Implementing a statin switching programme in primary care: patients' views and experiences

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Switching of patients' prescribed medicines within a therapeutic class is a common strategy to reduce prescribing costs, and in England a standard methodology has been promoted for switching processes.
- Previous work to date suggests many patients are sceptical of generic products and switching may reduce compliance.
- Patients' views on switching in general and the processes used have not been widely sought.

WHAT THIS STUDY ADDS

- Patients may be less accepting of therapeutic switching programmes than is currently assumed.
- Patients lacked understanding of the reason for the switch, despite standard letters and information leaflets being used, and few sought consultations.
- Greater explanation of switching, possibly with involvement of community pharmacists, could lead to improved patient understanding and acceptance.

INTRODUCTION

Estimates suggest £200 million could be saved on prescribing costs in England by implementing medication switches. Few studies have evaluated patients' views or understanding of therapeutic switches.

AIM

To obtain patient and pharmacist perspectives on switching from atorvastatin to simvastatin within an English Primary Care Trust (PCT).

METHOD

All patients undergoing this switch, in seven self-selected East Lancashire practices, were sent postal questionnaires covering demographics, experiences and views regarding switching, with no reminder. Practice pharmacists implementing switches in these practices were interviewed about processes and their views on these.

RESULTS

Pharmacists' switching process involved a standard letter offering a telephone consultation or appointment, plus an information leaflet. They considered most patients accepted switches, with few requesting consultations.

Four hundred and ninety-four patients were identified and a response rate of 48.6% (240) obtained. The majority of respondents were happy with the switch (53.7%) and how they were informed (60.1%), with these findings being positively correlated. However over half (52.9%) did not understand the reason for the switch, particularly those with lower educational qualifications. Patients unhappy about switching perceived they had experienced side effects, or only learned of the switch on collecting a prescription or did not recall the consultation offer.

Respondents indicated a preference for future switches to involve a face-to-face consultation (59.8%), with two-thirds (65.2%) agreeing that community pharmacists should explain medication switches.

CONCLUSION

The standard process used, in line with nationally-designed templates, resulted in many patients being unhappy with or lacking understanding of switching statins, suggesting that improvements may be needed.

Introduction

In common with many countries there is encouragement from government in England to reduce expenditure on medicines through maximizing cost-effective prescribing [1]. The National Health Service (NHS) spends approximately £11 billion a year on medicines [1]. There are many options for reducing expenditure on medicines, using four main approaches: education, engineering, economics and enforcement [2]. One approach involves switching patients from relatively expensive medicines to more cost-effective alternatives without reducing therapeutic outcomes. The National Audit Office estimated in 2007 that £200 million a year could be saved by implementing these switches, in particular statins, which constituted 19% of the overall drugs bill at this time [3]. Atorvastatin 10 mg, atorvastatin 20 mg and simvastatin 40 mg are the most prescribed but with dramatically differing costs, due to the patent expiry of simvastatin in 2003. Switching one patient from atorvastatin 10 mg to simvastatin 40 mg, or from atorvastatin 20 mg to simvastatin 40 mg, creates an annual saving of £148 and £299 respectively [4], which, multiplied by the number of patients taking the higher cost drug, results in the potential for considerable savings.

Statin switches have been advocated for several years [5] and are included in the Department of Health 'Better Care, Better Value' indicators, designed to provide benchmarks of low cost prescribing, with a prescribing target of 69% for low cost statins (simvastatin and pravastatin) [6]. Many English Primary Care Trusts (PCTs) operate incentive schemes, encouraged by the Department of Health, which aim to encourage more cost-efficient prescribing, by allowing practices to keep a fraction of the money saved on medication switches [7]. Concerns have been expressed that changing statins may adversely affect patient outcomes in terms of lipid control [8]. While it is recognized that therapeutic substitution is often contentious due to the lack of evidence supporting equivalence [9], it has been suggested that in general no harm arises from switching statins, although this may be inconvenient for patients and switching can conflict with patient choice [9].

Guidelines on the switching process suggest that assessment of individual patient circumstances is required, involving review of records to ascertain responses to any previous statin use, that patients should be informed of the switch and involved in the process and that PCTs draw up their own Standard Operating Procedures (SOPs) [7]. Patients' opinions on switching could vary depending on how they are informed of the switch or level of information provided. There has however been little work evaluating patient views or understanding of these switches. One report of patient views on switching from atorvastatin to simvastatin concluded they were generally positive and understood why the switch was occurring. However it involved only 70 patients with a response rate of 37% [10]. A retrospective observational analysis of new statin users

reported that patients whose drug had been switched were 19% less compliant [11], while another study involving brand switching found that the majority of respondents surveyed agreed with this as a good idea to provide better value for money for the NHS [12].

The switch from atorvastatin to simvastatin also involves a change from a branded to a generic product. Surveys of patient and public views suggest that opinions of both therapeutic and generic substitution vary. One study found that only 13–22% of patients suffering from a chronic condition with significant potential health implications were willing to consider a therapeutic substitution [13]. A German study has found that a third of participants had negative views of the efficacy and safety of generics, believing them to be inferior to branded products [14] and two thirds of participants in an American study believed generics to be less safe with more side effects [15]. Patients with better knowledge of generics may be more prepared to switch to a generic drug [16] and a literature review has concluded that increasing patient education on generics through communication with healthcare professionals has a major impact on patients' perceptions of the safety and efficacy of generics [17]. Negative opinions resulting from concerns about switching or generic products may further reduce statin patient compliance which is already relatively low, with studies indicating up to 40% of patients stop taking their prescribed statin after 3 years [18].

Pharmacists employed by PCTs are frequently involved in implementing therapeutic and generic switches, while community pharmacists are aware of changes to prescriptions in regular customers, but may not be informed about specific switching decisions. Patients have a right to understand why their medicines are being switched and should be involved in decisions about them. Exploration of patients' understanding of therapeutic switches is important so that pharmacists can help to improve their involvement in decisions, since it is suggested that if patients are educated about their choices and understand more about their own care, this renders treatments more effective [9].

The aim of this study was to evaluate the processes used in switching patients from atorvastatin to simvastatin for the purpose of increasing cost-effective prescribing from the perspectives of patients and the pharmacists implementing switches.

Methods

Setting and study sample
Approval to conduct this evaluation was obtained from a University Research Ethics Committee and East Lancashire PCT. The study involved patients and practice pharmacists from seven self-selected practices within the Trust. Patients included were over 18 years of age and had undergone a switch from branded atorvastatin to generic simvastatin during the previous 12 months. Three practice-based

pharmacists, who had implemented the switches in the seven practices, identified the patients from medical records and provided address labels for the researchers to distribute postal questionnaires. This method ensured no patient details left the practices and assured patients of complete anonymity. The three pharmacists also agreed to be interviewed.

Patient questionnaire

A questionnaire was devised by the research team and assessed for face and content validity by the practice pharmacists and GPs. It included demographic questions, questions about the switching process, including how patients were informed and whether they had a consultation, and sought views on this plus switching in general, using a series of statements developed from the literature together with a five-point Likert scale and questions about perceived side effects following the switch.

The questionnaire was distributed in January 2011 along with a covering letter and a freepost envelope for return to the research team. Six weeks were allowed for questionnaire return before the study was closed. No reminder was possible due to the method used.

Pharmacist interview

A structured telephone interview schedule was created and again assessed for face validity by the commissioning pharmacist. This covered the pharmacists' experience of medicine switches, how SOPs were used, patient identification, consultation options, perceived compliance with switches and any feedback received from patients. Responses to individual questions were recorded on paper during the conversation.

Data analysis

Patient questionnaire Questionnaire data were analyzed using Statistical Package for the Social Sciences v17. Open questions were categorized after identifying common themes and used to illustrate the quantitative findings. Associations between ranked variables were assessed using Spearman's correlation coefficient and those involving dichotomous variables using contingency chi-squared tests. Sub-group comparisons were made using Mann-Whitney U test.

Pharmacist interviews The interviews were analyzed in simple themes relating to the questions asked.

Results

From the seven practices, 494 patients were identified as having been switched from atorvastatin to simvastatin and were sent a questionnaire. Of these, 248 were returned, but eight were invalid due to failure to complete, and omitted from the results conferring a valid response rate of 48.6%.

Reasons given for non-completion included 'never used a statin', 'no longer taking a statin', 'not been switched' and 'switched back to atorvastatin'.

Demographic data

These are given in Table 1. Respondents were predominantly male, with the majority being aged between 55 and 74 years and most were entitled to free prescriptions. Almost all were of White ethnicity, and almost 40% had no educational qualifications, with a further 20.4% having attained GCE standard or advanced level. Those who had attained lower educational qualifications of GCE or below were more likely to receive free prescriptions (chi-squared test $P = 0.008$).

Views on statin switching processes

Just over half of the respondents to each question either agreed or strongly agreed that they were happy being asked to switch statin, 123 (53.7%) agreed and 134 (60.1%) strongly agreed they were happy with the method and manner of the switch, but fewer than half (99; 47.1%) agreed that they understood the reason for the switch, with a further 47 (22.4%) being unsure. (Table 2) This latter question also had the highest non-completion rate (30). There was a positive correlation between respondents who were happy being asked to switch statin and those who were happy with the method by which it was explained (Spearman's $r = 0.624, P < 0.001$).

Respondents entitled to free prescriptions and those with lower educational qualifications showed higher levels of agreement with the statement 'I do not understand why my statin has been switched' (Mann Whitney U, $P = 0.004$ and $P = 0.006$ respectively).

The majority of respondents agreed that the NHS should switch medicines in response to evidence, although fewer agreed that medicines should be switched in response to national guidelines, and there was even less

Table 1

Demographic characteristics of patient participants ($n = 240$)

Characteristic		n (% of total*)
Gender	Male	133 (55.9)
Age group (years)	18–54	32 (13.4)
	55–64	75 (31.4)
	65–74	73 (30.6)
	75 or over	59 (24.7)
Ethnicity	White	175 (97.9)
	Asian/Asian British	5 (2.1)
Educational status	No formal qualifications	91 (39.6)
	GCE qualifications	47 (20.4)
	Further educational qualification	71 (30.9)
	Degree	21 (8.8)
Pay for prescriptions	Yes	43 (16.9)
	No	197 (83.1)

*After allowing for missing data.

Table 2

Views of patients about switching of statins and medicines in general

	Strongly agree % (n)	Agree % (n)	Not sure % (n)	Disagree % (n)	Strongly disagree % (n)	Missing data (n)
I am happy being asked to switch my statin	10 (23)	43.7 (100)	21.8 (50)	9.6 (22)	14.8 (34)	(11)
I am happy with the method and manner in which the statin switch was explained to me	12.6 (28)	47.5 (106)	17.9 (40)	11.2 (25)	10.8 (24)	(17)
I do not understand why my statin has been switched	10.5 (22)	20 (42)	22.4 (47)	28.1 (29)	19 (40)	(30)
The NHS should switch medication in response to evidence found in medical research	28.9 (68)	56.6 (133)	9.4 (22)	2.1 (5)	3 (7)	(5)
The NHS should switch medication if national guidelines advise it	9.3 (21)	45.4 (103)	29.5 (67)	10.1 (23)	5.7 (13)	(13)
The NHS should switch medication if this saves tax payers' money	10 (23)	23.4 (54)	18.6 (43)	25.5 (59)	22.5 (52)	(9)
The community pharmacist should explain in person why medication is being switched	21.6 (49)	43.6 (99)	17.6 (40)	12.3 (28)	4.8 (11)	(13)

agreement that saving taxpayers' money was a good reason for switching medicines (Table 2).

'A satisfactory procedure, well explained. I am totally in agreement with savings made on good evidence.' (female, aged 85 years or over)
'I don't think that changing medicine as a cost cutting exercise is a good enough reason to do so.' (male, aged 55–64 years)

Almost two-thirds (148, 65.2%) agreed that the community pharmacist should explain why medication is being switched. The majority of respondents (132, 55.9%), however, believed that the PCT was responsible for the switch, with a further 90 (38.1%) identifying the GP. Only four identified the pharmacist at the surgery and three the community pharmacist as being responsible.

'I cannot find out exactly who made the decision: the doctor blames the pharmacy and the pharmacy blames the doctor.' (male, aged 65–74 years)

In response to a question about the method by which they were informed of the statin switch, 159 (66.8%) claimed they were informed by letter, 35 (14.7%) by speaking with a pharmacist, doctor or nurse and 25 (10.5%) of the patients stated they were not aware of the switch until they collected their prescription. Of the patients informed by letter, only 77 (48.4%) were happy with the switch, although 93 (58.5%) were happy with the method. Of the 35 patients who spoke to a pharmacist, doctor or nurse, 27 (77%) were both happy with the switch and with the method of being informed. There was, however, no significant evidence of any difference in the proportion of patients who agreed they understood why their statin had been switched dependent on whether they had spoken to a health professional (17; 49%) or been informed by letter (70, 44%). In contrast, only one of the 25 respondents who claimed they were not aware of the switch until they collected their prescription agreed they understood the reason for the switch.

Of the 102 (42.9%) respondents who recalled being offered a consultation, 55 (53.9%) accepted this. There were 136 (57.1%) who did not recall being offered a consultation, 75 (55.1%) of whom indicated they would have liked one. Respondents offered a consultation were significantly happier being asked to switch statins, were happier with the method and manner undertaken to inform them of their switch and more understanding of the reason for the switch than those who were not offered a consultation (Mann-Whitney $P = 0.005$, $P < 0.001$ and $P = 0.019$, respectively).

Respondents' preferences for the method of informing about future switches were in favour of a private consultation, with 130 (55.3%) indicating this method, followed by 81 (34.5%) preferring a letter. One patient indicated other opportunities to change medicines should be used instead:

'Every patient on a repeat prescription has to undergo an annual review, this would surely be the best time to review and if necessary change to a more cost effective medication, it offers the opportunity to discuss, reassure and be consulted on an individual basis.' (female, aged 55–64 years)

A total of 42 (17.7%) respondents claimed to have experienced increased side effects since changing their statin, while eight (3.4%) had fewer and 182 (75.8%) had not detected any change. The remainder did not know or did not respond.

'I was switched to a statin I had previously had an extreme reaction to. So I was very unhappy that my records hadn't been checked before the switch.' (female, aged 55–64 years)

Among those who responded to both questions, only seven (5.9%) of 123 who agreed they were happy with the switch had experienced an increase in side effects, whereas 31 of 103 (30.1%) who disagreed or were unsure

that they were happy with the switch had more side effects (chi-squared $P < 0.001$).

Pharmacist interviews

Switching processes Information obtained from the interviews indicated that in all seven practices, practice pharmacists identify suitable patients by searching through practice computer records, then all patient records are audited to assess their suitability for switching. In some practices suitability is then confirmed by a GP. In all seven practices, patients were informed of the switch by letter sent by the practice pharmacist, plus an information leaflet, unless a face-to-face or telephone consultation was deemed necessary. The letter and information leaflet were agreed with the practice and were viewed by the pharmacists as providing enough information. A standard line in the template letter advised patients to make an appointment with the practice pharmacist, technician or nurse, or seek a routine GP appointment if they had concerns about their switch. The information leaflet explained that the reason for the switch was that simvastatin was the least expensive choice of statin and gave the NHS better value for money than more expensive alternatives. It suggested that if patients had questions they should contact the practice or their usual community pharmacist. The practice pharmacists interviewed considered that less than 10% of patients took up the offer of an appointment or contacted the practice.

Views on switching

Although standard practices are followed, one pharmacist was of the opinion that a face-to-face consultation would be better, while another was concerned that unknown language barriers may exist:

'The practice population is mainly white British but there is an assumption made that all patients can read English.' (PH2)

All felt that very few patients refuse the statin switch, but have very little feedback. One expressed the view that patients do not understand what is driving switches:

'Very few understand it is the government and see that it is the person giving out medications are responsible.' (PH3)

All were of the view that switching was appropriate, but one illustrated an appreciation of the patient perspective:

'A necessary evil. Don't like having to switch due to the inconvenience for the patient.' (PH3)

Discussion

This study has evaluated the processes involved in switching statins from both pharmacist and patient perspectives.

While there was a small majority of patient respondents who were happy with switching from atorvastatin to simvastatin, almost a quarter (24%) were not happy and 22% were unsure. There was also a significant proportion who were unhappy with the method of switching, a standard letter, including an invitation to make contact if they wished to discuss the change. Many felt they would have preferred a face-to-face consultation and did not take up the offer of this. Importantly, 10% of respondents claimed they were not informed at all, learning only of the change when they collected a prescription, and many claimed they did not understand why their medicine had been switched, despite the inclusion of an information leaflet with the letter.

Patients who were unhappy included those who had experienced side effects, those who claimed only to have learned about the switch when they collected a prescription and those who claimed not to have been offered a consultation. Those with least understanding about the switch were those with lower educational qualifications. Almost two-thirds expressed agreement that the community pharmacist should explain the reason for the switch, even though most respondents understood that it was not the community pharmacist who was responsible for it occurring. The proportion of respondents who claimed to have experienced an increase in side effects was 17.7%, including at least one in whom switching may not have been appropriate, due to a previous adverse reaction, while other respondents who did not complete questionnaires indicated they had been changed back to atorvastatin. This is in contrast to a previous study in which only one of 70 patients was changed back to their original statin because of side effects [10].

Our respondents were more positive about changing statins in response to evidence, rather than simply cost, although there were fewer supportive of national guidelines, perhaps indicating a lack of understanding of the evidence-based nature of these. Previous work has shown that patients may be in favour of changing medicine brand i.e. generic switching, to provide better value for money for the NHS [12], although there have been negative views expressed by consumers about both generic and therapeutic substitution [13, 17]. Views on generic substitution may be related to understanding [17]. Hence the lack of understanding found in the present study, which involved a therapeutic switch, is of concern, even though, in the opinion of the practice pharmacists implementing the switches, very few patients refuse switches. All seven practices in our study chose to implement switching by letter in most cases. Thus the finding that 10% of questionnaire respondents did not seem to recall its receipt is also of concern. A previous study found a much higher proportion (32%) who did not recall receiving a letter informing them of a switch [12].

Patients in this previous study were asked if a letter was the most appropriate way of informing of changes, to

which 88% agreed [12]. In our study however, where a range of options was given, over half the respondents expressed a preference for a face-to-face consultation. Given the numbers of patients undergoing switches, this would have a significant time and cost implication. However patient involvement is recommended by national guidance on switching and some mechanism of achieving this may need to be considered. One possibility is greater involvement of patients' regular community pharmacists, an option which many of our respondents favoured. Community pharmacists are well placed to explain the reason for the change in medicine at the time of dispensing, provided they have been fully informed by practice staff or the PCT in advance that a switching programme is taking place. They could provide a further copy of the information leaflet and reinforce the message about opportunities for consultations. Alternatively carrying out switching at a time when medicines are being discussed, such as annual reviews, would reduce the need for additional consultations. More consideration may also be required concerning the provision of leaflets in languages other than English.

This is the largest study to date evaluating patients' views of therapeutic switching and our valid response rate of 48.6% was good compared with other studies. No data were available to determine whether responders were representative of the population whose statin was switched and there is a potential response bias towards those who are unhappy with switching. Taking this into account, however, if all non-responders were happy there would still be over 21% of patients who were either not happy or unsure. The practices which chose to participate were self-selected and all used similar methods of identifying and informing patients. Hence it was not possible to determine whether different methods were viewed more or less satisfactorily by patients. Future work should look at different methods, perhaps in differing sub-groups of the population, and also explore patients' understanding of the reasons behind therapeutic switching further and explore further whether this is linked to views on its acceptability.

Competing Interests

REFERENCES

1 National Prescribing Centre. What you need to know about prescribing, the 'drugs bill' and medicines management: a guide for all NHS managers. 2008. Available at http://www.npc.nhs.uk/resources/nhs_guide_for_managers.pdf (last accessed 16 February 2012).

2 Garattini S, Bertele V, Godman B, Haycox A, Wettermark B, Gustafsson LL. Enhancing the rational use of new medicines across European healthcare systems: a position paper. Eur J Clin Pharmacol 2008; 64: 1137–8.

3 National Audit Office. Prescribing costs in primary care. 2007. Available at http://www.nao.org.uk/publications/0607/prescribing_costs_in_primary_c.aspx (last accessed 16 February 2012).

4 NHS Prescription Service. Drug tariff 2010. 2010. Available at http://www.drugtariff.com (last accessed 16 February 2012).

5 Moon JC. Switching statins: using generic simvastatin as first line could save £2bn over five years in England. BMJ 2006; 332: 1344–5.

6 Institute for Innovation and Improvement. NHS better care, better value indicators. 2006. Available at http://www.productivity.nhs.uk/Content/About (last accessed 16 February 2012).

7 National Prescribing Centre. Template for discussion points on statin switching. 2010. Available at http://www.npc.nhs.uk/therapeutics/cardio/cd_lipids/implement.php (last accessed 16 February 2012).

8 Atar D, Carmena R, Clemmensen P, K-Laflamme A, Wassmann S, Lansberg P, Hobbs R. Clinical review: impact of statin substitution policies on patient outcomes. Ann Med 2009; 41: 242–56.

9 Duerden MG, Hughes DA. Generic and therapeutic substitutions in the UK: are they a good thing? Br J Clin Pharmacol 2010; 70: 335–41.

10 Usher-Smith JA, Ramsbottom T, Pearmain H, Kirby M. Evaluation of cost savings and clinical outcomes of switching patients from atorvastatin to simvastatin and losartan to candesartan in a Primary Care setting. Int J Clin Pract 2007; 61: 15–23.

11 Thiebaud P, Patel B, Nichol M, Berenbein D. The effect of switching on compliance and persistence: the case of statin treatment. Am J Manag Care 2005; 11: 670–4.

12 Thompson A, Green S, Dubois S, Ansell A, Harewood E, Ayre J. Evaluation of patient satisfaction with switching medication. Prescriber 2006; 17: 27–35.

13 Harris International. Consumers' views on therapeutic substitution. 2008. Cited in: Johnston A. Challenges of therapeutic substitution of drugs for economic reasons: focus on CVD prevention. Current Med Res Opinion 2010; 26: 871-878.

14 Himmel W, Simmenroth-Nayda A, Niebling W, Ledig T, Jansen R-D, Kochen MM, Gleiter CH, Hummers-Pradier E. What do primary care patients think about generic drugs? Int J Clin Pharmacol Ther 2005; 43: 472–9.

15 Lambert Z, Doering P, Goldstein E, McCormick W. Predispositions toward generic drug acceptance. J Consum Res 1980; 7: 14–23.

16 Babar Z, Stewart J, Reddy S, Alzaher W, Vareed P, Yacoub N, Dhroptee B, Rew A. An evaluation of consumers' knowledge, perceptions and attitudes regarding generic medicines in Auckland. Pharm World Sci 2010; 32: 440–8.

17 Hassali MA, Shafie AA, Jamshed A, Ibrahim M, Awaisu A. Consumers' views on generic medicine: a review of literature. Int J Pharm Pract 2009; 17: 79–88.

18 Perreault S, Blais L, Lamarre D, Dragomir A, Berbiche D, Lalonde L, Laurier C, St-Maurice F, Collin J. Persistence and determinants of statin therapy among middle-aged patients for primary and secondary prevention. Br J Clin Pharmacol 2005; 59: 564–73.