Improving the Quality and Representativeness of the Treatment Center Program Data: Survey to Quantify the Magnitude of Misclassification of Opioid Product Identification

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Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.

This study is being conducted on behalf of the U.S. Food and Drug Administration by RADARS® System, a division of Denver Health and Hospital Authority.

Implied Consent

Within the last year, you completed a survey about your use of medications, tobacco, alcohol, drugs, and other health issues. Your answers about these topics are important, and you are invited to participate in this research study that asks additional questions about your use of medications. Policymakers and researchers can use information from this study to understand the ways people use medications and how they make decisions about ways to use medications. This survey should take about 15 minutes to complete.

Taking this survey is voluntary. You do not have to take the survey. If you start to take the survey and change your mind, you may stop. We will only use information you choose to enter into the survey before stopping. There will not be any penalty for not taking the survey or for stopping the survey. You will receive a token of appreciation, according to your panel's policy. We ask that you try to answer all questions. Some questions and sections are designed so that you do not have to answer.

Your answers will be kept secure to the extent permitted by law and are anonymous to the researchers. The researchers will not receive any information that can identify you. The survey panel that gives this survey will link a code to you so that the researchers can note if you have taken more than one survey or can ask your panel company to send you more surveys in the future. However, the researchers will never be able to identify you with this code.

RADARS® System, a division of Denver Health and Hospital Authority, conducts this study. For questions or concerns, you may call the research team at (303) 389-1610. For questions about your rights as a research participant, you may call the Colorado Multiple IRB at (303) 724-1055.

A1. I was provided with information about the survey, and I was told that information I provide will be kept secure to the extent permitted by law. I choose to take the survey. Select one.
     Yes
     No

Prescription Medication
12-Month Use

The questions below are about prescription pain relievers. These medications are used to treat acute, chronic, and nerve pain. Other uses include anesthesia, cough suppression, opioid replacement therapy, and digestion-related pain.

Some pain relievers are available without a prescription or are made illegally (not by a drug company). Do not include use of illegally made pain relievers in your answers below.

B1.1. Have you used the prescription **<<<Select pain reliever>>>** below **in the last 12 months**? Select yes or no.
>Yes
>No

Note: Respondents will be asked the question for each of the following 13 pain relievers: Buprenorphine, Codeine, Eluxadoline, Fentanyl made by a drug company, Hydrocodone, Hydromorphone, Methadone, Morphine, Oxycodone, Oxymorphone, Sufentanil, Tapentadol, and Tramadol. Order is randomized for each respondent; the randomized order of pain relievers in this question is retained for order of follow-up questions.

Formulation & Product 12-Month Use

Note: This is an example section. This section is repeated for all pain relievers the respondent selected in B1.1.

B2.1. You said that you used prescription **[pain reliever selected in B1.1]**. What **forms** of prescription [pain reliever selected in B1.1] have you used in the last 12 months? Select yes or no for each form.
>Yes
>No

Formulation
Pill such as a tablet or capsule ([list of all branded pain relievers] or other generics)
Patch ([list of all branded pain relievers] or other generics)
Implant ([list of all branded pain relievers] or other generics)
Oral film ([list of all branded pain relievers] or other generics)
Lollipop/lozenge ([list of all branded pain relievers] or other generics)
Liquid such as oral liquid, injection, spray, or drops ([list of all branded pain relievers] or other generics)
Wafer/disc ([list of all branded pain relievers] or other generics)
Other or unknown form of [pain reliever selected in B1.1]

Note: Only formulations and pain relievers applicable to the pain reliever are presented. Order is randomized for each respondent; randomized order of pain relievers in this question are retained for order of follow-up questions. All formulations are presented to the respondent on the same screen. Only formulations that the respondent selects "Yes" for above are presented in B3.1.

B3.1. Which of the following [pain reliever selected in B1.1] **pain relievers** did you use in the last 12 months? Select an answer for each pain reliever.
>Yes
>No
>I am not sure

Product List
Single ingredient pills
Generic [Brand name]® or generic single ingredient [pain reliever] pill
Other single ingredient [pain reliever] pill
Unknown single ingredient [pain reliever] pill

Combination ingredient pills
[Brand name]® pill
Generic [Brand name]® or generic combination ingredient [pain reliever] pill
Other combination ingredient [pain reliever] pill
Unknown combination ingredient [pain reliever] pill
Patches
[Brand name]® patch
Generic [Brand name]® generic [pain reliever] patch
Other [pain reliever] patch
Unknown [pain reliever] patch
Implants
[Brand name]® implant
Other [pain reliever] implant
Unknown [pain reliever] implant
Single ingredient oral films
[Brand name]® oral film
Other single ingredient [pain reliever] oral film
Unknown single ingredient [pain reliever] oral film
Combination ingredient oral films
[Brand name]® oral film
[Brand name]® oral film
[Brand name]® oral film
Generic [Brand name]® or generic combination ingredient [pain reliever] oral film
Other combination ingredient [pain reliever] oral film
Unknown combination ingredient [pain reliever] oral film
Immediate release liquids
[Brand name]® injection
Generic [Brand name]® or generic immediate release [pain reliever] injection
Other immediate release [pain reliever] liquid
Unknown immediate release [pain reliever] liquid
Extended release liquids
[Brand name]® injection under the skin
Other extended release [pain reliever] liquid
Unknown extended release [pain reliever] liquid

Note: Sub-categories are broken out by immediate release (IR)/extended release (ER) and single/combination ingredient as is applicable for each pain reliever. Order of pain relievers and generics is randomized for each sub-category, while anchoring "Other" and "Unknown" categories at the end of each sub-category. Apply the randomized order throughout the remainder of the survey. All pain relievers/sub-categories are presented to the respondent on the same screen. Only formulations that the respondent selects "Yes" for above are presented in B3.1. If the respondent selected "Yes" for a form in B2.1, they must select a pain reliever in a corresponding subsection of the pain reliever table in B3.1.

<u>Source, Frequency of Rx Refills</u>

Next, we will ask **where** you got each medication.

Note: This is an example section. Repeat this section for all pain relievers selected in B3.1.

Header: [Pain reliever selected in B1.1]

B4.1. When you used a **[pain reliever selected in B3.1]** in the last 12 months, where are all of the places you got it from? Select all that apply.

Sources
Healthcare provider or pharmacy with a prescription for you
Healthcare provider or pharmacy with a forged prescription
Treatment center
Friend or family member
Dealer
Taken from a pharmacy, clinic, or hospital without permission
Somewhere without a prescription while you were outside the U.S.
Internet without a prescription
Some other place

Note: The sources above will be randomly presented to participants, keeping "some other place" always at the bottom. The order in which they are presented in the first instance will be the order they are presented throughout the questionnaire. "Treatment center" will only be displayed for buprenorphine and methadone pain relievers.

Header: [pain reliever selected in B1.1]

B5.1. During the PAST 12 MONTHS, since [autofill date one year ago], how many times was a prescription for a **[pain reliever selected in B3.1]** filled for you at a pharmacy? This could be picked up by you or someone else, but it had to be prescribed to you. Enter a whole number.

    [Text Box] # of times

End of Survey Questions

C1. In your honest opinion, should we use your answers in our study? Your token of appreciation for taking this survey will not be changed by your answer to this question. Select one.
    Yes
    No