

CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)
FOCUS GROUP DISCUSSION GUIDE
PATIENT TOLERANCE FOR RISK AND UNCERTAINTY REGARDING USE OF ANTIBACTERIALS
APPROVED FOR SITUATIONS OF IMMEDIATE UNMET NEED

I. INTRODUCTION

A. Moderator Introduction

Good evening. I would like to welcome all of you to our session. My name is [Name] and I will be facilitating tonight's conversation.

B. Purpose and Procedures

[Chronically ill and recovered groups]

Thank you for taking the time to come here tonight. You were invited to participate in this discussion because you were identified as people with a chronic illness. You have either had an infection as a result of that, or you are at risk for developing an infection, particularly if you are hospitalized or are in other kinds of healthcare settings like rehabilitation centers or long-term care.

[Caretaker groups]

Thank you for taking the time to come here tonight. You were invited to participate in this discussion because you were identified as people who take care of someone who has a chronic illness. That person may already have had an infection as a result of their medical condition, or they are at risk for developing an infection.

[Healthy groups]

Thank you for taking the time to come here tonight.

We are conducting several focus groups to learn more about how people make decisions when faced with situations that involve some degree of uncertainty. In particular, tonight we are interested in exploring your understanding of how antibiotic drugs are developed and in learning about the thought processes you might follow when deciding whether to take a particular antibiotic.

I am not an expert in this area. My role is to listen to what you have to say and report it back to the researchers. In a focus group, there are no right or wrong answers, only opinions, and I'd like to hear from all of you about equally. Please feel free to share your ideas and opinions, even if they differ from what others have said. It's helpful to hear different points of view. Also, feel free to talk to each other as well as to me. If at any time during our discussion you do not feel comfortable answering a question that is fine.

This is an area that has not been well researched, so the information that you provide will help improve guidelines for communicating with future patients about antibiotics and infections.

We are audio recording our discussion to make sure we get all of your comments. But the information in the report will be summarized as group data only. So I want to assure you that everything you say will be confidential and that no comments will be associated with your names. Also, please be respectful of others' privacy and remember that what is said in this room, stays in this room.

Because we have limited time together, I may, for the sake of time, jump in and move the discussion forward. If you have any questions about our research or how your feedback will be utilized, please feel free to speak with me after the session.

Finally, please turn off any cellular phones, pagers, or other electronic devices for the duration of our discussion.

C. Participant Introductions/Warm-Up:

To get started, I would like to go around the room and have everyone introduce himself/herself. When you introduce yourself, please tell us your first name and, a little about yourself.

II. Discussion

A. Experiences with chronic illness

1. Can you describe any prior experience you've had with:
 - *[Chronically ill and recovered groups]*
chronic illness. In particular, please tell us if you have ever been hospitalized for a serious infection or if you have ever gotten an infection while you were in the hospital, a long-term care facility, or another healthcare setting?
 - *[Caretaker groups]*
taking care of a loved one with a chronic illness. In particular, please tell us if the person you take care of has ever been hospitalized for a serious infection or if that person has ever gotten an infection while they were in the hospital, a long term care facility, or another healthcare setting?
 - *[Healthy groups]*
being sick, especially if you had an infection. In particular, please tell us if you have ever been hospitalized because of illness or injury.

B. Attitudes toward and perceptions of medications/antibiotics

2. How would you describe your mindset or attitude toward taking medications in general?
3. When I say the word, "antibiotics," what immediately comes to mind?
4. How much confidence do you have in the antibiotics available today? Why do you say that?
5. How effective do you think they are? How safe do you think they are?
6. What, if anything, have you heard or read recently about antibiotics?
7. How would you describe your mindset or attitude toward taking "NEW antibiotics?" Why do you say that?
8. (Some of you talked earlier in the group about serious infections you or your loved one (picked up in a hospital or hospital-like setting.) or to healthy groups if they haven't talked about these kinds of infections ask): I'm wondering how serious you think hospital-acquired infections (or antibiotic resistant infections) generally are? What do you think happens if these serious infections aren't treated?

C. Definitions

We've just been talking about how you feel about taking "new antibiotics," which brings us to a discussion of how new medications, like antibiotics, are approved for use with the public. I'd like to know more about your impressions about the kinds of review and approval that are necessary before a medication can be made available to the public.

9. So, let's say that a scientist or company comes up with a new antibiotic they think will work for a particular kind of infection. What kind of research process do you think this drug will have to go through before it is approved for use with the public? What do you think about this process? (brief)

Now, I'd like to hand out a brief description of how antibiotics are developed and approved for use with the public. That way, for the purposes of this discussion, we can make sure that everyone is on the same page. You can follow along as I read this piece.

[Moderator passes around handout #1: The drug review process]

10. AFTER READING THE SUMMARY, ASK: What is your general reaction to what you just read/heard?

Then Probe:

- a. What, if anything, was new or surprising to you?
- b. What, if anything, was confusing?
- c. How much confidence would you have in the traditional drug review process as described?

[Moderator passes out handout #2: The Streamlined Development Program]

11. This piece describes the Streamlined Development Program which is a "rapid review process" for drug approval when there is an unmet need (meaning that there are few or no other options for patients). Take a moment and follow along as I read this handout.

If I had never heard of the Streamlined Development Program before, how would you describe it to me?

- a. Why is it used?
 - b. What are the trade-offs between the traditional drug review process and this rapid review process? (That is, what are the advantages and disadvantages of this shortened review process?)
 - c. How much confidence would you have in this type of rapid review process? Why?
 - d. What, if any, questions or concerns did this piece raise for you about streamlined review?
12. If I never heard of the problem of “antibiotic resistance” before, how would you explain it to me? Why does antibiotic resistance happen? How serious of a problem is it?

[Moderator passes out handout #3: Antibiotic resistance.]

We want to make sure that, for the purposes of this discussion, we are all on the same page about the definition of antibiotic resistance. Please take a couple of minutes to follow along as I read this description of antibiotic resistance.

13. What is your overall reaction to this piece?
- a. Did you learn anything new or surprising from reading this piece? If so, what?
 - b. What questions or concerns do you have about antibiotic resistance?
 - c. What does the issue of antibiotic resistance mean for the effectiveness of antibiotics that are currently available?

D. Scenario: Consideration of the tradeoffs involved in precision/uncertainty

Now I'd like to present a scenario to you:

[Chronically ill and recovered groups; healthy groups]

Now, let's imagine that you are in the hospital, and while there, you get a serious infection like pneumonia. The strain of pneumonia you have is resistant to the antibiotics that are currently on the market. However, you have the opportunity to take a newly developed antibiotic that has shown a lot of promise in treating infections like the one you have. While in clinical studies, this new antibiotic was shown to treat severe infections. Because of the urgent need for antibiotics that will treat resistant infections, it may be a drug that FDA rapidly approved through its “Streamlined Development Program,” in order to make it available quickly to seriously ill patients where there are limited or no other options available. It became available after a review of information that was considered adequate but less than the amount of information that has traditionally supported approval of other types of products. The FDA determined that the benefits of this product in treating a serious infection outweighed the risks.

It is important for doctors to determine the bug causing the pneumonia so they can match it to the right antibiotic. This will be done by doing cultures and other tests, but sometimes it takes 48 hours to get these test results back from the laboratory. If you are very ill and the doctors suspect you have a resistant bug, they can't wait for these results and need to treat you ASAP, because your chances for survival are improved with early treatment. Once the tests return, they can tailor or modify the antibiotic they have given you.

What do you think about that process?

[Caretaker groups]

Now, let's imagine that your loved one is in the hospital, and while there, that person gets a serious infection like pneumonia. The strain of pneumonia he or she has is resistant to the antibiotics that are currently on the market. However, the doctor offers your loved one the opportunity to take a newly developed antibiotic that has shown a lot of promise in treating infections like the one they have. While in clinical studies, this new antibiotic seemed to treat severe infections. Because of the urgent need for antibiotics that will treat resistant infections, it may be a drug that FDA rapidly approved through its "Streamlined Development Program," in order to make it available quickly to seriously ill patients where there are limited or no other options available. It became available after a review of information considered adequate but less than the amount that traditionally supported approval of other types of products. The FDA determined that the benefits of this product in treating a serious infection outweighed the risks.

14. I'd like to know more about what you think are the "pros" and "cons" of this new antibiotic which has gone through a rapid review? So, I'd like you to choose a partner in the group and take about three or four minutes to make a list of the pros and cons of this new antibiotic.

[After the group has finished, Moderator goes around the table and each pair reads their answers which moderator records in two columns on the flip chart].

- a. What are your reactions to this list? Anything to add?
 - i. What information would you need to know about the drug to make an informed decision about whether or not to take it? (MODERATOR LISTS ON FLIP CHART)
 - ii. Who would be the major "influencers" in your decision? Which one of these people would carry the most weight? Why?
 - iii. Now I'd like to know what you would do if you were in this situation/scenario. Would you take this antibiotic? (or urge your loved one take the antibiotic?)

Please write down on this worksheet what you would do and why. (After they are done, Moderator goes around the table and hears what each person would do and why; Moderator notes who said "no")

15. *[If there are people in the group who say that they wouldn't take it, ask if there is anything that would make them change their minds]*

For those of you who said you would not take the antibiotic: Can you think of anything that would make you change your mind and decide to take the antibiotic after all (for example, if you tried another treatment first and it did not work, or there were limited or no other options)?

Moderator draws a stick figure on the flip chart. This is Don, and he was in the hospital and while there, got an antibiotic resistant infection:

16. Under what circumstances would he take this drug? (record on flip chart)
17. Under what circumstances would he not to take the drug? (record on flip chart)
18. It's often difficult to make risk/benefits decisions because there is a lot of information to keep in mind at the same time. Imagine that you were in this situation. Looking back at the list of risks and benefits we generated earlier, [put up the flip chart page] which changes in either a risk or a benefit would make you more likely to choose to take the new antibiotic? (what levers can we move to increase the odds of your choosing to take the new antibiotic?)
19. Imagine this scenario: You are in the hospital and have a severe antibiotic resistant infection. If the infection is not treated, you would have a high risk of dying. There are no other options because this infection is resistant to all known antibiotics currently on the other antibiotics that will treat this infection on the market. The only choice is to take a new antibiotic which has undergone rapid review through the Streamlined Development Program.
 - a. Think aloud for a moment: tell me how you feel about taking this drug.
 - b. How comfortable would you be with taking this drug? Why?
 - c. How would you cope with the uncertainty surrounding this drug?

III. WRAP-UP

A. Review of issues

1. Moderator should briefly review the landscape of what was discussed.
2. How would you describe the situation or the trade-offs of taking or not taking the new (rapidly reviewed) antibiotic?
3. Is there anything else that we haven't talked about that you think would be helpful for the researchers to know?

B. Thank you and payment

We appreciate your valuable input. All of your comments have been very helpful, and I want to thank everyone for participating in this focus group session. If you filled out the forms before we started our discussion, you will receive payment from Duke within 6 weeks.