Antibiotic Use Campaign: Round 2 (R2) Concept/Materials Testing with Consumers
Attachment 1. Project Description and Burden

Project Description

Each year in the United States, at least 2 million people become infected with antibiotic-resistant bacteria and 23,000 of these individuals die as a result of their infections. Antibiotic resistance—the ability of microbes to resist the effects of an antibiotic—is a specific type of drug resistance caused in part by improper antibiotic prescribing by HCPs and the overuse of antibiotics by consumers. Antibiotics are among the most commonly prescribed medications, yet at least 30 percent are unnecessary, and even more are likely to be inappropriate when antibiotics are prescribed for the wrong drug, dose, or duration. Many bacteria have now become resistant to more than one type or class of antibiotic. Widespread overprescribing and inappropriate use of antibiotics is fueling resistance that compromises the effectiveness of these drugs in the future.

In 2003, CDC launched its *Get Smart* campaign as an effort to improve antibiotic prescribing and use in primary care settings. The campaign used a two-pronged approach of educating both healthcare professionals (HCPs) and parents about appropriate antibiotic use. In 2010, the program expanded to include educational materials for inpatient medical settings, such as hospitals and nursing homes.

Since its launch in 2003, the *Get Smart* campaign has been at the forefront of successful education efforts to reduce inappropriate prescribing and overuse. However, this looming public health crisis continues to grow as drug-resistant microbes evolve and more drugs in our supply lose their effectiveness against them. In response, CDC is launching a reinvigorated campaign in November 2017, with highly targeted, well-tested messages and creative strategies. The campaign will be a fully integrated national program designed to reach defined target audiences through many channels and tactics for the broadest reach and the most meaningful and effective impact.

CDC requests approval to test creative concepts developed on the basis of findings from a first round of research conducted. This information collection is necessary to update CDC's *Get Smart* campaign such that it appeals to and meets the needs of its intended audiences. Findings will be used to finalize campaign materials on the basis of feedback and preferences of the consumer and HCP audiences it will target. Ultimately, the campaign will increase consumer knowledge about appropriate antibiotic use, confidence that they can feel better without an antibiotic, awareness of the consequences of inappropriate antibiotic use, and confidence in their ability to talk to their HCP about appropriate use. In addition, the campaign will increase HCP awareness of the consequences of inappropriate prescribing, awareness of how to increase patient satisfaction without prescribing antibiotics when they are unnecessary, confidence to effectively communicate when antibiotics are needed, and awareness of vital importance of reassessing antibiotic therapy (hospitalists).

The campaign aims to reach HCPs with the highest prescribing rates and consumers most likely to use antibiotics unnecessarily. The message testing outlined in this GenIC focuses on consumers. Approval to test messages with consumers is being requested in a separate GenIC. The messages and materials are virtually identical for both groups, with one exception: message testing with HCPs includes testing of "Conversation Starters" that HCPs might use to initiate their conversations with patients about appropriate antibiotic use.

Method

We will conduct 12 online focus groups with consumers to test creative concepts—specifically, visual identifies, television ads, print ads, and antibiotic use talking points (HCPs only)—to assess general reactions, comprehension, ability to capture attention, readability, strong and weak points, personal/cultural relevance, and ability to motivate.

Participants

Per the recommendation of CDC's subject matter experts (SMEs), we are specifically targeting consumers who are most likely to take antibiotics unnecessarily (i.e., antibiotic demanders and expectors). *Demanders* are individuals who seek/request antibiotics when not necessarily indicated. *Expectors* are consumers who desire antibiotics when not necessarily indicated, though they do not directly request them. Demanders and expectors are further segmented into "self" and "caregiver" categories. Caregiver-demanders (CD) and caregiver-expectors (CE) desire antibiotics for children, whereas self-demanders (SD) and self-expectors (SE) desire antibiotics for themselves.

Exhibit 2. Consumer Online Focus Groups Segmentation Table

Activity	Self-Demanders	Caregiver-Demanders	Self-Expectors	Caregiver-Expectors	Total
	Healthy White Females 21–45 years	Healthy White Females 30-54 years Child ≤ 5 years	Healthy Hispanic Females 30–45 years	Healthy Black 1st Time Mothers 21–45 years Child ≤ 2 years	
Online FGs	3 (n=3)	3 (n=3)	3 (n=3)	3 (n=3)	12 (n=36)

Screening and Recruitment

Up to 36 consumers will participate in the online, synchronous focus groups. We will conduct 3 focus groups with 3 participants each with each type of consumer group. A professional recruiting firm will use a stratified, non-probability, purposive sample to recruit consumer participants. The recruiter will screen participants as follows:

- Self-demanders are healthy, White females aged 21 to 45 years who have previously requested antibiotics for themselves when sick.
- Caregiver-demanders are healthy, White mothers between the ages of 30 to 54 years with at least one child 5 years old or younger who have previously requested antibiotics for their children.
- Self-expectors are healthy, Hispanic women between 30 to 45 years of age who have previously expected, but not requested, antibiotics for themselves when sick.
- Caregiver-expectors are healthy, African American (AA) women between 21 and 45 years of age who are first-time mothers to children 2 years or under.

Half of consumer participants will be recruited from the U.S. south census region. The other half will be recruited from all other U.S. census regions. A professional recruitment firm will conduct all recruitment, including completing the consumer screener to determine eligibility and the appropriate PDIS with all eligible participants prior to the scheduled focus groups.

During the focus groups, consumers will be shown 9 concepts (i.e., 2–10 under List of Concepts for Testing).

Geography

Antibiotic prescribing rates are highest in the U.S. south census region. Thus, half of all consumer and HCP participants will be recruited from southern states and the other half will be recruited from other U.S. regions. Targeted states include: AZ, GA, IA, KY, LA, MO, MS, NE, NY, PA, OH, RI, TN, UT, and WV.

Incentives

We intend to provide incentives to all respondents in appreciation of their participation in focus groups and IDIs. Providing incentives is standard practice when conducting small group discussions and IDIs. Incentives are typically provided for focus group participants as a "stimulus to attend the session" and to help ensure the required number of individuals participate. We request approval for $35 for consumers.

Burden

Exhibit 1 describes the response burden associated with this information collection. Eligible consumers will participate in the screener (5 min), PDIS (5 min), and focus group (90 min). We expect to screen approximately 4x as many consumers as needed to recruit enough participants for the IDIs and focus groups.

Exhibit 1. Burden Table

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Consumers	Consumer Screener SD-SE	72	1	5/60	6
	Consumer Screener CD-CE	72	1	5/60	6
	Consumer PDIS SD-SE	18	1	5/60	1.5
	Consumer PDIS CD-CE	18	1	5/60	1.5
	FG Moderator Guide	36	1	1.5	54
Total					69

References

Centers for Disease Control and Prevention (CDC). (2013). Antibiotic resistance threats in the United States, 2013. Retrieved March 5, 2016 from https://www.cdc.gov/drugresistance/threat-report-2013/index.html.

Hicks, L., Bartoces, M., Roberts, R., Suda, K., Hunkler, R., Taylor, T., and Schrag, S. (2015). U.S. outpatient antibiotic prescribing variation according to geography, patient population, and provider specialty in 2011. Clinical Infectious Diseases, 60(9):1308–1316

Klein, E., Makowsky, M., Orlando, M., Hatna, E., Braykov, N., and Laxminarayan, R. (2015). Influence of provider and urgent care density across different socioeconomic strata on outpatient antibiotic prescribing in the USA. *Journal of Antimicrobial Chemotherapy*, 70, 1580-1587.

Krueger, R., and Casey, M. (2015). Focus groups: A practical guide for applied research, 5th Edition. Thousand Oaks, Calif: Sage Publications.

National Cancer Institute. (2001). Making Health Communication Programs Work. Retrieved April 28, 2017 from http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook/Pink_Book.pdf.

List of Attachments

Health Message Testing System Expedited Review Form

Attach 1_AU R2 Project Description and Burden Table 062117

Attach 2_Consumer Screener SD-SE FINAL 062117

Attach 3_Consumer Screener CD-CE FINAL 062117

Attach 4_Consumer PDIS SE-SD FINAL 062117

Attach 5_Consumer PDIS CE-CD FINAL 062117

Attach 6_Consumer Triad Guide_FINAL_062117

Attach 7_Verbal Consent IDI-FG FINAL 062117

Attach 8_Observer Confidentiality_FINAL 062117

List of Concepts for Testing

1. AU PSA Print Ad_Safe Play
2. AU PSA Print Ad_Status Update
3. AU PSA Print Ad_The Right Tool

4. AU Campaign Stimulus_TV Ads
5. Visual with slogan_A
6. Visual with slogan_B
7. Visual with slogan_C
8. Visual with slogan_D
9. Visual with slogan_E