FDA Generic Drug Substitution in Special Populations

Focus Group Guide- Older Adult Patients

Date:

Interviewer:

Note taker:

Overview of Purpose of the Study and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to participate in our study to better understand the alignment between clinical practice, drug labeling, and patient safety, sponsored by the US Food and Drug Administration (FDA). The study is being conducted by Auburn University and IMPAQ International. Each of you were selected to participate in this study because you have taken a generic medication within the last month, and are age 65 or older.

The discussion is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform patient safety of generics in special populations. As a thank you for participating in this study, you will be offered an honorarium of $75 for your time and travel expenditures.

If you change your mind about participating, you can request to stop at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, IMPAQ International, or the FDA.

Before we begin I would like to ask you if we may record our discussion. The recordings will be kept confidential and are intended to assist us in our notetaking and analysis of the information. If you agree to allow the discussion to be recorded, any data obtained in connection with this study will be made anonymous as soon as possible. We will protect your privacy and the data you provide by de-identifying the data, including assigning pseudonyms and removing any identifiable information from transcripts of the audio file. Notes and transcripts from the study will be saved in password protected folders on a password and firewall protected server at IMPAQ International. Audio recordings will be destroyed immediately upon completion of the project.

Do you have any questions about the recording or how it will be used? May I record?

If permission is verbally granted by all participants, START RECORDING! If not granted by ALL participants, DO NOT RECORD! Note taker will record responses.

Drug Labeling (Insert and Bottle Label)

First, I would like to ask you to describe what drug labeling information you discuss with your physician and pharmacist

1. **Do you know the differences and similarities between brand and generic medications? REQUIRED QUESTION**
2. **Do you believe there are differences between brand and generic medications that your doctor or pharmacist should discuss with you? REQUIRED QUESTION**
3. **Do you read the information on your drug bottle labels? How about the paper inserts inside the box or that came with the medication, do you read that? REQUIRED QUESTION**
    a. If so, did it have any special instructions for someone of your age or health condition?
        i. What were the special instructions?
        ii. Did you find the special instructions easy to understand?
        iii. Are there any other resources you used or information you received to find out any special instructions for someone of your age or health condition?
4. **What information from the generic or brand drug label from your current generic or brand drug did your doctor or pharmacist discuss with you? REQUIRED QUESTION**
5. **What administration instructions or information about the safety and effectiveness about your generic or brand medications did your doctor or pharmacist provide you? REQUIRED QUESTION**
    a. **Were you provided special instructions on the administration or the safety and effectiveness of your generic or brand medication based on your age or health condition from your doctor or pharmacist? REQUIRED QUESTION**
        i. If yes, how did those instructions regarding administration of drugs vary to what other patients get? In other words, how did your doctor tell you that these instructions were different from how other patients get instructions?
        ii. If not, were there any other resources you used or information you received to find out any special instructions for someone of your age or health condition after speaking to your doctor?
6. **Did your doctor make you aware of any differences in instructions between generic and brand medications? How about your pharmacist? REQUIRED QUESTION**
    a. If yes, what were they?
7. **Did your doctor make sure that you understood the special instructions provided? How about your pharmacist?**
8. **Was there information about your generic drugs would you have liked to have received or did you need that was not provided? REQUIRED QUESTION**
    a. If so, what information would you have liked or did you need that was not provided?
        i. Who should have provided that information?
        ii. How should it have been provided?
        iii. How will the information about generic drugs impact your willingness to take a generic alternative over a brand name drug?

   b. If not, were you satisfied with the information you received about the administration or safety and effectiveness of your generic drugs? How did the information about generic drugs you received impact your willingness for generic substitution?
9. Did you search for additional information about your generic drugs or special instructions for older patients?
   a. If so, what additional information were you able to find?
   b. Where did you find the additional information?

Close the focus group by asking if participants have any questions or additional thoughts and thanking them for their time and contribution to the study.

FDA Generic Drug Substitution in Special Populations

Focus Group Guide- Caregivers of Pediatric Patients

Date:

Interviewer:

Note taker:

Overview of Purpose of the Study and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to participate in our study to better understand the alignment between clinical practice, drug labeling, and patient safety, sponsored by the US Food and Drug Administration (FDA). The study is being conducted by Auburn University and IMPAQ International. Each of you were selected to participate in this study because your child has taken a generic medication within the last month, and you are age 19 or older.

The discussion is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform patient safety of generics in special populations. As a thank you for participating in this study, you will be offered an honorarium of $75 for your time and travel expenditures.

If you change your mind about participating, you can request to stop at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, IMPAQ International, or the FDA.

Before we begin I would like to ask you if we may record our discussion. The recordings will be kept confidential and are intended to assist us in our notetaking and analysis of the information. If you agree to allow the discussion to be recorded, any data obtained in connection with this study will be made anonymous as soon as possible. We will protect your privacy and the data you provide by de-identifying the data, including assigning pseudonyms and removing any identifiable information from transcripts of the audio file. Notes and transcripts from the study will be saved in password protected folders on a password and firewall protected server at IMPAQ International. Audio recordings will be destroyed immediately upon completion of the project.

Do you have any questions about the recording or how it will be used? May I record?

If permission is verbally granted by all participants, START RECORDING! If not granted by ALL participants, DO NOT RECORD! Note taker will record responses.

Drug Labeling (Insert and Bottle Label)

First, I would like to ask you to describe what drug labeling information you discuss with your physician and pharmacist

1. **Do you know the differences and similarities between brand and generic medications? REQUIRED QUESTION**
2. **Do you believe there are differences between brand and generic medications that your doctor or pharmacist should discuss with you? REQUIRED QUESTION**
3. **Do you read the information on your child's drug bottle labels? How about the paper inserts inside the box or that came with the medication, do you read that? REQUIRED QUESTION**
    a. If so, did it have any special instructions for someone of your child's age or health condition?
        i. What were the special instructions?
        ii. Did you find the special instructions easy to understand?
        iii. Are there any other resources you used or information you received to find out any special instructions for someone of your child's age or health condition?
4. **What information from the generic or brand drug label from your current generic or brand drug did your child's doctor or pharmacist discuss with you? REQUIRED QUESTION**
5. **What administration instructions or information about the safety and effectiveness about your child's generic or brand medications did your child's doctor or pharmacist provide you? REQUIRED QUESTION**
    a. **Were you provided special instructions on the administration or the safety and effectiveness of your child's generic or brand medication based on your child's age or health condition from your child's doctor or pharmacist? REQUIRED QUESTION**
        i. If yes, how did those instructions regarding administration of drugs vary to what other patients get? In other words, how did your child's doctor tell you that these instructions were different from how adult patients get instructions?
        ii. If not, were there any other resources you used or information you received to find out any special instructions for someone of your child's age or health condition after speaking to your child's doctor?
6. **Did your child's doctor make you aware of any differences in instructions between your child's generic and brand medications? How about your child's pharmacist? REQUIRED QUESTION**
    a. If yes, what were they?
7. **Did your child's doctor make sure that you understood the special instructions provided? How about your child's pharmacist?**
8. **Was there information about your child's generic drugs would you have liked to have received or did you need that was not provided? REQUIRED QUESTION**
    a. If so, what information would you have liked or did you need that was not provided?
        i. Who should have provided that information?
        ii. How should it have been provided?

iii. How will the information about generic drugs impact your willingness for generic substitution for your child's prescription?

b. If not, were you satisfied with the information you received about the administration or safety and effectiveness of your child's generic drugs? How did the received information about your child's generic drugs impact your willingness for generic substitution for your child's prescription?

9. Did you search for additional information about your child's generic drugs or special instructions for younger patients?
    a. If so, what additional information were you able to find?
    b. Where did you find the additional information?

Close the focus group by asking if participants have any questions or additional thoughts and thanking them for their time and contribution to the study.

FDA Generic Drug Substitution in Special Populations

Focus Group Guide- Prescribers and Dispensers

Date:

Interviewer:

Note taker:

Overview of Purpose of Study and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to participate in our study to better understand the alignment between clinical practice, drug labeling, and patient safety in generic drug utilization, sponsored by the US Food and Drug Administration (FDA). The study is being conducted by Auburn University and IMPAQ International. You were selected as a participant because you have prescribed or dispensed a medication within the last month, and you are age 19 or older.

The discussion is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform patient safety of generics in special populations. As a thank you for participating in this study, you will be offered an honorarium of $275 for your time and travel expenditures.

If you change your mind about participating, you can request to stop at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, IMPAQ International, or the FDA.

Before we begin I would like to ask you if we may record the discussion. The recordings will be kept confidential and are intended to assist us in our notetaking and analysis of the information. If you agree to allow the discussion to be recorded, any data obtained in connection with this study will be made anonymous as soon as possible. We will protect your privacy and the data you provide by de-identifying the data, including assigning pseudonyms and removing any identifiable information from transcripts of the audio file. Notes and transcripts from the study will be saved in password protected folders on a password and firewall protected server at IMPAQ International. Audio recordings will be destroyed immediately upon completion of the project.

Do you have any questions about the recording or how it will be used? May I record?

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Background

First, I would like to know a bit about your generic drug prescribing and dispensing patterns.

1. **Have you recently prescribed or dispensed a generic drug to a special patient population, such as a patient over the age 65 or younger than 18, a patient who is black, Latino, or other racial or ethnic minority, a patient who is pregnant, or a patient who has a disability? REQUIRED QUESTION**
    a. If so, what is an example of a recently prescribed or dispensed generic drug to X?
2. **Do you believe generic drugs may be more or less appropriate for special populations than others? REQUIRED QUESTION**

Drug Labeling (Insert and Bottle Label)

Next, I would like to switch topics a bit and ask you to describe what information you discuss with patients.

1. Do you believe generic drugs are as safe and efficacious as brand drugs?
2. **Do you discuss why you are prescribing or dispensing a brand or generic drug when communicating with patients? REQUIRED QUESTION**
3. What information from the generic drug label do you discuss with patients?
    a. How about brand drug label information?
    b. How does this information impact patients use or your dispensing of generic drugs?
4. **What administration instructions or information on efficacy and safety did you provide to the patient? REQUIRED QUESTION**
    a. Do you believe that special populations should receive additional information about brand or generic drugs that may be relevant to them?
    b. Do you/Have you provide/provided special instructions on the administration or information on efficacy and safety of generic drugs based on a patient's background (e.g. race, age, or disability status)?
    c. How have your instructions regarding administration or information on efficacy and safety of brand and generic drugs varied by patient population?
5. Do you ensure that the patient has understood the special instructions provided? How?

Administration Instructions

Now I would like to turn to how you would prefer to communicate administration instructions to patients. Why don't we start by discussing current administration instructions?

1. How do you remain current with clinical practice on generic safety and efficacy information? **REQUIRED QUESTION**
2. **Do you receive information and updates related to current clinical practice updates for special patient populations? REQUIRED QUESTION**
    a. Where do you receive information related to current clinical practice updates?

   b. How do you receive the information?
   c. How often do you receive the information?
3. Do you seek out additional information and updates related to current clinical practice for special patient populations?
   a. Where do you seek out information related to current clinical practice updates?
   b. How often do you seek out the information?
4. **What additional information or information provided in other ways better enable you to remain current on generic administration instructions or information on efficacy and safety for special patient populations? How about provide special instructions for these patients?** **REQUIRED QUESTION**

Close the focus group by asking if participants have any questions or additional thoughts and thanking them for their time and contribution to the study.