NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
SPECIAL HEALTH AUTHORITY

Single Technology Appraisal (STA)

Atrial fibrillation– Dronedarone

Report to the Appraisal Committee summarising public comments on the Appraisal Consultation Document (ACD) issued in December 2009 (including comments from patients, carers and health professionals)

1 Executive summary

In total 642 members of the public responded to the consultation on the draft guidance relating to the appraisal of dronedarone for the treatment of atrial fibrillation (AF). There were 541 letters and emails, and 151 web comments. Of the 151 web comments, 101 respondents identified themselves as patients, carers or members of the general public, and 50 respondents identified themselves as health professionals. The web comments were read and the key themes were identified, coded and analysed. This report summarises the findings.

All but two respondents disagreed with NICE's preliminary decision not to recommend dronedarone for the treatment of atrial fibrillation. Respondents argued that there is a clinical need for dronedarone, particularly given the lack of alternative treatments and the side effects associated with them. People were concerned that the decision had been made purely on cost grounds and that the costs associated with not allowing access to dronedarone had been underestimated.

Some respondents specifically challenged the process used by NICE, arguing that there should have been an arrhythmia specialist present at the committee meeting and that patient choice was not being considered properly.

There were also a number of comments relating to equity, equality and human rights in particular the availability of drugs in other countries.

2 Introduction

This report collates and summarises the public web comments on NICE's draft guidance recorded in its Appraisal Consultation Document (ACD) for the appraisal of dronedarone for the treatment of atrial fibrillation and atrial flutter (AF).

All emails, letters and web comments have been read by NICE, and this report collates the responses made through the website comment facility.

NICE would like to acknowledge the time and effort that members of the public put into preparing and sending comments as part of the consultation.

3 Numbers and format of comments received

In line with NICE's published process, the appraisal consultation document setting out NICE's draft recommendations was posted on NICE's website for the consultation period from 24 December 2009 to 28 January 2010 (timelines extended from standard 20 working days due to the Christmas period).

In total, 642 members of the public responded to the consultation. Of these, 320 letters were received where respondents added their contact details to a standard letter template provided by the Atrial Fibrillation Association (appendix 3), and 221 people contributed by individually written email or letter. As NICE requests that members of the public comment on ACD consultations by completing a form on the NICE website, the NICE Enquiry Handling team responded to the 221 letters and emails informing them of this facility. This report therefore summarises the 147 public comments received as web comments in line with NICE's processes, as well as 4 letters from people who were unable to use the web facility. There was a duplication of a single web comment: the duplicate was not counted as a separate response and therefore the points raised were only considered once.

The issues raised in the 101 comments received from patients, carers or members of the general public are quantified in the attached coding sheet (appendix 1) and described in sections 5 and 6 of this report. The issues raised in the 50 comments received by health professionals are summarised in section 7 of this report.

A petition signed by 187 UK arrhythmia clinicians and healthcare professionals is attached in appendix 2 along with an example of the standard template letter in appendix 3.

4 How NICE dealt with the correspondence

All letters and emails were read and responded to by members of NICE staff, as discussed above. Subsequently, all the web comments and eligible letters from patients, carers and members of the general public were read and collated by the Patient and Public Involvement Programme and Enquiry Handling team at NICE.

To produce a coding template, the Technology Appraisals technical team for the topic provided a list of key themes from the Consultee and Commentator groups' consultation responses. The Patient and Public Involvement Programme used these themes to create a comprehensive formal coding list, using knowledge of concerns raised by members of the public during previous

ACD consultations to add additional themes. The issues raised in the public responses were coded against this final list (Appendix 1). As the finalised coding sheet was designed to be comprehensive, not all codes were used. The numbers of respondents who raised each issue, along with the equivalent percentage figure, is shown on the coding sheet in Appendix 1. As there were 101 responses, the percentage figure is seen to be the same as the absolute figure in all but code 3 – number of respondents who disagreed with the decision and gave at least one reason why (91 responses; 90%). This report will therefore only quote absolute figures, without associated percentages.

All the web comments from health professionals were read by the NICE Technology Appraisals technical team and are summarised in section 7.

5 Main themes of comments received

All but two of the respondents objected to NICE's preliminary decision not to recommend dronedarone for the treatment of atrial fibrillation. Objections to NICE's decision focused on four main issues:

- Clinical effectiveness and the lack of suitable alternative treatments.
- Costs or cost effectiveness.
- The nature or implementation of the NICE process.
- Issues relating to equity, equality and human rights.

The sections below explore each of these themes in more detail. Quotes from individual responses are included to help illustrate some of the key issues.

6 Exploration of key themes in comments from patients, carers and members of the general public

6.1 Comments on clinical effectiveness

Comments on clinical effectiveness focused on the lack of alternative treatment options, the effect of AF on people's quality of life, and research evidence supporting the clinical effectiveness of dronedarone:

- Twelve respondents discussed how the current drugs do not control symptoms well, and eight mentioned amiodarone specifically. A further 42 respondents argued that patient access to dronedarone should take into account the limited alternative treatment options, and the side effects associated with them:

  "I am currently having to live my life without drugs because of the side effects of all other drugs on the market. The side effects are so bad that I would rather live life suffering AF 2 or 3 times a week than suffer the side effects of the other drugs. This causes an issue in quality of life for me at such a young age."

"Anything is better than Amiodarone which, although a highly effective antiarrhythmic, has serious side effects - I know!"

- Several respondents said that patients should be able to access dronedarone because there is a clinical need for alternative treatments for AF. Six people mentioned the lack of recent advances in AF drug development and two people reported that AF prevalence is high. A further two respondents reminded the Committee that there is increasing referral for expensive interventions and 14 people said that dronedarone is the only treatment shown to reduce hospitalisation:

  "Dronedarone is suitable for up to 55% of AF patients diagnosed with paroxysmal AF. As it has also been shown that the drug reduces hospitalisation and the incidence of stroke surely these alone offer considerable long-term savings?"

- Many respondents also reported negative personal experiences of the comparators (35 responses) and other quality of life issues, such as the effect of AF on ability to work and on personal and family relationships (14 people) and AF-associated fatigue (3 people):

  "So far I have tried three types [of current drugs] all of which have had adverse effects e.g. collapse, light headedness and a dreaded feeling of overwhelming tiredness, when I have to sit down and sleep for an hour, even in the middle of cooking a meal! ... Having been active all my life this hits me really hard. I have also always been used to travelling on my own to visit relatives and colleagues all over the country, but because of the side effects of my medications I have lost my confidence and am unable to do this. Which means my active life is virtually over."

- Four people mentioned benefit from the comparators, but also added that this benefit was associated with side effects:

  "I have been prescribed three drugs in the past 12 months, the latest one Flecainide seems to be working, at present, although the dose has been increased and the side effects are life changing for me!"

- No respondents mentioned personal experiences of taking dronedarone, whether in a positive or negative way.

One person agreed with the decision and others agreed with certain aspects of the decision, whilst still considering the overall decision to be wrong:

- Four people agreed that the relevant evidence on dronedarone had been appraised.

  "The recommendations seem to be fair based on the enquireies [sic] they have made so far in relation to Dronedarone"

- A further three people agreed that dronedarone is less efficacious than amiodarone:

  "Dronedarone studies do indeed suggest it is not as effective as amiodarone, though probably better than most other drugs."

6.2 Comments on costs/cost effectiveness

Respondents made a number of different observations about costs:

- Twenty one people said that treatment should be provided to AF patients regardless of cost and that the decision seemed to be based on cost alone:

  "It is clear that Dronedarone has beneficial qualities to such as myself and that your present recommendations have been overly influenced by the question of cost."

- Thirty nine felt that costs of alternative treatments to dronedarone, or of not providing treatment, had been underestimated:

  "AF can have a dramatic and very damaging effect on a patients quality of life threatening loss of work, inability to continue ones normal daily activities, serious damage to relationships. The cost to society of these would certainly outweigh the cost of a daily dronedarone prescription."

- Three people each raised other cost issues, such as the worry of not being able to continue to afford to self-fund treatment. One respondent also noted patients' own contributions to the NHS, as tax payers or as NHS or public sector employees.

Some respondents commented on whether there were subgroups that should be considered:

- Five people suggested dronedarone should be considered as a second-line therapy for people for whom other treatments had failed. Three people however suggested dronedarone should be a first-line treatment, for people who are contraindicated to the other treatments.

- Additionally, some respondents said that younger patients should be considered (4 people) whilst others (2 people) said that older people should be targeted.

6.3 Comments on the NICE process

Comments about the NICE process focussed on three perceived problems:

- Thirty one respondents criticised NICE for not having an arrhythmia specialist present at the first committee meeting, and/or urged NICE to have such a specialist present at the second meeting:

  "Please invite patient representatives and arrhythmia specialist clinicians to present to the second Appraisal Committee meeting on 24 February 2010 to ensure that all of the relevant evidence been taken into account by NICE"

- Ten people said that the NICE process doesn't take patient choice sufficiently into account:

  "Effectiveness [of dronedarone] appears comparible [sic] to that of existing drugs but with less side effects. Patients (and doctors) should have options and choice, which is a fundamental principle of the NHS."

- Additionally, eight people said that the proposed review date of 2012 was too far away.

6.4 Equity, equality and human rights

A number of respondents raised issues relating to equity or challenged the NICE decision within the context of human rights legislation:

- Twenty six respondents challenged the fact that NICE was restricting use of dronedarone when such restrictions did not apply to patients in other countries in Europe and in the United States:

  "The drug has been approved in other countries. Yet again, the UK lags behind."

- Additionally, 4 respondents argued that the decision contravened human rights legislation (right to life and/or right to private and family life) and one respondent claimed the decision was ageist.

7 Summary of comments from health professionals

The key themes in the comments received from health professionals are summarised as follows:

7.1 Need for alternative treatments for AF

- AF prevalence is high and increasing
- Current antiarrhythmic drugs (AADs) do not suit all people
- No new AAD available for ~ 25 years

7.2 Limitations of current AADs

- AF symptoms not well controlled by current AADs
- Lots of variation in individual patient response to AADs
- Lack of response to one AAD does not predict lack of response to another
- Current AADs not suitable for all patients. Class 1c contraindicated in ischaemic heart disease, sotalol contraindicated in LVD due to hypertension, both conditions are common to typical AF population (so only option is amiodarone).
- Sotalol and flecainide have increased mortality risks
- Amiodarone is used only as a last resort usually only for patients with limited life expectancy due to toxicity
- Amiodarone cannot be tolerated by a significant proportion of patients
- Only alternative for some patients (if dronedarone is not recommended) is catheter ablation which is expensive and only available to younger fitter people

7.3 Safety of dronedarone vs other AADs

- Dronedarone has a more favourable safety profile than amiodarone
- Some respondents agreed that the long-term safety of dronedarone unknown; however, the long-term effects of amiodarone are related to a molecule not present in dronedarone so it is logical to assume that dronedarone does not have these side effects

7.4 Disagreement with recommendation

- Most respondents agreed that use of dronedarone in the general AF population as per manufacturer's analysis would not be appropriate. Most respondents thought dronedarone should be allowed in:

    1. People for whom sotalol and class 1c drugs are contraindicated or fail (therefore only option is amiodarone)

- Others thought dronedarone should be allowed in:

    2. (Subset of above) Young people who need long term treatment and only option is amiodarone (sotalol and class 1c drugs failed/contraindicated)

    3. People who have developed side effects to amiodarone (only option then is ablation or nothing). Although many respondents thought the use of dronedarone after amiodarone would not be logical since amiodarone is more toxic

4. Anyone in whom an AAD is needed (after trial of beta-blocker)

5. People with predominantly paroxysmal AF without heart failure whom two other AADs have failed and do not wish to have ablation or in whom it is contraindicated

7.5 Evidence

- ATHENA population represents older with comorbidities in whom sotalol or class 1c would not normally be given therefore only option is amiodarone
- More weight should be given to the results of the ATHENA trial. dronedarone is the only AAD shown to reduce mortality and CV hospitalisations in high risk patients
- Most respondents agreed that the evidence shows dronedarone is less effective than amiodarone, and also that it has fewer side effects
- Some respondents agreed that a reduction in risk of stroke has not been proven; however some thought that consideration of reduced risk of stroke was important
- Disagreement with statement in ACD that dronedarone is less effective than other AADs (section 4.4) – evidence indicates dronedarone efficacy is less than amiodarone but comparable to sotalol and class 1c agents

7.6 Cost-effectiveness

- Dronedarone will be stopped (after a few weeks) if ineffective; this was not adequately considered in the cost-effectiveness analysis
- Costs of dronedarone would compare favourably to those of ablation
- Comparison should be between dronedarone and no treatment or with ineffective established treatment or with ablation
- Model does not reflect how AADs are used in practice (i.e. AADs prescribed to treat symptoms of AF episodes, and only required for a proportion of patients because most AF patients have either permanent or asymptomatic AF)

7.7 Implementation

- Dronedarone would initially be prescribed by arrhythmia specialists then by cardiologists when some comfort/experience was reached, not by general physicians for at least a few years

7.8 Review

- Recommend earlier review due to likely evolution of AF management strategies and expected new evidence

7.9 Other

- Some respondents commented that the Appraisal Committee has not adequately considered the importance of symptom control as opposed to stroke/mortality reduction; symptom control (improved QoL) is principal indication for AADs

- Some respondents commented that there was a lack of specialist expert input at the first Committee meeting

Patient and Public Involvement Programme
Enquiry Handling team
Technology Appraisals Programme

February 2010

Appendix 1

Coding form showing numbers, and percentages, of responses per category

Code		Total
	Overall	**101**
1	Agree with recommendations.	**2**
2	Disagree with recommendations, with no critique of issues.	**8**
3	Disagree with recommendations, with reasons given OR recommendations need to be reconsidered/ drugs should be provided.	**91**
4	Other, e.g. partially agree with ACD or no opinion stated.	**0**
	Quality of Life/ Clinical Effectiveness issues	
5	personal experience of benefit from dronedarone	**0**
6	personal negative experience of dronedarone	**0**
7	personal experience of benefit from comparator/s	**4**
8	personal negative experience of comparator/s	**35**
9	tiredness/ fatigue	**3**
10	other QoL - affect on relationships, work etc	**14**
	Costs	
11	Cost cutting exercise/ rationing/ costs shouldn't be considered	**21**
12	NHS costs mentioned/ the costs have been underestimated/ failed to consider costs.	**39**
13	The pharmaceutical companies should reduce the price.	**0**
14	I am self funding treatment and worried that I will not be able to continue paying for my treatment	**1**
15	Other cost issues	**2**
	Need for alternative treatments for AF	
16	AF prevalence is high and increasing	**2**
17	[duplicated code - was not used]	**N/A**
18	No new AAD available for ~25 years	**6**
19	Increasing referral for expensive interventions e.g. catheter ablation	**2**
	Limitations of current AADs/ benefits of Dronedarone	
20	AF symptoms not well controlled by current AADs	**12**
21	Current AADs not suitable for all patients/ Dronedarone has fewer side effects	**42**
22	Class 1c agents (flecanide and propafenone) have limited use due to cardiovascular contraindications	**0**
23	Sotalol and flecanide have increased mortality risks - should be considered	**0**
24	Amiodarone is used only as a last resort (despite being the most efficacious drug available)/ has significant side effects/ cannot be tolerated by lots of people	**8**
25	Dronedarone is only AAD shown to reduce CV hospitalisation (specifically in an AF population with increased CV risk and in whom other options are limited)	**14**

	Suggested subgroups	
26	People in whom other AADs have failed (i.e. second line AAD)	**5**
27	People are contraindicated (i.e. first line AAD) (particularly those who cannot have ablation)	**3**
28	E.g. younger people with structural heart disease - may need long term treatment (amiodarone is only option but they don't want to be exposed to it long-term)	**4**
29	E.g. older people without structural heart disease - clinicians do not want to give them class 1c agents for extended periods (...mortality risk?)	**2**
30	E.g. people who have tried amiodarone with significant side effects and in whom dronedarone would be the only option e.g. older people who already have liver, thyroid, lung problems due to amiodarone (i.e. second line AAD)	**0**
	Problems with appraisal	
31	No arrhythmia specialist at the meeting/ urge NICE to have an AF clinician at the Feb 2010 meeting	**31**
32	Patient choice was not adequately considered - many people would choose an option that has fewer side effects despite less efficacy	**10**
33	Comparators (esp. amiodarone) would not be approved by NICE if assessed in similar way to dronedarone	**0**
34	Comparators are not directly comparable equivalents	**0**
35	NICE = uninformed decision makers/ bureaucrats/ accountants	**0**
	Agreement with appraisal	
36	Agreement that all relevant evidence on dronedarone has been taken into account	**4**
37	General agreement that dronedarone is as efficacious as sotalol, and class 1c agents (but there is a lack of head to head evidence to prove this)	**0**
38	General agreement that dronedarone is less efficacious than amiodarone	**3**
	Equity, equality and human rights	
39	Drugs are funded in other countries (USA, Europe, Scotland)	**26**
40	Haman rights legislation promising right to life regardless and/or right to private and family life	**4**
41	Disability discrimination.	**0**
42	Some people can afford private treatment while others can't.	**0**
43	Other equality issues - e.g. ageism	**1**
44	National Insurance/tax payer/NHS worker for many years.	**1**
	Others	
45	review date too long to wait	**8**

Appendix 2 – Petition

Appendix 3 – Sample template letter

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Professor Mike Rawlins
Chairman
NICE
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WC1V 6NA

January 28th 2010

Dear Professor Rawlins and Professor Clark

ACD on dronedarone (Multaq) for the treatment of atrial fibrillation

As healthcare professionals representing the leading professional societies, we are writing to urge you to rethink your preliminary decision on the appraisal of dronedarone.

Atrial Fibrillation is the commonest sustained arrhythmia that is seen in clinical practice, and its importance has been acknowledged by NICE in Clinical Guideline 36 (http://www.nice.org.uk/Guidance/CG36/NiceGuidance/pdf/English).
AF is estimated to consume 1% of the NHS budget, and as the prevalence of AF is likely to double over the next 50 years the burden of the illness will continue to grow. Current drug therapies are only modestly effective and do not suit all patients. There are very few drugs available in practice to maintain sinus rhythm, Flecainide, Propafenone, Sotalol and Amiodarone. The use of all of these drugs are limited in clinical practice by contra-indications, particularly ischaemic heart disease and heart failure, side effects, particularly with amiodarone, and a lack of efficacy. The alternatives to treatment include AF ablation, a valuable alternative, but expensive and only really available to younger and fitter patients. Furthermore, it is still difficult to access AF ablation easily (patients traveling to specialists centres for treatment), and along with higher cost to the NHS, there is greater risk for the patient. It is therefore not uncommon in more elderly patients or those who have endured symptomatic AF for many years, to reach the end of the line with conventional therapies. Such patients default to rate control strategies very quickly.

New choices in anti-arrhythmics are therefore much needed. Dronedarone will be the first anti-arrhythmic drug to be released in the UK since the 1980s. Whilst dronedarone is not intended as a panacea, it would have an important role in the management of atrial fibrillation for many patients. Dronedarone would be a valuable alternative when other options, already highlighted, fail or are contra-indicated.

We are therefore extremely concerned that the draft NICE guidance on dronedarone published on 24 December 2009, would deny us, as clinical experts, a safe, effective and promising new treatment option for appropriate patients with AF.

It is our view that denying dronedarone to UK patients will be extremely detrimental to those patients who would benefit and currently have no acceptable treatment option that is safe, symptom-controlling and cost-effective for the NHS. In the USA

and Europe dronedarone has already been approved and clinicians are beginning to gain experience with its use in AF patients. It is said to be "a leading option for younger patients who may need to be on long term therapy, and for older patients either unable to tolerate or who were already suffering liver, thyroid and lung issues due to amiodarone[1]".

We believe dronedarone should be recommended for use as a second line anti-arrhythmic for those patients in whom other anti-arrhythmic drugs have failed to control AF or are not tolerated and who are unable to be referred for catheter ablation treatment.

We would make this recommendation on the basis of the following observations:

1) Many patients suffer extremely debilitating symptoms as a result of atrial fibrillation despite good rate control. They must be considered for rhythm control.

2) Many patients find that currently available anti-arrhythmic drugs are either ineffective or not tolerated, (in some studies amiodarone had to be stopped because of side effects in 40% of patients).

3) While catheter ablation can be highly effective, it is an expensive therapy, and is not effective in everyone. Access to this treatment is inevitably limited.

4) Many patients prefer drug therapy to catheter ablation.

5) The CHADS2 risk stratification scheme (plus several other risk factors) can be used to identify patients at high cardiovascular risk (as was done in the ATHENA trial) for whom Dronedarone would be the best treatment option.

6) If dronedarone is effective in preventing AF and maintaining sinus rhythm its costs will compare favorably to those incurred by catheter ablation procedure. However, if dronedarone is not effective in preventing AF then it will be stopped and its costs to the NHS will be minimal.

7) If the draft NICE guidance on dronedarone (Multaq) were to remain unchallenged it would deny doctors and their patients of a first-in-class, first-in-a-generation treatment option and in so doing this guidance would go against providing choice to suitable patients, and thus undermine what is a fundamental principle in the NHS.

Signed by 187 UK arrhythmia clinicians and healthcare professionals

Dr	[redacted]	[redacted]	Consultant Cardiologist
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Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	GP & GPSI Cardiology
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist

Dr	[redacted]	[redacted]	Electrophysiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Clinical Lecturer in Cardiology
Dr	[redacted]	[redacted]	Consultant Cardiologist
Prof	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	
Dr	[redacted]	[redacted]	Past President, British Pacing & Electrophysiology Group (now HRUK
Dr	[redacted]	[redacted]	
Dr	[redacted]	[redacted]	Consultant Cardiologist

Dr	[redacted]	[redacted]	Chair Department of Cardiology
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Dr	[redacted]	[redacted]	Consultant Cardiologist
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Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	GP
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Mr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Reader in Medicine and Consultant Cardiologist
Prof	[redacted]	[redacted]	Consultant Cardiologist
Prof	[redacted]	[redacted]	Professor of Clinical Cardiolgy
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	
Dr	[redacted]	[redacted]	
Dr	[redacted]	[redacted]	Consultant Physician & Cardiologist
Dr	[redacted]	[redacted]	GPwSI Cardiology
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
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Prof	[redacted]	[redacted]	
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Dr	[redacted]	[redacted]	Consultant Cardiologist

Dr	[redacted]	[redacted]	Consultant Cardiologist
Prof	[redacted]	[redacted]	Consultant Cardiologist and Professor of Cardiovascular Medicine
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
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Prof	[redacted]	[redacted]	Consultant Cardiologist
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Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	GP
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	
Dr	[redacted]	[redacted]	Cardiac Electrophysiology
Dr	[redacted]	[redacted]	Consultant Cardiologist
Dr	[redacted]	[redacted]	Consultant Cardiologist
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	BHF Heart Function Nurse Specialist
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Senior Chief Technician
Mr	[redacted]	[redacted]	Arrhythmia sp nurse NNUH
Ms	[redacted]	[redacted]	BHF Arrhythmia Nurse Specialist
Ms	[redacted]	[redacted]	Heart Failure Specialist Nurse
Mr	[redacted]	[redacted]	Arrhythmia Nurse
Mr	[redacted]	[redacted]	Cardiology for PWSI
Ms	[redacted]	[redacted]	CNS - Cardiology
Ms	[redacted]	[redacted]	BHF Arrhythmia Clinical Nurse Specialist
Ms	[redacted]	[redacted]	Cardiac Physiologist
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Cardiac Rhythm Management Clinical Nurse Specialist
	[redacted]	[redacted]	Senior Nurse
Ms	[redacted]	[redacted]	Community Cardiology staff nurse
Mr	[redacted]	[redacted]	RGN
Ms	[redacted]	[redacted]	Cardiology Nurse Counsellor
Ms	[redacted]	[redacted]	Cardiology Nurse Counsellor
Dr	[redacted]	[redacted]	Paediatric Cardiologist
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Heart Rhythm Nurse Specialist
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse Practitoner
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Mr	[redacted]	[redacted]	Cardiac Specialist Nurse
Ms	[redacted]	[redacted]	Arrhyhtmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Heart Failure Specialist Nurse
Ms	[redacted]	[redacted]	BHF Care Coordinator
Ms	[redacted]	[redacted]	
Ms	[redacted]	[redacted]	BHF Arrhythmia Specialist Nurse
Mr	[redacted]	[redacted]	Arrhythmia Nurse

Ms	[redacted]	[redacted]	Senior Nurse/Arrhythmia Research Manager
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Mr	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	BHF Lead Nurse
	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Senior Cardiac Nurse Specialist
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Ms	[redacted]	[redacted]	Arrhythmia Nurse
Mr	[redacted]	[redacted]	Arrhythmia Nurse
Mr	[redacted]	[redacted]	
Ms	[redacted]	[redacted]	Senior Project Manager Cardiac and Stroke Network
Mr	[redacted]	[redacted]	Cardiology for PWSI
Mr	[redacted]	[redacted]	Chairman of Trustees GUCH Patients Association
Ms	[redacted]	[redacted]	
Mr	[redacted]	[redacted]	Berkshire East PCT
Mr	[redacted]	[redacted]	
Ms	[redacted]	[redacted]	
Mr	[redacted]	[redacted]	
Mr	[redacted]	[redacted]	
Mr	[redacted]	[redacted]	
Ms	[redacted]	[redacted]	Stroke Coordinator
Ms	[redacted]	[redacted]	
Mr	[redacted]	[redacted]	
Mr	[redacted]	[redacted]	

Professor Peter Clark
Chair, Appraisal Committee D
National Institute for Health and Clinical Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BD

Dear Professor Clark

Dronedarone for the treatment of Atrial Fibrillation

I am unable to respond via the internet consultation, so am writing this letter to you in the hope that you will enable my voice to be heard by the NICE Appraisal Committee.

I am writing to urge you to rethink your preliminary decision on the appraisal of Dronedarone. I am extremely concerned that the draft NICE guidance on Dronedarone published on 24 December 2009, would deny patients a safe, effective and promising new treatment option due to financial costs rather than also considering the burden of AF to the individual, their family and the NHS.

Denying UK patients Dronedarone on the NHS will be extremely detrimental. Leading arrhythmia specialists have described Dronedarone as an exciting and innovative treatment, while both Europe and the USA have already approved its use.

I believed that patients and doctors aspire to have a choice, including options for managing AF; current NICE guidance would go against providing choice and thus what is a fundamental principle in the NHS.

Extensive trials in both the UK and globally, have shown Dronedarone reduces the incidence of AF to a level at least equal to that of current anti-arrhythmic drugs available but with the incredible bonus of far fewer side effects than commonly experienced with current drugs. It is also a fact that Dronedarone is suitable for up to 55% of AF patients diagnosed with paroxysmal AF. As it has also been shown that the drug reduces hospitalisation and the incidence of stroke surely these alone offer considerable long-term savings?

I implore NICE to re-think. Take expert opinion from UK leading AF specialists who see the suffering and misery of AF on a daily basis. Please listen again to the patient representatives, who, as your report states, highlighted the desperate need for more options in managing AF without the feared side affects which can and are currently, an equal devil to AF.

I ask you to involve AFA representatives and arrhythmia specialist clinicians to present to the review committee on 24 February 2010 to hear the reality of AF and how this drug would bring relief, restoration of quality of life, reduce burden and costs on medical services and save lives.

As explained, in the spirit of equal opportunity, I would be grateful if you would ensure my views are considered by your colleagues considering whether patients have access to Dronedarone.

Yours sincerely