

Demand, appropriateness and prescribing of 'lifestyle drugs': a consultation survey in general practice

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Ashworth M, Clement S and Wright M. Demand, appropriateness and prescribing of 'lifestyle drugs': a consultation survey in general practice. *Family Practice* 2002; **19**: 236–241.

Background. The simultaneous launch of orlistat and sildenafil in 1998 provoked much media attention, particularly around the role of lifestyle drugs and their potential costs if controls were not established. Fears were also expressed that primary care would be overwhelmed by demand, and little information was available about the attitude of GPs to their new role as prescribers of lifestyle drugs. Partly in response to these concerns, tight prescribing guidelines and licensed indications, for sildenafil and orlistat, respectively, were issued.

Objective. Our aim was to describe levels of demand for orlistat and sildenafil in general practice, whether this demand was translated into a prescription, adherence to prescribing guidelines/licensed indications and the GP perception of appropriateness of an NHS prescription for either of these drugs.

Method. We carried out an observational study in primary care conducted over a 6-week period during 1999. Twenty-seven GPs were recruited, each from a different practice. All GP consultations were recorded for the study period and the GP completed a structured questionnaire each time sildenafil or orlistat were discussed in a consultation.

Results. Sildenafil was discussed in 0.5% (68/13 394) of consultations and orlistat in 0.3% (42/13 394). GPs thought that a corresponding NHS prescription would be highly appropriate in 57 and 74% of cases, respectively, although for both lifestyle drugs, nearly 20% of GPs thought such prescriptions were inappropriate. An NHS prescription was issued in 43% of consultations in which sildenafil had been discussed and 33% in which orlistat had been discussed. Five out of 29 NHS sildenafil prescriptions were issued to patients failing to fulfil the requirements of prescribing guidelines; similarly, one out of 14 orlistat prescriptions fell outside licensed indications. There were four examples of NHS prescriptions for sildenafil which were given even when the GP thought the drug to be inappropriate, whereas orlistat was never given when the GP thought it inappropriate.

Conclusions. Levels of demand for the two lifestyle drugs, sildenafil and orlistat, were modest when compared with earlier media predictions. Neither was there evidence that GP was pitted against patient in their negotiation concerning a lifestyle drug NHS prescription since most GPs agreed with their patients that such a prescription was appropriate. Prescribing guidelines and licensed indications were generally adhered to, but the modest level of demand raises questions about expanding the guidelines for sildenafil.

Keywords. Lifestyle medication, patient demand, prescribing.

Received 30 March 2001; Revised 15 October 2001; Accepted 7 January 2002.

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Introduction

The term 'lifestyle drug' first appeared in the *Concise Oxford Dictionary* in 1999 and was defined as, "a pharmaceutical product characterized as improving quality of life rather than alleviating disease".¹ This definition has been challenged, particularly because of the implicit dissociation of illness and lack of well-being.

It is hard to be certain where the dividing line might be drawn between an essential medicine to treat an illness and a 'lifestyle drug' to improve well-being.² With the British launch in September 1998 of both orlistat (Xenical) and sildenafil (Viagra), the debate intensified. Are impotence and obesity to be considered merely as conditions diminishing enjoyment of life—an inconvenience rather than an illness? Or should these conditions be re-defined as health needs with long-term complications, such as depression or increased cardiovascular mortality, every bit as serious as the more traditionally defined diseases? Beyond the philosophical debate, there was much media coverage of these two drugs at their launch, which may have both stoked demand and provoked fears that GPs would be inundated with requests for treatment.

Little research has been undertaken on the level of demand from patients for lifestyle drugs, nor the response from doctors to such requests. Both sildenafil and orlistat were labelled by the media as lifestyle drugs, and for this reason these drugs were chosen as the basis of this study. A literature search failed to locate any studies about orlistat in this context. The early literature about sildenafil suggested that demand might well be high and sometimes inappropriate: one survey reported that 6% of GPs had faced demands for sildenafil from healthy males seeking to enhance their potency,³ thus adding to the perception that sildenafil could sometimes be an indulgent luxury. Recreational use has also been highlighted.⁴ It was hardly surprising that at the time of sildenafil's launch, a quarter of GPs thought it should not be prescribed on the NHS under any circumstances.⁵

The British political situation was complicated by a rationing debate.⁶ Doctors were advised in a Department of Health circular not to prescribe sildenafil on the NHS until further guidance had been drawn up. It was the first time that the NHS had refused funding for a licensed drug of proven benefit to large numbers of people.⁷ Not for another 8 months was definitive guidance released. This took the form of statutory restrictions, introduced on 1 July 1999, requiring GPs to issue NHS sildenafil prescriptions for impotence only when the patient satisfied one of six medical criteria published by the government, or had been receiving treatment on or before September 1998, or was suffering 'severe distress'.⁸ Controversially, these criteria excluded impotence caused by psychological factors, ageing and drug side effects. Patients not fulfilling these criteria could only be given private prescriptions of sildenafil. Nevertheless, many NHS prescriptions had been issued prior to 1 July 1999. One reason why doctors may have ignored the initial Department of Health circular was that the British Medical Association had already received independent legal advice that this guidance was unlawful.⁹ To complicate matters further, Pfizer, the manufacturers, staged a successful High Court challenge to the initial guidance

in May 1999. The early guidance was ruled unlawful because it, "deterred doctors from exercising their duty to use clinical judgement".⁹

Debate about orlistat was less intense, although the licensed indications effectively restricted it to the most obese [those with a body mass index (BMI) >30 kg/m², or >28 kg/m² and associated risk factors] who were also prepared to lose 2.5 kg in the month prior to receiving a first prescription. Consequently, for orlistat too, there were elements of rationing, albeit less explicit ones, ensuring that patients had 'earned' their course of orlistat by prior demonstration of a firm resolve to lose weight. The position on prescribing to the moderately obese or those without prior documented weight loss has never been clarified. An NHS prescription in these circumstances would be in breach of the prescribing licence but, unlike the situation with sildenafil, no provision has been made for GPs to offer private prescriptions to that proportion of patients with a perceived need, yet who fell outside the strict licensing criteria.

Given the fears of unprecedented demand for lifestyle drugs coupled with attempts to restrict their supply, we aimed to describe the levels of demand, and translation of demand into prescriptions, for sildenafil and orlistat in general practice. We chose a time well after the launch of these two drugs to avoid the height of media interest which may have stoked short-term demand, although the implementation of the sildenafil guidelines did receive some media coverage. We also timed the survey to straddle the pre- and post-implementation period. Coupled with this, we aimed to survey GP opinion about the perceived appropriateness of demand.

Method

Participants

Twenty-seven GP members of STaRNet (South Thames Primary Care Research Network) took part in this study. They were located in 27 practices distributed throughout South-East England. These GPs varied widely in their experience (mean years since qualification, 10.7; range 3–27), gender (20 male; seven female), practice size (mean number of GP principals, 5.1; range 1–8), setting (six inner city, 17 urban/suburban, one rural, three mixed), practice training status (16/27 were in training practices) and deprivation levels (11/27 practices received deprivation payments).

Timing of survey

The 6-week data collection period was from 1 June to 9 July 1999, inclusive.

Procedure

Participating GPs recorded anonymized data for all consultations in routine surgeries during the data collection period. The total number of patients seen during the

study period was recorded. For all consultations where sildenafil or orlistat were discussed, additional information was obtained:

- demographic and clinical details about the patient
- fulfilment of prescribing criteria: for sildenafil, the criteria for NHS prescriptions;⁸ and for orlistat, the licensed indications
- the perceptions of the GP about the appropriateness of an NHS prescription [measured on a 6-point scale, anchored, 'not at all appropriate' (0) to 'highly appropriate' (5)]
- assessment of psychological distress [measured on a 4-point scale ranging from no distress (0) to severe distress (4)]
- whether a prescription was issued.

To maximize recording, a bright sticker reminding the GP about the study was attached to the GP's computer and GPs were remunerated for their time. After the study, each GP was asked if they were confident that they had included all cases presenting during the study period and, if not, how many may have been omitted ('one or two', 'a few', 'several').

Sample size

Given the exploratory nature of the study and the fact that the parameters on which sample size calculations are based were largely unknown, it was decided to obtain the highest feasible consultation number. This was achieved by maximizing the number of GPs (all consenting STaRNet GPs) and the data collection period (the longest acceptable period over which GPs indicated that they would be willing to log all consultations).

Data analysis

Data were analysed using SPSS for Windows, version 7.5. Because the data were skewed, non-parametric tests were used throughout.

Results

Consultations surveyed

A total of 13 394 consultations were recorded by the 27 participating GPs, averaging 82.7 consultations per GP per week.

Levels of demand

Sildenafil was discussed in 0.5% (68/13 394) consultations and orlistat in 0.3% (42/13 394) consultations. Two GPs had substantially higher consultation rates. One had a sildenafil consultation rate of 70 per 1000 patients seen when all others had a rate under 20; 15% (4/27) had no consultations at all during the study period in which sildenafil was discussed. Similarly, another GP had an

orlistat consultation rate of 59 per 1000 patients seen when all others had a rate under 12; 44% (12/27) had no consultations in which orlistat was discussed. Many were follow-up consultations after previous prescription of one of these drugs: 37% (25/68) of patients discussing sildenafil and 29% (12/42) of those discussing orlistat had received a previous prescription. Most GPs (89%) were confident that they had not missed any consultations for either of the lifestyle drugs; three GPs thought that they may have missed 'one or two' consultations.

Appropriateness of demand

GPs perceived that an NHS sildenafil prescription was highly appropriate (appropriateness rating 4 or 5) in the majority of consultations where this had been discussed (57%, 39/68). However, for a significant minority of consultations (19%, 13/68), GPs felt that an NHS script was inappropriate (appropriateness rating 0 or 1). Factors related to this perception of the appropriateness of an NHS script are summarized in Table 1. GPs felt that the majority of those discussing sildenafil were experiencing significant (47%, 32/68) or severe (10%, 7/68) psychological distress; however, in three consultations (4%), the GP felt that there was no distress and in 26 consultations (38%), the distress was only 'minor'. None of the participating GPs believed that the patients they saw were requesting sildenafil for recreational use.

For orlistat, GPs perceived that an NHS prescription was highly appropriate in 74% (31/42) of consultations in which it had been discussed. Factors associated with this perception of appropriateness are summarized in Table 1. Again, there was a significant minority of consultations, 19% (8/42), in which GPs felt that it was inappropriate. Psychological distress was recorded as severe in 12% (5/42), significant in 36% (15/42), minor in 48% (20/42) but, in 5% of consultations (2/42), GPs felt that there was no distress.

Prescribing indications

Fulfilment of the six medical criteria listed in the Department of Health guidelines⁸ occurred in 49% (33/67) of consultations in which sildenafil was discussed; a further six patients fulfilled the guidelines by having received impotence treatment in September 1998, raising the total consultations satisfying Department of Health criteria to 58%. In 16% (11/67), the cause of impotence was thought to be 'other medical factors'; psychological factors accounted for 27% (18/67) and 7% (5/67) were 'unknown cause'. Data were missing for one case.

For orlistat, the BMI prescribing requirements were fulfilled by 90% (36/40): 35 out of 40 had a BMI >30 kg/m² and one had a BMI between 28 and 30 kg/m² and associated medical risk factors. Even though some did not fulfil the BMI prescribing requirement, all were still overweight (BMI >25). Data were missing for two cases.

TABLE 1 Factors associated with GP perception of the appropriateness of an NHS 'lifestyle drug' prescription

	Statistical test and value	P-value
Sildenafil		
Cause of impotence on the 'approved list' of medical conditions	Mann-Whitney U, 187.0	<0.001
Other medical causes of impotence	Mann-Whitney U, 281.5	0.58
Impotence attributed to side effects of concurrent medication	Mann-Whitney U, 265.5	0.02
Psychological distress	Spearman's ρ , 0.42	<0.001
GP is younger	Spearman's ρ , 0.31	0.01
GP is female	Mann-Whitney U, 237.5	0.052
Training practice	Mann-Whitney U, 478.5	0.38
Orlistat		
BMI >30 kg/m ²	Mann-Whitney U, 33.0	0.02
Medical conditions that increase health risk	Mann-Whitney U, 124.5	0.04
Psychological distress	Spearman's ρ , 0.34	0.03
Patient is male	Mann-Whitney U, 83.0	0.03
GP is younger	Spearman's ρ , 0.31	0.01
GP is female	Mann-Whitney U, 33.5	0.20
Training practice	Mann-Whitney U, 67.0	0.01

Significant *P*-values indicate that an NHS prescription is more likely to be thought appropriate in the presence of the given factor.

Prescriptions issued

Of all consultations in which sildenafil was discussed, 43% (29/68) resulted in an NHS prescription. A further 18% (12/68) resulted in a private prescription. Five of the NHS scripts (17%) were given to patients not fulfilling the Department of Health guidelines, even though none had other medical reasons for impotence and they were not seen as more distressed than the remainder (Mann-Whitney U = 138.0, *P* = 0.66). One private script was given when the patient was eligible for an NHS prescription.

A prescription was given in 33% (14/42) of consultations in which orlistat was discussed. Ten were repeat prescriptions but, of the four new prescriptions, one was given when there was no evidence of a preceding weight loss over 2.5 kg. Two of the repeat prescriptions were given when the BMI conditions were not fulfilled.

NHS prescribing and appropriateness ratings

NHS prescriptions were more likely to be issued for both sildenafil and orlistat when the GP felt that such a prescription was appropriate (Mann-Whitney U = 261.0, *P* = 0.0001; Mann-Whitney U = 84.5, *P* = 0.002, respectively). Occasions did arise when NHS prescriptions for sildenafil were issued even though the GP thought it inappropriate: in two cases, the indication was on the approved list; in one case the patient was distressed; and in one, a previous NHS script had been given. In contrast, orlistat prescriptions were never given when the GP thought such a script inappropriate.

Some GPs recorded that they perceived NHS prescriptions for sildenafil as appropriate (scores 4 or 5) even when such a patient was not eligible for an NHS prescription. Twenty-eight (42%) cases where sildenafil was discussed were outside the NHS guidelines and in

five of these (19%) the GP perceived that an NHS prescription would have been appropriate.

Discussion

Having surveyed over 13 000 consecutive consultations in a wide range of general practices throughout South-East England, we found only a very modest demand for the two lifestyle drugs, sildenafil and orlistat. There may well have been an initial surge in demand, but our survey, some 9 months after the launch date of both drugs, suggests that the worst fears of the politicians have not been realized. Early predictions circulated of a sildenafil cost burden to the NHS exceeding £1000 million per year,⁶ whereas true primary care costs in England were £11.5 million (July 1999–June 2000).¹⁰ Comparable costs for orlistat were £5.4 million.¹⁰

In retrospect, it can be seen that the issues raised by the simultaneous launch of two lifestyle drugs were not so unique after all. At the time, it seemed that GPs would be subjected to undue prescribing pressure, against their better judgement. On the contrary, our results suggest that in most cases, far from opposing the prescription, GPs thought that a lifestyle drug, on NHS prescription, was appropriate. In not one case did we find the GP giving orlistat when they thought it inappropriate. Sometimes, prescriptions of sildenafil were given when it was thought inappropriate, but the overall picture does not suggest undue pressure to prescribe since, in many more consultations, no NHS prescription was issued in spite of the GP thinking such a request was appropriate. Of the factors studied, being a younger GP was the only feature common to both lifestyle drugs which was significantly associated with the perception of prescribing

appropriateness. Older GPs were probably more resistant to the idea that such prescribing, on the NHS, was appropriate. Just as the launch of so-called lifestyle drugs triggered the realization that many other treatments could be termed 'lifestyle', so it rapidly became clear that prescribing pressure was not a new phenomenon^{11,12} and that prescribing decisions have long been influenced by societal factors rather than solely by clinical facts.¹³

Intervention by politicians was mainly because of the financial implications of new treatments with potentially large and hitherto unmet demand. Initially, GPs were in the difficult position of having potentially torn allegiances to their patients and to the Department of Health. Again, this situation is not new and budgetary constraints have long influenced prescribing.¹⁴ Moreover, we did not find widespread evidence that GPs were flouting the prescribing guidelines nor licensed indications. By and large, most prescriptions were issued according to these requirements and many patients fulfilling the conditions were not given prescriptions (and presumably received lifestyle advice instead or awaited further assessment).

Our study may have underestimated demand. A few of the GPs were not confident that they had recorded all relevant consultations, and repeat prescriptions without a consultation were not studied. In surveying appropriateness, we have concentrated exclusively on the doctor's perspective, and further study would be useful to determine the degree of agreement between the views of patients and their doctors regarding the appropriateness of lifestyle drugs. Although we have surveyed over 13 000 consultations and two lifestyle drugs, the representativeness of our sample could be questioned since the number of GPs was relatively small. GP research networks are known to be somewhat unrepresentative, selecting GPs who favour change and innovation.¹⁵ Furthermore, research networks often attract or recruit practices with research experience and/or higher levels of computerization. As such, the recorded GP opinion and practice in this survey may not have truly reflected national general practice.

Our survey did not come up with evidence to suggest that patients themselves were seeking to redefine lifestyle drugs, requesting them for largely non-medical reasons. No examples were found of patients requesting orlistat when not overweight. No example of recreational sildenafil use was recorded.

High levels of demand for lifestyle drugs and a culture of prescribing outside Department of Health recommendations could have propelled politicians into much tighter prescribing guidelines. Under a third of sildenafil prescriptions were issued privately, and it could be argued that, far from tightly rationing sildenafil, the government may have been too generous initially, permitting NHS prescriptions for so many indications. Most European countries have not funded it at all.² On the other hand, now that demand has been found to be lower than early expectations, it might be time to review the

guidance on NHS prescribing. Equally, low demand may be a pointer to the success of prescribing restrictions; our study does not allow us to extrapolate the likely consequences of relaxing these restrictions. We did not canvass GP opinion about changing the guidance, but it appears inconsistent to exclude causes of impotence such as drug side effects; this supposition is supported by the significant finding of high perceived appropriateness of sildenafil prescribing in these circumstances.

In conclusion, the early predictions about overwhelming demand for lifestyle drugs appear not to have been fulfilled. Most GPs experienced low levels of demand and largely confined their prescribing to the guidance and licensed indications which consequently limited NHS supply. With less alarmist fears to cloud the discussion, the wider debate can now take place about how tightly lifestyle drugs should be regulated. We hope that our exploratory study of GPs' practices and perceptions regarding two so-called lifestyle drugs will help to inform this debate.

Since completion of this study, the Department of Health have conducted their own public consultation about the eligibility criteria for NHS prescribing of sildenafil. The result of this consultation was announced in October 2001 with the decision that the list of medical conditions qualifying patients for NHS prescriptions would remain unchanged.

Acknowledgements

We would like to thank all the STaRNet lead GPs who participated in this study. We would particularly like to thank Mike Morris for help with the initial study design. This work was funded through the STaRNet Research Network by the NHS R&D Directorate, South East and London Regions. The views expressed here are those of the researchers and not necessarily those of the funders.

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