

October 3, 2014

NEW METHODS FOR EVALUATION OF IMPACT OF FDA DRUG SAFETY COMMUNICATIONS

APPENDIX II. Interview script for Healthcare Providers/Prescribers

I. INTRODUCTION/BACKGROUND (5 minutes)

Good morning/afternoon/evening. My name is _____ and I am calling as part of a study being conducted by physicians at Harvard Medical School and Brigham and Women's Hospital. I'm calling about the study relating to drug safety information communication in which you agreed to participate. If you complete this interview, we will send you or a charity of your choice \$150 as a thank you for your participation. If you choose not to accept the honorarium for any reason, please let us know. Is this a good time for us to talk? [IF NO, ARRANGE A TIME TO CALL BACK.]

This interview will focus on new safety issues that arise related to drugs on the market. We will be focusing on sedative/hypnotics. First, let me confirm that you have written at least one prescription for Ambien (also called zolpidem) or Lunesta (also called eszopiclone) in the past year. Is that right? *If no, thank the potential respondent for his/her time and end the interview. If yes, continue.*

One note before we continue: I am not medically trained and am following an interview script – I am not a qualified source of drug information. Also, if there is a question that you would rather not answer, please just let me know and we will skip that question. This interview is being recorded so that our team can accurately capture everything that you say.

We are interested in how you learn information about safe prescribing, how you communicate this information to patients, and how you think that patients perceive this information. We hope to use your responses, along with those of other prescribers, to make information about drug safety as helpful to patients as possible in the future. Let's begin...

II. PRESCRIPTION DRUG SAFETY (10 minutes)

First, I would like to know where you get information about prescription drug safety. What is your primary source for drug safety information? That is, what source do you use most often, and why?

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1. Do you learn about prescription drug safety from the official drug labeling? Just so we're clear, the label I'm referring to is the official information in the PDR and that is sometimes provided with prescription drugs.
 - i. If no, why not? [GO TO 2.]
2. Do you learn about prescription drug safety from manufacturer sales representatives?
 - i. If no, GO TO 3.
 - ii. If yes, what sort of safety issues do you discuss with the drug reps?
3. Do you learn about prescription drug safety from medical journals?
 - i. If no, why not, THEN GO TO 4.
 - ii. If yes, what types of safety information do you learn from medical journals?
4. Do you use any sort of physician-directed online information sources, like Medline or Epocrates?
 - i. If no, why not? THEN GO TO 5.
 - ii. If yes, which one? Why? Have you ever worried about the quality of information found in these physician-directed online sources?
5. Do you learn about prescription drug safety from the FDA?
 - i. If no, GO TO 7.
 - ii. If yes, what sort of information does the FDA provide, and how do you learn about it?
6. Do you learn about prescription drug safety from patients?
 - i. If no, GO TO NEXT SECTION.
 - ii. If yes, what sort of information do patients provide?
7. Are there other sources of drug safety information that you use? *PROMPT, IF NECESSARY*: The lay media, that is, TV, radio, newspapers, magazines, Internet? Colleagues? Others?
 - i. If no, GO TO 6.
 - ii. If yes, what sort of information do these sources provide that you don't receive from other places? Do you do anything different based on this information?

III. PRESCRIBING SLEEPING PILLS (10-15 minutes)

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Next, I'd like to ask you about prescribing sedatives/hypnotics for sleep.

8. Thinking about when you prescribe a sedative/hypnotic to a patient to take before bedtime to help them sleep, can you tell me what you generally tell the patient when giving them the prescription?

IF DOES NOT MENTION, PROBE FURTHER: How do you describe its advantages? How do you describe its side effects, and how to recognize them? Do you talk about the duration of therapy? Do you suggest alternative therapies?

9. Please describe how the safety information that you discuss with a patient changes by type of sedative/hypnotic you prescribe?

10. Please describe how the safety information that you discuss with a patient changes for different patients?

11. What have patients have told you regarding their adverse experiences with sedatives/hypnotics?

PROBE FURTHER: Where do patients say they get their information? What actions do you take when patients disclose adverse experiences, including change dosages or switch to different drugs?

IV. SAFETY INFORMATION AND SLEEPING PILLS (10-15 minutes)

Let me read you some drug safety information about Ambien. Ambien can be an effective sedative/hypnotic, but also has risks. People might feel drowsy and have trouble staying alert for several hours in the morning after they took it. During that time, patients' safety might be at risk when taking part in activities requiring alertness, like driving or operating heavy machinery. Next-morning drowsiness is greatest with the long-acting forms of Ambien. Women appear to be more susceptible to getting drowsy the next morning after taking Ambien. Because of this, the company was required to lower the recommended dose.

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12. Does this safety information sound familiar to you?

- i. *If no, GO TO 13 below.*
- ii. *If yes, where do you recall learning about this safety information?*

PROMPT, IF NECESSARY: journals, colleagues, Internet, lay media, drug reps. Do you commonly discuss all of these details with your patients? Why or why not?

13. Can you describe your reaction to Ambien and its use after learning this information?

*PROMPTS [Use different tense depending on whether they've ever heard this information before]:
Were/Are you concerned about prescribing the drug? Why or why not? Did/will you reduce the dose, choose other drugs instead, have specific conversations with your patients about this information, or ask about these side effects among your patients.*

14. Did a patient ever contact you about side effects like the ones I've described?

- i. *If no, GO TO 15 below.*
- ii. *If yes, what were their specific concerns? What was your advice or what did you do as a result of these concerns?*

15. What additional information would you like to have to incorporate this drug safety information into your prescribing practices related to Ambien?

PROMPTS: For example, would you want to know about data on which the safety warning was based? Would you want to know how other sedatives/hypnotics compare with respect to this risk? Would you want to know the urgency of the warning?

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16. Can you describe what you think is the most effective mechanism to disseminate drug safety information about Ambien to **physicians**?

17. Can you describe what you think is the most effective mechanism to disseminate drug safety information about Ambien to **patients**?

That's all of the questions I have for you. Is there anything I haven't asked about that you would like to discuss? Thank you for your time and your insights. I appreciate your speaking with me.