

Putting NICE guidance into practice

**Patient decision aid: user guide
for healthcare professionals**
**Implementing the NICE guideline on
atrial fibrillation (CG180)**

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This is a user guide for healthcare professionals that relates to a [decision aid](#) intended to help people with atrial fibrillation make informed decisions about taking anticoagulants. The decision aid and user guide accompany [Atrial fibrillation: the management of atrial fibrillation](#) (NICE clinical guideline 180)

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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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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 atrial fibrillation patient decision aid

This PDA has been produced to support implementation of the recommendations relating to anticoagulation in the [NICE clinical guideline on the management of atrial fibrillation](#) (AF).

The [NICE guideline](#) recommends that anticoagulation should be considered for men with a [CHA₂DS₂-VASc](#) score of 1 or more and offered to men and women with a [CHA₂DS₂-VASc](#) score of 2 or more, taking their bleeding risk into account. The guideline recommends that anticoagulation may be with apixaban, dabigatran etexilate, rivaroxaban or a vitamin K antagonist, and includes the relevant technology appraisals for [apixaban](#), [dabigatran etexilate](#)

and [rivaroxaban](#). It recommends that the options for anticoagulation are discussed with the person and the choice based on their clinical features and preferences.

The [NICE guideline](#) makes no recommendations for using one anticoagulant over another and no analysis compared the efficacy and safety of apixaban, dabigatran or rivaroxaban (the novel anticoagulants, or NOACs) with each other or with warfarin, so no similar comparisons have been made in this PDA. The [NICE guideline](#) recommends against the use of aspirin monotherapy solely for stroke prevention to people with atrial fibrillation and makes no recommendations about use of dual antiplatelet therapy, so these options are not discussed in the PDA.

The PDA is intended for use by people newly-diagnosed as having AF and also people with AF whose anticoagulant therapy is being reviewed. Like the [NICE guideline](#), the PDA assumes that health professionals will use 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 several different text-based and graphical ways, because these have been shown to be valuable in helping people make 'preference-sensitive' decisions ([Fagerlin et al. 2011](#)). Production of the PDA has been undertaken as a pilot to help inform NICE's approach as to the best way to support shared decision-making by use of decision aids. It has been 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 with atrial fibrillation facing decisions about anticoagulation. It has been overseen by an [expert steering group](#) including 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 jackpot if 1 ticket is bought is very small – of the order of 1 in 14 million¹. If 10 tickets are bought, the chance of winning would increase in **relative** terms by 10 times (1000%). But the absolute risk of winning has increased 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 National Lottery example. However, in **absolute** terms the chance of winning increases from 1 in 250 to 10 in 250, or 1 in 25. The absolute increase in chance of winning is 9 in 250, or 3.6%. This is much greater than in the National Lottery example, because the baseline risk of winning was much greater.

Presenting the information

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

¹ This is simplified for the purposes of analogy. Although there are 13,983,816 possible combinations of numbers in the National Lottery, on average more tickets than this are 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.

information about matters such as the need for blood tests. Healthcare professionals should try to 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, the person making the decision may have different views.

For example, consider the risk of ischaemic stroke in people with atrial fibrillation and a CHA₂DS₂-VASc score of 2. A healthcare professional might say only that 'over the course of a year, 975 people in 1000 will not have an ischaemic stroke', or they might say only that 'over the course of a year, 25 people in 1000 will have an ischaemic stroke'. The first phrase could create greater reassurance, and the second greater concern, especially if either were said with particular emphasis and expression. Best practice recommends presenting the data in both ways. It is also necessary to convey the irreducible uncertainty; that is, it is impossible to know what will happen to any individual person and say whether he or she will benefit from the treatment or not. Using a form of words similar to that below has the best chance of communicating benefits and harms fairly, accurately and in a balanced way. The example relates to the benefits of anticoagulants in people with AF and a CHA₂DS₂-VASc score of 2; similar wording could be used to present the side effects of treatment.

'Imagine there were 1000 people like you. If none of the 1000 took an anticoagulant, over the next year, and on average, 25 people would have an ischaemic stroke, but that means that 975 people would not. If all 1000 people took an anticoagulant, over that time 975 of them would not have a stroke, just as if they had not taken an anticoagulant. Eight people would still have a stroke, despite taking an anticoagulant. However, 17 people would be saved from having a stroke, because they took an anticoagulant. We can't say if you would be one of the 17 people who benefit from taking an anticoagulant, or one of the 983 people for whom taking an anticoagulant makes no difference to what would have happened anyway. We also can't say what would happen in subsequent years.'

Source of data, methods and limitations

Choice of question topics

The questions examined in the PDA were based on those developed for the Option Grid relating to dabigatran etexilate in atrial fibrillation (see www.optiongrid.org). These were used because of the careful approach taken in the development of Option Grids to ensure that the questions considered are the ones most important to people facing the decision. The [expert steering group](#) reviewed the questions and answers.

Source of information on monitoring requirements, adverse effects and interactions

The information on monitoring requirements, adverse effects and interactions was based on the manufacturers' summaries of product characteristics for [apixaban](#), [dabigatran](#), [rivaroxaban](#) and [warfarin](#), the [British National Formulary \(BNF\)](#) and [NICE Clinical Knowledge Summaries](#).

Source of data on efficacy and safety for graphical information

The cost–effectiveness model for the NICE guideline used data from the Swedish atrial fibrillation (SAF) cohort study to estimate incidence rates for thromboembolic and haemorrhagic events ([Friberg et al. 2012](#)). From the studies identified by the guideline's prognostic reviews, this data source was considered optimal to estimate baseline risks for the following reasons:

- The study was one of the largest cohort studies retrieved in the systematic review, containing 182,678 individuals with a diagnosis of atrial fibrillation who were treated as an inpatient or outpatient at Swedish hospitals between July 2005 and December 2008. Average follow-up was 1.5 years.

- The study gave event incidence rates according to each risk stratification. These rates were derived from the same cohort allowing consistent estimates of the related risks of bleeding and ischaemic stroke.
- In the absence of a similar UK study, it was felt that a Swedish population was an appropriate substitute

The data used in the PDA for the outcome of ischaemic stroke relate to the 90,490 warfarin never-users, adjusted for aspirin use, to give the risk in an 'untreated' population. [Friberg et al. \(2012\)](#) state the number of events per 100 patient years at risk and these have been multiplied by 10 to give the number of events per 1000 people per year.

The data for the outcome of major bleeds, which includes intracranial haemorrhage, relate to the 48,599 people on warfarin only. For HAS-BLED score 0, no events were recorded in warfarin users so it has not been possible to produce a graphic to illustrate risk in this population. As with the risk of ischaemic stroke, [Friberg et al. \(2012\)](#) state the number of events per 100 patient years at risk and these have been multiplied by 10 to give the number of events per 1000 people per year.

For both outcomes it has been assumed that a person can have only 1 stroke or bleed per year. Few individuals in the SAF cohort had a CHA₂DS₂-VASc score greater than 5 or a HAS-BLED score greater than 4, and the data are therefore limited, so the effects of anticoagulant treatment on people with scores greater than these have not been illustrated in the PDA.

Methods

Relative risks (RRs) were derived from the hazard ratios (HRs) used in the network meta-analysis in the [full guideline](#). It was assumed that the HR of any event is equal across the range of the CHA₂DS₂-VASc scores or HAS-BLED scores (the proportional hazards assumption).

The HRs have been converted to RRs using the formula in Appendix L.3.18.6 of the full guideline (note, only mean HRs were used):

$$RR = 1 - e^{(HR \times \ln(1 - CGP))} / CGP$$

Where CGP is the control group probability²

For ischaemic stroke, the RRs derived from HRs stated in Appendix M.3.2.2 and figure 207 of the [full guideline](#) have been applied to the rates of ischaemic stroke in the untreated population (see above) to estimate the benefits of anticoagulation. For major bleeds, the RRs derived from HRs stated in Appendix M.3.4.1 and table 180 have been applied to the rates of major bleeds in anticoagulant users (see above) to estimate the risk in non-users.

Data were manipulated in Microsoft Excel and Excel was used to generate bar graphs. Cates plots were created using [VisualRx](#) (www.nntonline.net/visualrx/).

Limitations

The PDA is intended to give some sense of the magnitude of risks and benefits from anticoagulation but the figures provided have a measure of uncertainty for the following reasons:

- The risks of ischaemic stroke and major bleeds are derived from observational data, and users of the PDA are referred to the limitations of these data discussed by [Friberg et al. \(2012\)](#).
- It is possible to display only the risk over 1 year based on the data available.
- The network meta-analysis is also subject to limitations, as discussed in Appendix M of the [full guideline](#).
- It is not practicable to indicate graphically the uncertainty indicated by 95% confidence intervals around hazard ratios and relative risks.

² Taken as the rate per patient year at risk from [Friberg et al. 2012](#)

- The HAS-BLED score includes an assessment of 'labile INRs': clearly this would not apply to people taking a NOAC instead of warfarin or people not taking an anticoagulant, introducing an additional limitation to the comparisons of bleeding risk.
- It has not been practicable to distinguish between the risks of intracranial and extracranial bleeds, even though the consequences of these for an individual, and the values attached to them, may be different.

These limitations should be considered when using the PDA.

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