FOCUS GROUP GUIDE

Introductions

Hello, my name is Uby, and I will be your facilitator for today's session. Thank you all for being here and agreeing to participate in our focus group discussion; before we begin, here are a few things you should know.

First, this session is being recorded. This recording will allow us to transcribe and interpret the ideas that are being shared today. If you choose to have your camera on, you can indicate that you want to speak by raising your hand. You can also turn off your camera if you feel more comfortable and use the 'Raised hand' emoji to indicate that you want to speak.

Second, your participation in this discussion is voluntary. If at any point, you come across any prompts or questions that you are uncomfortable with, you can choose not to answer them. You can also withdraw from this study at any time by letting me know in writing.

We are going to share some personal experiences today and I will try to go around the room to make sure everyone gets the opportunity to speak, so to protect the confidentiality of everyone here, I am asking that we avoid discussing anything shared in this session with anyone else or anywhere else.

Finally, to thank you for your time, you will all receive a $50 Amazon gift card. E-gift cards will be delivered to your emails tomorrow while physical gift cards will be mailed to your addresses tomorrow. You will receive it as you have indicated in the response to this invitation, however, if you would like to receive it in a different way than you had previously indicated, please let me know.

With that,

I'd like us to start by sharing our individual experiences with stroke. Each one of you is here for one of the following reasons.

- *Either you have experienced a stroke.*
- *You are at risk of a stroke, or*
- *You are the decision maker, friend or family member of someone who falls into one of those two categories*

We will go around the room and you can share as much or as little as you feel comfortable sharing. Would anyone like to go first/Let us start with…

Thank you all for sharing.

This session is about the way that people provide consent to participate in clinical trials. Clinical trials are studies or experiments in which different treatments are compared to each other to figure out which one is best.

We try to get permission to include someone in a clinical trial; it shouldn't happen without their knowledge or against their wishes. This is what we mean by consent. Typically, consent happens when an eligible

patient is given a document called a consent form that includes all the important details about a study. They then choose whether to participate or not after reviewing that document and discussing with their doctors and the research team. You gave consent to participate in this focus group. Ideally, consent should be informed, unrushed, and uncoerced.

For some slow progressing conditions like cancer, patients can review the information about a clinical trial at their leisure, think it over, talk it over with family and friends, and take as much time as they need to ask questions and make a decision they feel comfortable with. For an emergency condition like stroke, this kind of approach is often not possible. Stroke is an emergency condition where the brain is not getting blood and begins to die. Treatments for stroke need to be given as soon as possible to save as much of the brain as possible, so consenting to participate in a clinical trial for stroke has to be rushed and sometimes waived. Also, conditions like stroke often make people unconscious, or unable to speak or understand; these problems mean they are usually unable to read a consent form and give their own consent to participate in a clinical trial. Finally, because of the emergency nature of the situation, patients can feel pressured to sign forms when they are presented by the medical team. So, stroke provides some problems to getting consent from patients.

At the same time, we think that clinical trials are important to advance the care of patients with stroke and other emergency conditions. Therefore, we are trying to figure out how we can improve the consenting process for research trials for emergency conditions like stroke.

Does that make sense?

Does anyone have any questions before we begin?

1. Our first question will be about the process of giving consent.
   As we described earlier, the standard approach is when an eligible patient is given a document called a consent form that includes all the important details about a study. The patient can then decide if they want to participate in that study and document their consent by signing the consent form.

    a. Has anyone been asked to give consent to participate in a clinical trial?
    b. Can you tell us about your experience?
    c. What do we think about this approach in regard to stroke?
    d. What potential strengths or issues do you see with this approach in regard to stroke?

Nowadays, if a person is eligible for a clinical trial but can't provide their own consent there are two common practices. One is to try to obtain consent from a family member, friend, or caregiver. This is called surrogate consent.

Let me give you a scenario; a 75-year-old man has a stroke while at home with his daughter who is also his caretaker. Upon arriving at the emergency room, a team of physicians assess the patient and discover that he is eligible to participate in a clinical trial for a new treatment. However, the stroke has caused the

patient to lose some ability to think and talk, so the physicians speak to his daughter instead to get her permission for her father to be enrolled in the trial and receive treatment with the new drug.

2. What do we think about this approach?
    a. How does it compare to the standard approach?
    b. What potential strengths or issues do you see with this approach?
3. Has anyone had to make a similar decision for someone else?
    a. What was that experience like/how did that make you feel?
4. Has anyone had a health decision, or a similar decision made for them by a family member, loved one, or someone else?
    a. How did that make you feel?

Another approach is to enroll the patient without getting consent, administer the treatment as necessary, and get consent afterwards, when the patient can understand and make decisions again. This is called deferral of consent. It is important to note that this is now the most widely used approach for participation in acute stroke trials.

Imagine a similar scenario to the one we just discussed but instead, the patient's daughter is informed of new COVID-19 guidelines that do not allow any family members or visitors into the emergency room with the patient and she is asked to wait outside the hospital. The physicians attempt to contact the patient's daughter to get her permission for her father to be enrolled in the trial and receive the new treatment but cannot reach her. They then make the decision to enroll the patient into the trial, administer the treatment and inform the patient when his condition improves or inform his daughter when she becomes available.

5. What do we think about this approach?
    a. How does it compare to the standard approach?
    b. How does this compare to surrogate consent? (Which do you prefer, and why?)
    c. What potential strengths or issues do you see with this approach?
6. Has anyone here been enrolled in a trial by deferred consent?
        a. What was that experience like? How did you feel about this approach in terms of respecting your wishes?

The next question is about the idea of advance directives. This topic might be sensitive, but it will help us understand how patients perceive this concept. Advance directives are instructions that patients give to their family and medical team to guide medical decisions if they ever become unable to speak on their own behalf. These may be written down or may only be oral instructions. For example, it is common to give an advance directive that a patient would not want to be resuscitated (DNR) if she or he ever had a catastrophic health condition or if you wanted to have your organs donated after you die.

7. Have you ever given an advance directive?
    a. Please tell us a little bit about your experience.
    b. What were your main considerations?

The next question is about the idea of advance consent. Advance consent is a kind of advance directive about providing consent to participate in clinical trials. It means that a person who could be eligible to

participate in a clinical trial in the future if they ever were to have a stroke could give consent before they have had their stroke, when they are feeling well and have had time to think it over and ask questions.

8. How would you feel if someone approached you about participating in a clinical trial in the future?
    a. What are the things you would want to know?

9. Let me give you a scenario. A physician has identified that their patient is at risk of a stroke. She tells the patient about this risk, but they also inform the patient that there is an ongoing clinical trial testing a specific new treatment that could potentially be beneficial to the patient if, for whatever reason, they suffer stroke within the next year. They discuss the details, risks and benefits of the new treatment and ask the patient if they would be interested in enrolling in this trial, if, as discussed, they did suffer a stoke and were eligible for the trial.
    a. How do you feel about this approach?
    b. How does this compare to the previous approaches we discussed? Which do you prefer and why?
    c. What are the potential strengths and drawbacks of this approach?

10. Similarly, a doctor has identified that her patient is at risk of having a stroke. She tells her patient about this risk and that there might some medical trials that could be eligible for if he does have a stroke within the next year. The doctor asks if the patient wants to give his consent to participating in any trial he qualified for if he did have a stroke. The doctor explains that once the patient would be enrolled in one of those trials, he would be asked to give his consent at some point after that.
11.
    a. How does this compare to the more specific approach we just discussed? Which do you prefer and why?
    b. What are the potential strengths and drawbacks of this approach?

12. Are there any factors that would make you more likely to consider advance consent for participation in a stroke trial?

13. Are there any factors that would make you less likely to consider advance consent for participation in a stroke trial?

14. Before we wrap up today, is there anything else you'd like to add?

Thank you very much for your time.