

FDA Opioid Study
Interviews with Health Care Providers

Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications

Overview:

1. Introduction & Consent (5 minutes)

The interviewer will provide background information about the project and get consent to proceed.

2. Discussion (50 minutes)

- General Issues Related to Opioids
- Prescribing Practices
- Patient/Provider Communication
- Education and Training
- Issues Related to Opioids: Role of Prescribers
- Role of the FDA

3. Closing (5 minutes): Thank you and incentive information.

I. Introduction & Consent

INTERVIEWER: Hello and thank you for making time to talk with me today.

My name is [] and I work for RTI International, a not-for-profit research organization located in Research Triangle Park, North Carolina.

The Food and Drug Administration has contracted with RTI to conduct interviews that will help them understand healthcare providers' perspectives with regard to opioid use, misuse, and abuse.

Informed Consent

Before we begin, I would like to review a few items:

Consent Form. I understand that you received a consent form via e-mail in preparation for today's interview and returned the signed version. Is that the case? Do you have any questions/concerns? Just a few highlights...

- **Participation.** Your participation is voluntary and you can stop participating at any time. If at any time you are uncomfortable with any question, you can choose not to answer.
- **Privacy.** Your name and contact information will not be given to anyone else and no one will contact you after our discussion is over unless you give permission.
- **Audio Recording.** We will be audio recording the interview today and someone will be taking notes while we talk. To make sure that we capture everything people say today, we are making an audio recording of this discussion, which will later be transcribed. We will provide the FDA with a transcription and audio recording of our discussion. However, your name and any identifying information about you will not be included nor associated with the project or the report in any way.
- **Reporting.** As part of this study, we will write a report for the FDA summarizing what we learned from these interviews. We will not use your name or any identifying information in the report.

Do you have any questions before we begin?

Do I have your consent to participate? [get a verbal "yes" then continue]

II. Discussion

Issues Related to Opioids: General

1. From your perspective, what are the most important issues related to opioids?
 1. **Probe:** Why do you think the use of opioids has become a public health crisis? What factors have contributed to this epidemic? What do you think is the biggest factor?

Prescribing Practices

2. For which conditions do you typically prescribe opioids?

[ASK IF NOT MENTIONED]

- Back pain
- Neck pain
- Headache
- Arthritis
- HIV

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3. Which types of opioids do you typically prescribe?
- Probe: Do you typically prescribe immediate release or short acting opioids, extended release/long acting opioids (ER/LA), or both?
 - Probe: Do you typically prescribe opioids for short-term or chronic use?
 - What do you know about abuse-deterrent opioids? What experience do you have with them?
 - What do you know about opioid reversal drugs (e.g. Narcan, Evzio, and naloxone)? What experience do you have with them?
4. How do you make decisions about whether or not to prescribe opioids for a patient?
1. **Probe:** How do you balance the risks and benefits of opioids when considering them for your patients with non-cancer-related pain?
 2. **Probe:** How does a patient's request for opioids influence your decision to prescribe them?
 3. **Probe:** How do you decide how long to keep a patient on an opioid? How do you monitor/assess this decision?
 4. **Probe:** How does your decision-making process differ when you are prescribing opioids for acute versus chronic non-cancer pain?
 5. **Probe:** When, or in what types of situations, are you most likely to discuss alternatives to opioids to your patients with chronic non-cancer pain? What alternatives do you present them? When, or in what type of situations do you recommend alternatives to opioids?
5. How have your prescribing practices changed over the last few years and why?
1. **Probe:** How has the increased attention and debate about opioids affected your prescribing?
 - Has it changed the types of problems for which you prescribe opioids? The kinds of patients to whom you prescribe opioids? The kinds of opioids you prescribe (e.g. immediate release vs extended release/long acting?)
 2. **Probe:** To what extent do you use the opioid labeling to inform your prescribing decisions?
 3. **Probe:** How do you keep up-to-date on changes made to the opioid labeling?
 4. **Probe:** How do you learn about new opioid medications? Can you walk me through how you learned about the last new opioid that you prescribed?
 - 5.

6. What experiences with opioid misuse and or abuse have you had among your patients? How did you handle those issues? Why do you think those occurred/didn't occur? What things could have been done differently or have you started doing differently since having those experiences?
 - What do you know about **medications** to help treat those who are addicted to opioids, or medication-assisted treatment (MAT)? (e.g. methadone, buprenorphine, and naltrexone) What experience do you have with them?
7. Which organizations, federal agencies, or professional societies affect how you make prescribing decisions and how?
8. What processes and/or strategies do you use to minimize risk when prescribing opioids? Are those processes/strategies the same for acute and chronic pain? For different types of opioids?
 1. How do you identify patients at high risk for misuse, abuse or addiction?
 2. **Probe only as needed:** Opioid treatment agreements, Prescription Drug Monitoring Programs, medication call-backs, or urine drug screens screening for risk factors for misuse?
 3. **Probe:** If they use more than one, ask: Which ones do you find most useful? Which ones are most problematic to implement, why? Have you stopped using any processes/ strategies to minimize risk because you found it was not useful? If so, which one(s)?
 4. **Probe only as needed:** What strategies or processes do you use when *managing* patients on chronic opioids?

Patient-Provider Communication

9. What information do you give to patients when you prescribe opioids to them for the first time? When you re-prescribe? When you prescribe to patients who have been prescribed opioids by a previous healthcare provider?

Can you share the key steps you take when communicating information on the risks associated with opioids to patients? The benefits? What, if any patient education tools do you use to communicate this information? Where do you obtain these tools (e.g. provide only if needed, e.g. – drug company website, FDA, CDC,) ER/LA REMS Program? (If not mentioned)

What are your long-term goals and/or expectations for what the opioid you are prescribing will accomplish for the non-cancer chronic pain patient? What do you think are these

patients' goals or expectations? What do you discuss with them related to goals of the treatment?

10. What do you tell your patients about the evidence (or lack of evidence) of the effectiveness of opioids in relieving chronic non-cancer pain?
11. What are your main challenges in communicating with patients about opioids?
 1. **Probe:** What have you found is the best way to engage patients in discussing issues related to misuse and abuse?
 2. **Probe:** What do you think health care providers can do to improve their communication with patients about opioids?
 3. **Probe:** What resources do you refer patients to for additional information? What resources would be helpful for you to provide or refer patients to?

Education and Training

12. Can you tell me briefly about any training or resources that you have received related to opioids?
 1. **Probe:** Who was the sponsor or developer of the program? How have these trainings informed your current practice? How have they changed the way that you prescribe opioids? How have they affected the way you prescribe opioids for acute pain? Chronic pain? If they haven't affected your prescribing practices, why not? What would be needed to change your prescribing?
13. What other kinds of resources or training would be helpful to you in addressing issues of misuse and abuse opioids (both potential and actual)?
 1. **Probe:** from whom/where do you want to get this information—peers, government agencies, journals (which), conferences (which), medical/professional associations (which), medical/professional websites (which), drug manufacturers?
14. Are you familiar with the ER/LA opioid analgesics risk evaluation and mitigation strategy (REMS)? Have you taken an ER/LA REMS CE? What was helpful about it? What wasn't? How do you think the ER/LA REMS could be made more effective? How do you feel about proposals to expand the REMS to immediate release opioids?
15. How do you feel about proposals to make training mandatory for healthcare providers who want to prescribe opioids? About proposals to require healthcare providers to enroll in limited access programs before they can prescribe opioids?

Issues Related to Opioids: Role of Prescribers

16. What role do you think prescribers play related to opioid misuse and abuse? Related to addiction?
17. Past research has shown that some health care providers are aware of opioid misuse, and abuse but generally but don't believe it's a concern in their own practices. Why do you think that is? What can be done to overcome this disconnect?
18. What can providers do to address issues related to opioid misuse and abuse in both their own practices and on a larger scale? Which of these methods do you think is most effective at curbing the misuse/abuse of opioids and why?
19. What do you think patients can do to help?

Role of the FDA

Next we're going to talk more about the Food and Drug Administration.

20. What do you think the FDA's role is in addressing problems related to opioids?
 1. **Probe:** How do you think the FDA could help prescribers reduce the risks of opioids in their patients?
21. What information or guidance have you received from the FDA about opioids? How have you received this information?
 1. **Probe:** What additional information do you think FDA should be providing to healthcare providers about opioids? How would you like to receive this information?

Conclusion

These are all of my questions. Is there anything else you would like to share before we wrap up?