Attachment D. Case Studies Interview Guide

Form Approve

OMB No: xxxx-xxxx

Exp. Date: xx-xx-xxxx

Public Reporting burden of this collection of information is estimated at 1 hour, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.  An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.  Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NW, MS D-74, Atlanta, GA 30333; Attn:  PRA (xxxx-xxxx).

**Introduction**

Hello, I’m (*NAME*) from Abt Associates. Thank you for taking the time to speak with us. I have [insert name(s)] on the phone with me.

As a reminder, Abt Associates is working with the Centers for Disease Control and Prevention (CDC) to evaluate the effects of your health system’s policies and guidelines regarding chronic pain management and opioid prescribing, including access to medications for opioid use disorder (MOUD). This interview aims to get a better understanding of your health system’s experiences with implementing such policies and guidelines, and their effects on patient outcomes. This study is funded by the CDC.

We’d like to talk with you because of your involvement with a case study related to pain management and opioid prescribing.

[DESCRIBE STORY HERE]

**If a clinician or health care staff is involved:**

## Oral consent

Before we begin, I want to read a few points about this interview:

* Your participation is voluntary.
* This interview will last approximately 30 minutes.
* Your name and affiliation will be shared with CDC and included in the acknowledgements in any report or publication; however, we will not attribute our findings to you or your organization explicitly.
* You can decline to answer any question, without affecting your continued participation in the interview or your relationship with the CDC.
* The principal risk of participating in this session is a small risk of loss of confidentiality. The team has many procedures in place to reduce this risk.
* This study has a “Certificate of Confidentiality” from the CDC to protect your privacy. Unless you consent , researchers cannot share or release information that may identify you[[1]](#footnote-1), with a few exceptions[[2]](#footnote-2) (please see footnotes).
* Do you understand these details about the interview and agree to proceed?

We also would like to record the interview so we do not miss anything. The recording will not be shared with anyone outside Abt Associates or CDC.

* May we record this interview? Yes \_\_\_\_\_ No \_\_\_\_\_
* Do you have any questions before we get started?

1. What is your role in [insert health system] (e.g., clinician, health care staff)?
2. How long have you been in this role?
3. What is your role in chronic pain management? In this interview, by “chronic pain management” we are also including prescribing of opioid medications, nonpharmacologic therapies, and/or non-opioid medications for chronic pain, as well as opioid use disorder (OUD) assessment and treatment when indicated.
4. Can you tell us about this example we identified, from your perspective?
   1. What happened?
   2. Who was involved and how?
   3. What would you highlight as the key lessons learned from this example?
   4. Was there anything you would consider a success? Why?
   5. Were there any challenges or barriers? If so, how were those overcome?
   6. What was the outcome?

**If a patient is involved:**

## Oral consent

Before we begin, I want to read a few points about this interview:

* Your participation is voluntary.
* This interview will last approximately 30 minutes.
* We will not attribute our findings to you or your health system explicitly.
* You can decline to answer any question, without affecting your continued participation in the interview or your relationship with the CDC.
* The principal risk of participating in this session is a small risk of loss of confidentiality. The team has many procedures in place to reduce this risk.
* This study has a “Certificate of Confidentiality” from the CDC to protect your privacy. Unless you consent and say it is okay, researchers cannot share or release information that may identify you[[3]](#footnote-3), with a few exceptions[[4]](#footnote-4) (please see footnotes).
* Do you understand these details about the interview and agree to proceed?

We also would like to record the interview so we do not miss anything. The recording will not be shared with anyone outside Abt Associates or CDC.

* May we record this interview? Yes \_\_\_\_\_ No \_\_\_\_\_
* Do you have any questions before we get started?

1. How long have you been a patient in [insert health system]?
2. Can you tell us a bit more about (fill in with details)?
   1. What happened?
   2. Who was involved and how?
   3. Was there anything about this experience that you call a success?
   4. Were there any issues? If so, how were those overcome?
3. *[Note to interviewer: Please only ask 3a. and/or 3b. if relevant and not already covered]:* 
   1. Have you ever been prescribed opioids? Have you ever adjusted/changed your opioid therapy?
   2. Have you ever been prescribed medications used to treat opioid use disorder, such as buprenorphine, methadone, or naltrexone?
4. How long have you seen your clinician in [insert health system]?
5. As a patient there, what do you think of the changes in how chronic pain is treated at [insert health system], which could include changes in how opioids are prescribed for chronic pain?
6. What was your initial response to these changes?
7. How do you feel about these changes now?
8. What was the communication between you and your clinician like? What worked well and what did not in terms of communication?
9. What was the end result?
10. If you are comfortable, could you share a little bit more about your pain condition?

1. Unless you consent, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. [↑](#footnote-ref-1)
2. The Certificate does not protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable (contagious, infectious) diseases, and threats of harm to yourself or others.  The Certificate cannot be used stop a federal or state government agency from checking records or evaluating programs. The Certificate does not stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also does not stop your information from being used for other research if allowed by federal regulations.

   Researchers may release your information when you consent. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research.  The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.  [↑](#footnote-ref-2)
3. Unless you consent, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena. [↑](#footnote-ref-3)
4. The Certificate does not protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable (contagious, infectious) diseases, and threats of harm to yourself or others.  The Certificate cannot be used stop a federal or state government agency from checking records or evaluating programs. The Certificate does not stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also does not stop your information from being used for other research if allowed by federal regulations.

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