NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

# Patient decision aid: user guide for healthcare professionals

## Implementing the NICE guideline on lipid modification (CG181)

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This is a user guide for healthcare professionals that relates to a decision aid intended to help people make informed decisions about taking a statin for primary prevention of cardiovascular disease. The decision aid and user guide accompany Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease (NICE clinical guideline 181). It is not suitable for use in the context of familial hypercholesterolaemia or secondary prevention of cardiovascular disease.

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**The decision aid and user guide are not NICE guidance.**

The guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.

Implementation of the guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in the guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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# Contents

## Background to patient decision aids

A patient decision aid (PDA) is a tool that presents evidence-based estimates of the benefits and risks of the available treatment options in sufficient detail that people are better able to judge their value (Stacey et al. 2014). In contrast to health education materials, which simply provide broad background information, PDAs are tailored to a person's health status and help them to make specific, personal choices about their treatment. Importantly, they are intended to supplement or support the interaction between the person and their healthcare professional, rather than replace it. The values and perceptions of individual people, and their attitudes to risk, may be different from those of their healthcare professional (Thornton 2003). Using PDAs in a consultation may help to improve a person's knowledge of the options and outcomes and give them more realistic expectations (Stacey et al. 2014).

It is particularly important to give people information supported by high-quality evidence-based statistics when they are confronting 'preference-sensitive decisions'. These are decisions that involve trade-offs (for example, between quality and length of life or between different aspects of quality of life), and the right choice for the person will depend on the importance they give to these trade-offs. The uncertainty that people often feel about such decisions may be reduced by providing quantitative information about the risks and benefits of each treatment option (Fagerlin et al. 2011).

## Scope of the lipid modification patient decision aid

This PDA has been produced to support implementation of the recommendations relating to primary prevention of cardiovascular disease (CVD) in the NICE clinical guideline on lipid modification. It is not suitable for use in the context of familial hypercholesterolaemia or secondary prevention of cardiovascular disease.

The NICE guideline recommends that, before offering statin treatment for primary prevention, the benefits of lifestyle modification should be discussed with the person after initial CVD risk assessment. Management of all other modifiable CVD risk factors should be prioritised with the person. If, after a reasonable time period, lifestyle modification has been ineffective, statin treatment should be offered to people who have a 10% or greater 10-year risk of developing CVD using the QRISK2 assessment tool. Like the NICE guideline, the PDA assumes that healthcare professionals will  se a drug's summary of product characteristics to inform decisions

made with individual patients. It is expected that healthcare professionals will take into account all the relevant circumstances when using the PDA.

The PDA presents information in different text-based and graphical ways, because these have been shown to help people make 'preference-sensitive' decisions (Fagerlin et al. 2011). Production of the PDA was undertaken as part of a pilot scheme to help inform NICE's approach as to the best way to support shared decision-making by using decision aids. It was produced according to an agreed process that ensures the accuracy of the information it contains and also that the content is likely to be useful to people deciding whether or not to take statins for the primary prevention of CVD. It was overseen by an expert steering group, which included clinical experts, patient representatives and experts on PDAs.

## Using the patient decision aid

### *The difference between absolute and relative risk*

Many people struggle to understand the difference between changes in absolute risk and changes in relative risk. Relative reductions in risk of harm or relative increases in risk of side effects can give misleading impressions of the size or importance of the effect. One way to explain this is to use the analogy of buying lottery tickets. The chance (or risk) of winning the National Lottery Lotto game jackpot is very small if 1 ticket is bought – of the order of 1 in 14 million[1]. If 10 tickets are bought, the chance of winning would increase in **relative** terms by 10 times (1000%), but the absolute risk of winning would increase from 1 in 14 million to only 10 in 14 million, or 1 in 1.4 million. Although the risk of winning is increased by a large amount in relative terms, the **absolute** increase in the chance of winning is still very small (it has increased by 9 in 14 million, or by about 0.00006%). This is because the baseline risk of winning (the chance before the intervention of buying more tickets) was low.

This can be compared with a small, club raffle in which only 250 tickets are sold. If 1 ticket is bought, the chance of winning is 1 in 250. If 10 tickets are bought, the chance of winning would increase in **relative** terms by 10 times (1000%), the same as in the Lotto example. However, in **absolute** terms the chance of winning increases from 1 in 250 to 10 in 250, or 1 in 25. The

[1] This is simplified for the purposes of analogy. Although there are 13,983,816 possible combinations of numbers in the National Lottery Lotto game, more tickets than this are usually sold, some combinations are more popular than others, and some may not be chosen at all, so the chance of an individual ticket winning the jackpot may be less than 1 in 14 million.

absolute increase in chance of winning is 9 in 250, or 3.6%. This is much greater than in the lottery example, because the baseline risk of winning was much greater.

### *Presenting the information*

Recommendations on good practice in shared decision-making are given in the NICE clinical guideline on patient experience in adult NHS services. Healthcare professionals should present the information in a balanced way and make clear that, although they may well have a view on the choice they would make if they were in the person's situation, they accept that the person making the decision may have a different view from them about the balance of risks, benefits and consequences of treatment.

It is important to avoid framing information in a way that results in an unbalanced picture of either benefits or harms. This relates both to the numerical information about the benefits and risks of treatment and also the information about matters such as the need for blood tests. For example, consider a conversation with a person with a 10% 10-year risk of CVD. A healthcare professional might say only that 'over 10 years, 90 people in 100 will not develop coronary heart disease or have a stroke'; or they might say only that 'over 10 years, 10 people in 100 will develop coronary heart disease or have a stroke'. The first phrase could create greater reassurance, and the second greater concern, especially if either were said with particular emphasis and expression. The NICE guideline on patient experience in adult NHS services recommends presenting the data in both ways. It is also necessary to explain that it is impossible to know what will happen to an individual person or say whether or not he or she will benefit from the treatment. Using a form of words similar to that below has the best chance of explaining benefits and harms fairly, accurately and in a balanced way. The example relates to the benefits of statins in people at 10% 10-year risk of CVD; similar wording could be used to present the side effects of treatment.

> 'Imagine there were 100 people like you. If none of the 100 took a statin, over the next 10 years, and on average, 10 people would develop coronary heart disease or have a stroke, but that means that 90 people would not. If all 100 people took a statin for 10 years, over that time 90 of them would not develop coronary heart disease or have a stroke, just as if they had not taken a statin. Six people would still develop coronary heart disease or have a stroke, despite taking a statin. However, 4 people would be saved from developing coronary heart disease or having a stroke, because they took a statin.

> We can't say if you would be 1 of the 4 people who benefit from taking a statin, or 1 of the 96 people for whom taking a statin makes no difference to what would have happened anyway. We also can't say when in the 10-year period the heart disease or stroke might occur.'

Some people dislike the idea of '100 people like me', so an alternative explanation for someone with a 10% 10-year risk of CVD is:

> 'If you don't take a statin, out of 100 possible futures for you, we expect that in 10 of them you will develop coronary heart disease or have a stroke in the next 10 years, but that means that in 90 of them you will not. If you take a statin for 10 years, out of the 100 possible futures, in 6 of them you will develop coronary heart disease or have a stroke in the next 10 years, and in 94 of them you will not. We can't say which of those possible futures will actually happen to you, and we also can't say when in the 10-year period the heart disease or stroke might occur.'

## Source of data, methods and limitations

### *Choice of question topics*

The expert steering group reviewed and agreed the questions and answers.

### *Source of information on adverse effects and interactions of high-intensity statins*

The NICE guideline recommends that when a decision is made to prescribe a statin, a statin of high intensity[2] and low acquisition cost should be used. Atorvastatin 20 mg is recommended as the first choice statin and initial dose for primary prevention. Therefore, reference is made to that drug and dose in the PDA, and information that relates to atorvastatin at high-intensity doses has been preferentially selected for production of the PDA. Information on monitoring requirements, adverse effects and interactions was based on the manufacturers' summaries of product characteristics for atorvastatin, the NICE full guideline on lipid modification and advice from the MHRA (MHRA 2012, MHRA 2014).

[2] See appendix A of the guideline for statin classification.

For the graphical representation of the risk of new-onset type 2 diabetes mellitus, data taken from the SPARCL study (Amarenco et al, 2006) were used. This double-blind, randomised controlled trial compared atorvastatin 80 mg daily with placebo in people with a recent stroke or transient ischaemic attack (TIA). The median follow-up was 4.9 years. This is the only study identified in the guideline systematic review that compared higher-dose atorvastatin with placebo and reported rates of new-onset diabetes. Data on the incidence of new onset type 2 diabetes in people without known diabetes or fasting blood glucose of ≥7.0 mmol/litre at baseline were published by Waters et al. (2011). Data were manipulated in Microsoft Excel and the same programme was used to generate the bar graph. The Cates plot was created using VisualRx.

### *Source of data and method for graphical information on efficacy of high-intensity statins*

The NICE guideline recommends estimating a person's risk of cardiovascular disease using QRISK2. This estimates a person's risk of the composite outcome of fatal or non-fatal stroke, transient ischaemic attack (TIA) or coronary heart disease (angina or myocardial infarction). The relative distribution of first cardiovascular events within this composite used in the health economic model for the guideline was taken from the systematic review by Ward et al. (2005), and this was used in the preparation of this PDA (table 1).

Risk ratios for the effects of statins versus no treatment were taken from the guideline systematic review (table 41 in chapter 11 of the full guideline on lipid modification). In keeping with the recommendation in the guideline to use a statin of high-intensity (and low acquisition cost) for primary prevention, the risk ratios for high-intensity statins compared with no treatment were used. As in the health economic model for the guideline (appendix L of the full guideline), the risk ratio from a related outcome was used for outcomes which were not meta-analysed in the guideline systematic review (for example, the risk ratio for stroke was also applied for TIA). The risk ratios used are given in table 2. The risk ratio for each event was assumed to be constant over time and for all age and sex groups.

**Table 1 Relative distribution of first cardiovascular events, excluding heart failure and peripheral arterial disease**

| Age (years) | Stable angina[1] | Unstable angina[1] | MI[1] | TIA[1] | Stroke[1] | CVD death[2] | Total |
|---|---|---|---|---|---|---|---|
| ***Men*** | | | | | | | |
| **45–54** | 0.31 | 0.11 | 0.30 | 0.06 | 0.13 | 0.10 | 1.00 |
| **55–64** | 0.33 | 0.07 | 0.17 | 0.09 | 0.21 | 0.13 | 1.00 |
| **65–74** | 0.21 | 0.08 | 0.17 | 0.10 | 0.27 | 0.16 | 1.00 |
| **75–84** | 0.19 | 0.08 | 0.16 | 0.08 | 0.34 | 0.14 | 1.00 |
| ***Women*** | | | | | | | |
| **45–54** | 0.33 | 0.12 | 0.08 | 0.16 | 0.23 | 0.09 | 1.00 |
| **55–64** | 0.35 | 0.07 | 0.09 | 0.10 | 0.29 | 0.11 | 1.00 |
| **65–74** | 0.20 | 0.05 | 0.12 | 0.07 | 0.38 | 0.17 | 1.00 |
| **75–84** | 0.15 | 0.03 | 0.10 | 0.10 | 0.46 | 0.15 | 1.00 |

[1] Non-fatal events

[2] Death from cardiovascular causes

**Table 2 Risk ratios (95% confidence intervals) for high-intensity statins versus no treatment**

| Outcome | Risk ratio | 95% confidence interval |
|---|---|---|
| **Non-fatal stable angina** | as MI | – |
| **Non-fatal unstable angina** | as MI | – |
| **Non-fatal MI** | 0.46 | 0.37 to 0.59 |
| **Non-fatal TIA** | as stroke | – |
| **Non-fatal stroke** | 0.80 | 0.70 to 0.91 |
| **Death from cardiovascular causes** | 0.73 | 0.61 to 0.88 |

The effect of high-intensity statins was calculated for each age and sex group and for 7 levels of 10-year cardiovascular disease risk by applying the appropriate risk ratio to each of the outcomes in the composite QRISK2 outcome and then multiplying the sum of the products by the baseline 10-year risk to obtain an estimated on-treatment 10-year risk. The number of first cardiovascular events per 100 people on high-intensity statin treatment over 10 years for a given baseline 10-year cardiovascular disease risk is given by:

Events per 100 over 10 years = R x ([0.46UA+0.46SA+0.46MI]+[0.80TIA+0.80ST]+[0.72CVM])

*Where*

R = events per 100 people not on treatment over 10 years

UA = relative proportion of non-fatal unstable angina

SA = relative proportion of non-fatal stable angina

MI = relative proportion of non-fatal MI

TIA = relative proportion of non-fatal TIA

ST = relative proportion of non-fatal stroke

CVM = relative proportion of cardiovascular mortality (death from cardiovascular causes)

Data were manipulated in Microsoft Excel and the same programme was used to generate bar graphs. Cates plots were created using VisualRx.

## *Limitations*

The PDA is intended to give some sense of the magnitude of risks and benefits from high-intensity statins in primary prevention of CVD, but the figures provided have a measure of uncertainty. The modelling relied on a number of assumptions as described above and is also subject to the limitations of the data on which it is built. These limitations should be considered when using the PDA.

In particular, it was only practicable to use point estimates of the relative distribution of first cardiovascular events. It is not practicable to indicate in a graph or image the uncertainty indicated by 95% confidence intervals around relative risks. Moreover, for a given overall CVD risk, the differences in distribution of first events by age and sex resulted in the calculated point estimates of absolute effects of high-intensity statins being slightly different in different age and sex groups (table 3). In absolute terms, for a given overall CVD risk, the estimated number of events prevented was highest in men aged 45–54 years and lowest in women aged 75–84 years, with greater differences at higher 10-year CVD risks. It should be noted that these

point estimates have a measure of uncertainty and the statistical significance of the differences has not been tested. For simplicity in representing the benefits from statin therapy, and taking into account the limitations arising from using point estimates as above, the expert group agreed that the mean absolute effect on first cardiovascular events should be represented.

**Table 3 Absolute benefits of high-intensity statins per 100 people over 10 years**

| | 10% 10-year risk | | | 15% risk 10-year risk | | | 20% risk 10-year risk | | | 25% risk 10-year risk | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Events – not on treatment | Events – on treatment | Events prevented | Events – not on treatment | Events – on treatment | Events prevented | Events – not on treatment | Events – on treatment | Events prevented | Events – not on treatment | Events – on treatment | Events prevented |
| ***Men*** | | | | | | | | | | | | |
| **45–54 years** | 10 | 6 | 4 | 15 | 8 | 7 | 20 | 11 | 9 | 25 | 14 | 11 |
| **55–64 years** | 10 | 6 | 4 | 15 | 9 | 6 | 20 | 12 | 8 | 25 | 15 | 10 |
| **65–74 years** | 10 | 6 | 4 | 15 | 9 | 6 | 20 | 13 | 7 | 25 | 16 | 9 |
| **75–84 years** | 10 | 6 | 4 | 15 | 10 | 5 | 20 | 13 | 7 | 25 | 16 | 9 |
| ***Women*** | | | | | | | | | | | | |
| **45–54 years** | 10 | 6 | 4 | 15 | 9 | 6 | 20 | 12 | 8 | 25 | 15 | 10 |
| **55–64 years** | 10 | 6 | 4 | 15 | 9 | 6 | 20 | 12 | 8 | 25 | 15 | 10 |
| **65–74 years** | 10 | 7 | 3 | 15 | 10 | 5 | 20 | 13 | 7 | 25 | 17 | 8 |
| **75–84 years** | 10 | 7 | 3 | 15 | 10 | 5 | 20 | 14 | 6 | 25 | 17 | 8 |
| ***Mean*** | ***10*** | ***6*** | ***4*** | ***15*** | ***9*** | ***6*** | ***20*** | ***13*** | ***7*** | ***25*** | ***16*** | ***9*** |

## Table 3 Absolute benefits of high-intensity statins per 100 people over 10 years (continued)

| | 30% 10-year risk | | | 35% risk 10-year risk | | | 40% risk 10-year risk | | |
|---|---|---|---|---|---|---|---|---|---|
| | Events – not on treatment | Events – on treatment | Events prevented | Events – not on treatment | Events – on treatment | Events prevented | Events – not on treatment | Events – on treatment | Events prevented |
| ***Men*** | | | | | | | | | |
| **45–54 years** | 30 | 17 | 13 | 35 | 19 | 16 | 40 | 22 | 18 |
| **55–64 years** | 30 | 18 | 12 | 35 | 21 | 14 | 40 | 24 | 16 |
| **65–74 years** | 30 | 19 | 11 | 35 | 22 | 13 | 40 | 25 | 15 |
| **75–84 years** | 30 | 19 | 11 | 35 | 22 | 13 | 40 | 26 | 14 |
| ***Women*** | | | | | | | | | |
| **45–54 years** | 30 | 19 | 11 | 35 | 22 | 13 | 40 | 25 | 15 |
| **55–64 years** | 30 | 19 | 11 | 35 | 22 | 13 | 40 | 25 | 15 |
| **65–74 years** | 30 | 20 | 10 | 35 | 23 | 12 | 40 | 26 | 14 |
| **75–84 years** | 30 | 21 | 9 | 35 | 24 | 11 | 40 | 28 | 12 |
| ***Mean*** | ***30*** | ***19*** | ***11*** | ***35*** | ***22*** | ***13*** | ***40*** | ***25*** | ***15*** |

## Expert steering group

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