Dear [Participant's Name and Title],

I hope this message finds you well. I am reaching out to you on behalf of the FDA-funded grant to understand the factors influencing generic drug use *(U.S. FDA grant #U01FD005486-01).* We are conducting semi-structured interviews among a variety of stakeholder groups. The purpose of these interviews is to ask formulary managers, large purchasers of pharmaceuticals, and policymakers about their thoughts on generic drugs, what other information they'd like to have about generic drugs, and how they receive healthcare-related educational materials.

Please let us know if you would be able to participate in an interview this fall. ***If so, you may reach the research team at FDAGDUseStudy@impaqint.com, responding to this email, or by calling Gavriella Frank at (443) 259-5290 to schedule a convenient interview date and time.***

We have identified you as a possible participant of the [Name of Key Group], but would welcome your feedback. We would also appreciate any recommendations you have for additional interviewees among the following groups:

- formulary managers (hospitals, PBMs, other)
- large purchasers of pharmaceuticals (e.g., for hospitals, retail group purchasing)
- policymakers (local, state or federal level)

Interviews are conducted via telephone and the estimated time commitment is approximately 60 minutes. Any information collected as part of the interview will remain confidential and will not be shared with anyone outside of the Auburn-IMPAQ research team. As a thank you for your participation, an honorarium of $# will be offered.

Thank you for considering this request for your much-needed participation.

Regards,

[Insert Name and Title]
[Insert Telephone Number and Email Address]

DEPARTMENT
OF HEALTH OUTCOMES
RESEARCH AND POLICY

AUBURN UNIVERSITY

HARRISON SCHOOL
OF PHARMACY

7/19/2016

Dr. Lucie Yang
Food and Drug Administration (FDA)
Office of Generic Drugs
Telephone: 301-796-5112
Email: Lucie.Yang@fda.hhs.gov

Dear Dr. Yang,

This document is to explain the rationale of adding an invitation email script for key informant interviews (KIIs) for Aim 2 of the FDA funded U01 project "Educating Groups Influencing Generic Drug Use" (grant #1U01FD005486-01), which is a collaborative grant between Auburn University/IMPAQ LLC (PIs: Jingjing Qian and Ilene Harris) and FDA's Office of Generic Drugs to conduct a study to understand the roles of key influencers of generic drug use and the extent of their influence on generic drug use. We submitted OMB clearance for this aim on March 15, 2016 and received approval on March 22, 2016.

The purpose of the invitation email script is to reach out to possible respondents identified as representatives of the policymaker, large purchaser and formulary management groups. We concluded that an invitation email is ideal for representatives from these groups because these groups are more difficult (and expensive) to recruit using national contact lists. For these reasons, more targeted recruitment is necessary.

We will still provide the information letter for participants of these groups (letters have been approved by RIHSC, IRB registration number 16-014D) to review the details of the study information and ask for consent to participate prior to asking any questions. As this email script only represents an additional avenue for recruiting potential study respondents, it has no impact on the amount of time participants will be asked to invest in the study. Rather than being recruited via telephone as other participants are, they will receive an email from a team member and may choose to respond with their willingness to participate. Burden will not change.

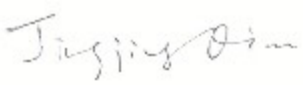
We apologize that we did not include this email script in our original OMB submission. Due to the limited timeline before our recruitment on August 1, 2016, we would like to request a quick review turnaround time, if possible.

Thank you for your consideration. Please feel free to contact me if you have any questions.

Sincerely,

022 Foy Hall, Auburn, AL 36849-5506; Telephone: 334-844-5152; Fax: 334-844-8307

www.auburn.edu



Jingjing Qian, PhD
Assistant Professor
Department of Health Outcomes Research and Policy
Auburn University Harrison School of Pharmacy
Auburn, AL 36849-5506
Phone: 334-844-5818
Email: jzq0004@auburn.edu

Auburn Letterhead

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As part of your participation in this research study, you will speak to one of our team's researchers via telephone regarding your current and desired methods of receiving information related to available generic medications. Your total time commitment will be approximately 60 minutes or one hour.

The risks associated with participating in this study are minimal. Your protected health information will not be used or disclosed to a third party. If you participate in this study, what the research team learns from your study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $50.

If you change your mind about participating, you can withdraw 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 or IMPAQ International. However, your decision to participate or withdrawal may impact your receipt of the incentive. Incentives are only distributed upon completion of the interview.

If you agree, interviews will be recorded. However, 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 transcriptions.

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If you have questions about this study, please ask them now or contact Jingjing Qian at (334) 844-5818 or jzq004@auburn.edu or Ilene Harris at (443) 259-5250 or iharris@impaqint.com.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334)-844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

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Co-Investigator's Signature Date

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As part of your participation in this research study, you will speak to one of our team's researchers via telephone regarding your current and desired methods of receiving information related to available generic medications. Your total time commitment will be approximately 60 minutes or one hour.

The risks associated with participating in this study are minimal. Your protected health information will not be used or disclosed to a third party. If you participate in this study, what the research team learns from your study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $175-$375.

If you change your mind about participating, you can withdraw 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 or IMPAQ International. However, your decision to participate or withdrawal may impact your receipt of the incentive. Incentives are only distributed upon completion of the interview.

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Personal information collected in connection to your incentive (i.e. W-9) form will be saved in password protected folders on a password and firewall protected server at IMPAQ International. This information is being collected in order to withhold necessary tax payments on your behalf and will remain confidential.

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As part of your participation in this research study, you will speak to one of our team's researchers via telephone regarding your current and desired methods of receiving information related to available generic medications. Your total time commitment will be approximately 60 minutes or one hour.

The risks associated with participating in this study are minimal. Your protected health information will not be used or disclosed to a third party. If you participate in this study, what the research team learns from your study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $150-$200.

If you change your mind about participating, you can withdraw 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 or IMPAQ International. However, your decision to participate or withdrawal may impact your receipt of the incentive. Incentives are only distributed upon completion of the interview.

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As part of your participation in this research study, you will speak to one of our team's researchers via telephone regarding your current and desired methods of receiving information related to available generic medications. Your total time commitment will be approximately 60 minutes or one hour.

The risks associated with participating in this study are minimal. Your protected health information will not be used or disclosed to a third party. If you participate in this study, what the research team learns from your study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $150.

If you change your mind about participating, you can withdraw 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 or IMPAQ International. However, your decision to participate or withdrawal may impact your receipt of the incentive. Incentives are only distributed upon completion of the interview.

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As part of your participation in this research study, you will speak to one of our team's researchers via telephone regarding your current and desired methods of receiving information related to available generic medications. Your total time commitment will be approximately 60 minutes or one hour.

The risks associated with participating in this study are minimal. Your protected health information will not be used or disclosed to a third party. If you participate in this study, what the research team learns from your study may better inform how information is provided related to generic medications. Your participation will greatly contribute to our research which will support the promotion of generic drug utilization.

If you change your mind about participating, you can withdraw 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 or IMPAQ International.

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As part of your participation in this research study, you will speak to one of our team's researchers via telephone regarding your current and desired methods of receiving information related to available generic medications. Your total time commitment will be approximately 60 minutes or one hour.

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Investigator's Signature Date

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Printed Name

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Co-Investigator's Signature Date

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Printed Name

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Patients

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because you are currently taking or have taken a prescribed medication within the last month and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $50.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

First, I would like to know a bit about your generic drug use.

1. What generic drug(s) have you taken within the last six months?
    a. Are you currently taking **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        i. If so, how long have you been taking **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        ii. If not, how long did you take **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        iii. If not, why did you stop taking **X**? **[Fill in drug name based on the name of one of most recent generic drug prescriptions taken]**
        iv. Are you currently taking something else instead of **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
2. Was X prescribed to you by your physician or did your pharmacist suggest taking **X** as an alternative to the drug prescribed to you by your physician? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as safe and work as well as brand name drugs? Why or why not?
2. What caused you to feel this way about generic drugs?
3. Who or what has the most influence on whether or not you take generic drugs?
    a. How do each of the following groups or factors influence which drugs you take, both brand and generic drugs? **[Ask only those key groups or factors that were not discussed in question 3]**?
        i. Physician
        ii. Pharmacy
        iii. Insurance
4. How do you learn if a generic alternative to a brand you have either been prescribed or had filled is available?
    a. Do you ever ask your physician or pharmacist if a generic alternative to the brand is available?
5. What information or source of information could cause your views on the safety of generic drugs? How about their effectiveness?

Information Needs

Now I would like to turn to how you got information about X and how you would have preferred to receive the information or would like to get information about generic drugs in the future. Why don't we start by discussing…

1. What kind of information did your physician/pharmacist provide you when s/he prescribed you **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
    a. How did s/he give you that information, for instance was it told to you or were you given a pamphlet?
2. What information about X would have been helpful when it was being prescribed? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
3. How would you have preferred to receive the information about **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]** Would you have preferred it being told to you and in a pamphlet, online, or another way?
4. What are other ways you have gotten information related to X when you needed it?
5. How would additional information or information provided in other ways influence your views on generic drugs?
6. Do you have any suggestions on how to make information about generic drugs easier to get for patients like you?

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Caregivers

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because a loved one is currently taking or has taken a prescribed medication within the last month and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $50.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

First, I would like to know a bit about your role as a caregiver…

1. Are you providing care for a friend or family member?
2. How long have you been providing care on her/his behalf?
3. Have you helped her/him in making medical decisions, such as getting or filling prescriptions?

Now, I would like to ask a few questions about her/his medications…

4. What generic drug(s) has s/he taken within the last six months?
    a. Is s/he currently taking **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        i. If so, how long have s/he been taking **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        ii. If not, how long did s/he take **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        iii. If not, why did s/he stop taking **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
        iv. Is s/he currently taking something else instead of **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
5. Was **X** prescribed to her/him by her/his physician or did her/his pharmacist suggest taking X as an alternative to the brand drug prescribed to her/him by her/his physician? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
6. Were you present when the prescription was being made or filled?
    a. If so, did **[name's]** physician or pharmacist discuss the prescription with **[name]** or with both of you? **[Fill in the care recipient's name based on the information provided above]**

    b. If not, why not?
        i. Are you usually present?
        ii. Have you been involved in the discussion with **[name]** regarding a prescription? **[Fill in the care recipient's name based on the information provided above]**

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as safe and work as well as brand name drugs? Why or why not?
2. What caused you to feel this way about generic drugs?
3. Who or what has the most influence on whether or not **[name]** takes a generic drugs?

    a. How do each of the following groups or factors influence which drugs **[name]** takes, both brand and generic drugs? **[Ask only those key groups or factors that were not discussed in question 3]**?
        i. Physician
        ii. Pharmacy
        iii. Insurance
4. How do you or **[name]** learn if a generic alternative to a brand you have either been prescribed or had filled is available? **[Fill in the care recipient's name based on the information provided above]**
    a. Do you ever ask **[name's]** physician or pharmacist if a generic alternative to the brand is available? **[Fill in the care recipient's name based on the information provided above]**
5. What information or source of information could cause your views on the safety of generic drug to change? How about on how effective they are?

<u>Information Needs</u>

Now I would like to turn to how you got information about **X [Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]***and how you would have preferred to receive the information or would like to get information about generic drugs in the future for* **[name]**. *Why don't we start by talking about…*

1. What kind of information did **[name]** physician/pharmacist provide you when s/he prescribed her/him **X**? **[Fill in the care recipient's name and recent prescription drug based on the information provided above]**
    a. How did the physician or pharmacist give you that information, for instance was it told to you or were you given a pamphlet?
2. What information about **X** would have been helpful when **[name]** was prescribed **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
3. How would you have preferred to receive the information about **X**? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]** Would you have preferred it being told to you and in a pamphlet, online, or another way?
4. What are other ways you have gotten information related to **X** when you needed it? **[Fill in drug name based on the name of one of the most recent generic drug prescriptions taken]**
5. How would additional information or information provided in other ways influence your views on generic drugs?
6. Do you have any suggestions on how to make information about generic drugs easier to get for patients like **[name]** and caregivers like yourself?
    a. How about making the information stand out amongst the large amount of information you receive about all kinds of generic drugs?

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Physicians

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because you have prescribed a medication within the last two weeks and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $175-$375.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

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

1. Have you ever prescribed a patient a generic drug(s)?
    a. If so, have you prescribed a patient a generic drug(s) in the last month?
        i. What were the last three generic drugs you've prescribed?
            1. How long have you been prescribing X [pick one of the three to focus on for this question]?
            2. How often do you prescribe X [the name of the drug selected for question 1 above]?
    b. If not, why not? **[Skip to beliefs section]**

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as effective and safe as brand name drugs? Why or why not?
    a. If not, what could be done to make generics as effective as brand name drugs? What about as safe?
2. Who or what has the most influence on whether or not you prescribe generic drugs?
    a. How about what types or categories of generic drugs you prescribe, who or what has the most influence on what type or category of generic drug you prescribe?
        i. Can you describe how each of these factors or groups influence they type or category of generic drug you prescribe?
    b. How do each of the following groups or factors influence which drugs you prescribe, both brand and generic drugs [ask only those key groups that were not discussed in question a above]?
        i. Policy/policymakers
        ii. Patients and/or caregivers
        iii. Pharmaceutical companies
        iv. Insurance providers including Medicare and Medicaid
        v. Colleagues/other physicians
        vi. Wholesalers or corporate distributers
3. Have you ever prescribed generic drugs as per a patient's suggestion/preference? Please describe.
4. What information or source of information could cause your views on the effectiveness and safety of generic drugs to change?

Information Needs

Now I would like to turn to how you got information about X drug and how you would have preferred to receive the information or would like to get information about other generic drugs in the future. Why don't we start by discussing…

1. Where do you receive information regarding the generic drugs you recently prescribed?
    a. How did you receive that information, for instance was the information shared with you verbally or did you receive written material on the drug's effectiveness and safety?
        i. By/from whom?
    b. How would you have preferred to receive the information about these generic drugs? Would you have preferred it being shared with you in a presentation, pamphlet, online, publication, or another way?
    c. What information about these drugs was helpful when you prescribed it?
    d. What are other ways have you gotten information related to other generic drugs when you needed it?
    e. How would additional information or information provided in other ways influence your views on which drugs to prescribe?
    f. Do you have any suggestions on how to make information about generic drugs easier to get for physicians like you?
        i. How about making the information stand out amongst the large amount of information you receive about various generic drugs available?
2. How about brand name drugs? Where do you receive information regarding the brand name drugs you recently prescribed?
    a. Is there a method you would have preferred receiving the information in, such as in a presentation, pamphlet, online, publication, or another way?
    b. What information about brand name drugs is the most helpful in your decision to prescribe them?
    c. How would additional information or information provided in other ways about generic alternatives influence your views on which drugs to prescribe?

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Pharmacists

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because you have dispensed a medication within the last two weeks and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $150-$200.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

First, I would like to know a bit about your generic drug advising patterns.

1. Approximately how many prescriptions does your pharmacy dispense each day?
    a. Approximately what proportion of the prescriptions dispensed is generic?
2. Have you ever advised a patient to take a generic drug(s) alternative upon receiving a prescription for the brand-name equivalent?
    a. If so, please describe
    b. If not, why not?

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as effective and safe as brand name drugs? Why or why not?
    a. If not, what could be done to make generics as effective as brand name drugs? What about as safe?
2. Who or what has the most influence on whether or not you dispense generic drugs?
    a. How about what types or categories of generic drugs you advise, who or what has the most influence on what type or category of generic drug you advise?
        i. Can you describe how each of these factors or groups influence they type or category of generic drug you prescribe?
    b. How do each of the following groups or factors influence which drugs you prescribe, both brand and generic drugs [ask only those key groups that were not discussed in question a above]?
        i. Physicians
        ii. Policy/policymakers
        iii. Patients and/or caregivers
        iv. Pharmaceutical companies
        v. Insurance providers including Medicare and Medicaid
        vi. Colleagues/other pharmacists
        vii. Wholesalers or corporate distributers
3. Have you ever modified a prescription to a generic as per a patient's suggestion/preference? Please describe.
4. What information or source of information could cause your views on the effectiveness and safety of generic drugs you dispense to change?

Information Needs

Now I would like to turn to how you got information about X drug and how you would have preferred to receive the information or would like to get information about other generic drugs in the future. Why don't we start by discussing…

1. Where do you receive information regarding the generic drugs you recently dispensed?
    a. How did you receive that information, for instance was the information shared with you verbally or did you receive written material on the drug's effectiveness and safety?
        i. By whom?
    b. How would you have preferred to receive the information about these generic drugs? Would you have preferred it being shared with you in a presentation, pamphlet, online, publication, or another way?
    c. What information about these drugs was helpful when you dispensed or advised it?
    d. What are other ways have you gotten information related to other generic drugs when you needed it?
    e. How would additional information or information provided in other ways influence your views on which drugs to dispense or advise?
    f. Do you have any suggestions on how to make information about generic drugs easier to get for pharmacists like you?
2. How about brand name drugs? Where do you receive information regarding the brand name drugs you recently prescribed?
    a. Is there a method you would have preferred receiving the information in, such as in a presentation, pamphlet, online, publication, or another way?
    b. What information about brand name drugs is the most helpful in your decision to dispense or advise them?
    c. How would additional information or information provided in other ways about generic alternatives influence your views on which drugs to dispense or advise patients to choose?
        i. How about making the information stand out amongst the large amount of information you receive about various generic drugs available?

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Formulary Managers

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because you were identified as having a role in the prescription drug formulary process within the previous six months and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $150.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

First, I would like to know a bit about how the process works for getting generic drugs from manufacturers to patients.

1. Could you please describe the process?
2. What is your role in this process?
3. Which groups do you think your role in this process impacts?
4. What type of formulary do you manage? **[If not answered as part of the response to question 2 above]**
    a. How did you come to manage this formulary?
    b. Have you previously held other positions in which you managed a formulary?
    c. Have you held any other positions in which you played an integral role in the utilization of generic drugs?
5. What is the role of large purchasers in generic drug utilization?
6. What is the role of physicians in generic drug utilization?
7. What is the role of pharmacists in generic drug utilization?
8. What is the role of patients in generic drug utilization?
9. What is the role of policymakers in generic drug utilization?

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as effective and safe as brand name drugs? Why or why not?
    a. If not, what could be done to make generics as effective as brand name drugs? What about as safe?
2. Who or what do you believe has the most influence on inclusion of a generic drug on formularies over their brand alternative? Why?
    a. How about what types of generic drugs are included, who or what has the most influence on policymakers in deciding what type or category of generic drug is prescribed and ultimately dispensed?
3. Are there ever circumstances when formulary managers like yourself prefer brand drugs over their generic alternatives? Please describe.
4. What role does cost have on generic drug utilization?
    a. May you provide a few examples?
    b. How about on the decisions regarding formularies?
5. What information or source of information could cause the views of the effectiveness and safety of generic drugs to change?
6. What information or source of information do you feel would have the greatest impact on generic drug utilization?

Information Needs

Now I would like to turn to how you got information about generic drugs and what you think would have been a more effective way to receive that information. Why don't we start by discussing…

1. Where do you receive information regarding safety and effectiveness or cost savings of generic drug(s)?
    a. How did you receive that information, for instance was the information shared with you verbally or did you receive written material on the drug's effectiveness and safety or cost savings?
        i. By whom?
    b. How would you prefer to receive information about generic drugs?
        i. For example, would you have preferred it being shared with you in a presentation, pamphlet, online, or another way?
2. What are other ways have you gotten information related to other drugs, such as brand name drugs, when you needed it?
3. How would additional information or information provided in other ways influence your views on which generic drugs should be utilized more often?
    a. How about other groups, such as physicians, pharmacists, patients, large purchasers or policymakers?
4. Do you have any suggestions on how to make information about generic drugs easier to get for formulary managers like yourself?
    a. How about making the information stand out amongst the large amount of information you receive about various generic drugs available?

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Policymakers

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because you were identified as having a role in the policymaking process for prescription drugs within the previous six months and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

First, I would like to know a bit about how the process works for getting generic drugs from manufacturers to patients.

1. May you please describe the process?
2. Do policies that your organization is responsible for impact access to generic drugs?
    a. If so, may you describe how?

    b. If not, what policies other organizations are responsible for have the greatest impact on access to generic drugs? **[Skip question 3]**
3. What is your role in this process for getting generic drugs from manufactures to patients?
    a. How does your role fit into the policy that influences the utilization of generic drugs?
        i. How long have you been in this role?
        ii. Have you held any other positions in which you played an integral role in the utilization of generic drugs?
    b. How many people do you think your role in this process impacts?
4. What is the role of large purchasers in generic drug utilization?
5. What is the role of physicians in generic drug utilization?
6. What is the role of pharmacists in generic drug utilization?
7. What is the role of patients in generic drug utilization?
8. What is the role of formulary managers in generic drug utilization?

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as effective and safe as brand name drugs? Why or why not?
    a. If not, what could be done to make generics as effective as brand name drugs? What about as safe?
2. Who or what do you believe has the most influence on generic drug utilization? Why? And how does that person or factor impact your decision making on generic drug related policy?
    a. How about what types of generic drugs are utilized, who or what has the most influence on what type of generic drug is prescribed and ultimately dispensed?
    b. What role does cost have on policy intended to encourage generic drug utilization?
        i. May you provide a few examples?
3. What information or source of information could cause your views on the effectiveness and safety of generic drugs to change?
4. What information or source of information do you feel would have the greatest impact on generic drug utilization?

Information Needs

Now I would like to turn to how you got information about generic drugs and what you think would have been a more effective way to receive that information. Why don't we start by discussing…

1. Where do you receive information regarding safety and effectiveness or cost savings of generic drug(s)?
    a. How did you receive that information, for instance was the information shared with you verbally or did you receive written material on the drug's effectiveness and safety or cost savings?
        i. By whom?
    b. How would you prefer to receive information about generic drugs?
        i. For example, would you have preferred it being shared with you in a presentation, pamphlet, online, or another way?
2. What are other ways have you gotten information related to other drugs, such as brand name drugs, when you needed it?
3. How would additional information or information provided in other ways influence your views on which generic drugs should be utilized more often?
4. Do you have any suggestions on how to make information about generic drugs easier to get for policymakers like yourself?
    a. How about making the information stand out amongst the large amount of information you receive about various generic drugs available?

FDA Educating Groups Influencing Generic Drug Use

Telephone Key Informant Interview Guide- Large Purchasers

Date:

Participant Number:

Interviewer:

Overview of Purpose of Call and Introductions

Hello [Name]. My name is [Name]. I am joined by my colleague [Name]. Thank you for agreeing to be participate in our study to better educate groups influencing generic drug use, based on their unique educational needs, 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 possible participant because you have been identified as someone involved in prescription drug purchasing decisions for a commercial entity within the previous six months and are age 19 or older.

The interview is expected to take approximately 60 minutes. What I and the research team learn from this study may better inform how information is provided related to generic medications. To thank you for your time, by participating in this study, you will be offered an honorarium of $150.

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, the Department of Health Outcomes Research and Policy or IMPAQ International.

Do you have any questions about the study or your role in the study? Do you wish to continue with the interview?

Before we begin I would like to ask you if we may be recorded. 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 interview 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 transcriptions.

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

If permission is granted, START RECORDING!

Background

First, I would like to know a bit about how the process works for getting generic drugs from manufacturers to patients.

1. May you please describe the process?
2. What is your role in this process?
    a. How do you/does your company make decisions about which generics to purchase?
        i. Are decisions driven by price or data? Please describe. **[If not already answered]**
        ii. How do these decisions change as new prices or data become available? **[If not already answered]**
    b. Which groups or types of people do you think your role in the process for getting generic drugs from manufacturers to patients impacts?
3. Have you previously held any other positions in which you played an integral role in the utilization of generic drugs?
4. What is the role of policymakers in generic drug utilization?
5. What is the role of physicians in generic drug utilization?
6. What is the role of pharmacists in generic drug utilization?
7. What is the role of patients in generic drug utilization?
8. What is the role of formulary managers in generic drug utilization?

Beliefs

Next, I would like to switch topics and ask you a few questions regarding your views on generic drugs.

1. Do you think generics are as effective and safe as brand name drugs? Why or why not?
    a. If not, what could be done to make generics as effective as brand name drugs? What about as safe?
2. Who or what has the most influence on generic drug utilization?
    a. How about what types or categories of generic drugs utilized, who or what has the most influence on what types or categories of generic drug that are utilized?
        i. Can you describe how each of these factors or groups influences the type or category of generic drug utilized?
    b. How do each of the following groups or factors influence which drugs are utilized, both brand and generic drugs? **[Ask only those key groups that were not discussed in question a above]**
        i. Policy/policymakers
        ii. Patients and/or caregivers
        iii. Pharmaceutical companies
        iv. Insurance providers including Medicare and Medicaid

v. Colleagues/other physicians
vi. Wholesalers or corporate distributers

c. What role does cost have on generic drug utilization?
    i. May you provide a few examples?
    ii. How about on the decisions you or your company make regarding which drugs or types of drugs to purchase?

3. What information or source of information could cause your views on the effectiveness and safety of generic drugs to change?
4. What information or source of information do you feel would have the greatest impact on generic drug utilization?

Information Needs

Now I would like to turn to how you got information about generic drugs your company is purchasing and what you think would have been a more effective way to receive that information. Why don't we start by discussing…

1. Where did you receive information regarding the generic drug(s) your company most recently purchased?
    a. How did you receive that information, for instance was the information shared with you verbally or did you receive written material on the drug's effectiveness and safety?
        i. By whom?
    b. How would you have preferred to receive the information about the generic drugs you were purchasing? Would you have preferred it being shared with you in a presentation, pamphlet, online, or another way?
    c. What information about generic drugs would be most helpful in deciding which to purchase for your pharmacy?
2. What are other ways have you gotten information related to other drugs, either brand or other generic drugs available when you needed it?
3. How would additional information or information provided in other ways influence your views on which drugs to purchase?
4. Do you have any suggestions on how to make information about generic drugs easier to get for large purchasers like your company?
    a. How about making the information stand out amongst the large amount of information you receive about various generic drugs available?