

Educating Groups Influencing Generic Drug Use

Focus Group Guide- Patients/Caregivers

Date:

Moderator:

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 educate groups influencing generic drug use, based on their unique educational needs. The study is being conducted by Auburn University and IMPAQ International and is funded by the U.S. Food and Drug Administration (FDA). Each of you were selected to participate in this study because you are age 19 or older and a patient or caregiver.

The discussion is expected to take approximately 60 minutes. I and the research team aim to learn and discuss your thoughts on the content, format, channel, and satisfaction of one example of educational materials developed specifically for your stakeholder group. To thank you for your time spent participating in this study, you will be offered an honorarium of a \$25 mailed check after completion of the focus group.

If you change your mind about participating, you can 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 If you choose to withdraw, your data can be withdrawn as long as it is identifiable.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, the Department of Health Outcomes Research and Policy, IMPAQ International, or the FDA.

Personal information collected in connection to your honorarium will be saved in password protected folders on a password and firewall protected server at Auburn University. This information is being collected in order to withhold necessary tax payments on your behalf and will remain private.

Having heard this information, you must decide if you would like to participate in this study. If you decide to participate, your signature will indicate your willingness to participate. *(Give participants time to sign the consent form and incentive information collection form)*

Before we begin I would like to ask you if we may audio 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 false names after our discussion and removing any identifiable information from transcripts of the audio file. Electronic notes and transcripts from the study will be saved in password-protected folders on a password- and firewall-protected server at Auburn University. Audio recordings will be destroyed immediately upon completion of the records.

Focus Group Protocols – Patients/Caregivers

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.

Demonstration of the example of educational material for patient/caregiver group:

First, I would like to show you an example of an educational material regarding generic drugs we designed for the patients and caregivers. Here is a printed handout summarizing the safety and efficacy of generic drugs and similarities and differences between brand and generic drugs. (Give participants about 3 minutes to read the handout and lead discussion with the following questions):

Content questions

- 1. Does this handout provide adequate information for you about the safety and efficacy of generic drugs?**
 - a. If yes, which part of the information do you think is most important for patients/caregivers like yourself?
 - b. If no, what additional information would you like to see provided that would increase your understanding/knowledge of the safety and efficacy of generic drugs?
- 2. Does this handout provide adequate information for you to know about the differences and similarities between brand and generic drugs?**
 - a. If yes, which part of the information do you think most explains the similarities and differences between brand and generic drugs?
 - b. If no, what additional information would you like to see provided that would increase your understanding/knowledge of the differences and similarities between brand and generic drugs? How can the content be improved to fit your knowledge needs regarding generic drugs?
- 3. Was there any new information regarding generic drugs that you learned upon your review of the handout?**
 - a. If yes, which part of the information?
 - b. If no, where did you get the information regarding generic drugs before?

Format questions

- 4. Do you think the information in this handout is presented in a simple, easily understood format?**
 - a. If no, do you have any suggestions on how to make the materials easier to follow for patients/caregivers like yourself?
- 5. How satisfied are you with the format (i.e., printed handout, layout, design, organization of the content, etc.) used to present the information in this handout?**
 - a. Do you have any suggestions on how to improve it?

Focus Group Protocols – Patients/Caregivers

Channel questions

6. Where do you prefer to receive a handout with information regarding generic drugs like this? (such as a clinic, pharmacy, hospital, mailed from doctor's office, online, email, etc.) Why?
7. With whom do you prefer to discuss the information regarding generic drugs using a handout like this? Why?

Satisfaction questions

8. Can you please share whether you find the information regarding generic drugs in this handout to be useful for patients/caregivers like yourself?
9. Can you please describe your overall satisfaction with the information regarding generic drugs in this handout?
10. Can you please describe how you would change the handout to improve your satisfaction with it?
11. How will you apply the information regarding generic drugs in this handout in your future generic drug use?
12. Would you recommend this handout to other patients/caregivers if they are interested in information regarding generic drugs?

(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).

Focus Group Protocols – Formulary Managers, Large Purchasers, and Policymakers

Educating Groups Influencing Generic Drug Use

Focus Group Guide- Formulary Managers, Large Purchasers, and Policymakers

Date:

Moderator:

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 educate groups influencing generic drug use, based on their unique educational needs. The study is being conducted by Auburn University and IMPAQ International and is funded by the U.S. Food and Drug Administration (FDA). Each of you were selected to participate in this study because you are age 19 or older and among the formulary manager, large purchaser of drugs, and policymaker stakeholder group that has an important role in generic drug use.

The discussion is expected to take approximately 60 minutes. I and the research team aim to learn and discuss your thoughts on the content, format, channel, and satisfaction of one example of an educational material developed specifically for your stakeholder group. To thank you for your time spent participating in this study, you will be offered an honorarium of a \$25 mailed check after completion of the focus group.

If you change your mind about participating, you can 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, the Department of Health Outcomes Research and Policy, IMPAQ International, or the FDA.

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Having heard this information, you must decide if you would like to participate in this study. If you decide to participate, your signature will indicate your willingness to participate. *(Give participants time to sign the consent form and incentive information collection form)*

Before we begin I would like to ask you if we may audio 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 false name 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 Auburn University. Audio recordings will be destroyed immediately upon completion of the records.

Focus Group Protocols – Formulary Managers, Large Purchasers, and Policymakers

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

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Demonstration of the example of educational material for formulary manager/large purchaser/policymaker group:

First, I would like to show you an example of educational material regarding generic drugs we designed for the formulary manager/large purchaser/policymaker group. Here is a printed handout presenting an email/newsletter for formulary manager/large purchaser/policymaker about FDA generic drug approval process, generic drug bioequivalence profile, and generic drug market availability and access. (Give participants about 3 minutes to read the handout and lead discussion with the following questions):

Content questions

- 1. Does this email/newsletter provide adequate information for you to understand the FDA generic drug approval process? What about bioequivalence profile, market availability, and access?**
 - a. If yes, which part of the information do you think is most important for formulary managers/large purchasers/policymakers like yourself?
 - b. If no, what additional information would you like to see provided that would increase your knowledge regarding generic drugs? How can the content be improved to address your knowledge needs regarding generic drugs?
- 2. Was there any new information regarding generic drugs that you learned upon your review of the email/newsletter?**
 - a. If yes, which part of the information?
 - b. If no, where did you get the information regarding generic drugs before?

Format questions

- 3. Do you think the information in this email/newsletter is presented in a simple, easy access format?**
 - a. If no, do you have any suggestions on how to make the materials easier to follow or access for formulary managers/large purchasers/policymakers like yourself?
- 4. How satisfied are you with the format (i.e., print vs. email, layout, design, organization of the content, etc.) used to present the information in this email/newsletter?**
 - a. Do you have any suggestions on how to improve it?

Focus Group Protocols – Formulary Managers, Large Purchasers, and Policymakers

Channel questions

5. From whom do you prefer to receive an email or newsletter with information regarding generic drugs like this? (such as FDA, professional associations, insurance companies, pharmaceutical companies, etc.) Why?

Satisfaction questions

6. Can you please share whether you find the information regarding generic drugs in this email/newsletter to be useful for formulary managers/large purchasers/policymakers like yourself?
7. Can you please describe your overall satisfaction with the information regarding generic drugs in this email/newsletter?
8. How would an email or newsletter with information regarding generic drugs like this help you with your work related to generic drugs (can be purchasing, revising prescription formularies or health policies, etc.)?
9. Would you recommend this email/newsletter to other formulary managers/large purchasers/policymakers if they are interested in information regarding generic drugs?

(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).

Educating Groups Influencing Generic Drug Use

Focus Group Guide- Prescribers/Pharmacists

Date:

Moderator:

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 educate groups influencing generic drug use, based on their unique educational needs. The study is being conducted by Auburn University and IMPAQ International and is funded by the U.S. Food and Drug Administration (FDA). Each of you were selected to participate in this study because you are age 19 or older and among the prescriber/pharmacist stakeholder group that has an important role in generic drug use.

The discussion is expected to take approximately 60 minutes. I and the research team aim to learn and discuss your thoughts on the content, format, channel, and satisfaction of one example of educational materials developed specifically for your stakeholder group. To thank you for your time spent participating in this study, you will be offered an honorarium of a \$25 mailed check after completion of the focus group.

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Focus Group Protocols – Prescribers/Pharmacists

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Demonstration of the example of educational material for prescriber/pharmacist group:

First, I would like to show you an example of educational material regarding generic drugs we designed for prescribers and pharmacists. Here is a printed handout presenting an email/newsletter for prescribers and pharmacists about safety and efficacy of generic drugs, as well as information on access and cost of generic drugs. (Give participants about 3 minutes to read the handout and lead discussion with the following questions):

Content questions

- 1. Does this email/newsletter provide adequate information for you to understand the safety and efficacy about generic drugs? What about access to and cost of generic drugs?**
 - a. If yes, which part of the information do you think is most important for prescribers/pharmacists like yourself?
 - b. If no, what additional information would you like to see provided that would increase your knowledge regarding generic drugs? How can the content be improved to address your knowledge needs regarding generic drugs?
- 2. Was there any new information regarding generic drugs that you learned upon your review of the email/newsletter?**
 - a. If yes, which part of the information?
 - b. If no, where did you get the information regarding generic drugs before?

Format questions

- 3. Do you think the information in this email/newsletter is presented in a simple, easy access format?**
 - a. If no, do you have any suggestions on how to make the materials easier to follow or access for prescribers/pharmacists like yourself?
- 4. How satisfied are you with the format (i.e., printed handout, layout, design, organization of the content, etc.) used to present the information in this email/newsletter?**
 - a. Do you have any suggestions on how to improve it?

Focus Group Protocols – Prescribers/Pharmacists

Channel questions

5. From whom do you prefer to receive an email or newsletter with information regarding generic drugs like this? (such as FDA, professional associations, insurance companies, pharmaceutical companies, etc.) Why?

Satisfaction questions

6. Can you please share whether you find the information regarding generic drugs in this email/newsletter to be useful for prescribers/pharmacists like yourself?
7. Can you please describe your overall satisfaction with the information regarding generic drugs in this email/newsletter?
8. How would an email or newsletter with information regarding generic drugs like this help you discuss generic drugs and treatments options with your patients?
9. How would an email or newsletter with information regarding generic drugs like this help you prescribe/dispense generic drugs for your patients?
10. Would you recommend this email/newsletter to other prescribers/pharmacists if they are interested in information regarding generic drugs?

(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).