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Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Patient Experiences with REMS Programs Patient Interview Guide

A. INTRODUCTION (5 minutes)

Good **[morning/afternoon/evening]**. May I speak with **[patient's/caregiver's name]**?

Hi, my name is **[your name]**, and I am calling as part of a U.S. Food and Drug Administration-sponsored research study on a medication safety program by researchers at Harvard Medical School and Brigham and Women's Hospital in which you agreed to take part. We are studying the safety measures required by the U.S. Food and Drug Administration on a drug you took **[drug name]**.

To verify your ability to participate in this study, we'd like to ask you a few questions.

- Have you started taking **[drug name]** in the past year?
[or are you the caregiver of person who has started taking **[drug name]** in the past year?]
- What is your sex?
[or what is the person's sex?]
- Are you 18 years of age or older?
- What is your occupation? [Exclusions: FDA employees, pharma employees, consumer research organizations, health care professionals]

Thank you for confirming your ability to participate in this study.

The entire interview will last approximately one hour. If you complete this interview, we will send you a \$50 Amazon gift certificate as a token of appreciation for your participation, or donate the money to a charity of your choice. Is this still a good time for us to talk? **(IF NO: ARRANGE A TIME TO CALL BACK.)**

I am not a medical doctor and am not able to offer medical advice about your treatment plans. If there is a question that you would rather not answer, we can skip it. This interview is being recorded so that our team can accurately record your responses. Your answers will be kept anonymous and not shared outside the study team. Let's begin.

[Note for caregiver interviews: asterisked questions=ask about patient; double asterisked questions=ask about both caregiver and patient.]

B. BACKGROUND (5 minutes)

1. How did you first learn about [drug name]?
2. How long (did you take/have you been taking) [drug name]?*
 - a. (IF NO LONGER TAKING: When did you stop taking [drug name]?)
 - b. How frequent (were/are) your (refills/infusions)?
3. Did you have difficulty finding a healthcare provider that could prescribe you [drug name]?
4. Do you recall the type of healthcare provider who prescribed the drug (i.e., MD/PA/NP)? If so, what were their credentials?
 - a. When did you start seeing this provider?
 - b. Did you start seeing him/her because of the medical condition that requires you to take [drug name]?
 - c. Do you recall the specialty of the healthcare provider who prescribed the drug for you? If so, what was it?
5. Tell me a bit about your medical condition that led you to take [drug name]. When were you first diagnosed?*
 - a. What was your health like when you were prescribed [drug name]?
 - b. Had you tried other drugs or other treatments before [drug name]? If yes, what was your experience with those drugs/treatments?
6. As far as you know, what benefits are patients expected to get from taking [drug name]?
7. Similarly, what side effects are you aware of that are associated with taking [drug name]?

C. QUESTIONS ABOUT REMS (“Safety Program”) (15 minutes)

Let’s now move to talking about certain safety issues related to [drug name].

8. When you were first prescribed the drug, do you remember having any safety discussions with your prescriber about [the safety issue related to the REMS drug]?
 - a. If yes, what did you talk about? **[IF NO, GO TO #10]**
 - b. Was there one or multiple conversations? Did these safety conversations continue throughout treatment based on changes in your health status?

9. **[IF YES TO #8]** Were there certain materials with your provider that were particularly helpful in understanding how to use the drug safely with respect to [the safety issue related to the REMS drug]?
 - a. Follow-Up Questions:
 - i. Did your provider go over any materials with you? Can you describe those materials?
 - ii. Did you ever refer back to any of these materials for information during treatment?
 - iii. Were there materials other than those your provider gave you that you used to understand how to use the drug safely.

10. Are you aware that the FDA required a special safety program for [drug name]?
 - a. **IF YES TO #10:** How did you learn about the safety issue related to [drug name]?
 - i. In your own words, could you describe the risk this special safety program is designed to address?
 - b. **IF NO TO #10, EXPLAIN:** The FDA’s special safety program is called Risk Evaluation and Mitigation Strategies or REMS. The purpose of the REMS program is to ensure the [drug name] is used in a way that its benefits outweigh its risks. Bosentan was required to have a REMS program because of its risk of birth defects in case of pregnancy, as well as its risk of liver injury.
 - i. Follow-Up: Were you made aware of these risks when you were first prescribed the drug?

11. **(Did/would)** knowledge of the safety program impact your willingness to take the drug at the time you were prescribed it? Why or why not?

D. ENROLLMENT (15 minutes)

12. Let's go back to the time you first discussed taking this drug with your provider. What was your experience learning about the drug, and the process to start taking it after that initial conversation?
 - a. Were other physicians, nurses, or other health care providers involved in this process? If yes: who, and what was their involvement?

13. Did your provider order any tests before prescribing the drug for you?
 - a. If so, do you remember what tests?
 - b. How did you feel about those tests?
 - c. Follow-Up: Where did you have those tests done?
 - d. How did you learn about the testing site? How burdensome was it to get the tests done?

14. Did you receive special paperwork or sign an enrollment/agreement form related to the FDA-required safety program before starting your treatment with [drug name]? **[IF NO, SKIP TO #16]**
 - a. If YES, were there specific rules and requirements that you agreed to follow? If so, what were they?

15. **[IF YES TO #14]** What did you think about the enrollment/agreement form?
 - a. Follow-Up Questions:
 - i. What did you think about the rules and requirements of the safety program?
 - ii. Did the enrollment/agreement form affect your experience with [drug name]? If so, how? (PROBE: Did the form provide useful information? Do you think it helped you and your provider make decisions together?)

16. How did your experience starting [drug name] compare to your experiences starting other prescription drugs?
 - a. Did you have any insurance-related issues getting [drug name]? If so, why? (PROBE: **cost of the drug, additional paperwork, etc.**)

E. ACCESSING AND ADHERING TO MEDICATION (15 minutes)

17. How do you get [drug name]?
- PROBE AS NEEDED: Do you use a specialty pharmacy? Do you go to an infusion center or a hospital setting to take your medication?
 - Is this similar to or different from how you get your other medications related to your condition? Please explain.
18. Have you ever had to switch healthcare providers to continue taking [drug name]? If so, why?
19. Have you ever decided to not pick up a prescription for [drug name] or considered doing so? If so, why?
- (Was/is) the cost of [drug name] a problem for filling your prescription?
 - (Did you have/have you had) issues with your insurance? If so, what?
20. Did you experience/have you experienced any difficulty getting questions about [drug name] answered? If yes, please explain.
21. Did you experience any side effects while taking [drug name]? If yes, did you have any conversations or other contact with your provider or the drug company about the side effects?

Provide background: As part of the bosentan REMS program, patients must have monthly liver testing and female patients that can get pregnant must get monthly pregnancy tests and agree to take to an approved form of birth control.

22. What was your experience with required testing while on treatment?
- Monthly liver testing
 - Monthly pregnancy testing (if applicable)
23. Overall, how has your experience been getting [drug name]? Has it been easier, more difficult, or about the same compared to other medications prescribed for your condition? If so, how?

F. WRAP UP & DEMOGRAPHICS (5 minutes)

24. Given what we've discussed today, is there anything you wish you'd known before starting [drug name]? If so, what?

25. Given the insights you've shared, how, if at all, do you think the drug safety system can be improved?

That's all of the questions I have for you. Is there anything I haven't asked about that you would like to discuss about [drug name]?

Before we end the interview, I'd like to ask you some demographic questions. If you do not feel comfortable answering a specific question, please let us know. As a reminder, your participation in the project will remain anonymous.

- In what state do you live?
- What is your sex? **
- Please select the age category in which you fall. **
 - 18-25 years
 - 26-33 years
 - 34-41 years
 - 42-49 years
 - 50-57 years
 - 58-64 years
 - 65 years or above
- Race: Which of the following best describes your race? Mark one or more
 - White
 - Black or African-American
 - American Indian or Alaska Native
 - Asian
 - Native Hawaiian or Other Pacific Islander
- Are you Hispanic, Latino, or Spanish origin?
 - Yes
 - No

- Please select the highest level of schooling you have completed.**
 - Less than high school
 - High school or GED
 - Some college or a 2-year associates degree
 - College degree
 - Master's degree
 - Advanced health-related degree (for example, MD, DDS, health-related PhD)
 - Advanced non-health-related degree (for example, JD, non-health related PhD)

- Please select the income bracket in which your family falls.
 - Less than \$15,000
 - \$15,000-\$29,999
 - \$30,000-\$49,999
 - \$50,000-\$74,999
 - \$75,000-\$100,000
 - Greater than \$100,000

Thank you. We will be in touch soon regarding your token of appreciation. Would you like to provide the address that we can use to send your gift card now or do you prefer to follow up with this information via email?

If additional questions arise, please contact this study's principal investigator, Dr. Ameet Sarpatwari at 617-525-8890.

Thank you for your time and your insights. I appreciate your speaking with me.