



SPECIAL REPORT



ED TREATMENT IN THE PHARMACY

Viagra Connect[®], a branded sildenafil 50mg, was made available as a pharmacy medicine in the UK in 2018. Since then, two studies have been published that look into supply through pharmacy and how it has impacted on men's health. Pharmacists can use the findings to consider how they can improve the services they offer to men in their pharmacy and have a greater impact on men's health in their area.

Viagra Connect[®] is licensed for men over 18 years of age affected by erectile dysfunction (ED). ED may also be called erection problems (EPs) or impotence. Both the terms EP and ED are used in this report.

This report gives a summary of a PASS results assessment report and a paper that was published in the *International Journal of Clinical Practice*, and then considers what it could mean in practice.

1. J Lem, J Collins. Survey of Pharmacists to Evaluate the Effectiveness of the Viagra Connect[®] National Additional Risk Minimisation Measures (aRMMs) in the United Kingdom (UK). July 2019.

2. Lee L, Maguire T, Maculaitis M, Emir B, Li V, Jeffress M, Li J, Zou K, Donde S, Taylor D. 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; 2020/12/01; 75 DO 10.1111/ijcp.13849; International Journal of Clinical Practice

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1. RISK MINIMISATION REPORT

Summary

A web-based study of UK pharmacists to assess the effectiveness of Viagra Connect[®] additional risk minimisation measures programme

Additional risk minimisation measures (aRMMs) were implemented to support the reclassification of sildenafil citrate 50mg from a prescription only medicine (POM) to a pharmacy medicine (P) in the UK. These aRMMs were training materials and an optional checklist for pharmacists to assist them in making supply decisions. The aim of this study was to evaluate the effectiveness of these aRMMs by assessing participation in training, knowledge of the key risk messages (KRM) and whether the checklist was used. This was a web-based survey of a random sample of community pharmacists. The survey was completed by 345 pharmacists (40.3% of whom were male, aged 41-60 years) between 28th January and 31st March 2019.

A high knowledge of the KRM was displayed, and nearly all reported use of the checklist at supply and said that the training materials were useful or very useful. The study concluded that the aRMMs were effective for education and subsequent consultations, ensuring supply decisions for Viagra Connect[®] were appropriate.



Key findings and discussion

Pharmacists widely used the training materials and found the checklist helpful for consultations, and would take a risk averse approach if in doubt of making supply and refer the patient to their GP.

Most pharmacists correctly responded to questions about concomitant diseases which may be contributing to erectile dysfunction (ED).

The lowest correct response rate had 41.4%, to the following question:

Men who had a heart attack or stroke more than six months ago should NOT be supplied Viagra Connect®, but should be referred to their GP.

The correct answer, FALSE, was only given by 41.4% of respondents. Viagra Connect® can be supplied to those who were affected more than six months ago, assuming that their cardiovascular health is stable.

This response could be related to being risk averse and wanting to refer potential cardiac issues to a GP, or a misunderstanding of the supporting training materials.

Areas that did not meet the target of 80% correct in relation to the use of Viagra Connect® with other medicines were that the following patients are not suitable for supply:

- Riociguat users (riociguat is predicted to increase the risk of hypotension if used with sildenafil)
- Patients using other strength sildenafil or other ED treatments on prescription.

Other areas that did not meet the 80% target and may be useful revision points for pharmacists and pharmacy team members were:

- Headache and nausea are common side-effects of sildenafil and do not need medical referral
- Hypertension and hypercholesterolaemia are possible causes of ED
- Use of beta-blockers is not a contraindication (those on alpha-blockers should be referred to their GP for a lower dose)

The findings may have implications for future product launches; the study found that pharmacists said that printed materials in the mail was the most popular format, followed by online training. Of those who did not complete the training, most said that they were not aware of the training available (some were already trained due to offering a related PGD), so ensuring wide reach and awareness of training materials is key to a successful POM to P reclassification.

53% of pharmacists reported that discussing Viagra Connect® in the pharmacy made some patients uncomfortable and less willing to disclose information, but only 5.2% of pharmacists felt uncomfortable counselling on the product, so putting patients at ease seems to be an ongoing area for development.

IN PRACTICE



Consider the areas below to help identify actions for you or the team.

Training:

- Can all new pharmacists/returning workers/locums access the training and checklist?
- Is there a need to revise some of the areas that were not identified correctly in the study, or pass on to others involved in consultations?

Current consultation process:

- Do customers prefer to use the consultation room?
- How welcoming is the pharmacy?
- Is there room for improvement in relation to consultation skills?

Pharmacists widely used the training materials and found the checklist helpful



2. LONGITUDINAL STUDY

Summary

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

A one-year prospective real-world study (March 2018 to April 2019) was conducted to track men's health behaviour; particularly how they used healthcare, as well as quality of life both before and after the availability of sildenafil as a pharmacy medicine (sildenafil-P) in the UK.

The quality of life (QoL) outcomes were measured using the following tools:

- Self-Esteem and Relationship questionnaire (SEAR) is a validated measure focusing on the impact of ED on psychosocial functioning and wellbeing. It is a 14-item measure focusing on the impact of ED on psychosocial functioning and wellbeing
- 2-item Patient Health Questionnaire (PHQ-2) is a screening tool for major depressive disorder
- Ratings of sexual satisfaction (1-5 responses to a single question)

Linear models were used to assess the association of sildenafil-P use with total physician/nurse practitioner and pharmacist visits. The survey was completed by 1,162 men at all the follow-up time points, with around 55% reporting moderate or severe ED. Of these 234 reported using sildenafil-P at some point, while 928 were never users of sildenafil-P.

ED is often a result of underlying conditions (such as hypertension and hypercholesterolaemia) and it has an impact on a man's quality of life. Despite this, men often delay seeking treatment as they do not want to discuss ED with their GP. The reclassification was expected to increase access to healthcare visits for men.

The study did find that the reclassification of sildenafil 50mg was associated with a higher number of visits to physicians/nurse practitioners or pharmacists for any reason and better ED-specific quality of life in the 12 months following the switch.

The reclassification was associated with a **higher number of visits to physicians, nurse practitioners or pharmacists**



Key findings and discussion

ED adversely affects a patient's QoL and is associated with physical and psychological conditions, including performance anxiety and depressive symptoms. ED is both underdiagnosed and undertreated, and an increased uptake of treatment could improve wellbeing. Conversations about ED can also lead to early diagnosis and subsequent management of co-morbidities.

Increased public awareness of the availability of phosphodiesterase-5 inhibitors has been shown to shorten the time between someone having symptoms and accessing treatment. Pharmacy availability will facilitate broader access to treatment, and more opportunities for health conversations by pharmacists.

Sildenafil-P users tended to be younger than non-users (54.87 vs 60.06 years).

The most reported risk factors for ED were being overweight, hypertension and hypercholesterolaemia. Lifestyle factors to consider were smoking and alcohol use. Around 1 in 5 of those surveyed reported using any prescription medicine for ED. Overall, just under 63% had never tried anything.

Approximately 17% of men screened positive for depression on the PHQ-2 at baseline and 12-month follow-up.

Sildenafil-P users reported significantly more visits to physicians/nurse practitioners and to pharmacists for any reason, and sildenafil-P users reported marginally more pharmacist visits for sexual functioning discussion than never-users.

The results suggest that men are following the recommendation of pharmacists to see their GP within 6 months of first supply of sildenafil-P, which is important for the secondary prevention of cardiovascular disease, diabetes and depression.

The results suggest that the reclassification has resulted in men seeking further advice on other health issues from pharmacists.

Sildenafil-P users had statistically significant higher SEAR total score, sexual relationship score and self-esteem score compared with never-users. However, the SEAR overall relationship score was lower for sildenafil-P users.

IN PRACTICE



Many men may still not be getting treatment for their erection problems (EPs); raising awareness and making pharmacists accessible for consultations may help improve this.

Having conversations with men about EPs may lead the way to having conversations about other associated medical conditions and referral to other HCPs, such as diabetes, hypertension, or high cholesterol. It may be worth considering adding services to help screen for these conditions if not already offered.

Mental health check-ups and sharing referral options when offering ED services may give men the opportunity to seek appropriate advice and counselling.

Discussing the smoking status of men during a consultation can be an opportunity to discuss support for stopping, and to give advice about the association between smoking and ED.

- Are you confident to discuss sexual functioning, mental health and other related health issues associated with EPs?
- What are the local signposting options?
- Can you improve how you and the team seek to engage with men in your local area?
- How can you use EP consultations to effectively engage with your customers and raise awareness of other health services and healthy lifestyle advice?

TO FIND OUT MORE ABOUT VIAGRA CONNECT® VISIT:

- pharmacymagazine.co.uk/viagraconnect-learning
- hcp.viagraconnect.co.uk
- pharmacymagazine.co.uk/viagraconnect-mens-health

