

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	A World Café Approach - Exploring the Future Vision of Oral Anticoagulants for Atrial Fibrillation (AF) Patients in Ireland
AUTHORS	Murphy , A; Brosnan, Stephen; McCarthy, Stephen; O'Raghallaigh, Paidi; Bradley, Colin; Kirby, Ann

VERSION 1 - REVIEW

REVIEWER	Job Harenberg Heidelberg University, Heidelberg
REVIEW RETURNED	03-Feb-2020

GENERAL COMMENTS	<p>This is a very interesting a specific approach to identify items for improvement of anticoagulant therapy in patients suffering from NVAf.</p> <ol style="list-style-type: none"> 1. The investigational approach is very worthwhile to be extended to a larger group of patients, <ol style="list-style-type: none"> a. to include patients on warfarin – not willing to change to NOACs – and thus to generate a control group b. inclusion of NOAC antidotes, c. fear of bleeding in patients and practitioners, and how to overcome them d. introduction of point of care methods for detection of NOACs f.e. in urine to improve patient's assurance of active anticoagulation, e. explanation of improvement of AC with NOACs by reduction of pharmaco-economic analyses, f. fear to forget medication by use of an App g. and other patient-physician interactive aspects 2. The participants showed be described for a better understanding 3. The personal experience of patients with other patient group 4. The INR values before changing – and for control patients before and after participation in a prospective larger study 5. The individual responses of the few patients are anecdotal and do not add substantial information to the literature 6. Some limitations are included into the discussion but many others need to be included (see above) 7. The title does not reflect the content of the manuscript. The wording Stake-holders needs to be clarified. At present it looks likely to the reader that the authors report on a meeting with a patient group. 8. The meeting was well organized but seems too low to draw conclusions with sound scientific basis.
-------------------------	---

REVIEWER	HAIBO ZHANG BEIJING ANZHEN HOSPITAL, CAPITAL MEDICAL UNIVERSITY CHINA
REVIEW RETURNED	06-Mar-2020

GENERAL COMMENTS	<p>Thank you for the opportunity to review this manuscript describing an interesting discussion about AF management with World Café approach. Warfarin has been used in AF patients as stroke prevention for many years but still has some big problems, such as blood test for INR regularly, bleeding risk, interactions with other medicines, et al. NOACs have been proved no need for INR monitoring test and recommend by many guidelines. But their adoption has been slower in some countries, like Ireland and China. There are indeed some barriers like costs, clinician's lack of adherence to the guidelines for anticoagulant prescriptions, lack of the integrated care systemic, shortage of care providers. The innovation of this article is the describe of the real world problems around the AF anticoagulation management.</p> <p>It should be noted that, almost everyone believe that the advanced technologies, like wearable trackers, will bring AF patients more effective management because it may provide the doctors more follow up data in very short time. However not all doctors like this approach, just as this multi-stakeholder focus group described. The new technologies place additional workloads on the busy doctors and clinics as they increase the accessibility of clinicians to patients and patients to clinicians. As a clinician I totally agree with this point. The redesign of the AF medical pathway should include moving AF treatment out of the hospital and into the community pharmacy. AF treatment will last life long time and requires multiple healthcare professionals. In addition, improvements in patient education and health literacy will also improve doctor-patient communications and AF management results.</p> <p>In summary, this paper concluded that the evidence and guidelines recommend is one thing, the detailed management system is another thing. Significant operationalisation issues and barriers to effective management still persist. The results of this study can be used to inform clinical and policy initiatives to generate evidence-based treatment-pathways that will bring more effective management for so many AF patients.</p>
-------------------------	---

REVIEWER	Shahzad Salmasi University of British Columbia Canada
REVIEW RETURNED	20-Apr-2020

GENERAL COMMENTS	<p>Introduction:</p> <p>first paragraph: "can used" should be changed to "can be used".</p> <p>Lines 41-42: I think what the authors mean is that AHA ACC have provided guidelines on use of NOACs not just any clinical guidelines.</p> <p>Lines 45-50: Perhaps it would be good to provide actual NOAC prescribing rates in Ireland if such data is available.</p>
-------------------------	--

	<p>Much of the introduction is not relevant to the research questions. While comparison of warfarin versus NOACs is important, the differences of these medications is not the main reason for their underprescribing. The main reason is fear of bleeding which applies to both.</p> <p>Lines 52-57: Shared decision making (which also involved communication and education) is recommended by all guidelines not just NICE.</p> <p>From the objective, I cannot tell if this paper is going to provide patient perspective, clinician perspective or the perspective of other stakeholders on the issue.</p> <p>Overall, introduction is very lengthy and out of focus. Not clear from the introduction what aspect of NOAC therapy is the focus of the study: the decision making? the underprescribing? poor adherence/persistence? the management of adverse effects? deviation from guidelines? lack of access? lack of clinician knowledge? Absence of AF specialized clinics? What is the issue exactly that this study is trying to address?</p> <p>Very little is stated about how AF is currently managed in Ireland which makes it hard to put the findings in context. What are the main challenges currently faced in Ireland with regards to OAC use that this study is trying to address?</p> <p>Methods: Why was the focus group not audiotaped? If participants were all clinicians why were they recruited from department of Economics? Abstract says 10 participants but Methods says 11. The number of participants in the study should be in results not methods. Did you have an interview guide? Please refer to the CONSORT checklist and ensure all items have been reported in your manuscript. Please submit your completed checklist to the journal. Unclear what the authors mean by "transcribed" in step 1 of the analysis since no audio files of the focus group were available to be transcribed. Why was only one focus group? How did the authors ensure they have captured all perspectives with such small sample size? What was the sampling strategy? Setting is not clear. Was this done at a conference? at a university campus? what was the rationale for the setting chosen? Why was the patient not one of the participants?</p> <p>Not clear from the methods what aspect of NOAC therapy is of interest in this study: the prescribing decision making? the keeping patients on therapy for long time? the switching between VKA and NOAC? the management of adverse effects? Reasons for deviation from guidelines? The interruption of NOACs periprocedure? Providing an interview guide and revision of the objective should help with this.</p> <p>From supp table 4 it seems there were 4 rounds. Did all participants participate in all 4 rounds? Please include the round topics in the methods so the reader can be informed of the 4 main aspects of OAC therapy that were discussed</p>
--	--

	<p>and were the focus of the study,</p> <p>Results: Number of participants should be stated here. Time for the overall focus group discussion should be reported. Was this a 5 hour discussion or a half hour chat?</p> <p>Representative quotes should be provided for each theme, preferably in a table format.</p> <p>Characteristics of the participants should be reported. How many years of experience providing care to AF patients? How many years of schooling? There needs to be a table for this.</p> <p>Introduction was more focused on NOACs and their underuse, the overall theme that participants were asked to discuss was very broad and results are not focused on NOACs. Again, manuscript is not focused and the purpose of the study is unclear because of these discrepancies.</p> <p>Methods says participants involved academics but theme 1 it is stated that "both patients and academics" identified a break down in communication. Were there patient participants?</p> <p>Theme 1.2: it is unclear what is meant by integrated medical pathway.</p> <p>1.2c: AF treatment is currently guided by ECG results, INR, validated bleeding and stroke scores and clinical guidelines. I am assuming the same is true in Ireland and hence am not sure what the participant meant by "AF management should be evidence-based in the future"</p> <p>1.3: provide examples of what exact technology the participants referred to (smart watches to detect AF? tests to detect OAC levels in blood? Technology to ask for a refill online? etc...). Please refrain from using generic sentences such as "potential benefits of technology for transforming the AF treatment process including increased accessibility, improvements in efficiency and increased diagnosis" and explain how exactly they envisioned such improvements and with what technology.</p> <p>Discussion: 2nd paragraph: The cost effectiveness of routine screening by ECG and validity of smart watches is actually not evident and still under investigation not "evident"</p> <p>Not clear how complexities of OAC therapy can complicate preventive healthcare given that in the results this "preventive healthcare" was primarily focused on screening and detecting AF.</p> <p>3rd paragraph: This is the first time the presence of a cardiologist is mentioned.</p> <p>"Focus groups may also be less appropriate for exploring sensitive and private topics in detail, given the interactive nature of the approach" ...but your topic was not sensitive, this therefore does not apply. Please avoid the use of generic limitation sentences that do not apply to your study.</p>
--	--

	<p>Rate of uptake should be mentioned in results not discussion. Discussion is not the place for new study related information</p> <p>"The results of this study can be used to inform clinical and policy initiatives to generate a fit for purpose, evidence-based treatment-pathway(s) that will ensure the right patient gets the right care at the right time" how does it exactly do that? please avoid the use of generic, sound-good sentences that are not informative</p>
--	---

VERSION 1 – AUTHOR RESPONSE

<p>Reviewer: 1 Job Harenberg</p> <p>This is a very interesting a specific approach to identify items for improvement of anticoagulant therapy in patients suffering from NVAf.</p> <p>1. The investigational approach is very worthwhile to be extended to a larger group of patients,</p> <ol style="list-style-type: none"> a. to include patients on warfarin – not willing to change to NOACs – and thus to generate a control group b. inclusion of NOAC antidotes, c. fear of bleeding in patients and practitioners, and how to overcome them d. introduction of point of care methods for detection of NOACs f.e. in urine to improve patient's assurance of active anticoagulation, e. explanation of improvement of AC with NOACs by reduction of pharmaco-economic analyses, f. fear to forget medication by use of an App g. and other patient-physician interactive aspects 	<p>Re 1a: We thank the reviewer for their comment on extending the analysis to larger group and concur this would add to the study. In the submission we outlined the difficulties experienced with recruitment. We have now included this as a suggestion for further research.</p> <p>Re 1 b-g: With regards to the inclusion of additional sub topics: the study adopted a World Café Approach, the themes detailed in the analysis emerged from the discussion, that is to say they were not prescribed.</p> <p>The topics listed by the reviewer are all very important and relevant issues in the area of anticoagulation and would need to be addressed in separate analyses. Our study is the first of its kind in an Irish setting by bringing together multi-stakeholders to begin exploring the current and future management of anticoagulation patients while contributing to the development of clinical guidelines etc.</p> <p>We recognise that the study is just a starting point and indicate further investigation is warranted to examine the representativeness of the results as well as the feasibility and operationalisation of the issues. The conclusion has been amended to reflect this. The method chosen, World Café, reflect this also. As previous research demonstrates this approach can be used to explore the impact of existing and potential issues As previous research demonstrates it can be used to explore the impact of existing and emerging issues, for example in the case of pharmacy practices in Ireland (Kavanagh et al 2020) and to demonstrate how a small number of user representatives (i.e. patient personas) can support consideration of larger, more diverse populations (Putnam et al 2009).</p> <p>Putnam C, Rose E, Johnson EJ, Kolko B.</p>
---	--

	<p>Adapting user-centered design methods to design for diverse populations. <i>Information Technologies & International Development</i>. 2009;5(4).</p> <p>Kavanagh, O. N., Moriarty, F., Bradley, C., O'Hagan, J., Stack, G., & Kelly, D. (2020). More than coffee—a World Café to explore enablers of pharmacy practice research. <i>International Journal of Pharmacy Practice</i>.</p>
2. The participants showed be described for a better understanding	We recognize the motivation behind the reviewer's comment here with regards to greater detail on the participants nevertheless their anonymity needs to be preserved. We have included additional information in an additional Supplementary Table (no 5).
3. The personal experience of patients with other patient group	As indicated previously we outlined the difficulties experienced with recruiting patients and have acknowledged this as a limitation in the paper.
4. The INR values before changing – and for control patients before and after participation in a prospective larger study	Collecting clinical data as suggested by the reviewer is beyond the scope of the current study.
5. The individual responses of the few patients are anecdotal and do not add substantial information to the literature	As indicated previously we outlined the difficulties experienced with recruiting patients and have acknowledged this as a limitation in the paper. A unique feature of the paper is the opportunity for dialogue between multiple stakeholders. We acknowledge this approach results in a wide rather than a deep breath of information. As indicated above this paper aims to serve as a starting point and future research should further explore each stakeholder group in further detail. This is now included in the discussion section.
6. Some limitations are included into the discussion but many others need to be included (see above)	We concur with the reviewer and have added to the text on limitations.
7. The title does not reflect the content of the manuscript. The wording Stake-holders needs to be clarified. At present it looks likely to the reader that the authors report on a meeting with a patient group.	<p>The title has now been changed: A World Café Approach - Exploring the Future Vision of Oral Anticoagulants for Atrial Fibrillation (AF) Patients in Ireland.</p> <p>As outlined in the methods section the focus group consistent of representatives from multiple stakeholder groups: patients, pharmacists, doctors etc. Further details on the group are now presented in Supplementary Table 5.</p>
8. The meeting was well organized but seems too low to draw conclusions with sound scientific basis.	We acknowledge the reviewer's comment here and have added to the text in the conclusion for greater transparency and in recognition of its limitations
Reviewer: 2 HAIBO ZHANG Thank you for the opportunity to review this manuscript describing an interesting discussion	We thank Reviewer 2 for their comments and their recognition of the innovation of the article. We are glad the experiences captured in the

<p>about AF management with World Café approach. Warfarin has been used in AF patients as stroke prevention for many years but still has some big problems, such as blood test for INR regularly, bleeding risk, interactions with other medicines, et al. NOACs have been proved no need for INR monitoring test and recommend by many guidelines. But their adoption has been slower in some countries, like Ireland and China. There are indeed some barriers like costs, clinician's lack of adherence to the guidelines for anticoagulant prescriptions, lack of the integrated care systemic, shortage of care providers. The innovation of this article is the describe of the real world problems around the AF anticoagulation management.</p> <p>It should be noted that, almost everyone believe that the advanced technologies, like wearable trackers, will bring AF patients more effective management because it may provide the doctors more follow up data in very short time. However not all doctors like this approach, just as this multi-stakeholder focus group described. The new technologies place additional workloads on the busy doctors and clinics as they increase the accessibility of clinicians to patients and patients to clinicians. As a clinician I totally agree with this point. The redesign of the AF medical pathway should include moving AF treatment out of the hospital and into the community pharmacy. AF treatment will last life long time and requires multiple healthcare professionals. In addition, improvements in patient education and health literacy will also improve doctor-patient communications and AF management results. In summary, this paper concluded that the evidence and guidelines recommend is one thing, the detailed management system is another thing. Significant operationalisation issues and barriers to effective management still persist. The results of this study can be used to inform clinical and policy initiatives to generate evidence-based treatment-pathways that will bring more effective management for so many AF patients.</p>	<p>study are representative of international trends.</p>
<p>Reviewer: 3 - Shahrzad Salmasi</p>	<p>We wish to thank Reviewer 3 for their detailed and thorough comments and suggestions on our paper. Where possible we have amended the text to take onboard their feedback/suggestions.</p>
<p>first paragraph: "can used" should be changed to "can be used".</p>	<p>This typo has been amended.</p>
<p>Lines 41-42: I think what the authors mean is that AHA ACC have provided guidelines on use of</p>	<p>Yes, text has been amended so this is clearer.</p>

NOACs not just any clinical guidelines.	
Lines 45-50: Perhaps it would be good to provide actual NOAC prescribing rates in Ireland if such data is available.	The introduction has been revised and numbers prescribed NOACs and shift in expenditure on NOACs and warfarin has been added.
Much of the introduction is not relevant to the research questions. While comparison of warfarin versus NOACs is important, the differences of these medications is not the main reason for their underprescribing. The main reason is fear of bleeding which applies to both.	In light of the reviewers comments we have amended the introduction, with a clearer objective: This paper is a reflection of some key challenges facing AF patients and healthcare professionals prescribing and managing AF treatment, identified using a World Café methodology via a multi-stakeholder focus group. Further context on NOAC uptake in Ireland has been provided, as Reviewer 2 indicated NOAC uptake has been slower in some countries such as Ireland and China. We are cognisant of the BMJ Open's broad readership and therefore have retained some general background on NOACs/ warfarin for the non-specialist reader.
Lines 52-57: Shared decision making (which also involved communication and education) is recommended by all guidelines not just NICE.	Text amended to reflect this
From the objective, I cannot tell if this paper is going to provide patient perspective, clinician perspective or the perspective of other stakeholders on the issue.	We acknowledge the reviewers comment and have amended the text to indicate it is multiple perspectives.
Overall, introduction is very lengthy and out of focus. Not clear from the introduction what aspect of NOAC therapy is the focus of the study: the decision making? the underprescribing? poor adherence/persistence? the management of adverse effects? deviation from guidelines? lack of access? lack of clinician knowledge? Absence of AF specialized clinics? What is it the issue exactly that this study is trying to address? Very little is stated about how AF is currently managed in Ireland which makes it hard to put the findings in context. What are the main challenges currently faced in Ireland with regards to OAC use that this study is trying to address?	The introduction has been amended with some unnecessary text removed; inclusion of greater context for Ireland and a clearer description of the scope of the paper are included.
Methods: Why was the focus group not audiotaped?	The focus group was not audio recorded, instead there were two scribes to ensure accurate scribing. The authors considered audio recording the discussion however decided it would have a potentially inhibiting effect. While such an effect may have diminished with exposure, there would too have been technical difficulties in recording the breakout group discussions and the plenaries. Our approach is consistent with Eaton et al (2019) who suggests using scribes provides comparable data to transcribing raw data but

	<p>is economically superior.</p> <p>Eaton, K., Stitzke, W.G.K., Ohan, J.L. (2020) Using Scribes in Qualitative Research as an Alternative to Transcription. TWR The Qualitative Report. 24 (2) Available at: https://nsuworks.nova.edu/cgi/viewcontent.cgi?article=3473&context=tqr</p>
If participants were all clinicians why were they recruited from department of Economics?	The focus group was organized by the authors as part of ongoing collaborative research on anticoagulants involving academics from the Department of Economics and the Department of General Practice in an Irish university. Clinicians were recruited by authors from these two departments from their networks, local research groups, hospitals, primary care etc.
Abstract says 10 participants but Methods says 11. The number of participants in the study should be in results not methods.	We apologies for typographical errors. The description of the participants is now consistent throughout the paper.
Did you have an interview guide?	We did not conduct interviews. We adopted the World Café approach and the schedule including topics is included on the revised Supplementary Table 4.
Please refer to the CONSORT checklist and ensure all items have been reported in your manuscript. Please submit your completed checklist to the journal.	The CONSORT checklist is preliminary used for randomised control trials (http://www.consort-statement.org/) so not applicable here. We do acknowledge the need for a quality checklist and have now included the SRQR. This is referred to in the manuscript and provided on a Supplementary Table.
Unclear what the authors mean by "transcribed" in step 1 of the analysis since no audio files of the focus group were available to be transcribed.	There were two scribes at the focus group, they scribed the dialogue; this clarification has been made in the text on Table 1 also.
Why was only one focus group? How did the authors ensure they have captured all perspectives with such small sample size? What was the sampling strategy?	A convenience sampling strategy was adopted – see additional details in methods section. We accept not all perspectives are captured with a small sample size – this is explored in the limitations section and the discussion has been revised to reflect this.
Setting is not clear. Was this done at a conference? at a university campus? what was the rationale for the setting chosen?	<p>The focus group was not part of a conference; it was a dedicated meeting of the invited participants. The meeting was held in a neutral venue on a university campus. The location was chosen owing to its central and convenient location for participants - an approach advocated by Breen (2006).</p> <p>Rosanna L. Breen (2006) A Practical Guide to Focus-Group Research, Journal of Geography in</p>

	Higher Education, 30:3, 463-475, DOI: 10.1080/03098260600927575
Why was the patient not one of the participants?	Yes the patient was a participant. See Supplementary Table 5
Not clear from the methods what aspect of NOAC therapy is of interest in this study: the prescribing decision making? the keeping patients on therapy for long time? the switching between VKA and NOAC? the management of adverse effects? Reasons for deviation from guidelines? The interruption of NOACs periprocedure? Providing an interview guide and revision of the objective should help with this.	Our study explores the current situation and future vision for managing AF patients with oral anticoagulants. It is the first of its kind in an Irish setting and is an important starting point to developing clinical guidelines in an Irish setting. Nevertheless we recognise that the study is just a starting point and indicate further investigation is warranted to examine the representativeness of the results as well as the feasibility and operationalisation of the proposals. The topics listed by the reviewer are all very important and relevant issues in the area of anticoagulation and would need to be addressed in separate analyses. Supplementary Table 4 now lists the topics per round. They were purposefully broad so as to encourage and enable discussion, as per the World Café approach. This approach assumes expertise in this area in order to explore complexities within their own profession through conversation.
From supp table 4 it seems there were 4 rounds. Did all participants participate in all 4 rounds? Please include the round topics in the methods so the reader can be informed of the 4 main aspects of OAC therapy that were discussed and were the focus of the study,	Additional details on focus group, topics and participation is now provided in the revised Supplementary Table 4 and in the methods section.
Results: Number of participants should be stated here.	Details of the participants are now moved to Results section as recommended by the reviewer.
Time for the overall focus group discussion should be reported. Was this a 5 hour discussion or a half hour chat?	Supplementary Table 4 provides a detailed breakdown of the schedule for the day.
Representative quotes should be provided for each theme, preferably in a table format.	Tables 2 and 3 provide representative quotes for each theme.
Characteristics of the participants should be reported. How many years of experience providing care to AF patients? How many years of schooling? There needs to be a table for this.	We have provided additional details on the participants in Supplementary Table 5. As mentioned in the limitations section the participants were from a similar geographical location, providing any further information (such as that suggested by the reviewer) would jeopardise the anonymity of the participants.
Introduction was more focused on NOACs and	As indicated above the introduction has been

their underuse, the overall theme that participants were asked to discuss was very broad and results are not focused on NOACs. Again, manuscript is not focused and the purpose of the study is unclear because of these discrepancies.	redrafted.
Methods says participants involved academics but theme 1 it is stated that "both patients and academics" identified a break down in communication. Were there patient participants?	Yes there was one patient participant; this comment was dealt with above.
Theme 1.2: it is unclear what is meant by integrated medical pathway.	A definition has been provided and terminology is changed to "medical care pathway" for better understanding.
1.2c: AF treatment is currently guided by ECG results, INR, validated bleeding and stroke scores and clinical guidelines. I am assuming the same is true in Ireland and hence am not sure what the participant meant by "AF management should be evidence-based in the future"	The structure of the sentence in 1c has been rearranged to more accurately capture the intended sentiment.
1.3: provide examples of what exact technology the participants referred to (smart watches to detect AF? tests to detect OAC levels in blood? Technology to ask for a refill online? etc...). Please refrain from using generic sentences such as "potential benefits of technology for transforming the AF treatment process including increased accessibility, improvements in efficiency and increased diagnosis" and explain how exactly they envisioned such improvements and with what technology.	The results provided are based on the discussion within the focus group, wherein no specific device or application was explicitly discussed, rather the participants discussed technology at a macro level. The text has been amended to reflect this and contextualize the results provided.
Discussion: 2nd paragraph: The cost effectiveness of routine screening by ECG and validity of smart watches is actually not evident and still under investigation not "evident"	Text has been amended.
Not clear how complexities of OAC therapy can complicate preventive healthcare given that in the results this "preventive healthcare" was primarily focused on screening and detecting AF.	We have provided additional text to this sentence for clarity.
3rd paragraph: This is the first time the presence of a cardiologist is mentioned.	The text indicates specialisms; the clinician with cardiology expertise is not a cardiologist. The addition of Supplemental Table 5 provides additional information on the participants.
"Focus groups may also be less appropriate for exploring sensitive and private topics in detail, given the interactive nature of the approach" ...but your topic was not sensitive, this therefore does not apply. Please avoid the use of generic limitation sentences that do not apply to your study.	This text has been removed
Rate of uptake should be mentioned in results not discussion. Discussion is not the place for new	As per the previous suggestion details on the participants is moved to the results section, this

study related information	includes the response rate. We have retained reference to this low response rate in the discussion when discussing the limitations.
"The results of this study can be used to inform clinical and policy initiatives to generate a fit for purpose, evidence-based treatment-pathway(s) that will ensure the right patient gets the right care at the right time" how does it exactly do that? please avoid the use of generic, sound-good sentences that are not informative	The text in the discussion has been amended as recommended.

VERSION 2 – REVIEW

REVIEWER	Harenberg Heidelberg University, Germany
REVIEW RETURNED	14-Jun-2020

GENERAL COMMENTS	The important comments of the reviewers were incorporated into the revised version of the manuscript. One minor issue: Please change "AF" to "NVAF" throughout the manuscript.
-------------------------	--