Offering statins to a population attending health checks with a 10-year cardiovascular disease risk between 10-20%

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Abstract

Background

In 2014 the UK National Institute for Health and Care Excellence recommended reducing the threshold for offering statin therapy to patients from a 10 year modelled risk of cardiovascular disease (CVD) of 20% to 10%.

Aim

To describe the response of patients in UK primary care with a CVD risk between 10-20% to an invitation to attend a consultation to discuss statins.

Design and Setting

Review of electronic medical records at one GP practice in the East of England.

Method

We invited all patients who had attended an NHS Health Check at the practice, had a QRisk® score between 10-20% and were not prescribed statins to attend designated clinics in the practice to discuss starting statins. We reviewed the medical records to identify those who had attended the clinics and those who had chosen to start a statin.

Results

Of 410 patients invited, 100 (24.4%) patients attended the designated clinics and 45 (11%) chose to start a statin. Those who chose to start a statin were older and with a higher QRisk® than those did not. Among those who attended, individuals who started a statin had a higher QRisk® than those did not and were more likely to be current or ex-smokers.

Conclusions

The proportion choosing to start a statin was substantially lower than previously estimated. Large population based studies with long-term follow-up are needed to assess the impact on health and workload of this change in guidance.

What is already known about this topic?

In 2014 NICE recommended reducing the threshold for offering statin therapy to patients for primary prevention of cardiovascular disease from a 10 year modelled risk of CVD of 20% to 10%. At the time this generated widespread controversy but little is known about the impact of this guidance in real life.

What does this article add?

Our study is the first to report the effect of this change in guidance in practice. One in four patients with a modelled risk of 10-20% took up the offer of a consultation to discuss statins, and one in ten started a statin. This is considerably lower than estimated by NICE.

INTRODUCTION

In 2014 the UK National Institute for Health and Care Excellence (NICE) updated its guidance on primary prevention of cardiovascular disease (CVD) and recommended reducing the threshold for offering statin therapy to patients from a 10 year modelled risk of CVD of 20% to 10% (1,2). This change in risk threshold generated widespread controversy (3). It is estimated that the new guidance will make 4.5 million more people eligible for statins and according to NICE will save up to 4,000 lives and prevent 8,000 strokes and 14,000 non-fatal heart attacks over 3 years (2). However, there are concerns over the potential increased risks of harm and limited evidence of benefit to those at lower (10%) risk.

These population benefits and concerns will only be seen if a sufficiently high proportion of people at lower cardiovascular risk wish to first consider taking a statin and then actually take it (4). However, there is increasing recognition that people are reluctant to start treatment. Expert opinion from NICE (5) suggested that up to 20% of the population between 10-20% risk would choose not to take statins following discussion with their healthcare professional, but there are limited data from this specific group. Whilst the accompanying costing report also did not anticipate these changes having a significant resource impact (5), there were concerns over the increased workload the change in guidelines would generate for GPs, particularly at a time when resources within the NHS are already under pressure.

We aimed to describe the response to an invitation to patients with a CVD risk between 10-20% to attend a consultation to discuss statins in order to estimate the impact of the updated guidance in UK primary care.

METHOD

Setting

This study was performed in a National Health Service Primary Care Practice in Cambridgeshire, UK serving a predominantly white population of 11,588 patients with a deprivation score of 6.5 (IMD) (6).

Patients

We searched the practice electronic records to identify all patients who had attended an NHS Health Check at the practice between 1st April 2011 and 1st December 2014 and who had a QRisk® score ≥ 10% and <20% recorded at the time of that health check. Patients had initially been invited based on registration date with the practice and at the time of that health

check had been given lifestyle advice by a practice nurse and then informed that only those with a QRisk® over 20% would be contacted and informed of their risk. The patients in this study had, therefore, received lifestyle advice but no direct feedback about their risk or discussion about statins. We reviewed the records of those with a previous or current prescription for a statin to identify current users (those who had received a prescription for a statin between 1st October 2014 and 1st December 2014), prior users (those with one or more prescriptions for a statin in the records but none between 1st October 2014 and 1st December 2014), and those with a documented intolerance to statins.

Intervention

Prior users of statins were contacted by the surgery and invited to book an appointment to discuss the new guidance and alternative statin preparations. Current users and those with a documented intolerance to statins were not contacted. All other patients were sent a letter informing them of the recent change in NICE guidance and that they were in the group which had previously not been offered statin medication but which may benefit. A patient information leaflet was enclosed providing more information on the new recommendations, how the risk of heart disease or stroke is calculated, what statins are and how they work, the benefits and harms of taking statins, and generic lifestyle advice (Appendix 1). The information on the benefits of statins was taken from the National Prescribing Centre Statins Patient Decision aid which is freely available at http://www.webarchive.org.uk/wayback/archive/20140627120928/http://www.npc.nhs.uk/therapeutics/cardio/cd_lipids/resources/pda_Lipids.pdf and included the same iconographs as in that document. The information on the harms of statins was taken from the published literature (7).

In the information leaflet patients were encouraged to take steps to improve their lifestyle where possible and were invited to make an appointment in designated clinics if they wanted to discuss starting a statin or any of the other information in the leaflet. Designated clinics were then held in the surgery by one of the practice GPs (JUS) for these patients. Letters were sent out in batches of 100 over an 8 week period to ensure appointments in the clinics were available. During clinic appointments patients were told their own QRisk® score based on their initial health check. In addition, the effect of changes in lifestyle and increased age both since the previous health check and into the future was illustrated using the online QRisk® calculator available at www.qrisk.org. Discussions around the benefits and risks of statins were based on the information already provided in the patient information leaflet.

Those patients initially reluctant to take statins were offered the opportunity for further review in the future and were advised of the date on which they would be invited for a follow-up NHS Health Check (5 years after their initial Health Check).

Data collection

At the time of the initial search of the practice electronic records, data were extracted for age on 1st December 2014, gender, ethnicity, most recent smoking status, BMI, systolic blood pressure, total cholesterol:HDL ratio, recorded family history of ischaemic heart disease in a relative < 60 years, history of diabetes, chronic kidney disease, atrial fibrillation, or rheumatoid arthritis, prescriptions for antihypertensive drugs (excluding those used for erectile dysfunction), and number of repeat tablet medications (excluding paracetamol, codeine, ibuprofen and drugs prescribed for erectile dysfunction).

Contemporaneous entries were recorded in patient medical records at the time of review in each of the separate clinics held in the surgery as part of routine clinical practice. Four weeks after the last letters were sent out, we searched the practice electronic records to identify all those who had attended the designated clinics and those who had been started on a statin. We manually searched the medical records of those patients reviewed in the clinics to extract the recorded reason for declining, if applicable, and the records of those patients who did not attend the clinics but had been started on a statin.

Analysis

All analyses were performed using Stata version 12 and data values are expressed as mean (SD). Fisher's exact test and Student's unpaired *t*-test were used to compare groups for categorical and continuous variables respectively. Logistic regression was used to compare characteristics of those attending the clinics and those subsequently starting a statin. To account for collinearity between the QRisk® score and the individual risk factors separate logistic regression was performed with all the risk factors included in the QRisk® score. Ethnicity was excluded as it was only available for 172 of the 413 patients and as the practice population is 94.4% white British (6) it was unlikely that any effect of ethnicity would be seen. Statistical significance was set at p<0.05.

RESULTS

1,646 patients had attended an NHS Health Check in the practice. The mean (SD) age was 58.1 (9.1) years and 54.6% were male. 1016 (61.7%) had a QRisk® <10%, 452 (27.5%)

a score ≥10% and <20%, and 178 (10.8%) a score ≥20%. Of the 452 with a QRisk® ≥10% and <20%, statins had been prescribed to 20 within the 2 months prior to December 2014, ten had a history of taking a statin in the past and four had recorded intolerance of statins. Five patients had moved out of the area. Letters and information leaflets were sent to the remaining 413 patients.

Those 413 patients had a mean (SD) age of 64.8 (6.1) years and 56.2% were male. The QRisk® scores were distributed throughout the range from 10-20% with the mean (SD) 13.9 (2.6) (Figure 1).

On medical record review two patients had died and one had been started on a statin following a stroke. Of the remaining 410, 100 (24.4%) patients had attended the designated clinics. At those appointments, 7 patients had a QRisk® below 10% following changes in lifestyle and 42 (10.2% of all those invited and 42% of those who booked an appointment to discuss statins) chose to start a statin. Five patients chose to have a blood test for an up-to-date lipid profile. None of those 5 subsequently chose to start a statin. Three other patients had started taking a statin having made appointments with other GPs in the practice specifically to discuss the letter that they had received. Of the original 410 patients a total of 45 (11.0%) chose to start a statin.

The characteristics and distribution of QRisk® score of all 410 patients, those attending the surgery, and those choosing to start a statin are shown in Table 1 and Figure 1. There were no statistically significant differences between those who attended and those who did not. Those who chose to start a statin were older and with a higher QRisk® than those who did not and, of those who attended, those who started a statin had a higher QRisk® than those who did not and were more likely to be current or ex-smokers than non-smokers.

None of the risk factors included in the QRisk® score (age, bmi, gender, smoking status, anti-hypertensive medication, systolic BP, chol:hdl ratio, family history of IHD in a first degree relative <60 years, or deprivation) were associated with attendance at the surgery and neither were the QRisk® score, the number of current repeat medications or the time since the initial health check. Among the initial 410 patients, age was the only risk factor associated with starting a statin, with older patients more likely to choose to start a statin (OR 1.12 (95% CI: 1.01 to 1.24)), and those with a higher QRisk® also more likely to start a statin (OR 1.14 (1.01 to 1.28)). Among the patients who attended the surgery, increasing age and QRisk® were also associated with starting a statin (OR 1.19 (1.03 to 1.36) and 1.34 (1.13 to 1.60) respectively). In this group, both ex-smokers and current smokers were also more

likely to start a statin than non-smokers (OR 11.9 (1.05 to 127.7) and 2.93 (1.06 to 8.12) respectively).

The most common documented reasons for not wishing to start a statin were either not wanting to take medication (n=23) or preferring to initially change lifestyle to reduce risk (n=12). Other reasons included concern about side effects in general (n=5) and preferring to wait a few years and then reassess (n=5) (Table 2).

DISCUSSION

Summary

To our knowledge this is the first study to report the uptake of statins amongst people with a 10-year CVD risk of between 10 and 20%. It shows that in a group that had previously attended a Health Check, one in four took up the opportunity to discuss starting statins and one in ten chose to start a statin. Those who attended the surgery represented a cross-section of the entire group invited whilst those who chose to start a statin tended to be older with higher CVD risk.

Strengths and limitations

The main strength of this study is that the study population is a well-defined cohort of patients who had all attended an NHS Health Check in the same practice. As the same template had been used for data entry, the coding of risk factors was consistent and there was very little missing data. Holding designated clinics in the practice for capacity reasons also meant that patients all saw the same GP and received the same lifestyle advice and information on the benefits and risks of statin therapy. Whilst every attempt was made to provide this information in a uniform and non-influential manner, it is, however, possible that the consultation style affected their choice and in routine practice GPs and nurses may differ in their approach to these discussions. The response by patients to updated guidance as in this study may also differ from the response to contemporaneous discussion of their risk using only the updated NICE guidance. The initial letter also did not provide an individual risk estimate. It is, therefore, possible that some of the patients who attended the clinics did so just to find out their QRisk® score and that, if that had been included in the letter, the number attending the practice would have been smaller. It is also possible that some patients chose to discuss statins with other GPs in the practice. We think this number is low, however, as only three patients started a statin outside the specific clinics and all GPs were advised to ask patients to book into the separate clinics if they wished to discuss the letter that they had

received. Another limitation is that the practice is in an area of low deprivation with a predominantly white British population and low prevalence of cardiovascular disease risk factors. This makes the findings potentially less generalizable to other UK populations and caution is needed when extrapolating to the wider NHS.

Comparison with existing literature

The distribution of CVD risk amongst those who had attended a health check in the practice was similar to that reported in other studies: 10.8% had a CVD risk ≥20% compared to two other studies which reported 10.5% (8,9); and 38.3% had a risk ≥10% compared to 33.3% reported across 3 PCTs in London (8). No direct comparison is available for the response rate to the letters of invitation (24%) but it was lower than the uptake of initial health checks in Cambridgeshire (37%) (10).

The low rate of initiation of statins (11%) is consistent with other studies, albeit in different groups of patients. Reports from the NHS Health Check programme showed that even in people at high cardiovascular risk (≥ 20%) prescription of statins increased from 25% to only 45% (11); up to 40% of first-time statin users prefer to use diet control before initiating statin therapy (12); 5% of people on the streets of London would choose not to take a statin even if it gave them another five years of life (13); and people responding to a US based internet survey would pay an average of $1445 (£948; €1265) to avoid taking one pill a day for cardiovascular disease prevention.

Implications for research and/or practice

In 2013-2014, 1,382,864 people had an NHS Health Check in England (10). Whilst caution is needed extrapolating the results of this observational study in one GP practice to the wider NHS, if the findings were applied to that population, offering statin treatment to all those with a risk between 10-20% would potentially result in an additional 380,287 people being offered statins and 95,535 additional nurse or doctor led consultations. This is less than the 25% increase in GP appointments included in the sensitivity analysis in the NICE costings report (5). However, at a time when general practice is under significant pressure, even this small increase may have resource implications. GP surgeries offering Health Checks need to be aware of this potential increase in workload.

The proportion (42%) choosing to start a statin after discussion is also lower than the 80% estimated in the costings report (5) and highlights both the reluctance of the majority of people at low risk to take statins and the difficulty of implementing population-based

strategies with small benefits to individuals. It also means that the long term benefits of these additional consultations will be smaller than expected. Nevertheless, if 42% of patients chose to start a statin, in England 41,831 patients would have been prescribed statins in 2013-2014 and using data from a Cochrane systematic review of statin therapy (14) this would have led to 36,811 additional patients taking statins long-term and the prevention of 267 deaths from all causes, 751 CVD events and 237 strokes and an estimated 371 new cases of diabetes over 5 years.

The effect of the reduction in risk threshold may also have additional effects beyond the prescription of statins. The most common reasons for not starting a statin in this study were either not wanting to take medication or preferring to initially change their lifestyle. Having been faced with the option of a statin it is, therefore, possible that more people would be encouraged to make changes to their lifestyle, if only to avoid having to take statins in the future. The true impact of this change in guidance will, therefore, only be clarified by large population based studies with long-term follow-up.

ACKNOWLEDGEMENTS

ETHICAL APPROVAL

As this study was a quality improvement project carried out within routine NHS clinical care, no ethical approval was required.

AUTHOR CONTRIBUTIONS

All authors were involved in the design of the study and interpretation of data. JUS wrote the first draft and all other authors critically revised the manuscript. All authors have seen and approved the final version.

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Table 1. Characteristics of patients

Characteristic	All (*n*=410)	Attended (*n*=103)	Started statin (*n*=45)
Age (years)	64.7 (6.12)	65.5 (6.11)	66.6 (5.96)*
Males	231 (56%)	55 (53%)	23 (51%)
Smoking status			
Non-smoker	229 (56%)	62 (61%)	22 (50%)**
Ex-smoker	142 (35%)	35 (34%)	18 (41%)
Current smoker	35 (9%)	5 (5%)	4 (9%)
BMI (kg/m^2)	27.3 (4.82)	26.7 (4.11)	26.6 (4.45)
Deprivation			
Highest tertile	370 (91%)	94 (92%)	38 (86%)
Middle tertile	37 (9%)	8 (8%)	6 (14%)
Lowest tertile	1 (0.2%)	0 (0%)	0 (0%)
FH IHD < 60 years	105 (26%)	22 (21%)	8 (18%)
QRisk 10-year CVD risk	13.9 (2.64)	13.7 (2.6)	14.7 (2.3)*/**
Systolic blood pressure	132.7 (13.8)	131.2 (13.8)	133.1 (14.8)
Cholesterol:HDL	4.06 (1.07)	3.97 (1.09)	3.97 (1.12)
Antihypertensive medication	21 (5%)	4 (4%)	2 (4%)
Diabetes	1 (0.2%)	0 (0%)	0 (0%)
Chronic kidney disease	1 (0.2%)	0 (0%)	0 (0%)
Atrial fibrillation	6 (1.5%)	1 (1%)	0 (0%)
Rheumatoid arthritis	3 (0.7%)	1 (1%)	1 (2%)
Regular medication			
None	232 (57%)	55 (53%)	23 (51%)
1-3 medications	153 (37%)	43 (42%)	20 (44%)
>3 medications	25 (6%)	5 (5%)	2 (4%)
Time since health check (months)	28.0 (10.3)	28.1 (9.82)	28.0 (10.6)

Data presented as mean (SD) unless specified

* p<0.05 compared to all others who had chosen not to start a statin

**p>0.05 compared to those who had attended but chosen not to start a statin

Table 2. Reasons for not choosing to start a statin

Reason	n
Not keen on medication	23
Prefer to initially change lifestyle	12
Concern about side effects in general	5
Prefer to wait a few years then reassess	5
Undecided at present	3
Concern about developing diabetes	2
Concern about the impact on travel insurance	1

Figure 1. Distribution of Qrisk® scores amongst all patients sent a letter, those who attended clinics and those starting a statin
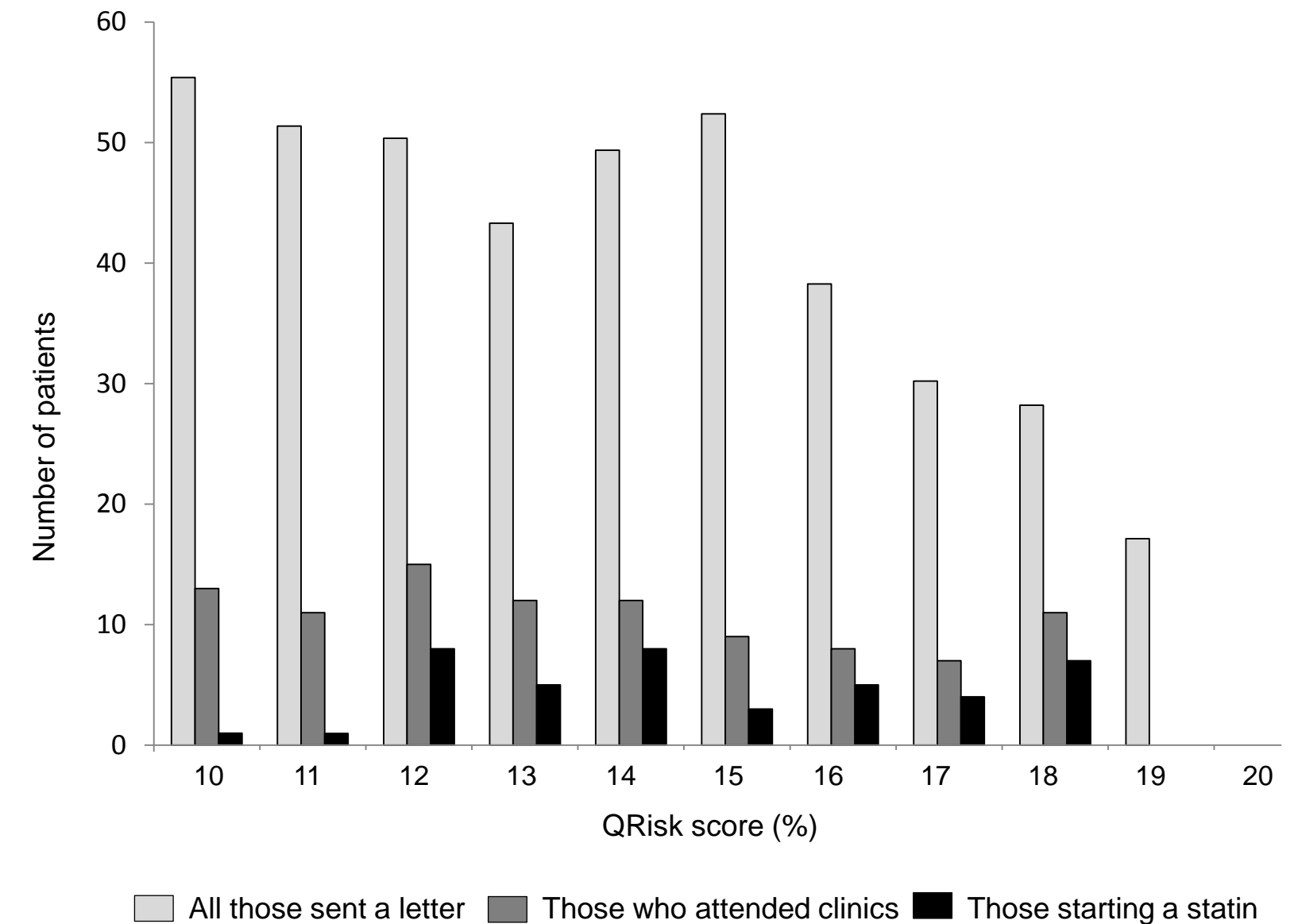
PATIENT INFORMATION LEAFLET

Your personal Statin Decision

What are the new recommendations?

For many years medications called statins have been prescribed for patients who have previously had a stroke or heart disease (angina, previous heart attack etc) and for people who have a risk of having a heart attack or stroke of 20% or greater over the next 10 years. Recently, however, the National Institute for Health and Care Excellence (NICE) has recommended that GPs offer statin medications to individuals whose estimated risk of having a heart attack or stroke in the next ten years is between 10% and 20%.

How is risk of heart disease or stroke calculated?

We currently calculate people's risk by using a tool called the 'QRisk'. This calculates an individual's risk using a combination of age, blood pressure, gender, ethnicity, smoking status, diabetes status, family history of heart disease, cholesterol, body mass index (which reflects a combination of your height and weight), and postcode. The risk is presented as an estimated percentage risk of developing heart disease or stroke in the next ten years. A risk of 10% means that if there were 100 people with the same age, blood pressure, gender etc as you, then our best estimate is that 10 of them will have a heart attack or a stroke in the next 10 years. Although QRisk is the most sophisticated available tool, it is only able to give an estimated risk. A high risk does not mean you are destined to have a heart attack or a stroke, and a low risk does not mean you are without risk. Lifestyle factors, such as diet and physical activity, which we know are important in preventing heart attacks and stroke, are also not directly included in QRisk, although they do have a beneficial effect on weight, and blood pressure which are included.
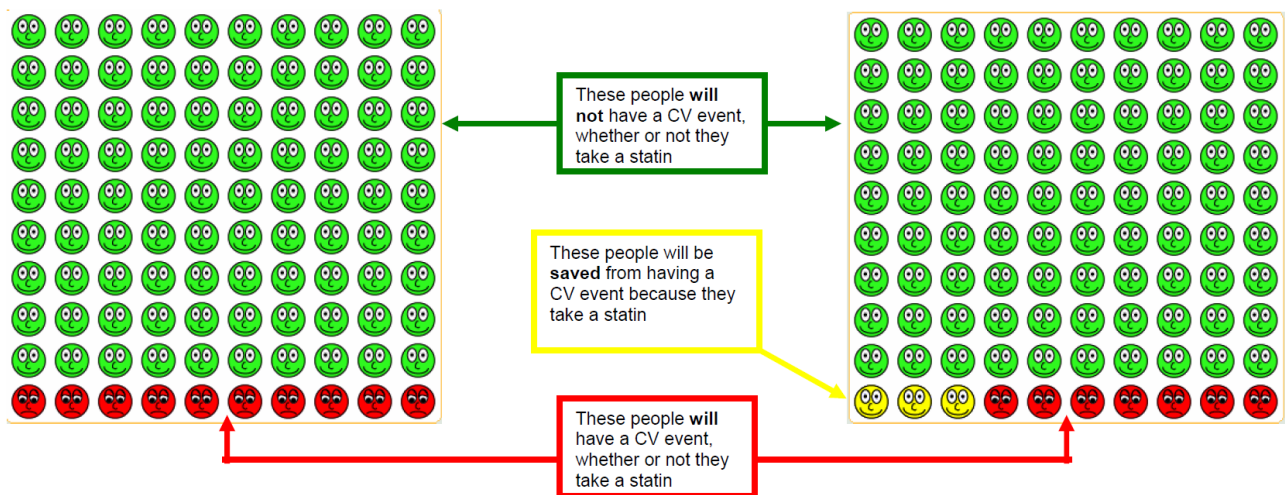
What are statins?

Statins are a group of drugs that help prevent heart attacks and strokes. Examples include Simvastatin, Atorvastatin and Pravastatin. They mainly work by lowering the cholesterol, a type of fat in the blood that leads to blockage of blood vessels, They may also reduce risk of heart attack and stroke in other ways, for example by reducing inflammation.

What are the benefits of taking statins?

There is good evidence to show that statins can reduce risk of stroke or heart disease by about a quarter (25%). The benefit you will get depends on your individual risk and someone at higher risk is likely to benefit more than someone at lower risk.
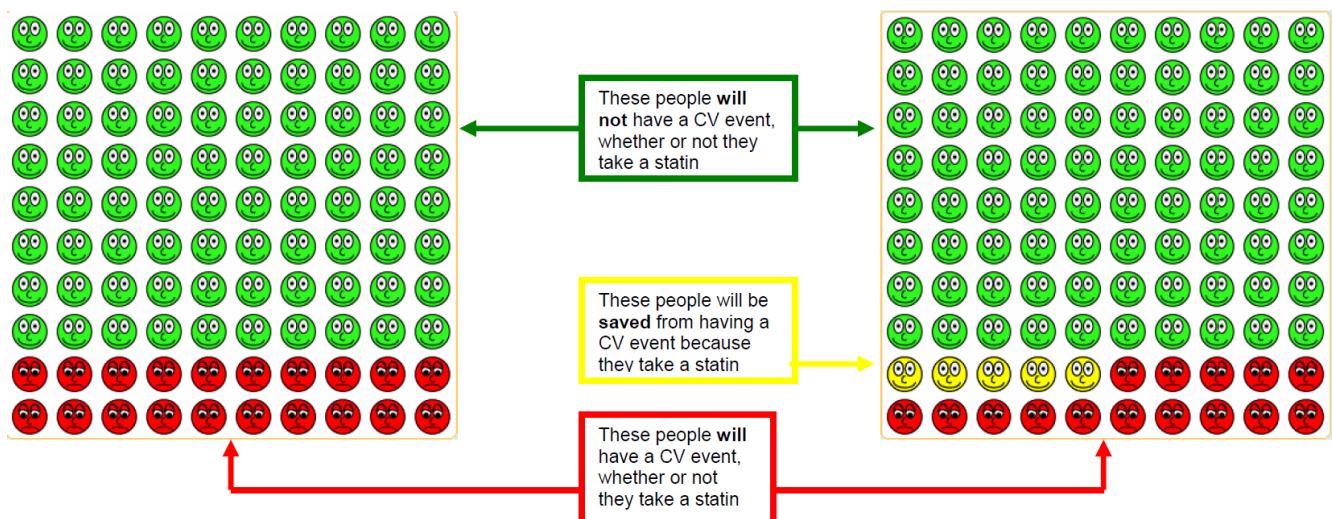
For example, for 100 people with a 10% risk, about 10 of them will have a heart attack or stroke over the next 10 years. If all 100 take a statin for 10 years:

- About 3 people will be 'saved' from having a heart attack or stroke (the yellow faces)
- About 90 people will not have a heart attack or stroke – but would not have done even if they had not taken a statin (the green faces)
- About 7 people will still have a heart attack or stroke even though they took a statin (the red faces)

These people **will not** have a CV event, whether or not they take a statin

These people will be **saved** from having a CV event because they take a statin

These people **will** have a CV event, whether or not they take a statin

By comparison, for 100 people with a 20% risk, about 20 of them will have a heart attack or stroke over the next 10 years. If all 100 take a statin for 10 years:

- About 5 people will be 'saved' from having a heart attack or stroke (the yellow faces)
- About 80 people will not have a heart attack or stroke – but would not have done even if they had not taken a statin (the green faces)
- About 15 people will still have a heart attack or stroke even though they took a statin (the red faces)

These people **will not** have a CV event, whether or not they take a statin

These people will be **saved** from having a CV event because they take a statin

These people **will** have a CV event, whether or not they take a statin

What are the harms of taking statins?

Statins, like all medications, can cause side effects. Most people, however, tolerate them well and don't experience any problems. The most common side effects include:

- Muscle aches and pains (about 10 out of 100 people but it is difficult to know exactly as muscle aches and pains are very common in people not taking statins)
- Inflammation of the liver that almost always reverses on stopping the medication (approximately 1 in 1000 people taking a statin for 4 years)
- A small increased risk of developing diabetes (about 1 in 200 people taking a statin for 4 years)

Very rarely these side effects can be serious. Some patients also report effects on memory and energy levels, although as with muscle aches and pains it is difficult to estimate how common this is as these are also very common in people not taking statins. There is no evidence that statins cause cancer or dementia or increase your risk of dying from other diseases.

What should I do now?

Whether you chose to take a statin or not, we would encourage you to take steps to improve your lifestyle where possible. In particular, the recommendations are:

- To stop smoking
- Eat a healthy diet
    o Rich in wholegrain starches and low in sugar and saturated and unsaturated fat with saturated and mono-unsaturated fats replaced with olive oil or rapeseed oil
    o With at least 5 portions of fruit and vegetables per day
    o With at least 2 portions of fish per week, including a portion of oily fish
    o With at least 4 to 5 portions of unsalted nuts, seeds or beans, peas or lentils per week
- Keep physically active, aiming to do at least 150 minutes of moderate activity that makes you out of breath or 75 minutes of vigorous activity per week and muscle-strengthening activities on 2 or more days a week
- Work towards achieving and maintaining a healthy weight
- Limit alcohol intake to 3-4 units per day for men and 2-3 units a day for women (a unit is approximately half a pint of ordinary lager, bitter or cider, half a glass of wine or one measure of spirits)

Further details are available on the NHS Choices website under the 'Live Well' tab (www.nhs.uk/livewell) and in the Healthy Living leaflet available in the practice. As well as reducing your risk of heart attack and stroke, improving your lifestyle will also reduce your risk of developing other long-term conditions, including cancer.

If you would like to discuss starting a statin or any of the other information in this leaflet then Dr Usher-Smith is holding separate clinics in the surgery so please contact the practice and ask to make an appointment in one of '*Dr Usher-Smith's health check clinics*'.