A qualitative study of barriers to the use of statins and the implementation of coronary heart disease prevention in primary care

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SUMMARY

Background: *Statin prescribing to prevent coronary heart disease is well below recommended levels. Studies suggest that the prescribing behaviour of doctors may be the biggest factor in the wide variation in statin prescribing in general practice. Understanding doctors' perceptions offers some insight into why variation occurs.*

Aim: *To understand general practitioners' (GPs') views about barriers to statin prescribing, statin prescribing guidelines, and the successes and barriers to coronary prevention in primary care.*

Design of study: *Qualitative analysis of semi-structured interviews.*

Setting: *General practices in mid and south Bedfordshire.*

Method: *Interviews with 26 GPs.*

Results: *GPs spoke of a variety of barriers to initiating statin treatment specifically, and coronary heart disease prevention generally. Barriers to statin prescribing included: concerns about cost; increased workload and adherence to treatment; variation in treatment targets for lowering cholesterol; and concerns about medicalisation, lifestyle, and health behaviour. GPs found it difficult to prioritise patients for statin treatment, their statin treatment targets varied, and many found primary prevention risk assessment tools difficult to interpret. Coronary prevention was limited by practice space and organisational issues, by problems with recording and retrieval of electronic data, and by limited doctor and nurse time. GPs suggested that funded nurse time, nurse-led heart disease clinics, and better use of electronic data would improve primary care coronary prevention.*

Conclusion: *There are complex barriers to statin prescribing and coronary prevention in general practice, which may explain some of the variation that exists. Further studies of patients' views of statins may provide more information. More resources, improved guidance, and better dissemination of guidance may only address some of the issues.*

Keywords: *statins; prescribing; coronary prevention.*

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Introduction

THE National Service Framework document for coronary heart disease,[1] published in 2000, requires general practitioners (GPs) to identify patients both with, and at high risk of developing, coronary heart disease, and subsequently to provide structured, systematic care to reduce the risks of cardiovascular events. Substantial primary care workload implications may be unrealistic within the suggested time frame.[2] Despite GPs' knowledge[3] of the evidence that statin prescribing substantially reduces cardiovascular mortality and morbidity in those with cardiovascular disease, prescribing remains well below recommended levels, with significant variation in prescribing. In a survey of 1319 patients with coronary heart disease,[4] 63% took aspirin, but only 17% had adequate lipid control. Primary prevention statin prescribing is also low, with only 3% of high-risk patients receiving lipid-lowering drugs in England.[5] Doctor-prescribing behaviour[6] may be one of the main factors explaining a 60–fold variation in statin prescribing, that cannot be accounted for by demographic differences alone.[7]

It is known that doctors vary in their prescribing patterns and their use of guidelines, and there is some understanding of why this variation takes place.[8,9] However, there is a need to understand the specific reasons behind the large variation in statin prescribing, and the relatively low prescribing of statins to high-risk groups. This study aims to identify GPs' views of the barriers to prescribing of statins, their views of the use of statin guidelines, and their views of the barriers to, and successes in, implementation of coronary heart disease prevention in primary care.

Method

Sampling

The study consisted of qualitative interviews with GPs. A database of all GPs in mid and south Bedfordshire was purposively sampled, selecting GPs with a diversity of sex, year of qualification, practice size and location (urban and suburban, or rural), and previous participation in a county-wide lipid-lowering audit. An invitation letter, explaining the project, the time commitment and the background of the researchers (one a GP, one a nurse researcher), was sent. Within 2 weeks, the doctors were contacted by telephone to discuss participation and an interview was arranged. Eleven doctors declined, and three had left their practice. Other GPs with the same sampling characteristics were invited in their place. After 26 interviews, 'saturation point' was reached,[10] with no new themes emerging from the data.

HOW THIS FITS IN

What do we know?

Statin prescribing in general practice is well below recommended levels, with a wide variation between practices and doctors.

What does this paper add?

Concerns about cost, workload, patient compliance, medicalisation of healthy individuals, and health behaviour act as barriers to initiation of statins by GPs. GPs vary in how they approach prioritisation of patients for statin treatment, and the cholesterol lowering targets they aim for.

Data collection

GPs, with one exception, were interviewed in their own practice, by either researcher (JK or LD), using a semi-structured interview schedule; this allowed the participants to raise new issues and discuss issues in more depth. Both researchers explained their own perspective, as primary care clinicians and researchers with a need to understand the issues and difficulties practitioners face in implementing coronary prevention. Approximately one-quarter of the participants were known to the researchers, although the researchers had not worked directly with the doctors or had regular contact with any participant they interviewed.

Interviews included questions about practice systems for coronary prevention, the doctor's own views and prescribing of lipid-lowering drugs, the use of guidelines and risk assessment tools for coronary prevention, and the barriers and possible solutions to coronary prevention in general practice. Participant GPs were shown, and asked to comment on, the 1998 Standing Medical Advisory Committee guideline, *The use of statins*.[11]

All interviews were audio-taped, and transcribed verbatim by an experienced transcriber. Responder validity was assessed by sending a summary of the interview data to all participant GPs.[12] Nineteen (73%) GPs returned a feedback questionnaire, with 17 recording a moderate or high level of recognition of their views, and no new or differing views reported. Two GPs felt that the summary report only partly represented their views.

Analysis

Both researchers independently listened to interview tapes and examined a proportion of the transcripts, before deriving a first coding frame independently. Meetings were held regularly to discuss, modify, and agree a final coding frame for analysis, based both on the research questions and on emerging themes. The coding frame was subsequently applied to the interview data independently by both researchers using QSR NVivo software, with one researcher coding all the data, and the other coding 11 out of 26 interviews. Six interviews were compared for agreement in coding. A total of 137/155 (88%) of the document paragraphs were coded using the same code or subcode from the coding frame.

Coding reports of the major themes were read and reread, to identify and synthesise the range and weight of views of the participants into a coherent picture. Summary reports of each of the key themes were compared with the original interviews, to examine associations and links and provide interpretations.

Results

The characteristics of the 26 participating GPs from 21 practices are shown in Table 1.

Barriers to initiating statin prescribing

GPs raised a range of issues that appeared to influence, or act as a barrier to, statin prescribing.

Concerns about cost and cost-effectiveness. Many GPs raised the issue that statins were expensive drugs; several mentioned being put under pressure to keep within prescribing budgets and at the same time encouraged to prescribe expensive statins:

> *'The down side for the practice is that it is expensive and it's a lot of patients who will be on it for life. Once you start someone on it, it is for life, so it is expensive in terms of cost of drugs ... I think there is massive external pressures on us for every single thing we prescribe and I think the statins thing is rather bizarre in that we were heavily penalised for overspending on our drug budgets when we were spending heavily on statins, and we still have that pressure on drug budgets with negative budgets and target payments and all the rest of it, and now we have the National Service Framework telling us that we ought to be prescribing more. So on the one hand we are being told to prescribe more and on the other hand we are being told to do it without spending any money. So yes, it is crazy.'* (Dr 15.)

Several GPs made prescribing decisions based on an assessment of cardiovascular risk, irrespective of cost:

> **JK:** *'Do you have many general concerns about more widespread prescribing of these drugs?'*

> **Dr 9:** *'Yes, expense really and whether locally the health service can afford it. They are very expensive but the cost-effective analyses suggest that we should be doing that so I think that the argument has been won, certainly for secondary prevention, and I think should be won for the primary preventing and high-risk groups but for low-risk groups that's really sort of almost a political decision.'*

Concerns about workload. The impact of increased statin prescribing on primary care workload was widely reported:

> *'It is time-consuming in terms of following up because people do need to be followed up and they do need to have blood tests.'* (Dr 15.)

> *'I have no problem monitoring but of course it takes nurses' time to take the blood samples. What I tend to do is see them after a fortnight after they have started on it and I check their LFTs [liver function tests], cholesterol level,*

Table 1. Characteristics of participating GPs.

Characteristic	*n*
Practice size	
1–3 partners	12
4+ partners	14
Practice location	
Urban/suburban	11
Rural/semi-rural	15
Sex	
Male	18
Female	8
Year of qualification	
Before 1980	12
1980 or later	14
Participation in previous county-wide audit of statin use	
Yes	13
No	13

and in particular I am checking their LFTs. That's the important one after a fortnight I find. I don't therefore routinely do blood tests, say once a year even, I think once I have got it down, if it's down safely then it is up to them to look after their diet to a degree and I will say do it every 5 years. But it involves nurse time, costs of having blood tests done and in my time to look at it.' (Dr 13.)

Concerns about adherence to treatment. GPs expressed a view that some patients would be unhappy about taking medication a long-term basis, especially if they are already taking several other drugs:

'When you say they have to be on them for an indefinite period, that puts them off. That's one of the things that puts off the patient because they don't want to take it life long. The compliance is a problem despite you telling them once you are gone you have got to be on this.' (Dr 14.)

'Diabetic patients or hypertensive patients may already be on several medications already, you know, hypoglycaemics, antihypertensives, perhaps two to three, aspirin; and then if you are inflicting another tablet, then it's difficult and you are given the realms of polypharmacy. It can be very difficult and I am sure the compliance must drop considerably for such patients.' (Dr 9.)

Concerns about medicalisation. A few GPs raised this issue that treating high cholesterol in primary prevention led to medicalisation of healthy people, who then needed to attend for blood tests and monitoring:

'Then of course there are patient factors ... medicalisation of society, the philosophical thing really in that you are perfectly well until you go to the doctor and come out with high cholesterol. It's a bit like treating asymptomatic hypertension.' (Dr 9.)

Concerns about the effects on health behaviour. Several doctors were worried that prescribing statins would encourage individuals to take less responsibility for their own health:

'I always worry, you know, the patients who are taking these drugs, they think they can do as they like, and they forget about their lipid-lowering diet.' (Dr 11.)

'It also can encourage people to believe that they are immortal almost and that the drug is going to protect them and that is not actually what it does, and it may actually encourage people to take less responsibility for their own illness which again is not good.' (Dr 15.)

Many doctors felt that for coronary prevention there was undue emphasis placed on statin prescribing. Half the doctors in this study felt that lifestyle factors, such as smoking, dietary changes and exercise, should be addressed before prescribing statins:

'I have always felt that other methods of reducing the risk of coronary heart disease such as cessation of smoking and loss of weight and exercise, I would tend to want to get those in place before I would start using a drug, I have always practised that way.' (Dr 3.)

LD: 'Is there anything else that you want to add?'

Dr 22: 'Only that I think one of the most important things is this smoking cessation. I guess again because of the people I see, being young, that is what I hammer. That's where I go and I find I am reasonably successful at persuading people to give up smoking. By no means 10% of the people I try to persuade to give up smoking, give up, but even if a few people giving up smoking at a young age makes a huge difference, and probably a bigger difference even than a lot of these other things that you can do at a later stage, and I think so much more money should be spent on things like the [smoking] clinics that are now being run.'

Side effects. The majority of GPs felt that statins were well tolerated, but most mentioned some side effects, particular gastrointestinal (GI) problems and myalgia (Table 2). Most GPs did not see side effects as a significant barrier to prescribing:

'I have a few people come back with various side effects. GI side effects especially with the statins. What I have tried on a couple of people is an alternative statin. I have not had a person who has not been able to tolerate a statin of some description.' (Dr 4.)

Statin prescribing guidelines

GPs were asked to consider the approach taken to prioritisation in the Standing Medical Advisory Committee guide on the use of statins,[11] and also any other guidance they had used for prescribing.

Prioritisation of treatment. Many GPs agreed with guidance that statins should be prioritised to those with existing disease, but had concerns about ignoring those with lower risk:

Table 2. Statin side effects reported by GPs.

Side effect	Number of GPs reporting
Myalgia/cramps/myositis	13
Abnormal liver function	8
Gastrointestinal problems	15
Increased suicide risk	2
Sleep disturbance	1
Impotence	1

JK: *'... these people are lower priority than people who have existing disease, do you think that is an appropriate approach?'*

Dr 15: *'I think in terms of cost–benefit, it is an appropriate approach because people with an existing disease you are going to save lives and quality of life for less money spent in preventing. Primary prevention is going to be less cost-effective because the number of people you need to prescribe to prevent one event, so in that respect yes it is right, but whether it is right from an ethical point of view is difficult to answer.'*

Several GPs felt it was not possible to prioritise, and that statin prescribing in primary coronary prevention should be done at the same time as secondary prevention:

'... if we try and prioritise now and look at people with MI [myocardial infarction] *or angina now and forget about people with 30% risk, then that is exactly what is going to happen ... I think they should all be done concurrently.'* (Dr 5.)

'... where people are on high risk and with a 3% or more a year risk, that I think we should be treating those because I think that is fairly similar to benefiting people with heart disease already.' (Dr 9.)

Variation in statin treatment targets. GPs varied in their description of an acceptable cholesterol level for different patient groups. Over half of the GPs mentioned a specific target of lowering total cholesterol to below 5.0 mmol/l, with a range of other targets from 4.2–6.0 mmol/l. Some GPs had different targets for primary and secondary prevention:

'... it depends where you start. I think any improvement is going to be beneficial. We are told that you should be aiming for below 5 mmol/l of cholesterol' (Dr 23.)

'Primary prevention — something perhaps below 5.5 [mmol/l] *— and secondary prevention you are looking into something like 4.5 or less. That's roughly the figure that is in my head. Certainly with secondary prevention I try to keep people in the 4s, say 4.5.'* (Dr 3.)

Only a few doctors mentioned an alternative target of cholesterol lowering by 30%, and they had interpreted the guidance related to this differently:

'... we want to get cholesterol down and I think we want to get it below 5 [mmol/l] *if it's really high. If we achieve a 30% reduction then that's well worthwhile even if we don't get it below 5.'* (Dr 9.)

'The National Service Framework ... [says] *5 mmol/l, or reducing the cholesterol by 30%, whichever is the greater ... anybody who had had an MI, angina or any sort of occlusive arterial disease should have a statin in any case, no matter what their level was, so that their cholesterol level was reduced by 30%.'* (Dr 6.)

Barriers to the use of primary prevention risk assessment tools to guide statin prescribing. GPs were asked about their use of risk assessment tools to initiate statins in the primary prevention of coronary heart disease. Although all were aware of risk assessment tools for coronary heart disease prevention, only half of GPs used them in day-to-day practice. Many doctors had been to clinical meetings and discussed the tools, and were preparing to use them more:

'I have been using one on eMIMS [electronic Monthly Index of Medical Specialties] *in the last 6 months. Since eMIMS have produced their CD-ROM for the computer, I have looked at that a couple of times and I have actually used that in the presence of patients on a couple of occasions. But I have not yet become consistent in using a table like that.'* (Dr 3.)

Some had never used risk assessment tools with patients and two doctors had stopped using them: one because the tools were difficult to interpret with Asian patients; and the other because the doctor felt he could intuitively assess risk, having used the table previously. A small number of doctors appeared to initiate statins based on the level of cholesterol, and an intuitive risk assessment based on their other risk factors:

'I think a diabetic with a cholesterol of 7 or 8 mmol/l I would treat. I would try and get them down. I think a diabetic with a cholesterol of 6 and no other risk factors, I would probably leave alone but monitor. That is not strictly speaking following the Sheffield tables but a bit more empirical.' (Dr 15.)

The majority of doctors who used the tools, agreed with the principles and used them as a guide to start statin treatment:

'... anyone with a 10–year risk of 30% or more gets a statin.' (Dr 5.)

Some GPs disagreed with a cut off target for treatment, and some felt that the guidelines were inflexible:

'I think it is illogical that if someone is young and they have got a raised cholesterol, just because they are young, I do not understand why we should not be treating them early just because their risk is low because of their age. Over a time they will get to a stage where the risk is high and if we can prevent that becoming a problem then why shouldn't we prescribe it at an earlier

stage? I think in fact they are restrictive, a lot of these guidelines.' (Dr 2.)

Others commented that risk assessment tools were difficult to interpret easily:

'They are quite easy to read. It is a bit difficult to know what to do if somebody's risk is just under 30% or the borderline area. I think it is still controversial.' (Dr 18.)

'It looks off-putting and confusing, and not least the different dividing lines, with different levels of risk, 30% risk and 20% and so on.' (Dr 9.)

Many mentioned that the tools did not allow assessment of family history or ethnicity:

'I think family history is not mentioned on them, as I remember, which I think is probably a weakness.' (Dr 9.)

Barriers to coronary prevention implementation in primary care

As well as being asked specifically about statins, GPs were also asked to consider other aspects of coronary prevention in primary care, particularly what the problems and possible solutions were to improving coronary prevention. GPs listed a large number of barriers to improving coronary prevention. Several GPs reported problems with space, others raised organisational or managerial issues, especially storage and retrieval of electronic records. Most GPs were concerned about doctor and nurse time and workload. Concerns about patient attendance, compliance, patient lifestyle, and language barriers were repeatedly raised by the doctors:

'The main problem is compliance with (a) diet, (b) smoking habits, (c) exercise, and (d) treatment as well. I find that more so in the Asian population than the Caucasian population ... we have a language problem as well. Because I do not speak the languages that they all speak. The ethnic mix over there. I do not speak Punjabi; I do not speak Bangladeshi.' (Dr 4.)

Various suggestions were made for improving the implementation of coronary prevention, especially nurse-led coronary prevention clinics, which the majority of doctors thought would help improve coronary prevention in a systematic way. A few were more sceptical about patient attendance, or about the need to set up separate clinics:

'I am sure that once we have identified suitable patients, if we could persuade them like our diabetics or asthmatics to go to a nurse-led clinic, then there would be a lot more consistency in information gathering. Whether there would be more compliance from the patient is another matter, but there is evidence that nurses are very good at measuring things and very good at recording things. Nurses follow protocols and guidelines much better than doctors do, I think.' (Dr 3)

Most doctors wanted better information technology support, including improved data entry, notes summarising, recall systems, computerised templates, and reporting systems.

Discussion

Concerns have been expressed about the low levels of statin prescribing to at-risk groups in primary care. This study provides some insights into the complexities and difficulties faced by GPs in prescribing statins and implementing coronary prevention guidelines.

Summary of main findings

Several factors acted as barriers to initiating statins specifically, and coronary prevention generally. The most important factors affecting the initiation of statins appeared to be concern about cost, the large workload implications, patient compliance, concerns about medicalisation of healthy individuals with risk factors, and health behaviour. GPs varied in how they approached prioritisation of patients for statin treatment, and the cholesterol-lowering targets they aimed for. Delivering better coronary prevention was limited primarily by lack of nurse and doctor time, and by other practice organisational issues related to buildings, staffing, and use of computers. Many GPs also were concerned about patient lifestyle, language barriers, and attendance.

Strengths and limitations

There are several limitations to this study: it did not explore the issue of patient involvement in decision making for statin prescribing, or patient autonomy; instead it explored the issue entirely from the doctors' perspective. This study also needs to be seen as a snapshot view of doctors' prescribing behaviour, in an area which is rapidly changing, as doctors' prescribing practice changes over time, and is influenced by an accumulated weight of reading and guidance, which can lead to a sudden change in prescribing.[13]

Relationship to other work

It is known that cost is a major factor influencing prescribing decisions,[14] and the cost of statins is the subject of much discussion.[15,16] In this study many GPs felt uncomfortable about being in a position of rationing statins based on levels of risk, and yet trying to do the best for the individual patient. Several GPs adopted a utilitarian approach to prescribing,[17] arguing that treating those with the highest risk gave the greatest likelihood of benefit with a limited resource, matching the National Service Framework[1] approach of staged prioritisation. However, many GPs found that it was difficult to prioritise patients in practice, and adopted an egalitarian standpoint, wishing to give maximum benefit to each individual patient.

Many doctors in this study were concerned about medicalising healthy patients with high cholesterol. Recent approaches to coronary prevention have blurred the distinction between health and illness, and have expanded the inclusiveness of the 'patient', something which concerned Illich,[18] and others worried about 'medical imperialism', a concept close to the views expressed by these GPs.

A holistic approach to coronary prevention, addressing lifestyle changes, as well as prescribing, was thought important by doctors in this study. However, difficulties in influencing

change in smoking, diet, and inactivity were also a source of frustration, which may have influenced prescribing, as has previously been reported.[19] Whether statin prescribing, and resultant cholesterol lowering, acts as a disincentive to lifestyle changes, as suggested by some doctors, is worth further exploration.

Guidelines that have suggested two alternative treatment targets for lowering cholesterol — a target value or a percentage reduction[1,11] — appear to have been difficult to interpret by the doctors in this study. Most aimed for a specific cholesterol target (which varied), rather than a percentage reduction. This may have led to some patients not being treated as recommended by these guidelines. We know that guidelines appear to be used more often if they are disseminated by an active educational intervention, if there is recognition of an authoritative and unbiased source of evidence, if they are flexible enough to incorporate local viewpoints, or if there is local involvement in their development, and if there is resonance with the GP's usual practice.[20] These findings suggest that strategies for National Service Framework implementation will need to take account of local factors that affect differing interpretation.

There was self-reported variation in how doctors make decisions to prescribe statins, according to the type of patients that they see, or to what extent they prefer non-drug treatment. Such variation may reflect complex clinical situations, where there is real factual uncertainty in individual patients, and difficult decisions to be made about rationing.[21]

Only half of the doctors in this study were regularly using primary prevention risk assessment tools. Problems with tools included the lack of inclusiveness of ethnicity and family history, difficulties interpreting charts, and lack of time. Others have identified that the use of tools may not improve the estimate of risk,[22] and the lack of allowance for ethnicity and socioeconomic group may actually exacerbate inequalities in health.[23] It is unlikely that all the issues and difficulties in approaching primary prevention highlighted by this study would be addressed simply by making risk assessment tools easier to use.

Implications of findings

Many doctors in this study suggested care could be improved in patients with coronary heart disease by using a systematic approach in a clinic, with a nurse following a set protocol, provided this was sufficiently resourced. There is evidence to support this approach in terms of improving health outcomes,[24] but clinics do not address all the issues raised here.

This paper has important implications for National Service Framework implementation. Implementation might be more consistent if guidelines took into account not only evidence, but also the practicalities of implementation. This might, for example, lead to clearer guidance on treatment targets for cholesterol lowering, specifying a percentage reduction in cholesterol only. An increasing plethora of guidelines sent to GPs will not in themselves improve clinical care. More consistent delivery against National Service Framework targets will need interventions that take account of the complex picture presented here involving doctors' perceptions, doctor–patient relationships, education, service management,

and infrastructure resources. This paper suggests specific issues in these areas that those involved with National Service Framework delivery may usefully take into account.

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