacist and physician/nurse practitioner visits over time are reported. QoL-related outcomes were assessed via Self-Esteem and Relationship Questionnaire (SEAR), 2-Item Patient Health Questionnaire, and ratings of sexual satisfaction. Generalized linear models were used to assess the association of sildenafil-P use with total physician/nurse practitioner and pharmacist visits and QoL-related outcomes at 12 months. **Results:** Overall, 1162 men completed the survey at all 5 time-points. The mean  $\pm$  SD age was  $59.02 \pm 12.06$  years; 55.42% reported having a moderate-to-severe ED. Hypertension (37.52%) and hypercholesterolemia (31.50%) were the most common risk factors for ED. At baseline, 62.99% were not using any ED treatment. After adjusting for baseline visits/other covariates, mean physician/nurse practitioner (3.68 vs 2.87;  $P = .003$ ) and pharmacist visits for any reason (2.10 vs 1.34;  $P < .001$ ) at 12 months were significantly higher among sildenafil-P users than those who never used sildenafil-P. Sildenafil-P users had significantly higher SEAR total and domain (sexual relationship and self-esteem) scores at 12 months. **Conclusion:** Following the reclassification to pharmacy medicine in the UK, sildenafil-P was associated with a higher number of physician/nurse practitioner and pharmacist visits for any reason. Sildenafil-P use was also associated with better QoL, although group differences were small in magnitude.

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**Short running title:** Outcomes of Increasing Sildenafil Access

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**Data sharing:** The study data will be provided for non-commercial use upon request.

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