Comments on the ACD Received from the Public through the NICE Website

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As an accountant I do not like the use of averages. I would like to see the proposal set out the incremental costs of the proposal(by cost category) so that anyone can comment on all assumptions. Â You should include the effect of volume changes. Â It would be good to have a simple Excel model. Secondly, what costs would be saved by implementing the proposal. Â For example I visit the warfarin clinic every few weeks for my INR check. Â What would be the reduction in staff costs etc of the proposal. Â This should be put in a way that can be compared to actual cost changes. Â Again a Excel model would be helpful. Thirdly, what are the expected costs of addressing the problems of side effects (on Excel). Fourthly, how many strokes and other problems does the proposal expect to stop (again on Excel) Fifthly, a summary that shows the full incremental cost/benefit of the proposal (on Excel) that can be presented for audit. Â Finally, and perhaps the most important aspect is transparancy - the numbers should be published on the internet. Â Experience has taught me that all forecasts are (to a greater or lesser extent) wrong. Â We should all have the opportunity of learning.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 4:52:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I would like to add that as a younger AF patient, of 30 years old, on anti-coagulation therapy, current drug requirements for constant monitoring make forward planning very difficult and this it a great time consumer. I am very lucky to have an understanding employer who allows a good level of flexibility, but I know that most people are not so fortunate. As such, I would plead that any drug that can lessen this impact be given the utmost consideration as ultimately for some people this very treatment could make the difference between them maintaining a full working life and being unable to work and balance all the requisite appointments as it the case at present.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 3:51:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Unfortunately I have only just received the e-mail regarding this and comments have to be in by today. Obviously I cannot do any research into it but can only add my thoughts as things affect me as a person with AF
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It does appear to be expensive compared to Warfarin. However, without being able to analysise a warfarin clinics expenditure with regard to assessing and maintaining correct and safe INR levels it is difficult to comment.
Section 2 (The technology)	As a patient taking Warfarin I do not experience any adverse reactions from the drug. The food and drink choices do not pose a problem. There is only a problem if you make one.
Section 3 (The manufacturer's submission)	I do not feel qualified to comment on this
Section 4	The manufacturer developed a Markov model that compares

(Consideration of the evidence)	rivaroxaban (20 mg once a day) with warfarin (adjusted dose warfarin at 4.5 mg once a day, target INR 2.5, range 2.0 to 3.0), . I actually take a warfarin dose of 3mg daily to maintain an INR level of 2.5. However if on rivaroxaban I would have to take 20mg to achieve the same result.
Section 5 (Implementation)	I am sure that most PCTs would not include this new drug into their budgets as it does not appear to be proven as cost effective and there are no recognised benefits of taking Rivaroxaban over Warfarin.
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 3:42:00 PM

Role	Patient
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have AF. I think there should be a choice of treatments to include warfarin and this new drug because, if clinicians have a choice they can better match medication to patients. The cost of warfarin is not just measured in the price of the drug, but in the provision of regular blood tests for patients meaning that patients have to attend a clinic. There is a cost to the health authority in providing clinics, staff, testing and sending out results. Patients like myself with mobility issues have extra difficulties. It can be painful and stressful to have to remember to attends clinics at the right time, and repeated tests often cause pain and soreness in the arm, especially if you dont have good veins.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I sometimes have to he tested on a weekly basis. eg if Ive had to stop warfarin for a medical/dental proceedure it takes a long time to get my INR stable again. Im certain my tests cost a lot more than £242 pa.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 3:25:00 PM

Role	Patient
Other role	
Location	England

Conflict	no
Notes	I fully support any decisions taken by the AF Association.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	I can now have Dabigatran thanks to the AFA for which I am most grateful.
Section 7 (Related NICE guidance)	
Date	1/30/2012 3:15:00 PM

Role	Patient
Other role	
Location	Wales
Conflict	no
Notes	I am sure there must be many like me who would welcome the new alternatives to Warfarin. It is such a trouble having to remember to go to the local hospital and wait for an hour or more to give a blood sample when one additional pill a day for we aged pill takers would be easy. Our local phlebotomists, blood couriers, lab technicians and doctors and surgery staff could then devote more of their precious time to others who need their services. The new medications do cost more but the savings accrued by those of us who would no longer need to be monitored would surely be worth it. Jim Hynes. aged 81
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My response suggests that the new treatment would prove to be cost effective.
Section 2 (The technology)	In that case, is there a safer alternative product available?
Section 3 (The manufacturer's submission)	Has this medication been taken up by American hospitals in a country which treads very carefully in case patients sue for maltreatment?
Section 4 (Consideration of the evidence)	Warfarin has its risks. Which is greater?
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	Sooner, so far as patients are concerned surely.

Date	1/30/2012 3:07:00 PM

Role	NHS Professional
Other role	Specialty Registrar in Public Health
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	With an ageing population and an accompanying likely increase in Atrial Fibrillation (AF) in the future, NHS Southampton City welcomes the investigation into possible treatmetns for AF. However, after considering the evidence, NICE concludes that adjusted dose warfarin is the most cost effective treatment for prevention of stroke and systematic embolism in patients with AF. NHS Southampton City supports this view.
Section 2 (The technology)	On balance rivaroxaban appears to be of comparable safety to warfarin. In the ROCKET-AF trial, the primary safety endpoint (major bleeding and clinically relevant non-major bleeding) showed no statistically significant difference between the two treatments. However, as it is new to the market, it has not been possible to explore the long-term safety outcomes of rivaroxaban, which would be relevant in patients with AF who are likely to be taking it for many years.
Section 3 (The manufacturer's submission)	Unit costs: the required dose for rivaroxaban was equivocal. Â The manufacturers quote incremental cost effective ratios (ICER?s) per Quality Adjusted Life Year (QALY) for a dose of 10mg per day, but participants in the ROCKET-AF trial received 20mg per day. The manufacturers suggest that a dose of 10mg per day would cost £2.10 or £766.50 per year. The BNF 62 lists the price of 10mg rivaroxaban as £44.15 for a 10-tab pack. Eligible patients: the manufacturer asserts the prevalence of AF in 2010 to 1.4% in England. NICE uses the 2006 figure of 1.15%. All AF sufferers would be eligible for treatment.
Section 4 (Consideration of the evidence)	In the ROCKET-AF trial Rivaroxaban (taken in a dose of 20mg daily) showed no statistically significantly different clinical outcomes (ischaemic and haemorrhagic stroke and non-CNS systematic embolism) when compared to warfarin in intention-to-treat analysis (Hazard ratio 0.88 95% CI 0.75 to 1.03). Subgroup analysis suggested rivaroxaban was favourable in patients who had not previously received vitamin K (HR 0.72 95% CI 0.53 to 0.97). NICE concluded that warfarin may be more beneficial in a real-life setting due to the ROCKET-AF sample containing unusually severe AF cases. There may be some patients with AF that are unable to take warfarin, and so it is important that safe, effective alternative drugs are developed.
Section 5 (Implementation)	Cost effectiveness: INR monitoring costs per annum have been estimated differently by the manufacturers and NICE at £242 and £535 respectively. The manufacturers? inflated cost

	estimates of anti-coagulant monitoring for patients on warfarin drives down the ICER per QALY of rivaroxoban (£18,883). NICE estimates the ICER to be much higher at £62,568. Impact on Southampton?s population: Estimated prevalence of AF in Southampton is between 2731 and 3325 (using NICE prevalence estimates, or manufacturer estimates respectively). At the current cost per QALY estimated by NICE, rivaroxaban would require substantial Primary Care Trust resource use, which might not be sustainable considering the large numbers of patients with AF and the simultaneous demand on resources to provide other services.
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	At this time, more clarity is needed from the manufacturer about dose, prevalence of AF and monitoring costs on warfarin. We therefore support the NICE conclusion not to recommend rivaroxaban for the prevention of stroke and systemic embolism in people with AF, pending revised cost-effectiveness analysis.
Date	1/30/2012 2:38:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am on warfarin and it works. If Rivaroxaban will do the job better than Warfarin and if it has been tested to British standards then if in the long term it both saves money and prevents stroke to a larger extent than warfarin then go for it. My Consultant says that he would be very reluctant to prescribe for elderly patients and the condition of each patient must be taken into account. A relation of mine in the the US has had to be taken off it due to bleeding and was informed that his Consultant should not have prescribed Rivaroxaban as he was not a suitable candidate. He is now back on Warfarin. So it looks to me that you pay your money and take your chances. If it aint broke why try and fix it. I suggest that it would be bette to leave all patients on warfarin and supply each patient with a teste,just look at the cost savings in the long term. Kevin Dagg
Section 2 (The technology)	If implemented then all costs will come down.
Section 3 (The manufacturer's submission)	manufactors will always produce stats to support their product
Section 4 (Consideration of the evidence)	Not convincing
Section 5 (Implementation)	With the proposed changes to the NHS this seems irrelevant
Section 6 (Proposed	CONFUSION is the only comment

recommendations for further research)	
Section 7 (Related NICE guidance)	OUt of date
Date	1/30/2012 2:04:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	As a sufferer of Paroxysmal AF for many years I was initially treated with aspirin and Sotalol. However I was soon advised to have a Catheter Ablation to hopefully ease my symptoms. I was anxious about this procedure and spent several years fending it off. However, after another visit to my very patient consultant I decided to go ahead with the procedure. This, of course entailed commencing Warfarin in March 2010. I could never get stable with Warfarin. My INR was either too high or too low despite being careful to be consistent with my diet. I had to have weekly testing which hugely interfered with my work and lifestyle. I travel widely in the UK and abroad. In September 2011 after a particular bout of my INR swinging widely I suffered an embolic infart. I failed Warfarin. I had therapeutic clexane for cover and then was lucky enough to have a very forward looking GP with the advice of my consultant haematologist to prescribe Dabigatran from November 2011. This has proved to be incredibly helpful in all manner of ways to help me lead a normal and full life. Rivaroxaban needs to be available for the thousands of people who find Warfarin damaging.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 12:56:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Dear Sirs

	I am 65, white British, and am an UK resident. I had a stroke in Jan 2010 and discovered that I had Atrial Fibrillation. I have taken Warfarin subsequently aiming to keep my INR between 2.0 and 3.0. It is a nuisance to keep having INR checks frequently, whether in the UK or abroad, so I?d prefer a drug with a fixed dosage (even if it means taking twice-daily). I also have Chronic Lymphocytic Leukaemia (Stage A). There is no treatment at present, but there might soon. Â If such a cure conflicted with my Warfarin, it would be serious for me! I have had a Basal Cell Carcinoma excised from my forehead on Friday 27 Jan, and prescribed one week?s penicillin to help avoid infection. Â I?m told that some people find that their INR is raised as a consequence ? so I need yet another INR check in a few days time. Please can you approved other anti-coagulants than Warfarin for Atrial Fibrillation patients. Yours faithfully

Role	NHS Professional
Other role	Professor of Clinical Pharmacology, University of Â Glasgow
Location	Scotland
Conflict	no
Notes	I was Principal UK Investigator for ROCKET AF.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am concerned that this consultation document may not provide a fair appraisal of the potential role of Rivaroxaban for stroke prevention in people with atrial fibrillation. Â The standard drug, Warfarin, is highly effective in patients who are compliant with therapy and in whom INR remains in the therapeutic range. Although standards of anticoagulation control in the UK have improved dramatically in recent years, many Warfarin treated subjects have periods of variable length when INR falls outside the therapeutic range. Â In such patients, an alternative anti-thrombotic agent, such as Rivaroxaban, would provide a significant clinical advantage which cannot be determined by cost-effectiveness analysis in the whole population.
Section 2 (The technology)	Uniquely, participants in ROCKET AF had high risk of embolic events. These are the individuals in whom antithrombotic therapy is associated with the greatest absolute benefit. Â An alternative to Warfarin in such patients would represent an important therapeutic advance. Although lower risk patients were not included in ROCKET AF, the evidence from other studies (RE-LY and ARISTOTLE) suggest, as would be expected, proportional relative benefit across the range of risk.

Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Finally, the Appraisal Committees preliminary recommendations ignore patient preference and quality of life issues. Warfarin is cheap and effective but has a clinical pharmacological profile which makes this anticoagulant highly unpopular with patients. In 40 years of clinical research, the only occasions on which study patients have requested to stay on the new drug have been in trials with novel antithrombotic agents. It would be a cause for regret if cost-containment meant that access of British patients to a therapeutic advanced was denied or delayed.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 11:47:00 AM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	As a patient the monitoring appointments are sometimes disruptive and it can be difficult to travel to the appointment. Various other health issues may require an interruption in warfarin treatment which make it difficult to reach the relevant dose - requiring further/more frequent monitoring appointments. Doubt this is cost effective.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Is £242 per person for the cost of INR monitoring a realistic cost?
Section 2 (The technology)	I took rivaroxaban prophylactically following knee replacement surgery and had no side effects whatsoever
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 11:04:00 AM

Role	Patient
Other role	
Location	England
Conflict	no

Notes	Patient rep for South London Cardiac and Stroke network anticoagulation Panel
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There isnt a cost suggested for finger tip testing and monitoring of INR which might be cheaper
Section 2 (The technology)	I am amazed that a drug which may not have an antidote and which is caustic as the previous suggested ones are can cost so much. I dont think it is kind to inflict such medication on elderly people or high risk problems whilst the risk of bleeding is such a feature.
Section 3 (The manufacturer's submission)	There is a lot of detail about the dominance of the new medication in those who dont manage their warfarin which is well put but I have to take aspirin and warfarin and this is not a comparison I have seen addressed by the manufacturer.Thus far I have been ok - long term user-.
Section 4 (Consideration of the evidence)	Although there is a need to watch food and drink,and blood tests can be painful and frequent,warfarin is effective - well in my experience. If this drug is ever contemplated it must be a drug of last resort.
Section 5 (Implementation)	I remain of the view the introduction should only be for last resort and home INR monitoring should be examined more fully. I would welcome this as one who has to take aspirin and warfarin.
Section 6 (Proposed recommendations for further research)	There remains acceptance that warfarin alternatives are more caustic and dont have a specific antidote.
Section 7 (Related NICE guidance)	This seems good as more research may be available about other safer alternatives.
Date	1/30/2012 10:03:00 AM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Warfarin is not friendly for the patient, constant need to manage diet and fluid intake, wide variation and fluctuation in readings does not leve me feeling confident with this medication. Monthly blood checks is time consuming and for me living in a rural area a 25 mile round trip each time. Warfarin in my view is archaic and needs replacing with a modern drug
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	wher a peron hs had a blod clot stroke and also has AF i belive they should be offered tivoraxaban as this is prevention were this evidence of a stroke
Section 2 (The technology)	this in a par with Warfarin but with significant easier patient managment
Section 3 (The manufacturer's submission)	a better alternative to warfarin
Section 4 (Consideration of the evidence)	I have had one bllod clot stroke so the fear and risk fo me is high and real. Warfarin is not my drug of choice because of low confidence caused by wide variation in INR readings anf the inconvenient long term management

Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 9:46:00 AM

Role	Patient
Other role	
Location	N Ireland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/30/2012 9:46:00 AM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Cant comment, as the language used is far too technical for me,a lay person to understand!!
Section 2 (The technology)	None
Section 3 (The manufacturer's submission)	Sorry cant understand most of this..far,far too technical!!
Section 4 (Consideration of the evidence)	I am new to Warfarin(4 weeks) but its impact on my quality of life is significant. Todays technology MUST be able to produce better alternatives!
Section 5 (Implementation)	Patients,family,carers etc MUST have a say in these consultations. This is NOT the way to do it! What are you going to do about it?
Section 6	None

(Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	Why does it take so long?
Date	1/30/2012 9:42:00 AM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	feel it is unfair that af patients will be not allowed to benifit from this new med. inr checking costs far more at the moment esp if your dose cant be regulated.
Section 2 (The technology)	the technology far out wares warfarin it is more up to date and less risk
Section 3 (The manufacturer's submission)	full eplaantion covers all bases. promoting better lives for warfarin takers.. concern not many young peopl include in testing
Section 4 (Consideration of the evidence)	af causes upset in many lives the addition of warfarin and inr testing increase this pressure i havent worked for 18 months and i have to find an employer who will fit my inr apmt into my working day its very hard
Section 5 (Implementation)	get it out now
Section 6 (Proposed recommendations for further research)	af shoulkd have full access
Section 7 (Related NICE guidance)	go for it
Date	1/30/2012 8:28:00 AM

Role	Patient
Other role	Scientist
Location	England
Conflict	no
Notes	NICE appears to many of us who are tethered by warfarin to an anticoagulation clinic to be reaching conclusions more on the basis of individual biases than scientific data. When the US FDA and scientists in Scotland approve alternative drugs (like Dabigatran) and NICE doesnt, one has to suppose that the NICE panel is either arrogant ("we are smarter than the Americans and the Scots") or that it is letting its recommendations be influenced by something beyond the research findings. Year ago I read the autobiography of a doctor who was one of the worlds leading authorities on an obscure, rare, and deadly ailment. One day he himself developed the disease. He wrote something on the following lines: "Whenever I had to tell a patient that he or she had the disease, I would say I know how you feel. When I saw my test results and there was no escaping the fact that I now had the disease myself, I realized that I had

	had no idea at all of how my patients felt when I delivered the news. It was only when I myself was the one with the illness that I knew how they felt." I believe many members of the NICE panel on anticoagulants have (understandably) a similar inability to empathize with those of us who have the anxiety, inconvenience, and constraints on our lives imposed by the control and monitoring of INR levels and the uncertainty of how effective the warfarin is at any given time of reducing the risk of stroke without a high risk of bleeding. I see how clever panel members are at criticizing details of the research supporting the greater effectiveness and safety of other anticoagulants (and the much greater convenience for patients). What I dont see is much ability to weigh the methodological niceties, the clever criticisms, while at the same time having the empathy to take into account the human factors that make alternatives to warfarin so much more desirable to the patients themselves. If warfarin were so good, so safe, and so convenient I would not want to switch. But it is not, so I would take the quite small risk that further research will validate NICEs fastidious concerns. The evidence in favour of alternative anticoagulants is good enough for me and Im the patient. Try, please, to put yourself in my position when making your decision.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	NICE appears to many of us who are tethered by warfarin to an anticoagulation clinic to be reaching conclusions more on the basis of individual biases than scientific data. When the US FDA and scientists in Scotland approve alternative drugs (like Dabigatran) and NICE doesnt, one has to suppose that the NICE panel is either arrogant ("we are smarter than the Americans and the Scots") or that it is letting its recommendations be influenced by something beyond the research findings. Year ago I read the autobiography of a doctor who was one of the worlds leading authorities on an obscure, rare, and deadly ailment. One day he himself developed the disease. He wrote something on the following lines: "Whenever I had to tell a patient that he or she had the disease, I would say I know how you feel. When I saw my test results and there was no escaping the fact that I now had the disease myself, I realized that I had had no idea at all of how my patients felt when I delivered the news. It was only when I myself was the one with the illness that I knew how they felt." contd... next box
Section 2 (The technology)	I believe many members of the NICE panel have (understandably) a similar inability to empathize with those of us who have the anxiety, inconvenience, and constraints on our lives imposed by the control and monitoring of INR levels and the uncertainty of how effective the warfarin is at any given time

	of reducing the risk of stroke without a high risk of bleeding. I see how clever panel members are at criticizing details of the research supporting the greater effectiveness and safety of other anticoagulants (and the much greater convenience for patients). What I dont see is much ability to weigh the methodological niceties, the clever criticisms, while at the same time having the empathy to take into account the human factors that make alternatives to warfarin so much more desirable to the patients themselves. If warfarin were so good, safe, & convenient I would not want to switch. But it is not, so I would take the quite small risk that further research will validate NICEs fastidious concerns. The evidence in favour of alternative anticoagulants is good enough for me and Im the patient. Try, please, to put yourself in my position when making your decision.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 10:36:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Clinical familiarity with alternatives to warfarin is vital, given the low level of warfarin patients, at 18%, who are in the thereapeutic INR range. We need more consistently effective treatments, and not just one alternative i.e. dabigatran.
Section 2 (The technology)	There may be good clinical reasons to not give warfarin such as patient intolerance to warfarin
Section 3 (The manufacturer's submission)	Not qualified to comment
Section 4 (Consideration of the evidence)	Not agreed. The 55% compliance in rocket-AF id not borne out by other studies which are much more pessimistic at 18%. Being on warfarin is difficult for patient and clinician, and restructs the patients QoL. I think we need a number of real alternatives to warfarin available to clinicians
Section 5 (Implementation)	No comment
Section 6	Yes but just one alternative, dabigatran, is insufficient. What if

(Proposed recommendations for further research)	dabigatran has a serious problem needing withdrawal? If you dont allow anything else there will be no UK experience of alternatives.
Section 7 (Related NICE guidance)	Too far out in a rapidly moving field, when you have effectively banned its use.
Date	1/29/2012 9:03:00 PM

Role	Patient
Other role	health professional
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	there doesntappear to any consideration of people like myself who have multiple conditions one of which is AF.I have ahistoryn of strokes and TIAs.I take a huge quantity of drugs daily and my INR has been stable for 2 years. i would dearly like to cut down the numbers of drugs i take and reduce the risk of making amistake when counting out my warfarin dose
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 8:33:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	More effort should be applied to improving TTR for warfarin therapy. Considerable increases in TTR can be achieved through home monitoring and Vit K supplementation. This would improve health overall and reduce cost a lot more than new drugs which have marginal benefits, if at all.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Warfarin with proper monitoring using a home monitor reduces the number of strokes and increases TTR.
Section 5 (Implementation)	

Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 7:24:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The wording contained here is very difficult for me to understand - despite being highly educated. All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. so i take aspirin but already after only a year have stomach erosions which the consultant nurse blames on the aspirin. I NEED THIS ALTERNATIVE DRUG - PLEASE
Section 2 (The technology)	The wording contained here is very difficult for me to understand - despite being highly educated. Â All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. so i take aspirin but already after only a year have stomach erosions which the consultant nurse blames on the aspirin. I NEED THIS ALTERNATIVE DRUG - PLEASE
Section 3 (The manufacturer's submission)	The wording contained here is very difficult for me to understand - despite being highly educated. Â All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. Â so i take aspirin but already after only a year have stomach erosions which the consultant nurse blames on the aspirin. Â I NEED THIS ALTERNATIVE DRUG - PLEASE
Section 4 (Consideration of the evidence)	The wording contained here is very difficult for me to understand - despite being highly educated. All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. so i take aspirin but already after only a year have stomach erosions which the consultant nurse blames on the aspirin. I NEED THIS ALTERNATIVE DRUG - PLEASE
Section 5 (Implementation)	The wording contained here is very difficult for me to understand - despite being highly educated. Â All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. so i take aspirin but already after only a year have stomach erosions which the consultant nurse blames on the aspirin. I NEED THIS ALTERNATIVE DRUG - PLEASE
Section 6 (Proposed recommendations for further research)	The wording contained here is very difficult for me to understand - despite being highly educated. All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. so i take aspirin but already after only a year have stomach
Section 7 (Related NICE guidance)	The wording contained here is very difficult for me to understand - despite being highly educated. Â All I know is that I have AF, am terrified of having a stroke but cannot tolerate warfarin. Â so i take aspirin but already after only a year have stomach erosions which the consultant nurse blames on the aspirin. I NEED THIS ALTERNATIVE DRUG - PLEASE

Date	1/29/2012 5:34:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have taken part in a clinical trial of Apixiban, another oral anticoagulant.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Does the monitoring cost include staff pay & equipment? This total must be difficult to calculate as I know from my own experience my INR fluctuates quite widely and my monitoring visits are un-predictable because of this.
Section 2 (The technology)	See above comment. What are the extra costs for side-effects from warfarin as compared to rivaroxaban?
Section 3 (The manufacturer's submission)	Far too complicated for a patient to assess!
Section 4 (Consideration of the evidence)	It appears that the committee are manipulating the statistics to support their argument. I know that my quality of life was better on an anti-coagulant that didnt require monitoring antwhere near as much as warfarin does. Its far easier to remember 1 tablet per day than a warfarin dose that varies from day to day & also from week to week, if my INR has fluctuated. I also get more side effects from warfarin, which, together with the frequent visits for monitoring do impinge on my quality of life. The supposed difference in cost between the two types of treatment appear negligible, looked on in the light of my experiences.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 4:24:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Are the committee focused on the expenditure comparisons only and not the patients as is the impression 1.2 above
Section 2 (The technology)	From my point of view the advantages outweigh the disadvantages as a user.Again it seems the main focus is cost based.
Section 3 (The manufacturer's submission)	I am happy to accept the manufacturers submission my only concern could be what are the long term effects upon patients.The quality of life would certainly improve in such aspects as diet and hospital visits.

Section 4 (Consideration of the evidence)	Again I think in summary too much emphasis is being placed upon cost. My only other concern is the amount of studies csrried out. U.K.is thin on the ground but so long as the committee are satified then I feell there should be accceptance
Section 5 (Implementation)	The comparison stastics are consistently refeered to especially regarding bleeding.However I dont think enough consideration has been given throughout the report to patients quality of life costs of travel and inconvenience of hospital attendance and diet. The report seems to broadly ignore these or certainly its detail.I repaet again I think the new drugs should be accepted and that the committee should re consider its decision.
Section 6 (Proposed recommendations for further research)	I have not had time to read these to be able to comment constructively
Section 7 (Related NICE guidance)	What is going to happen upto this date? Are trials going to continue in U.K.? Surely this is too long and if as I have said previously that too much emphasis has been placed on cost then pro rata in 2014 the cost will have raised and will this drug be a prioity bearing in mind the extensive restructure which is currently taking place in NHS.I would suggest you consider the increase in staff costs at hospitals if warfarin continues
Date	1/29/2012 4:21:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The UK does not have available one of the newer anticoagulants, which are proved in world tests to be superior in many ways. To delay, as this recommendation will do, means that there will be more strokes, at a cost greater than the cost of the drug. Limited approval would be preferable. The trial of apixaban was stopped early because it was much better at prevention. Time delay means less chance to be stroke free.
Section 2 (The technology)	Looking at adverse reactions should not be a substitute for the overall benefits of a medication. Taken into account yes, but not used to prevent access if there are greater benefits for many patients. As a patient who needs this type of medication, and I have several factors to prefer it to warfarin, I think it should be available as soon as possible. At the moment I take asprin, and my chance of a stroke is greater. Â Should I have one the cost will be large and the effect on my life greater.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	

Section 7 (Related NICE guidance)	Other countries have approved this medication long before the suggested review date. UK patients are getting a poor service by the delay.
Date	1/29/2012 4:07:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I agree not to recommend rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation.
Section 2 (The technology)	The adverse reactions are a little worrying
Section 3 (The manufacturer's submission)	Obviously, the manfacturers will be biased
Section 4 (Consideration of the evidence)	I agree
Section 5 (Implementation)	I agree with the Secretary of State for Health and Social Services directions
Section 6 (Proposed recommendations for further research)	I agree with NICE guidance
Section 7 (Related NICE guidance)	The Guidance I feel shure that the Executive will make the right decision
Date	1/29/2012 4:03:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	My occupation prevents me from being a Warfarin patient so I presently take aspirin. If and when I have to go from Aspirin to Warfarin my professional life will be over so I am very dissapointed in your conclusions. Warfarin may be cheap but unless you are retired or unemployed it is not a practical drug. Rivaroxaban would have been ideal for my working life.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	Seems like good value,cheaper than being unemployed thru Warfarin
Section 3 (The manufacturer's submission)	Surely theres a case for giving it to some patients
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	

Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 3:51:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Atrial Fibrillation patient
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Cost effectiveness- in the last year I have had to have a total of forty blood tests. Not only are these disruptive to everyday living but if the costs of the tests,threee anti-coagulant nurses employed in this area, administrative time,telephone calls, sealed stationary to inform patients and first class postage are taken into account then cost effectiveness must be closer. In addition bearing in mind that very many patients spend a great deal of time outside their therapeutic level it must be safer.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 3:22:00 PM

Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have read through the whole of this document and can only understand/evaluate in a limited way. As a non medic but as a carer of a patient who has suffered long term cardio problems-may I make this appeal IF there are new /improved drugs out there that would benefit patient quality of life - Please,PLEASE enable them to be available for doctors to prescribe them to the benefit of their

	patients.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 2:52:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why is the monitoring cost, when methods of monitoring can very e.g. self-monitoring), included?
Section 2 (The technology)	It is important that the Committee considers the cost effectiveness . Warfarin is inexpensive, so any alternative that is expensive should be proportionately superior or otherwise discounted.
Section 3 (The manufacturer's submission)	The inadequacy of testing parameters and precudres as shown above, would seem to justify the Committees report, bearing in mind the very substantial increased cost.
Section 4 (Consideration of the evidence)	Supplying a substantially more expensive medication to people who are careless in using existing treatments should not be a cost borne by taxpayers. The high proportion of non-UK warfarin users in the manufacturers sample appears unsatisfactory. The incidence of problems associated with taking warfarin seems overstated. For all the reasons I have stated above, the Committeess decision not to approve the introduction of rivaroxaban appear fully justified.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 2:19:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	There needs to be an alternative for warfarin for people unable to maintain stable INR. Â Weekly blood tests are disruptive to life, expensive for NHS, mean travel is impossible and the INR fluctuations mean that the patient is not properly protected against stroke etc. Unsatisfactory experience of Warfarin can mean decreased compliance with the drug, which defeats the purpose.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 1:51:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Agree with preliminary recommendations and findings. Uncertainty around manufacturers submission around cost per QALY.
Section 2 (The technology)	The cost is lower than aquisition cost of dabigatran. The number possibly eligible under the licensed indication are more than actual number on warfarin. The financial impact therefore could be lot higher to NHS
Section 3 (The manufacturer's submission)	The manufacturers submission regarding TTR is lower than actual values in the UK, therefore figures used should reflect UK figures as making benefit of rivoroxaban higher than actually is in practice. cost of INR monitoring does not reflect UK practice
Section 4 (Consideration of the evidence)	From the network metaanalysis conducted by thye company, there are many uncertainties and unable to tell if superior to alternatives
Section 5 (Implementation)	
Section 6 (Proposed	Could both dabigatran and rivoroxaban be looked at together. Could NICE be clearer on cohort of patients who may benefit

recommendations for further research)	rather than suggesting an option within licensed indication.
Section 7 (Related NICE guidance)	
Date	1/29/2012 1:31:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have AF & been prescribed Warfarin. It is difficult to control needing regular tests and has side effects that are affecting my quality of life. I am hoping for rivaroxaban to be approved by Nice. I understand it has the same function as Warfarin without all the problems. Regards David
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 1:13:00 PM

Role	Patient
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no mention here of the benefits to patients. That is too important to leave out.
Section 2 (The technology)	There are hidden costs to Warfarin that arent mentioned here.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Check with patients please.

Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 12:32:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have been taking warfarin now for over 4 years and the major issues I have with this medication are as follows: A) I am currently having fortnightly blood tests to measure my INR which obviously puts some pressure on the NHS in terms of cost of these tests - postage etc. B) Taking the medication means I have to be extremely careful when doing gardening, DIY and other activities as the slightest injury means I bleed profusely if, as nearly always happens, that the skin breaks and blood begins to flow. C) Visits to the dentist are always risky if I need treatment by the dentist or the hygeinist. The blood flow into my mouth is distasteful and my teeth and lips get covered in blood which to be honest does not look particularly good in my role as a salesman. D) My cardiologist has advised that I will almost certainly be on anti-coagulation for the rest of my life and the long term effects of warfarin give me some concerns.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	1/29/2012 12:25:00 PM

Role	NHS Professional
Other role	
Location	England

Conflict	
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Agree that rivaroxaban in AF does not appear to be cost effective compared to adjusted dose warfarin with good control.
Section 2 (The technology)	The provisional cost of rivaroxaban is quoted as Â£2.10 per day and £766.50 annually (per patient). This is lower than the BNF cost for 10mg rivaroxaban, despite the dose for AF being higher than for VTE prophylaxis. There must therefore be uncertainties about the actual cost of rivaroxaban for the prevention of stroke or systemic embolus to the NHS, and consequently uncertainties about the relative cost-effectiveness of rivaroxaban compared to warfarin in the NHS. Under the proposed indication, all patients with non-valvular AF with CHADS2 score would be eligible for rivaroxaban. This would mean that approximately 1,146 patients per 100,000 would be eligible for rivaroxaban. This is more than the 2006 figures for the number receiving warfarin quoted in NICE's costing report Â on the management of atrial fibrillation, which suggested that 30% of currently-detected AF cases receive oral anticoagulants, while 36% receive aspirin, equating to approximately 384 patients per 100,000 receiving anticoagulation for atrial fibrillation.
Section 3 (The manufacturer's submission)	There were limitations to the generalisability of the research. The population in the ROCKET-AF trial had more severe disease than the UK population expected to be eligible to receive rivaroxaban. It is unclear whether apparent benefits from rivaroxaban seen in the ROCKET-AF trial would actually be achieved in people with more moderate disease. The Committee has asked the manufacture to provide a revised model with a baseline risk of strokes and other events more representative of people with AF in the UK. This should be derived from the General Practice Research Database or a UK GP practice-based survey.
Section 4 (Consideration of the evidence)	There were also limitations to the quality of the research. The results of a single large RCT have been submitted by the manufacturer. The ROCKET-AF trial compared rivaroxaban with dose-adjusted warfarin. The manufacturer submitted a network meta-analysis in people for whom anticoagulation therapy is considered suitable to compare rivaroxaban indirectly with aspirin and dabigatran etexilate. The estimates for rivaroxaban compared with dabigatran etexilate obtained from the network meta-analyses were unreliable and therefore the committee has been unable to say whether rivaroxaban is more effective or cost effective than these alternatives.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review	

of guidance)	
Date	

Role	NHS Professional
Other role	
Location	England
Conflict	
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Clinical Commissioning Consortia in Bradford and Airedale strongly endorse this recomendation. To recommend this treatment as an option for SPAF in the whole population would simply incur an opportunity cost that would be considerably greater than the benefit the technology brings. similar to the views we have already in the NICE appraisal of Dabigatran we do see that these new OAC agents have an important role in SPAF, but that their use (based on the balance of risk and benefit + affordability / opportunity cost) should be clearly limited to those who are unable to beenfit from the current standard of care - warfarin. It is important than NICE send out a VERY clear message to prescribers about absolute risk and benefit of RVX compared to Warfarin. This needs to be in paragraph 1 of the TA, as this is all that the majority of prescribers will EVER read
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	our interpretation of the ROCKET AF study is that the data on risk and benefit is not sufficient for this treatment to replace warfarin as the standard of care. We concur with the The evidence review group (ERG) when they identified several limitations with the manufacturer's model, including comparison with populations whose warfarin control (time in therapeutic ratio) was less satisfactory than generally expected in the UK. The ERG presented an alternative base-case ICER of Â£33,758 per QALY gained. The manufacturer of rivaroxaban has included higher INR monitoring costs associated with warfarin than estimated in the ongoing appraisal of dabigatran etexilate, and these are likely to be higher than the usual costs for NHS patients. Â The manufacture had estimated INR monitoring costs at Â£535 per person. The ERG considered that the manufacturer's cost-effectiveness model was particularly sensitive to assumptions about the cost of monitoring warfarin.
Section 4 (Consideration of the evidence)	ROCKET AF was NOT generalisable to UK AF population! Time in therapeutic range (TTR) for warfarin should be accounted for in the cost-effectiveness analysis. In the ROCKET-AF trial, which formed the basis of the manufacturer's submission, the mean TTR for warfarin was 55% (58% median). The ERG considered that this was lower than the TTR generally reported in the UK and in other clinical trials. This would make rivaroxaban appear more effective compared to warfarin as used in the UK, and consequently these results may not be applicable to UK practice.

Section 5 (Implementation)	We accept NICE is precluded from considering affordability. Should the TA committee reverse this ACD and recomend this medicine in all AF patients (as happened with dabigatran) the affordabilty is THE concern from commissioner perspective. It is important to remember that the levers commisisoners have to influence prescribing decisions (either in primary or secondary care) are weak - a headlong rush to switch patients from the standard of care to this medicine (which WILL happen on account of the "faf" factor associated with INR monitoring, the heavy promotion of the medicine to prescribers and to patients and the largely misinterpreted understanding of warfarin risks and benefits both in clinicians and patients) will not be in the best interests of patients, nor the taxpayer - this will not represent the most rational use of resources. As we have seen wit the Dabig TA, it would seem there is a dramatic under estimation of implementation cost (by a factor of 10 in the case of dabig). Commisisoners will obviously be considering which services would need to be decommisisoned to make way for this drug should NICE reverse its decision. obviously these would be circulatory services
Section 6 (Proposed recommendations for further research)	All of the new oral anticoagulants DO need to be considered together against Warfarin as the standard of care, using data from UK clinical practice and the UK cohort. We dont anticpate this will happen for commercial reasons, but the scientifically and clinically valid question remains! Will anyone take it on
Section 7 (Related NICE guidance)	
Date	