FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

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

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need:

Data on the use and misuse of prescription opioids are frequently collected via self-report (Substance Abuse and Mental Health Services Administration, 2019). However, data on the use of opioid products have often been grouped under the broader category of opioids or at the level of active pharmaceutical ingredient (e.g., hydrocodone), rather than product-specifically (e.g., Vicodin). Having accurate product-specific information about opioid use is helpful to the FDA for determining whether pharmaceutical interventions, such as abuse-deterrent formulations of prescription opioids, or other intervention efforts are effective in reducing the rates of abuse of specific products.

The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System provides data reports from surveys on the non-medical use of pharmaceutical products from Treatment Center Programs Combined. These reports are issued to pharmaceutical companies as well as regulatory agencies.

The goal of this project is to examine sources of sampling bias and misclassification within these surveys to improve the overall utility of these data to address FDA's regulatory needs.

This survey will identify sources of misclassification by inviting participants who endorsed use of specific opioid molecules in the Survey of Non-Medical Use of Prescription Drugs (NMURx), another proprietary RADARS survey, to participate in this follow-up survey. We will use these responses to obtain national estimates of the number of individuals in the general population who report use of the products that are surveyed on the "Treatment Center Programs Combined Questionnaire." In addition, the survey will reveal occurrences of misclassification found in that questionnaire.

2. Intended Use of Information:

We will use the data collected through this specific survey to quantify misclassification in self-report responses of drug use by using national utilization estimates to inform analyses for the FDA. We can use quantification of differences between self-report surveys and actual product utilization to adjust for existing measurement error. Analyses from previous task orders demonstrated that:

- Respondents in the Treatment Center Programs Combined appear to show a preference for selecting familiar product names on surveys;
- A large proportion of low-volume product endorsements are false-positives; and

- Respondents usually select the first item presented on a survey and within an active pharmaceutical ingredient.

3. Description of Respondents:

We will invite respondents who completed the NMURx parent survey and endorse past 12-month use of an opioid of interest to take the computerized NMURx Express follow-up survey. This is an ongoing survey administered by RADARS. These respondents are adult volunteers from the general population who have opted to participate in a commercial survey panel. Demographics from the parent survey are shown below; respondents will be a subset of the next launch of this survey.

Table 1. Nationally Estimated Demographic Characteristics
RADARS® System Survey of Non-Medical Use of Prescription Drugs Program
3rd Quarter 2018 through 1st Quarter 2019

Characteristics	Overall % (95% CI)
Sex	
Male	48.67 (48.21, 49.13)
Female	51.33 (50.87, 51.79)
Age Categories (years)	
18-24	12.23 (11.85, 12.62)
25-34	17.8 (17.43, 18.17)
35-44	16.39 (16.05, 16.73)
45-54	16.77 (16.42, 17.12)
55-64	16.66 (16.36, 16.97)
65 or Older	20.15 (19.83, 20.46)
Race/Ethnicity	
Hispanic	9.02 (8.73, 9.30)
American Indian or Alaska Native	1.73 (1.61, 1.85)
Asian	5.45 (5.22, 5.68)
Black or African American	10.29 (9.99, 10.58)

Characteristics	Overall % (95% CI)
Native Hawaiian or Other Pacific Islander	0.38 (0.32, 0.45)
Race/Ethnicity	
White	81.14 (80.76, 81.52)
Other	3.81 (3.62, 4.00)
Household Income	
Less than $25,000	18.14 (17.78, 18.50)
Between $25,000 and $49,999	26.57 (26.17, 26.98)
Between $50,000 and $74,999	22.33 (21.95, 22.72)
Between $75,000 and $99,999	14.76 (14.44, 15.09)
$100,000 or More	18.19 (17.84, 18.54)

4. Date(s) to Be Conducted:

As soon as OMB approval is obtained. We will anticipate launching the survey during the first quarter of 2021, with a study period of under 3 months.

5. How the Information Is Being Collected:

An online survey to the general adult population through a commercial survey panel.

6. Confidentiality of Respondents:

The information collected will be kept secure to the extent permitted by law. All responses will be completely anonymous. There will not be any demographics included within the survey; nor will we collect individual identifiers. At the completion of each survey, the data are downloaded from a secure hosting site and stored in their raw format on the Rocky Mountain Poison & Drug Safety (RMPDS) secure server. After the raw data file has been downloaded to the RMPDS secure server, a secondary analysis dataset is created from the raw dataset.

7. Amount and Justification for Any Proposed Incentive:

Compensation is approximately $1 USD for completing the survey. Multiple panels are used to recruit respondents into the survey, and the compensation method varies for each panel. For example, panelists often earn points by completing surveys, which they can then redeem for a chance to enter sweepstakes or some other reward. This aligns with the compensation from other surveys the panelists are invited to complete with comparable completion times.

8. Questions of a Sensitive Nature:

This survey inquires about the use of prescription drugs. The only sensitive question that relates to illegal behavior is related to the source of drug acquisition. We do not collect protected health information or information that could be used to identify the individual.

9. Description of Statistical Methods:

To estimate self-report utilization values within the past year, we will use the responses obtained from 1,100 NMURx Express survey respondents who had endorsed past 12-month use of an opioid drug product. The sample size of 1,100 was calculated, based on feasibility, using a 10-15% response rate of individuals who used a prescription opioid product in the past year in the NMURx 2019Q3 launch (n=7,692).

The NMURx Program standard is to report national estimates for products with 5 or more endorsements. With a follow-up sample of 1,100 individuals, we calculated a 95% probability of including approximately 5 cases for products with a past year use prevalence of 1%. This calculation is based on the hypergeometric distribution of sampling 1,100 cases from 7,500 respondents. The 1% prevalence is among individuals who report past year opioid use. This suggests a high probability of obtaining sufficient data to provide estimates on low volume molecules, such as tapentadol and hydromorphone. We estimate the relative standard error for products with very low prevalence to be approximately 50%. The relative standard error is below 30% for nearly 800,000 individuals who report past year use. At 1.4 million individuals who have used in the past year, the relative standard error is less than 20%.

BURDEN HOUR COMPUTATION: (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Online Survey	1,100	15 minutes	275 hours

REQUESTED APPROVAL DATE: May 2021.

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