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Title:

Are more men seeking help for erectile dysfunction? A time trend analysis

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Running title: Prescribing for Erectile Dysfunction

Title: Are more men seeking help for erectile dysfunction? A time trend analysis

Abstract

Background: Sildenafil and tadalafil are recommended first line treatment for Erectile Dysfunction (ED). Sildenafil was legally reclassified to a 'pharmacy' medicine in the United Kingdom in 2018.

Aim: To assess the prescribing patterns and costs associated with prescribing of ED drugs in England and to investigate the link between prescribing and deprivation, regional demography and legal reclassification.

Design and setting: Analyses of publicly available government data from various sources pertaining to primary care prescribing and demographics in England was conducted.

Methods: Prescribing and cost data for the last 10 years (2009-2019) were extracted and adjusted for inflation, male populations and regional deprivation.

Results: Between 2009 and 2019 the rate of prescribing, measured as the number of items per 1000 men, increased by 110%. In 2019, the rate of prescribing of ED medicines in the most deprived areas was 21.0% higher than the rate observed in least deprived areas. The Northern regions of England had approximately 50% higher rate of prescribing compared to London. A 0.5% annual increase in the number of prescription items was observed between 2018 and 2019, compared to 5.0% increase observed from 2017 to 2018.

Conclusion: The two-fold increase in the rate of primary care prescriptions in the last 10 years suggests that more men are being screened for or seeking help for ED. Higher rate of prescribing offers opportunity for monitoring of linked risk factors such as diabetes mellitus, dyslipidaemia, and vascular disorders in deprived populations. Reclassification of sildenafil had a modest impact on prescribing practices.

Keywords: Erectile dysfunction, deprivation, PDE-5I, prescribing practices, sexual dysfunction, sildenafil

How this fits in?

There is a dearth of research in relation to presentation and management of erectile dysfunction (ED) in primary care, particularly in the United Kingdom. This study shows that over the last 10 years, there have been over two-fold increases in the rate of primary care prescriptions for ED, accounting for the changes in population. The reclassification of sildenafil as a pharmacy medicine in 2018 seemed to have modest impact on the prescribing trend. It is very likely that more men are being assessed for ED or seeking help in primary care in England. In addition, data suggests that prescribing is linked with deprivation. There is an opportunity in primary care for assessment of linked risk factors in men who present with the symptoms.

Are more men seeking help for erectile dysfunction? A time trend analysis

Introduction

Erectile dysfunction (ED), 'the persistent inability to achieve or maintain an erection that is sufficient to permit satisfactory sexual performance', can affect the physical, emotional and psychosocial health of the sufferer.¹ ED can have both organic and psychogenic origin and can be a risk marker for underlying cardiovascular diseases (CVDs) and mental health conditions that may warrant further evaluation and treatment.^{2,3} Medications such as anti-hypertensives, antidepressants and antipsychotics can also lead to ED through their mechanisms of action.² A systematic review reported that men with ED have an increased risk of all-cause mortality [OR 1.26; 95% CI, 1.01-1.57] and CVD mortality [OR 1.43; 95% CI, 1.00-2.05].⁴

The global prevalence of ED has been estimated to range from 3% to 76.5%.⁴ A significant number of patients are known to suffer in isolation and do not seek help. Therefore, prevalence data are likely to be an under-estimate.⁵ It is common for men with ED to experience anxiety, depression, relationship difficulties and a lack of sexual confidence.^{2,3} These factors often lead to poorer quality of life for the sufferer, their partner and family.

Both pharmacological and non-pharmacological treatment options are available for the treatment of ED. The National Institute of Health and Clinical Excellence (NICE) in England, recommends using Phosphodiesterase type 5 inhibitors (PDE-5I) as first line pharmacological treatment option for men with ED. Four PDE-5Is are currently licensed in the UK and include sildenafil, tadalafil, vardenafil and avanafil.⁵ However, only sildenafil and tadalafil remain the drugs of choice.

Sildenafil was reclassified in March 2018 by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) to 'pharmacy only' medicine which allowed community and

online pharmacies to supply the drug to the patients without the need of a prescription.⁶ MHRA in the UK make decisions to alter the legal status of medicines from 'prescription only' medicines to 'Pharmacy' or 'General Sales List' categories (table 1).^{7,8} The decision to reclassify such medicines are primarily based on safety data.⁷ Such reclassifications are often expected to reduce the volume of prescribing and costs from the perspective of the NHS as patients are required to pay the price of the medicines at the point of purchase.

A cardiovascular risk assessment by a pharmacist in the community pharmacy is prerequisite to pharmacy supply of sildenafil.⁹ Such risk assessment is undertaken using a series of questions asked to the patients before a supply can be made. Sildenafil is still available on National Health Services (NHS) prescription as well along with the tadalafil, vardenafil and avanafil.

There is a lack of research in relation to presentation and management of ED in primary care, particularly in the United Kingdom (UK). To date, no longitudinal research has looked into the prescribing patterns and costs of PDE-5Is in English primary care settings. Given the association of ED with cardiovascular diseases (CVD) including diabetes, vascular disorders as well as mental health conditions,^{2,3,10} Understanding any link that exist between deprivation and ED drugs prescribing trend will enable targeted interventions to manage comorbidities and reduce health inequality.

The primary aim of this study was to investigate the trend in quantity and cost of prescribing of sildenafil and tadalafil in primary care settings in England between 2009 and 2019. Specific objectives related to the investigation of a) whether a prescribing trend of ED drugs is associated with deprivation and demography of various English geographical regions and b) whether the legal reclassification of sildenafil to 'pharmacy only' medicine has impacted on the trend in quantity and cost of prescribing of ED drugs in England.

Methods

Ethical consideration

This study represents secondary analysis of the information retrieved from publicly available anonymised datasets and does not warrant formal ethical approval.

Study Design

A secondary analysis of routinely collected data on the prescribing and dispensing of two ED drugs, sildenafil and tadalafil, within the NHS England primary care settings between January 2009 and November 2019, was conducted. This time period includes switches from patented medicines to generic drugs for both tadalafil and sildenafil as well as the reclassification of sildenafil to 'pharmacy only' medicine in March 2018.

Data Collection

Prescribing datasets were extracted from NHS Digital sources including OpenPrescribing.net¹¹ and Prescription Cost Analysis (PCA).¹² These included data on the number of items prescribed, cost of prescribing and prescribing patterns within specific clinical commissioning groups (CCGs) for both drugs. Data were adjusted for inflation using Bank of England inflation calculator based on ONS composite price index.¹³ Data were also adjusted for male population estimates for each year.¹⁴ All data were extracted, independently checked for accuracies and analysed using Microsoft Excel and SPSS V21. Prescription patterns in the 10 most and the 10 least deprived Clinical Commissioning Groups (CCGs) as per the Office of National Statistics (ONS) Index of Multiple Deprivation (IMD) in 2015 (table 2) were also extracted and analysed to explore the link between prescribing pattern and deprivation. The CCGs are clinically-led autonomous NHS bodies involved in planning and commissioning healthcare services for their locality. The 10 most deprived and the 10 least deprived CCGs covered a population of 1.38 million and 1.30 million respectively.

Results

Number of items prescribed for ED increased by 110% between 2009 and 2019 (figure 1). The increase in the number of items prescribed was mostly accounted for by sildenafil prescriptions which increased by 165%. There were 2,145,393 items for EDs prescribed in 2009 and 4,505,623 in 2019. The biggest year-on-year increase in the number of prescriptions was from 2014 to 2015 where an increase of 24% was observed.

The total items prescribed for sildenafil was relatively steady from 2009 to 2013 at around 48 items prescribed a year per 1,000 men. The prescribing increased rapidly from 2013 to 2017. The highest yearly increase occurred from 2014 to 2015 which showed a 42.1% increase. A 5.8% yearly increase in the rate of prescription was observed between 2017 and 2018. A 0.5% increase in the rate of prescribing between 2018 and 2019 was observed suggesting modest impact of reclassification on the prescribing practices. The number of items prescribed per 1000 men were 124.18 and 124.80 in 2018 and 2019 respectively.

The spending on primary care prescriptions for ED decreased by 71.0% from £77.4 million in 2009 to £22.4 million in 2019. The spending on sildenafil decreased by 90% and tadalafil decreased by 75%. The biggest decreases were seen after 2014 for sildenafil and 2018 for tadalafil (figure 1).

Insert Figure 1

Deprivation and Prescribing Patterns

The most deprived regions consistently showed higher rates of prescriptions for ED drugs. In 2019 there were 190.4 items prescribed per 1,000 men of all ED drugs in the most deprived region. This figure was approximately 21.0% higher compared the data from the least deprived regions where a total of 150.5 items were prescribed per 1,000 men.

In the most deprived regions, the yearly increases in prescription items were 9% in 2016, 4.5% in 2017 and 4.4% and 5.0% in 2018 and 2019 respectively. An overall 25% increase in prescription items was observed from 2015 to 2019. In the least deprived region, the rate of increase in the number of prescriptions was 39% during the same period (figure 2).

Insert Figure 2

Regional variations in prescribing

A wide variation in the rate of prescribing across the six English regions were observed. The North East and the North West regions had approximately 50% higher rate of prescribing compared to London. Rates of prescribing were 15.9, 15.3 and 10.3 items per 1,000 men each month respectively in these regions (figure 3).

Insert Figure 3

Discussion

Summary

The aim of this study was to investigate the trend in prescribing of drugs for ED in primary care settings in England and to assess the impact of deprivation, regional demography and legal reclassification of sildenafil on prescribing practices of ED drugs.

There was a persistent increase in the rate of prescribing for treatment of ED in men between 2009 and 2019 in English primary care. Sildenafil remained the most frequently prescribed medication out of the two drugs of choice. A strong link between deprivation and prescribing trends were observed across all data points. These can be linked to higher prevalence of risk factors of ED such as cardiovascular and mental health conditions with deprivation.¹⁵ A North-South divide was observed in the rate of prescriptions with higher

prescribing rates observed in the Northern regions of England compared to London and the Southern regions. While some of the regional variations are explained by the differences in deprivation level, London's younger population compared to the rest of the country¹⁶ could explain low ED prevalence and the observed low prescribing for ED. In addition, patient behaviours around use of online sources for access to sildenafil may be different across various geographical regions.

Data showed that reclassification of sildenafil to a pharmacy medicine from 'prescription only medicine' had modest impact on the trend of prescribing. It could be assumed that the reclassification of sildenafil would lead to a decrease in the number of items prescribed as people would be able to get their medicine directly from the pharmacy instead of needing to go to the doctors and wait for an appointment. It is important to note, however, that the pharmacy version of sildenafil costs approximately £20 for a pack of 4 tablets (as of April 2020) whereas the generic sildenafil prescriptions from a general practitioner only costs £9 for the same number of tablets. The higher cost of pharmacy version of the medicine compared to the prescription cost may dissuade patients from using pharmacy for accessing sildenafil. In addition, confidentiality and privacy have been cited as barriers to utilisation of sexual health services from pharmacy.¹⁷ The lack of long term monitoring and follow up in pharmacy settings may also discourage many patients from accessing the pharmacy version of sildenafil.

Comparison with existing literature

There is a lack of literature on the prescribing and management of ED in primary care. Previous studies have reported that many men do not seek help with sexual problems to avoid perceived embarrassment for themselves and their doctors.^{18,19} The observed increasing trend in the rate of prescriptions may have been contributed by various factors. These include inclusion of ED assessment for diabetic men in the Quality and Outcomes Framework (QoF) since 2013/2104.²⁰ The QoF required opportunistic screening, advice and

assessment of contributory factors and treatment options for ED in diabetic patients in primary care. In addition, media including social media may have contributed to increased knowledge and awareness of the condition amongst members of the general public given the licensing of newer PDE-5Is in recent years.

Our study shows that the introduction of generic versions of both sildenafil in 2013 and tadalafil in 2017 reduced overall spending on drugs used for ED. The expiry of the patent on sildenafil in June 2013 allowed the NHS to purchase generic sildenafil from other pharmaceutical companies for a competitive price subsequently reducing the price per item from £31.31 in 2012 to £2.53 in 2014.¹² This also allowed sildenafil to be removed from the Selected List Scheme which restricted prescriptions of certain drugs in May 2014 allowing more men access to the medicine on the NHS, potentially increasing the number of items prescribed.²¹ The patent on tadalafil also expired in November 2017 leading to a 49% decrease in cost per item from £49.40 in 2017 to £25.12 in 2018.

Implications for research and practice

The data suggests that more men are seeking help or being assessed for ED in primary care. The increased presentations and hence prescribing for EDs allows further opportunities to screen for the associated risk factors for ED. These include CVDs such as hypertension, coronary artery disease, peripheral vasculopathy; endocrine disorders such as diabetes, metabolic syndrome and hyperthyroidism; as well as assessment of psychogenic risk factors and medication induced ED.² Prescribers should be aware of wider organic and psychogenic nature and linked risk factors of ED including diabetes, vascular disorders and mental health conditions. Cause of ED needs to be established before treatment can commence and patients should be referred to specialist clinics where appropriate. Guidelines recommend that a physical examination including genitourinary, endocrine, vascular and neurological systems reveal any unsuspected diagnoses such as Peyronie's disease, pre-malignant or malignant genital lesions, prostatic enlargement or

irregularity/nodularity, or signs and symptoms suggesting hypogonadism are needed.^{2,3} It is however, unclear how often are patients screened for the red flag symptoms. Long term safety outcomes of PDE5 inhibitors are not understood. Prescribers should therefore reassess the continuous use of these drugs on a periodic basis.^{22,23}

Reclassification to allow 'pharmacy only' supply of drugs to free up general practitioner time and resources have faced successes and barriers in the past.²⁴⁻²⁶ For example, reclassification of drugs such as chloramphenicol eye products, mild steroids and antifungal products have been positively received by patients, general practitioners and pharmacists. However, reclassified pharmacy version of simvastatin was not adopted in practice to the same extent.²⁴ Research on community pharmacist and patient perspectives on the need, supply and aspects of risk assessments and referrals are warranted. General practitioners and patient experiences of access of sildenafil from pharmacy also need to be further explored.

Strengths and Limitations

This project included data from very large routinely collected datasets covering all primary care prescriptions in England. Deprivation data was based on CCG level and individual practice level variations were not accounted for. This study only included NHS prescriptions data and private prescriptions are not accounted for. We only included two PDE-5Is, sildenafil and tadalafil as our observation suggested that the rest of the PED-5Is accounted for negligible volume of prescribing and hence did not impact on the trend analysis. Similarly, community and online pharmacy sales of over-the-counter sildenafil was not included in the trend analysis. Some patients may avoid perceived embarrassment and confidentiality issues in face-to-face clinical consultations in primary care and community pharmacy¹⁷ by accessing medicines through online sources. We did not include other available treatments for ED including vacuum pump treatment and psychosexual therapies in our study. In addition, prevalence data of ED over time were considered for this study. The segmented

regression for different policy changes (e.g. Sildenafil patent expiry in June 2013, Tadalafil patent expiry in November 2017 and reclassification of Sildenafil from prescription medicine to pharmacy medicine in March 2018) could not be performed due to i) absence of monthly prescribing and spending (access was restricted to annual level for historical data prior to 2015) data and ii) inadequate time-points before and after different policy changes needed to conduct segmented regression analysis.²⁷

Conclusions

Results of this study suggest that more men are being screened for or seeking help with ED. The two- fold observed increase in the population adjusted rate of prescriptions over the last 10 years is less likely to be accounted for by other factors. Promotion of the sildenafil by pharmaceutical industries since being made available over the counter for pharmacy sales could have raised awareness of ED amongst general public. Higher rate of prescribing in deprived regions offers opportunity for monitoring of linked health conditions such as CVD and diabetes. Reclassification of sildenafil to pharmacy medicine had a modest impact on prescribing practices.

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Ethical approval: Not applicable

Competing interests: None

Acknowledgements: None

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Table 1. Legal classification of medicines in the UK

Prescription Only Medicines (POM)	Pharmacy (P)	General Sale List (GSL)
Available only under a prescription from a medical or a non-medical prescriber such as doctors, dentists or a healthcare professional with an independent prescribing qualification and authority	Available under the supervision of a pharmacist from a pharmacy registered with General Pharmaceutical Council (GPhC)	Available in general retail outlets such as supermarkets.

Adapted from^{7,8}

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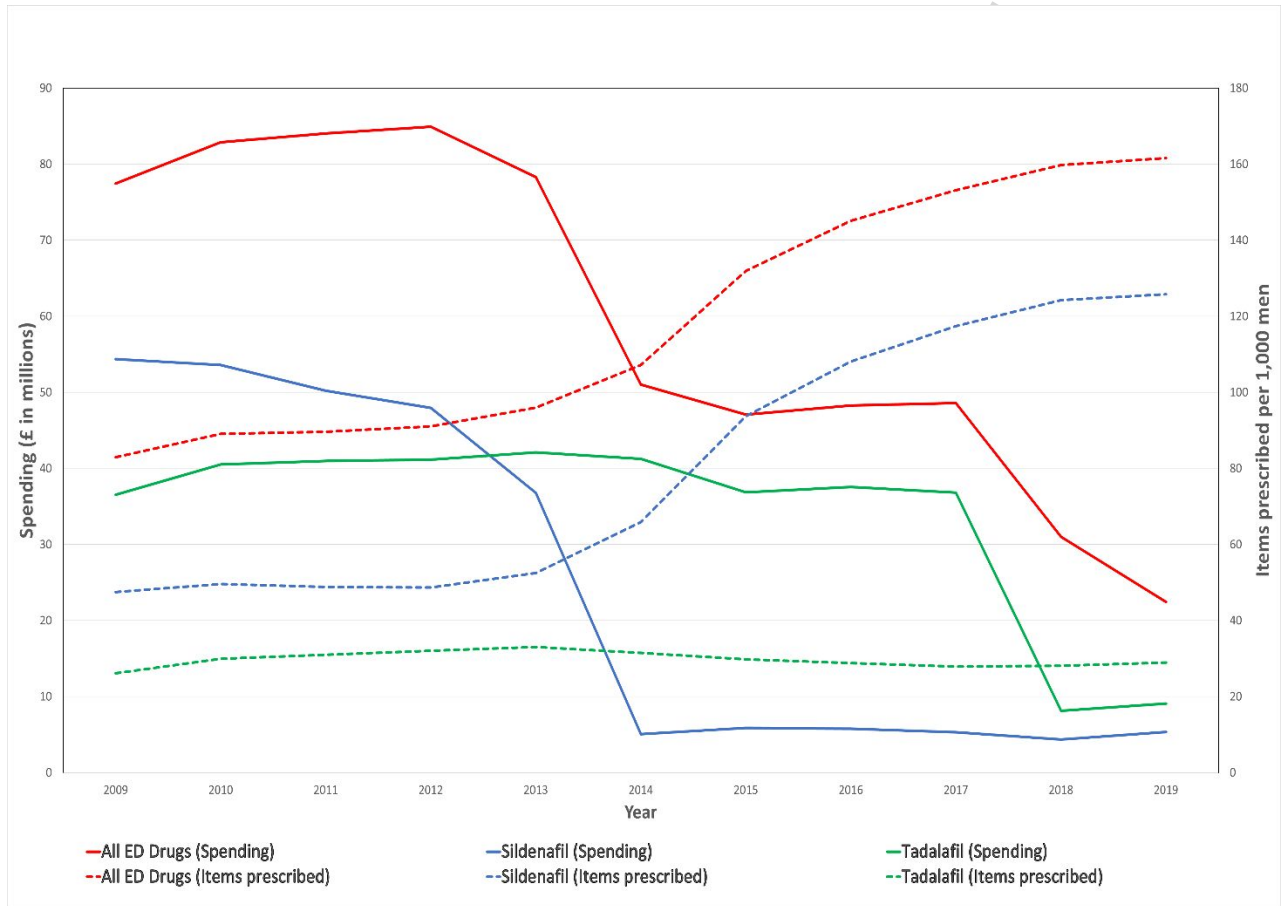
Table 2. Top 10 most and least deprived areas in England according to the index of multiple deprivation

10 most deprived CCGs (relevant commissioning regions)	IMD Rank	10 least deprived CCGs (relevant commissioning regions)	IMD Rank
NHS Bradford City CCG (North East and Yorkshire)	1	NHS Bracknell and Ascot CCG (South East)	200
NHS North Manchester CCG (North West)	2	NHS North East Hampshire and Farnham CCG (South East)	201
NHS Central Manchester CCG (North West)	3	NHS Windsor, Ascot and Maidenhead CCG (South East)	202
NHS Barking and Dagenham CCG (London)	4	NHS Chiltern CCG (South East)	203
NHS Sandwell and West Birmingham CCG (Midlands)	5	NHS Surrey Health CCG (South East)	204
NHS Blackpool CCG (North West)	6	NHS Horsham and Mid Sussex CCG (South East)	205
NHS City and Hackney CCG (London)	7	NHS Guildford and Waverley CCG (South East)	206
NHS Knowsley CCG (North West)	8	NHS Surrey Downs CCG (South East)	207
NHS Tower Hamlets CCG (London)	9	NHS Rushcliffe CCG (Midlands)	208
NHS Liverpool CCG (North West)	10	NHS Wokingham CCG (South East)	209

CCG: Clinical Commissioning Group IMD: Index of Multiple Deprivation

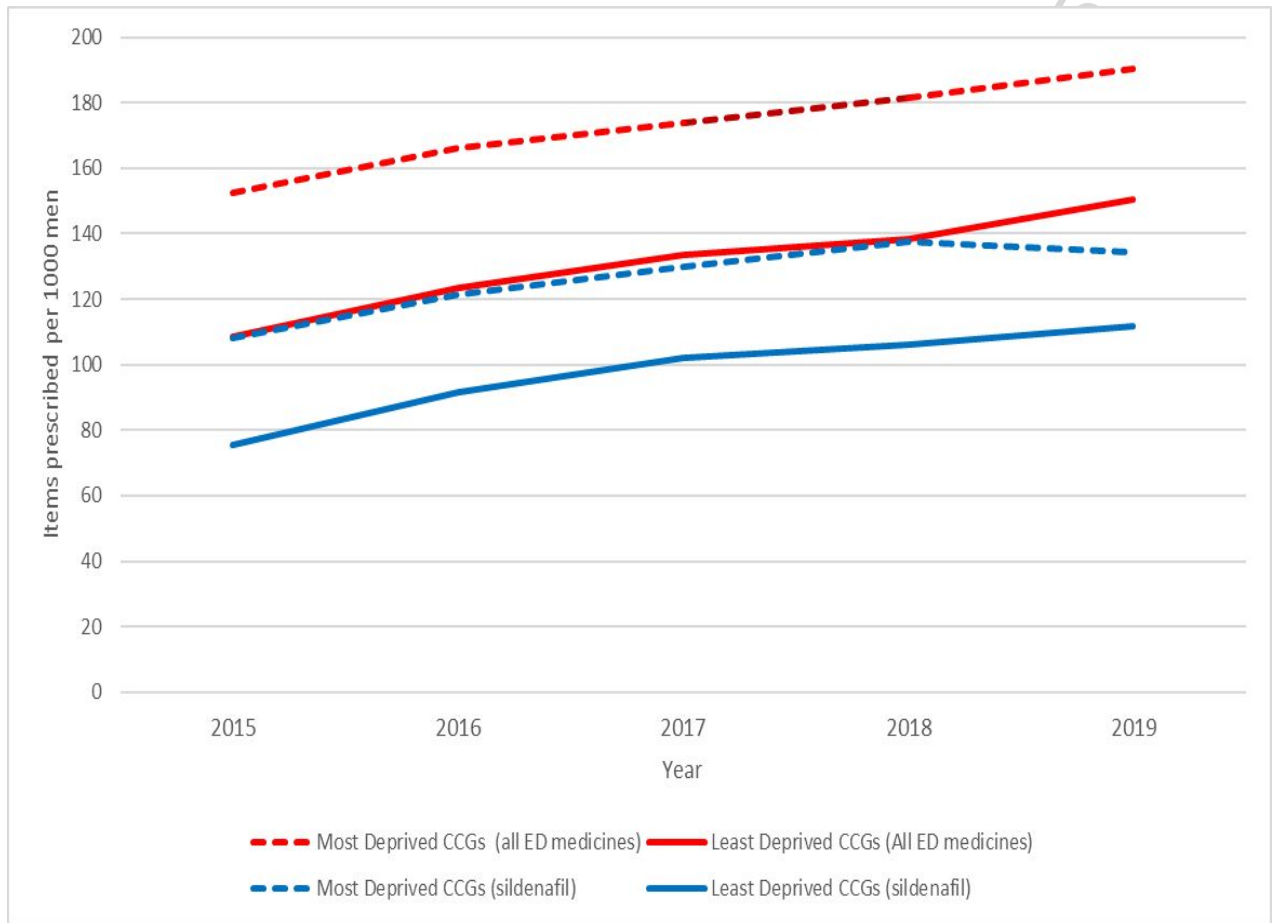
Figures

Figure 1. Volume and costs of prescribing for erectile dysfunction medicines from 2009 to 2019 in English primary care



ED: Erectile Dysfunction

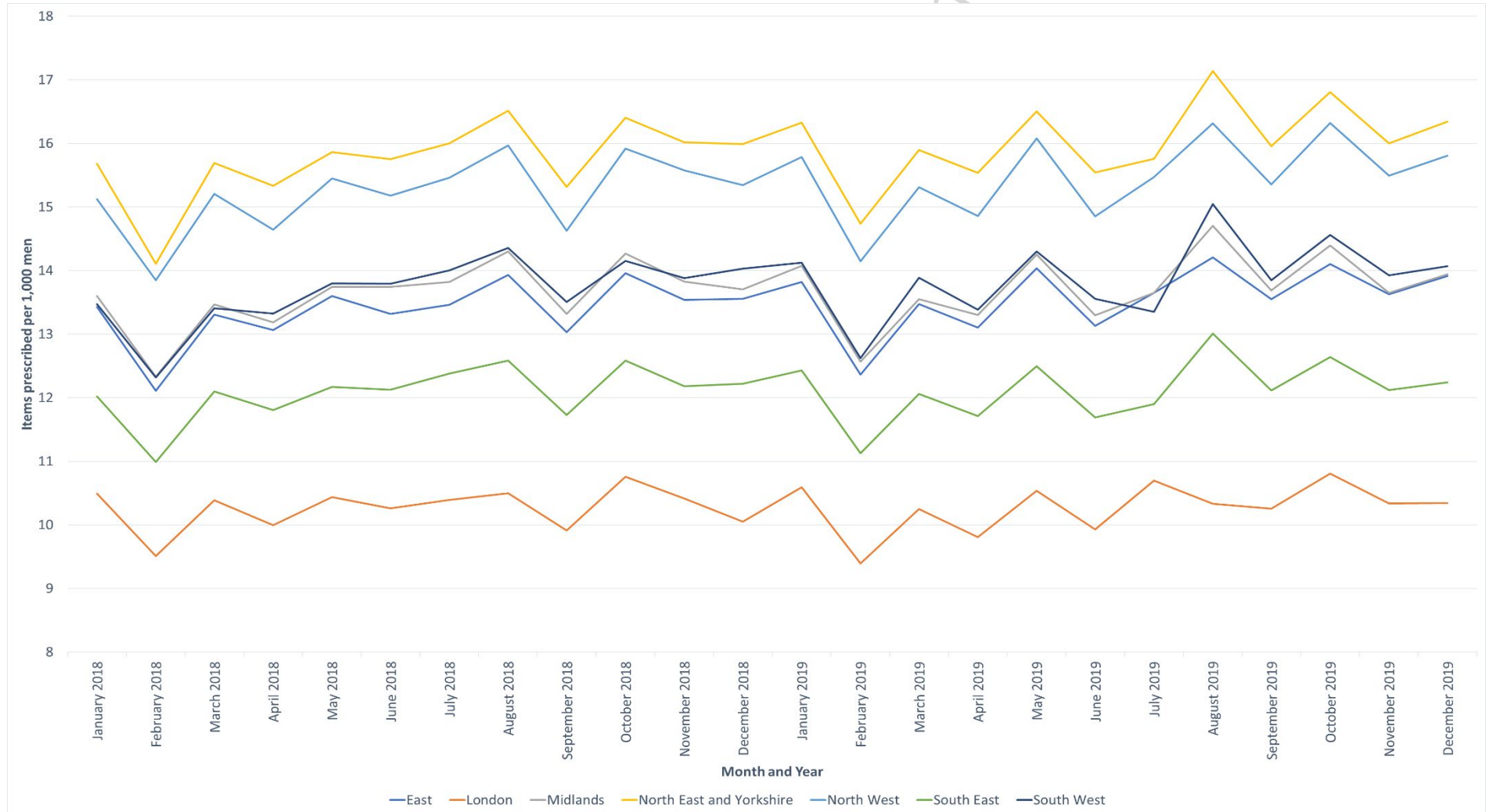
Figure 2. The number of items of erectile dysfunction medicines prescribed annually in the most and least deprived areas in England



CCG: Clinical commissioning Groups; ED: Erectile Dysfunction

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Figure 3. The number of erectile dysfunction medicine items prescribed per month in each NHS commissioning region in 2018 and 2019



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