Formative research to inform an education intervention on stroke prevention for a randomized control trial to improve treatment with anticoagulants in patients with atrial fibrillation

Interview Guide for Patients

I. Introduction

Hello, thank you for taking time out of your busy schedule to speak with me today. My name is [Name] and I will be moderating our conversation today.

We are interested in hearing your reactions to a draft educational packet of information on stroke prevention geared toward people with AFib. We would like your feedback about different aspects of these materials including their attractiveness, readability, acceptability and persuasiveness. During today's interview, we will review a letter to patients with AFib, an informational sheet, an educational brochure, and a pocket card. All these materials are currently in draft form. Your input at this early stage in the development process will be extremely valuable in helping us to develop the best materials possible for people with AFib.

There are no right or wrong answers to the questions I will ask, only opinions. Please feel free to share your candid thoughts and opinions. It's very helpful to hear your point of view.

If you agree, I would like to audio record the interview because I want to make sure I don't miss any of your comments. But, I want to assure you that everything you say will be confidential. If you don't want to the interview audio recorded, I will take detailed notes during the interview instead. Your name will not be written in the transcript produced from the recording. Because you have AFib and because we are recording the interview, the information is considered protected health information. All recordings will be destroyed after we publish the findings. Additionally, none of this information will be shared with your healthcare providers.

Participating in this interview is voluntary. The risks of taking part are very low. You are not expected to face any physical, social, or psychological risks. You can choose not to answer a question or you can stop participating at any time. This will not affect your health care in any way and will not cause any penalties or loss of benefits. All participants will receive $150.00 for taking part in the discussion. Information about who to contact if you have questions about the study, including the Duke IRB, can be found in the informational sheet provided to you.

Please keep in mind that if you do not feel comfortable answering a specific question, you do not have to.

Is it okay if I turn on the audio recorder now?

[If Yes, begin audio recording now.]

[If No, begin taking detailed notes.]

OK -- Let's get started!

II. Introduction.

Now I'd like to remind you about the purpose of the larger study. The purpose of that study is to find out if an educational intervention on stroke prevention can improve treatment with oral anticoagulants in patients with AFib.

To identify the patients who will receive the education materials, health plans will review the electronic health records of patients' with AFib, with which they already have access to assess the patients' quality and completeness of care. They will use those records to identify patients who might be at risk for stroke and who might benefit from taking oral anticoagulants. At first, they will not see the patient's names, as all information will be stored under a code. Eventually though, they will identify the patients by name so they can send those patients the letter and education materials, all in one packet. We're reviewing that packet today.

[Interviewer: Here is the detailed information about the approach, if questions are asked: health plans all contribute de-identified claims data to a central database to allow for safety monitoring. Health plans that already use patient data to assess quality and completeness of care, and the larger study would be another way of looking at those data. The purpose of looking at the database is that the approach can identify safety signals more quickly by using a centralized database. Only the health plans have the unique key to re-identify these patients and mail to them.]

III. Reaction to the draft contact letter

Now I'd like you to imagine that you are at home, and you have just picked up the mail from your mailbox. While sorting through your mail, you find this envelope [Hand out envelopes]. Let's us talk first about this envelope. Remember, all the document we will review today are in draft. We look to you to help us to improve the content.

<u>The "look" of the envelope</u>

1. What was the first thing you noticed when you looked at the envelope? That is, what first caught your eye?

    a. What words come to mind to describe the envelope?
    b. How "inviting" is the envelope?
    c. If you received this envelope in the mail, what would you likely do next? (Open it right away? Wait for later? Throw it away? Other?) Why?
    d. How, if at all, would you change the look of the envelope to make people with AFib more likely to open it?

        1. Who should be listed as the organization in the return address? (Inform participants of the organizations involved in the intervention and ask for feedback on which group would be best to use for the return address and reasons why). The options are Duke University, Harvard Medical Care, The Clinical Trials Transformation Initiative, or the FDA.
        2. What logo should be listed? (Show participants the logo options and ask for feedback on which would be best to use and reasons why)

The "look" of the letter

Now please open the envelope and glance at the letter.

2. What is the first thing you noticed when you looked at the letter?

    a. What words would you use to describe the look of the letter?
    b. How attractive or inviting do you think it is?
    c. What suggestions do you have for improving the look of the letter?

The content of the letter: Broad Brush impressions

Now take a few minutes to read the letter and then we will discuss it. Feel free to circle or mark-up anything on the letter that you want to talk about during our discussion.

3. What are your top-of-mind reactions to the letter?

4. Imagine that you are home and you just finished reading this letter. **Think aloud for a moment**: Tell me all your thoughts – good, bad and indifferent.

5. What do you like about the letter?

6. What don't you like about it?

7. What, if anything, is confusing about it?

8. Is there anything offensive or annoying about the letter? If so: What? What can be done to fix this?

9. How readable is it? What would you say could make it more readable?

The content of the letter: A detailed look

10. What would you say is purpose of the letter? That is, what action does the letter suggest you take?

    a. How clear is that message?
    b. How persuasive is it?
    c. What, if anything, do you think would make it more persuasive?

11. What is your reaction to the "sender" of the letter? [Note: The sender is their health plan/insurance company.]

Additional suggestions for changes to the letter

12. What are some of the other parts of the letter that you circled or underlined that you'd like to bring up?

13. What else do you think could be different or better about this letter?

   a. Is there anything that could be left out of this letter?
   b. Is there anything you think should be added?

14. If someone with AFib received this letter, how do you think they'd react to it? How likely do you think they would be to take action the letter suggests?

    a. What would make them *want* to take this action?
    b. What would make them NOT want to take this action? How could those barriers be overcome?
    c. What, if any, concerns would they have if they received this letter in the mail?

15. [Ask depending on recruitment for FGD] What about patients with AFib who are not part of patient forums. How do you think they'd response when receiving this letter?

Now let us talk about the informational sheet included with the letter. This is a document authored by Duke University and Harvard Medical School. They are responsible for the larger study. This document includes additional information that they want people with AFib to know.

The content of the informational sheet: Broad Brush impressions

16. What are your top-of-mind reactions to this document?

17. Imagine that you are home and you just finished reading this document. **Think aloud for a moment**: Tell me all your thoughts – good, bad and indifferent.

18. What do you like about the document?

19. What don't you like about it?

20. What, if anything, is confusing about it?

21. Is there anything offensive or annoying about this document? If so: What? What can be done to fix this?

22. How readable is it? What would you say could make it more readable?

The content of the informational sheet: A detailed look

23. What would you say is purpose of the document? That is, what action does the piece suggest you take?

    d. How clear is that message?
    e. How persuasive is it?
    f. What, if anything, do you think would make it more persuasive?

24. What is your reaction to the "writer" of the document? (if negative, what could make this better?)

25. What is your reaction to the graphic that is included in the document?

   a. What do you like about it?
   b. What don't you like about it?
   c. What, if anything, is confusing about it? What suggestions do you have to make the graphic clearer?

IV. Patient identification

Now I want us to talk about how patients are identified to receive the letter and educational materials. As you will recall, health plans will review electronic health records of patients' with AFib, with which they already have access to assess the patients' quality and completeness of care. They will use those records to identify patients who might be at risk for stroke and who might benefit from taking oral anticoagulants.

26. How do you think patients with AFib will feel about their health plan (health insurance company) accessing their electronic health records to identify whether they are at risk of stroke? (Probe: acceptable or not acceptable and why; feel an invasion of privacy or health plans have a right to access this information?)
    a. What would <u>*you*</u> think about this?

27. How do you think patients with AFib would feel about being identified as someone at risk for stroke through a letter in the mail by someone other than their health care provider? (Probe: acceptable or not acceptable for a health plan to tell person she/he is at risk and why; acceptable or not to receive individual health information about being at risk through the mail versus in person at doctor visit)

28. How do you think patients with AFib would feel about receiving a letter from their health plans suggesting that they talk to their doctor about taking OACs? (Probe: health plans perceived as an authority on health care?)

V. Reaction to the educational brochure

Now I'd like you to look at this educational brochure for patients with AFib. Take a few minutes to read it, and feel free to circle or underline anything you would like to talk about later in our discussion.

<u>Overall reactions to the educational brochure</u>

29. What are your overall reactions to <u>the look of</u> this brochure?

    a. How "inviting" is it?
    b. How, if at all, would you change the look of this brochure?
    c. What, if anything, could be done to make the brochure more attractive?

30. What are your overall reactions to this brochure?

    a. What did you like?
    b. What didn't you like?
    c. Was there anything confusing? Annoying?
    d. How believable is the information to you?
    e. Is there any information that people with AFib might not find believable?

    f. What is the tone of this piece? What do you think the tone should be?

31. What information in the brochure do you think patients with AFib would already know?

    a. What might be new information here to patients with Afib?
    b. Is there any information that patients with Afib might think _*is not believable?*_
    c. How persuasive is the message here to patients with AFib to talk to their provider about OACs?

32. What are the main messages this brochure is trying to get across?

    a. How clearly do these message come across [review message by message]?
    b. How persuasive do you find these messages?
    c. How could this piece be more persuasive?
    d. In general, how credible is this piece? How likely would you be to act on it? What might keep you from acting on it?

Section by section reactions

Now let's go through this piece section by section

[As appropriate, for each section ask]:

33. What are your general reactions about this section? (open-ended first, then probe):

    a. What do you like about it?
    b. What don't you like about it?
    c. What do you think would be new information for patients with AFib?
    d. What do you think should definitely be kept in this section?
    e. What do you think should be taken out of this section?
    f. What other changes would you like to see in this section?

34. Ultimately, what is the most important piece of information to include in this brochure?

Pocket card

Now let's look at the last educational piece. This information will eventually be turned into a pocket card and provided in the packet for patients. [Note: focus the discussion on the questions at the bottom of the pocket card – the risk calculation score at the top of the card cannot be changed; plus these risk questions were explored earlier in the FGD.]

35. What do you think are the main messages this pocket is trying to get across? [After open-ended question: Tell participants the main message: To calculate their CHADS-VASc score and take this card with them to their doctor to see if anticoagulants might beneficial for them.]

    a. How clearly does that message come across?
    b. How persuasive do you find that message?
    c. How could this piece be more persuasive?

d. In general, how credible is this piece? How likely would you be to act on it? What might keep you from acting on it?

VI. Web-based materials and access

The future study will also have a website that patients can access to learn more information about AFib and oral anticoagulants. I will now ask you questions about that website.

36. How do you think patients with AFib typically get information about AFib? (providers, brochures, websites, forums; if varies, what type of patients might get information from the different sources). Which source do you think is the preferred route?

37. If a website address was included in the education materials above, do you think patients with AFib would be interested or uninterested in checking it out? Why? What might motivate patients to go to the website?

38. What information would patients with AFib look for in a website?

39. Investigators of the future study might ask for patients who visit the website to take a survey about the educational materials they received in the mail. Do you think patients with AFib will be interested or uninterested in taking the survey? Why? What might motivate patients to take the survey?

40. As a last question, the investigators of the future study might send a postcard to patients asking patients to send it back if they would like to receive more written materials about AFib and the use of oral anticoagulants. What do you think patients with AFib will do with that postcard? Why?

VII. Closing

I'd like to thank you for taking the time to participate in the interview and for providing your feedback on the letters and educational materials. Your input will be really valuable as we continue to develop and refine materials for this educational intervention for patients with AFib.

Is there anything else you would like to say about making this education intervention for people with AFib the best that it can be?

Thank you.