FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "Testing Communications on Drugs" (0910-0695)

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumers — Terminology Routinely Used in CDER Communications

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

COVID-19 is a respiratory disease caused by SARS-CoV-2, a coronavirus discovered in 2019. The virus spreads mainly from person to person through respiratory droplets produced when an infected person coughs, sneezes, or talks[1]. The purpose of this project is to test consumer website content and videos produced by the FDA's Office of External Affairs (OEA) about US-Authorized or FDA approved COVID-19 vaccines. The website content and videos are for parents of children age 5-15 or for adults in the United States. The US Food and Drug Administration has approved vaccines for COVID-19 in the United States for people age 5 and older. Current rates of full vaccination in the US are around 65.7% with only 45% of eligible people having received a booster dose[2].

The FDA's OEA maintains these Q&A websites on COVID-19 for the FDA and creates videos to help answer questions related to the pandemic and vaccines. The website and videos seek to educate consumers about the benefits and risks of the COVID-19 vaccines and offer information about eligibility and boosters. The parents or caregivers of kids age 5-9 will view a Q&A material about COVID-19 vaccines for their age children and a video about long-term health consequences about COVID-19 vaccines. The parents or caregivers of kids age 12-15 will view a Q&A material about COVID-19 vaccines for their age children and a video about long-term health consequences about COVID-19 vaccines. The adults will view Q&A material related to adult vaccinations and a video about booster doses.

Communications science tells us that we must test messages with our intended audiences. Thus, FDA plans to test these communications using cognitive interviews with a small sample of 24 U.S. adults drawn from diverse consumer and healthcare professional (HCP) panels. The sample will include 12 parents/caregivers of children age 5-9 years old; 8 parents/caregivers of children age 12-15 years old and 10 adults.

Each month millions of people view the FDA website and consumer communication materials about COVID-19 vaccines. Attitudes and knowledge about COVID-19 vaccines change quickly, alongside new FDA authorizations and approvals of COVID-19 vaccines and boosters for different populations. FDA's OEA would like to know as soon as possible if the communication materials are responsive to consumer concerns and questions, and if they are helping people make decisions about getting themselves and their families fully vaccinated against COVID-19.

[1] https://www.cdc.gov/dotw/covid-19/index.html
[2] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-onedose-pop-5yr

This data collection is the 29th in a series of FDA rapid message tests submitted to OMB under generic clearance. These projects are part of FDA's effort to make target audience testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order[3] to improve how information is presented to consumers by applying behavioral science insights, and it meets repeated calls from FDA's Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public.

2. **Intended use of information:**

FDA's contractor Westat will test the Q&A content and videos with a small sample of target audience members to ensure the message meets its objectives without causing unintended negative effects. FDA's Risk Communication and Advisory Committee includes renowned experts and researchers in social sciences, marketing, health literacy, and related fields. From its very first meeting in 2008, the Committee has consistently advised and reaffirmed that testing communications with the target audience is necessary for FDA, and that using small samples is an effective approach for testing and communicating in a timely manner. In fact, research has shown that "saturation," or the point at which no new information or themes are observed, can occur with as few as 12 interviews, as described in Guest et al (2006).

FDA will use the collected interview data to refine its messaging by improving the comprehensibility for a higher public health impact. Specifically, FDA is asking Westat to gain insight to the following questions:

1. What main message(s) do participants get from the material?
2. Overall, how do participants feel about the information they read/saw and why/what specifically caused that reaction?
3. What are the materials recommending and are they described clearly?
4. Do participants understand from the material that the vaccine is safe and approved for children/adults?
5. What is unclear or hard to understand?
6. How much, if any, of the material's information is new to them and if so, what?
7. Do participants see themselves/their children as at risk for COVID-19?
8. How does the information in the QA change participants minds about getting themselves/their children vaccinated?
9. Does the information in the QA provide useful information for deciding whether participants want to get themselves/their children vaccinated?
10. How likely are adult/parent/caregiver participants to get/have their child/children vaccinated for COVID-19?
11. What would motivate/motivated participants to get themselves/their children vaccinated?
12. What in the information would cause participants to hesitate to get themselves/their children vaccinated?

[3] https://obamawhitehouse.archives.gov/the-press-office/2015/09/15/executive-order-using-behavioral-science-insights-better-serve-american

13. What additional information would participants like to see included?
14. Do the images and language in the video resonate with participants? (For the videos)
15. How well do participants think the visuals match the messages? (For the videos)

The data collected will not be statistically representative of the target audience population. Therefore, the data will not be used for making policy or regulatory decisions.

3. **Description of respondents:**

We will conduct 30 45-minute interviews with U.S. adults. Westat has partnered with Plaza Research, a recruitment specialist to recruit respondents from its general population panel. Plaza Research tracks and stores all database member activity and assigns a unique ID number which stays with the member throughout their entire membership. These tracking records consist of profile information provided during enrollment, profile updates, and past focus group or in-depth interview involvement. Plaza Research monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include individual vetting of contact information, and review of enrollment data, as well as review of screener questions, rescreening of participants before participation, and client feedback on past focus group and interview response.

We will use a participant screener to recruit a mix of 12 parents/caregivers of kids age 5-9 years old and 8 parents/caregivers of kids age 12-15 years old and 10 adults. To the extent possible, the participant pool will be diverse in terms of gender, age, race/ethnicity, and geography.

4. **Date(s) to be Conducted:**

We plan to conduct interviews in April 2022.

5. **How the Information is being collected:**

We will conduct all interviews remotely using telephone and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, or tablets. We will ensure that any materials provided to the participants for the test are compatible with these devices.

For each 45-minute interview, a trained interviewer will lead the discussion using a semi-structured interview guide that ensures consistency in major topics but allows flexibility in probing each participant on particular questions.

Note takers will chart their findings into a standardized reporting template so that all notes are organized in a consistent manner. Interviewers will review the notes to ensure accuracy. With the consent of participants, we will audio record each interview.

FDA staff will have the ability to listen to the interview sessions, and this will be made known to participants as part of the informed consent.

6. **Confidentiality of Respondents:**

We will provide all respondents with informed consent language that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. As part of the consent procedure, respondents will be asked whether they allow audio recording of the interview. Recording will not begin before participants have had the opportunity to ask for any clarification and provide consent. Participants will be asked to again confirm their consent when recording begins. Participants who do not allow audio recording will not be invited to participate in the interview.

No participant's identifiable information such as name will be included in the interview notes. All interview materials will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. Interview notes will be zipped electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to FDA, Westat will destroy all names and contact information of participants to protect their personal identity. Additionally, the interview notes and interpretive report delivered to FDA after message testing will omit all information that could be used to identify respondents.

All electronic data storage media that contain confidential, private, or proprietary information will be maintained within secure areas. Data collected in hard copy will be kept in locked cabinets when not in use.

FDA's Institutional Review Board (IRB) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

7. **Amount and justification for any proposed incentive**

For this project, Plaza Research will provide $50 incentives to participants at the end of each 45-minute interview in the form of a check. Plaza Research uses a "by-invitation-only" recruitment methodology and incentivizes panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time. Plaza's incentive scale is based on set time increments and is applied equally across all study topics, sponsors, and data collection modes. The table below details the previous incentives approved by OMB for this series of rapid message tests with consumers and healthcare professionals (HCPs).

Project #	Communication Tested	Population	Interview Length/Incentive	OMB approval date
1	Clinical Trials Brochure	Consumers	45 min/$50	8/4/2017
2	Caregiver Tipsheet	Consumers	30 min/$35	9/26/2017
3	Public Service Announcement Video about Generic Drugs	Consumers	30 min/$35	10/25/2017

Project #	Communication Tested	Population	Interview Length/Incentive	OMB approval date
4	Opioid Analgesics Patient Counseling Guide	Consumers	45 min/$50	11/27/2017
5	Vaccines and Seniors Brochure	Consumers	30 min/$35	5/10/2018
6	Public Service Announcements about Safe Disposal of Opioids	Consumers	30 min/$35	7/26/2018
7	Nicotine Dialogue Campaign Branding	Consumers	30 min/$35	8/23/2018
8	Testosterone Medication Guide	Consumers	45 min/$50	10/12/2018
9	Asthma Fact Sheet	Consumers	30 min/$35	2/12/2019
10	Transmucosal Immediate Release Fentanyl Risk Evaluation Mitigation Strategy Program Patient-Prescriber Agreement Form	Consumers	45 min/$50	4/4/2019
11	BeSafeRx Campaign Messages	Consumers	45 min/$50	5/17/2019
12	Safe Drug Disposal Notecard	Consumers	30 min/$35	6/28/2019
13	Medical Countermeasures	Consumers	45 min/$50	9/10/2019
14	Warnings on Opioid Packaging	Consumers	30 min/$35	10/22/2019
15	Messages About Cannabidiol (CBD)	Consumers	30 min/$35	1/2/2020
16	FDA's Purple Book Website	Consumers	45 min/$50	1/16/2020
17	Storyboards about Safe Disposal of Opioids and Other Medicines	Consumers	45 min/$50	4/14/2020
18	Medication Guide Template for Buprenorphine Products	Consumers	30 min/$35	5/13/2020
19	Retest Warnings on Opioid Packaging	Consumers	30 min/$35	6/19/2020
20	Search and Rescue Website	HCPs	45 min/$100 (primary care) or $150 (specialists)	9/23/2020
21	Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	Consumers	45 min/$50	12/9/2020

Project #	Communication Tested	Population	Interview Length/Incentive	OMB approval date
22	Additional Testing of Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	Consumers	45 min/$50	3/12/2021
23	Drug Safety Communication (DSC) Landing Page and Format	Consumers	45 min/$50	4/14/2021
24	Children's Cough and Cold Consumer Update	Consumers and HCPs	45 min/$50 45 min/$100 (primary care) or $150 (specialists)	6/3/2021

8. **Questions of a Sensitive Nature**

   We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' reactions to the messages and materials.

   Nevertheless, respondents will be told that they may skip any question that they do not want to answer or may stop participating at any time.

9. **Description of Statistical Methods**

   We do not plan to use formal statistical methods in this study but rather qualitative analysis methods. Our analysis approach is based on the Framework method, as described in Spencer et al (2003). Framework is a matrix-based approach to data management, which facilitates both case and theme-based analysis. The Framework method allows for data reduction through summarization and synthesis yet retains links to original data, in this case the interview notes. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The software will allow us to import interview notes, create links between the notes and the Framework matrices, and develop new queries or matrices as needed.

   The Framework method will allow us to recognize patterns within the data. Findings will be supported with verbatim participant quotes and grounded in accepted principles of health communications.

Bibliography

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. Field methods, 18(1), 59-82.

Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis practices, principles and processes. In *Qualitative research practice.* London: Sage Publications.

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)
Screener	1500	3	75
Interviews	30	45	23
		Total	**98**

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