

**Generic Drug Devices Focus Group
Moderator Guide
Updated 11/18/2021**

Introduction and Ground Rules

When moderator admits each participant, one by one, to the focus group, they will check to make sure that they have their sealed envelope next to them and that it hasn't been opened. If someone doesn't have their envelope, they will be told they are not able to participate in the focus group. If someone has opened their envelope, the moderator will make a note of that and will either replace that participant with one of the extras (if possible) or will admit the participant.

MODERATOR:

Welcome and thank you for participating in tonight's discussion. My name is _____, and I work for RTI International, a non-profit research organization. You have been asked to be part of tonight's discussion, because you said that [you/your family member] use an autoinjector prescription drug device. The Food and Drug Administration (FDA) is interested in hearing your opinions about and experiences with the autoinjector medicine that [you use/your family member] uses.

We're interested in hearing from you all today about your experiences and opinions. I'm not a medical professional or an expert on the topics we will discuss. My role is only to moderate today's focus group and make sure that everyone has the chance to express their ideas and opinions.

Review ground rules:

I want to go over a few ground rules for our discussion tonight. Our discussion will last about 90 minutes, and your participation is voluntary. You have the right to not answer any question or withdraw from the study at any time.

- If at any time you are uncomfortable with my questions, you can choose not to answer.
- If you are unclear about what I am asking, please do not hesitate to ask me to repeat the question or provide clarification.
- Since we are using Zoom for tonight's discussion, I want to point out two features that we'll be using:
 1. At the beginning I will ask some questions using the Poll feature. I will tell you when that happens, and a poll will appear on the screen. When the question and answers appear on the screen, I'd like you to answer the question. I won't be sharing the results. Your responses will only be seen by me and the RTI team; no one else in the group will see your responses.
 2. I will ask you some question using the Chat feature, which is located at the bottom of the screen. I will provide more details when we use the chat, but I wanted to let you know that your responses will only be seen by me and the RTI team.
- Everything we discuss today will be kept private to the extent permitted by law. Use only your first name or a nickname in the group. Only the recruiters have your full name and contact

information. This information will not be given to anyone at RTI or to anyone at FDA, and no one will contact you after this discussion is over.

- We ask that participants not audio record or share anything that we discuss today with anyone outside of the group. If you are speaking about someone else, please do not share their name or other identifying information.
- Our discussion will be audio and video recorded by the RTI team. The recordings will be transcribed and will help me write the final report summarizing the feedback from the various focus groups being conducted. The recordings and transcripts will be stored on password-protected computers at RTI and FDA. No names or identifying information will be included in the transcripts or mentioned in the final report created from these focus group discussions.
- Some members of the research team from RTI and FDA are joining the focus group virtually, but you won't see or hear them. They want to hear your opinions and experiences directly from you and make sure that I ask you all the questions I have for you. Near the end of our conversation, I'm going to check the chat to see if they have any last-minute questions for me to ask you.
- Please try to speak one at a time. I may occasionally interrupt when two or more people are talking at the same time to be sure everyone gets a chance to talk and that responses are accurately recorded. To help make sure everyone gets the chance to talk and to avoid having people talk over each other, I may call on people individually. If you are comfortable with it, you can also use the "hand raise" feature in Zoom to show that you would like to respond. You can either answer when called upon or feel free to say "pass" if you don't wish to answer.
- [FOR ADOLESCENTS] None of the answers you give will be shared with your parent or guardian. I would like us to keep what's said here in the group private, so please don't talk to anyone outside of this group about what we've discussed.
- Please make sure your video is enabled and minimize any distractions for the next 90 minutes. If you could put your phones away and make sure you are in a place where you can hear and be heard without too much background noise, I would appreciate it.
- Do you have any questions before we begin?

I. Warm Up.

First, I'd like to go around our Zoom room and introduce ourselves. I will call on people in the order that I see you on my screen. When we get to you, please let us know your first name or your nick name and one thing you'd be doing if you weren't here [today/tonight]

II. Experience with Current Drug Device

First, I'd like to start today's discussion by talking about your experiences with your current autoinjector medicine. We are going to start with a couple of poll questions. Let me know if you don't see the first poll question on your screen. As a reminder, these responses are confidential and no one else in the group will see your responses.

Poll Question #1: How long [have you/has your family member] been using an autoinjector?

- Less than a year
- Between a year and 5 years

<ul style="list-style-type: none"> Over 5 years <p>[MODERATOR to allow 1-2 minutes to answer the poll before announcing the next question.]</p>	
<p>Poll Question #1a (Caregivers only): Which family member of yours uses an autoinjector?</p> <ul style="list-style-type: none"> Child Spouse Parent Other <p>[MODERATOR to allow 1-2 minutes to answer the poll before announcing the next question.]</p>	
<p>Poll Question #2: How satisfied or dissatisfied are you with [your/your family member's] current autoinjector?</p> <ul style="list-style-type: none"> Very dissatisfied Somewhat dissatisfied Somewhat satisfied Very satisfied 	
<p>What do you wish someone had told you about the AI before using it for the first time?</p>	
<p>I am going to show you two more questions that will appear as a “poll” on your screen.</p>	
<p>Poll Question #3: Did you get training on administering the medication when [you/your family member] was <u>first</u> prescribed an autoinjector, even if it is different than the one [you/they] have now?</p> <ul style="list-style-type: none"> Yes No I don't remember <p>[MODERATOR to allow 1-2 minutes to answer the poll before announcing the next question.]</p>	
<p>Poll Question #4: If you got training, who gave it to you?</p> <ul style="list-style-type: none"> Doctor Nurse Someone in the doctor's office Pharmacist Someone else Didn't get training <p>[MODERATOR to allow 1-2 minutes to answer the poll before announcing the next question.]</p>	
<p>How long did it take before you were comfortable using [your/your family member's] AI? What were the hardest parts to learn?</p>	<ul style="list-style-type: none"> Which parts of using the AI] did training most help you learn?
<p>Is there anyone in the group who did not receive training about how to use their auto-injector medicine before using it for the first time? (If yes, continue to bulleted question)</p>	

<ul style="list-style-type: none"> Where did you look for and get your information about how to use the AI? <p>If you hadn't gotten training on the AI, where would you have looked for information?</p>	
What else would you have wanted to know?	

III. Thoughts on generic drugs

You're all here tonight, because you reported that [you use/you are a caregiver for someone who uses] some sort of Auto-injector.

First, I'd like to hear your thoughts about generic drugs. Before we start, I'd like to start with an exercise to get us thinking about what these products are. I'm going to show you a question on the screen.

[Moderator will click "share screen" and share a word document that says "What are some words, thoughts or feelings that come to mind when you hear the term 'generic drug'"]

[MODERATOR/NOTETAKER WILL WRITE A PROMPT (E.G., "GENERIC DRUG: THOUGHTS") IN THE CHAT]

What does "generic drug" mean to you? Please type your response using the chat feature. Your responses in the chat will go directly to me and my colleague [insert name]. We are the only one who can see your responses.

[MODERATOR GIVE PARTICIPANTS TIME TO TYPE RESPONSES IN CHAT]

Who would like to share what they typed in the chat?
 [MODERATOR ORALLY SHARE ANONYMIZED RESPONSES WITH THE GROUP TO PROMPT DISCUSSION]

Let's talk briefly about your responses.
 [MODERATOR NOTE SIMILARITIES/DIFFERENCES ACROSS RESPONSES]

Why did these words come to mind?

- What experiences made you think about these words/phrases?
- What have you seen or heard about generic drugs?
- Now that you've heard other comments, are there any other words or phrases that you would add?

<p>What do you think would be different if your current AI was replaced by a generic version? If your AI has been replaced by a generic version in the past, what differences did you experience?</p>	<ul style="list-style-type: none"> • size, shape, color, auto or pushbutton injector, ease of use, number of steps to use • efficacy of medicine, performance of device, consistency of dose • handling, training
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<p>IV. Journey Mapping</p>	
<p>Please open the sealed padded envelope that was sent to you and take out the folded print-out that says “Journey Mapping”. Leave the other smaller package sealed for now – we will get to that later.</p> <p>For this next exercise, you’re going to use that the packet of paper labeled “Journey Mapping” and your imagination.</p> <p>Please pull out your folded print-out. [MODERATOR: SHOW PRINTOUT..]</p> <p>We are going to break down the process of getting a refill for your autoinjector medicine into three steps.</p> <p>For this activity, we are going to take a somewhat different approach. At each step, I will present a different scenario, and I’d like you to <i>write down</i> (fill in the boxes) your responses: the steps that you’d take, the questions you might have, the emotions you might be feeling during that task, etc.</p> <p>After you complete the section, we will discuss, and I will ask you to tell me what you wrote down. I will also share my screen with a picture of where we are in the document to help guide you along.</p> <p>[MODERATOR ensures that participants understand exercise]</p> <p>Any questions?</p>	
<p>[MODERATOR SHARE SCREEN IMAGE OF JOURNEY MAP WITH first COLUMN HIGHLIGHTED]</p> <p>[MODERATOR: GO THROUGH STEPS WITH PARTICIPANTS, PROBING ON THOUGHTS, FEELINGS, AND BEHAVIORS (A-E BELOW), IF THEY AREN’T NATURALLY RAISED]</p> <ol style="list-style-type: none"> Feelings: Trust: In healthcare providers, efficacy of medicine, performance of device, consistency of dose Confused: not sure how to use the autoinjector medicine Self-efficacy (your belief in your ability to take action) Willingness to use generic device Actions to be taken: Contact healthcare provider, talk with pharmacist, ask for training 	
<p>[STARTING POINT]</p>	

<p>Ok, the first step says that it's time to get a refill for [your/your family member's] AI.</p> <p><i>Assume that you have a refill left, so you don't have to immediately go to the doctor.</i></p> <p>Go ahead and write your responses JUST for the 1st column on the worksheet for step 1, the starting point.</p>	
<p>[MODERATOR GIVE PARTICIPANTS TIME TO WRITE THEIR RESPONSES.]</p>	
<p>[THOUGHTS]</p> <p>What is the first thing that comes to mind when you realize it's time to get a refill for your device?</p>	
<p>What questions do you have?</p>	<ul style="list-style-type: none"> • What concerns do you have?
<p>[ACTIONS]</p> <p>What actions do you need to take?</p>	<ul style="list-style-type: none"> • Actions to be taken: Contact healthcare provider, talk with pharmacist, ask for training
<p>How do you take action?</p>	<ul style="list-style-type: none"> • How difficult or easy are these tasks? [ask about self-efficacy as needed] • Is there anything that would make these tasks easier?
<p>[FEELINGS]</p> <p>What are you feeling when you get a refill for your prescription?</p>	<ul style="list-style-type: none"> • Do any positive, negative, or neutral feelings come to mind?
<p>[SECOND STEP: The refill received is for a <u>generic</u> version of your autoinjector medicine instead of the your regular autoinjector]</p> <p>Take a look at the second column on your worksheet. [MODERATOR SHARE SCREEN IMAGE OF JOURNEY MAP WITH SECOND COLUMN HIGHLIGHTED]</p> <p>Now imagine that you get your AI from the pharmacy and, instead of the brand name, you get a <u>generic</u> version.</p> <p>To help you imagine this scenario, we mailed you examples of the branded and generic versions of the AI for each of you to hold and look at while you do this exercise.</p> <p>Please open the smaller sealed envelope. You should find a brand name EpiPen and a generic EpiPen, and the instructions for each. The EpiPen is this one [MODERATOR HOLDS UP EPIPEN] and the Generic EpiPen is this one [MODERATOR HOLDS UP GENERIC AI]. These are the trainer devices for both drugs. They are real, but they don't have a needle and don't have any medicine in them. Think of them like prototypes, or examples or the actual devices.</p>	

<p>As you think about this step in the scenario, and review the devices, fill out the boxes for step 2 (middle column) in the process. Following the same process as step 1, we will then discuss your responses.</p> <p>Remember to focus on Step 2 – your thoughts, actions, challenges, and feelings.</p> <p>[MODERATOR ALLOW TIME FOR PARTICIPANTS TO FILL IN]</p>	
<p>[THOUGHTS]</p> <p>What is the first thing that comes to your mind if your usual AI was replaced with this generic device?</p>	
<p>[FEELINGS]</p> <p>[IF NEEDED] How would you feel if your AI was switched to a generic version?</p>	<ul style="list-style-type: none"> • trust, fear, anxiety, relief (cost), confusion • What might influence those feelings? (e.g., discussions with providers, research) • [IF NEEDED] Trust: In healthcare providers, efficacy of medicine, performance of device, consistency of dose • [IF NEEDED] Confused: not sure how to use the drug device
<p>What questions would you have about a generic AI?</p>	<ul style="list-style-type: none"> • Who would you ask for an answer? • How difficult or easy would those questions be to get answered? • What concerns would you have?
<p>What else did you write down for this step?</p>	
<p>[THIRD POINT: It's time to use the generic drug device for the first time]</p> <p>Ok, now you are going to use the generic AI device for the first time.</p> <p>[MODERATOR SHARE SCREEN IMAGE OF JOURNEY MAP WITH THIRD COLUMN HIGHLIGHTED].</p> <p>Go ahead and fill out the column on the worksheet for this last step.</p> <p>[MODERATOR ALLOW TIME FOR PARTICIPANTS TO FILL IN]</p>	
<p>[THOUGHTS]</p> <p>What information would you need to use the device?</p>	<ul style="list-style-type: none"> • How would you get the information you need?

<p>What would you expect to happen while using the device? What steps are involved?</p>	<ul style="list-style-type: none"> • How do those expectations compare with what you'd expect with your regular device? • [IF NEEDED] Confused: not sure how to use the drug device • [IF NEEDED] Willingness to use generic device • [IF NEEDED] Trust: In healthcare providers, efficacy of medicine, performance of device, consistency of dose
<p>[FEELINGS] What feelings would you have while using the device?</p>	<ul style="list-style-type: none"> • How might these feelings be different than your experience with your regular device?
<p>What else did you write for this step?</p>	<ul style="list-style-type: none"> • What challenges might you face? [probe about self-efficacy as needed] • [IF NEEDED] Actions to be taken: Contact healthcare provider, talk with pharmacist, ask for training
<p>Now, looking across the three steps as a whole... At what point in the journey would you have the most questions?</p>	<ul style="list-style-type: none"> • How would these questions make you feel? • How would you get answers to these questions?
<p>What are some of the challenges that would arise if your AI was replaced with a generic device?</p>	<ul style="list-style-type: none"> • What would be the hardest parts about switching to a generic device? • What might help to address these challenges?
<p>What feelings arise at different points along the journey?</p>	<ul style="list-style-type: none"> • What positive emotions would you have? What negative emotions would you have? • How would you manage those feelings? • How might your feelings change as you progress?

V. General Discussion of Generic Drug Devices	
[MODERATOR CONFIRMS THAT PARTICIPANTS HAVE HAD A CHANCE TO REVIEW BRANDED AND GENERIC DEVICES]	
Now that you've seen the branded and generic device, what are your initial thoughts on how the generic device is similar or different from the branded AI?	<ul style="list-style-type: none"> • PROBE: size, shape, color, auto or pushbutton injector, ease of use, number of steps to use • PROBE: efficacy of medicine, performance of device, consistency of dose • PROBE: handling, training
What kind of training, if any, would you want before you used the generic AI?	<ul style="list-style-type: none"> • How would you get this training? <ul style="list-style-type: none"> • [user-initiated or healthcare provider-initiated]? • What if you couldn't get any training? How would you feel?

[FALSE CLOSE] I'm going to check the chat to see if I forgot anything or if my colleagues have any last-minute questions before we finish up.

Closing

I would like to thank you for participating in this virtual focus group today. This research was sponsored by the Food and Drug Administration also known as the FDA. FDA would like to thank you for sharing your opinions, as they will be very useful in helping them understand people's reactions and thoughts about the autoinjectors we talked about. Feel free to dispose of all the materials that we used today. Thank you!