Physician Experience Interview Guide: Alvimopan

Good [morning/afternoon/evening]. May I speak with [Dr. X]?

Hi, my name is [Y], and I am calling as part of a study on physician experiences prescribing alvimopan*, in which you agreed to take part. This research is being conducted by investigators at Brigham and Women's Hospital / Harvard Medical School and the US Food and Drug Administration (FDA).*

*Your participation in this interview is voluntary, and you may withdraw at any time. Your responses will be aggregated with other responses and analyzed in a de-identified manner. The entire interview will last approximately one hour. If you complete the full interview, we will send you a $100 Amazon gift certificate for your time and effort 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.)*

Section A: Prescribing and Training History
(expect to spend about 10 minutes on this section)

1. Approximately when was the last time you prescribed alvimopan?

2. Approximately how many—number and percentage—of your patients undergoing short bowel resection surgery have you prescribed alvimopan to over the last 3 years?

3. Before you started prescribing alvimopan, did you receive any training on its risks, benefits, and safe prescribing practices? If so, can you describe the training process?
    - **IF YES:** Probe on length of training, content, organizers, strengths, and weaknesses
    - **IF NO:**
        - What resources, if any, did you use to get information on alvimopan?
        - Do you think a training would have been useful? Why?

Section B: Patient Counseling
(Expect to spend about 35 minutes on this section.)

Now we'll turn to your experiences prescribing alvimopan. As you may know, the FDA requires a special safety program for the drug called a Risk Evaluation and Mitigation Strategy or REMS. The purpose of the REMS program is to ensure alvimopan is used in a way that its benefits outweigh its risks.

4. To your knowledge, why does alvimopan have a REMS program?

(Describe risks and benefits here if needed)

5. To your knowledge, what is the primary safe use requirement under the REMS program?

(If uncertain: Note that no more than 15 doses of the drug can be provided to a patient due to increased risk of myocardial infarction with long-term use.)

6. How concerned are you about the risk of myocardial infarction with long-term use of alvimopan? Why?

7. Do you usually have conversations with your patients before you start them on alvimopan?
    - If no, why? SKIP TO Q9.
    - If yes, PROCEED TO Q8.

8. Can you describe the conversations you have with patients before you start them on alvimopan?
    - What risks of alvimopan are you most concerned about and why?
    - What risks do you usually discuss with them?
    - How do your patients react to these risks?
    - Do you routinely inquire about immediate past use of narcotics?

9. Have you had patients seek another treatment option after hearing about alvimopan risks? If so, how frequently does this happen? Why?
    - Are there feasible alternatives to alvimopan? If so, what are they?

10. Do your patients receive from you or your team any other materials describing the risks of taking alvimopan? If YES, what materials?
    - For example, published articles or stories, links to manufacturer or non-manufacturer websites, or pamphlets or brochures produced by the manufacturer, you, or your institution.

Section C: Impact of Alvimopan REMS Program
(expect to spend about 10 minutes on this section)

11. Are you aware of processes in place at your hospital to ensure that the safe-use requirements around alvimopan are met? If so, can you describe them?
    - To the best of your knowledge, who is involved in those processes?

12. Does ensuring safe prescribing and use of alvimopan change your normal workflow around patient care (as compared to other drugs)? If so, how?

13. Has the prescribing limit on alvimopan had an impact on patient care? If so, how, how often does this occur, and what do you do?
    - Probe: if more than 15 doses are needed, discharge takes place within 7 days, etc.

14. Would you be more likely to prescribe alvimopan if it was not subject to the safe use requirement? Why?
    - Are there other factors that affect your decision to prescribe alvimopan? If so, what are they? (Probe: efficacy, availability of viable alternatives, tolerability, etc.)

15. Do you have any additional recommendations for improving safe prescribing and use of alvimopan overall?

Section D: Wrap-Up
(expect to spend about 3-5 minutes on this section)

That is all the questions I have for you. Is there anything I haven't asked about that you would like to discuss? What should we do with the honorarium? [If they would like it sent to them, ask for email address]. We will send it within the week.

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

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