

Health Message Testing System Expedited Review Form

1. Title of Study: (Please append screener and questionnaire)

Be Antibiotics Aware Educational Message/Materials Assessment

Overall Purpose/Background

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 healthcare professionals (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 response to this growing threat, CDC developed *Be Antibiotics Aware* (BAA), an educational effort consisting of messages and materials to raise knowledge and awareness among consumers and HCPs about appropriate antibiotic use and prescribing (see materials at <https://www.cdc.gov/antibiotic-use/>). This national BAA effort was launched during U.S. Antibiotic Awareness Week (November 13-19, 2017).

CDC requests approval to test the effectiveness and persuasiveness of BAA messages and materials as drivers to the expected outcomes of the effort, including increased consumer knowledge and awareness about appropriate antibiotic use, antibiotic resistance, and the difference between viral and bacterial infections and how each should be treated.

The data collection will use an online survey to gather information about consumer exposure to messages and materials; perceived effectiveness of materials and key messages; and knowledge about appropriate antibiotic resistance, the differences between viral and bacterial infections, and appropriate antibiotic use. Survey results will be used to determine the effectiveness/persuasiveness of *Be Antibiotics Aware* messages and materials and to improve, refine, and modify messages and materials.

This data collection will enable CDC to improve the BAA effort by ensuring quality and preventing waste in future dissemination of health information to the public.

2. Study Population: (Discuss study population and explain how they will be selected/recruited.)

Primary Audience: The BAA educational effort was released nationally. Therefore, the primary audience for the survey includes adults aged 18 years and older who live in the United States, do not prescribe antibiotics as part of their professional role, and are registered with an online panel provider.

To develop the BAA messages and materials, CDC conducted formative research with key consumer audiences most likely to take antibiotics unnecessarily (i.e., antibiotic demanders and exectors). “Demanders” include individuals who seek/request antibiotics when not necessarily indicated (e.g., for a virus). “Exectors” are individuals who desire antibiotics when not necessarily indicated, though they do not directly request them. Demanders and exectors are further segmented into “self” and “caregiver” categories. Caregiver-demanders and caregiver-exectors desire antibiotics for children, whereas self-demanders and self-exectors desire antibiotics for themselves. The key consumer audiences included:

- Self-demanders—White females aged 21 to 45 years who have previously requested antibiotics

for themselves when sick.

- Caregiver-demanders—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—Hispanic women between 30 to 45 years of age who have previously expected, but not requested, antibiotics for themselves when sick.
- Caregiver-expectors—African American women between 21 and 45 years of age who are first-time mothers to a child 2 years or under.

Through the formative research, CDC determined that many consumers lacked general knowledge about appropriate antibiotic use, antibiotic resistance, and the difference between viral and bacterial infections. In addition, CDC found that many consumers request antibiotics from their HCPs, even when an antibiotic is unnecessary. As such, educating consumers about appropriate antibiotic use is critical to reducing inappropriate antibiotic use and preventing antibiotic resistance.

Design and Analysis: This data collection uses a quasi-experimental proxy pretest design, also referred to as a retrospective pretest (RPTP or post-then-pre) design to assess BAA message/materials. The RPTP design administers the pretest assessment concurrently with the posttest by asking individuals to recall their knowledge or behavioral intentions since and prior to exposure to the BAA effort. It is a post-only design in which a pretest measure is constructed from data after the fact. This design is a convenient, reliable, and valid way to assess impact (by capturing both the pretest and posttest information at the same time) with data collected via retrospective thoughts or recollection to stand in for the pretest. Using this design requires that the proxy measures on the BAACS to test messages/materials are conceptually related to and correlated with the expected outcomes for the BAA effort.

Survey results will be used to improve, refine, and modify BAA messages and materials. We also will perform subgroup analyses to (1) determine whether BAA messages and materials reached key consumer audiences and (2) assess the effectiveness/persuasiveness of BAA messages and materials on raising knowledge and awareness among key consumer audiences relative to the general population.

Sampling: To achieve 80% power to detect a mean difference of 1 (taking into account the sampling design effect of clustering by states after stratification by region and the intraclass correlation [ρ , 0.05]), we need a sample size of 3194 individuals (50% exposed, 50% unexposed) in order to minimize the risk of disclosure of personal identifiers. Assuming a standard 33% response rate for an online survey, we anticipate collecting 1054 total responses (50% exposed, 50% unexposed).

	Recommended Sample Size			Expected Number of Responses		
	Exposed	Unexposed	Total	Exposed	Unexposed	Total
Consumers	1597	1597	3194	527	527	1054

The BAA educational effort is a nationwide campaign focused on adults over the age 18. In order to ensure that we collect responses—from individuals in different areas of the country (and thus, potentially different levels of exposure to the BAA campaign), we are using a two-level sampling approach. States were initially grouped by census region, with sampling from each region determined by a proportional allocation based on the size of the total population of the target audience residing in that region.¹ Following the regional grouping, individual states were chosen from within each region in order to

¹ The total population and percentage of the population 18+ were culled from the [Census Bureau's Population Division website](#).

maintain the proportional allocation of potential respondents at the state level. The above described proportions of exposed/unexposed respondents will be maintained in each region and state.

Regions and States			
Northeast	Midwest	South	West
Connecticut, New Hampshire, New Jersey	Illinois, Wisconsin, Missouri, Minnesota	Maryland, Virginia, Tennessee, Florida, Texas	Arizona, Colorado, Oregon

Attachments:

1. Project Description
2. HMTS Expedited Review Form
3. Be Antibiotics Aware Consumer Survey (BAACS)
4. IRB Exemption
5. BAA Campaign consumer materials
6. BAA Campaign HCP materials

Consumer Respondent characteristics:

Number of subjects: 1054
 Number of males: n~50% males
 Number of females: n~50% females
 Age range: Age 18 and older
 Racial/ethnic composition: Mix of racial and ethnic backgrounds
 Type of group/s: Adults 18 years of age or older who do not prescribe antibiotics as part of their professional roles
 Geographic location/s: United States - Specifically randomly selected states in the 4 US census regions 1, 2, 3 and 4.

3. Incentives: (If an incentive will be used, state what incentive will be offered and justify proposed incentives to be used in study.)

Incorporating modest incentives to aid in recruitment acknowledges respondents' efforts, boosts response rates, and may improve the quality of information collected. As a token of appreciation for participating in the survey, respondents will receive a point equivalent of \$10 to redeem online or at a retailer (commonly provided to survey panel respondents who complete on-line surveys). The "points" will not be sent from CDC, but instead be provided by an online survey panel provider to respondents who complete the survey. For this assessment, consumers will be offered survey choice "points" equal to \$10 in value.

4. Study method: (Please check one below)

Central location intercept interview:
 Telephone interview: CATI used: yes or no)
 Individual in-depth interview (cognitive interview):
 Focus group:
 Online interview:
 Other: (describe): **Online (or Web-based survey)**

5. Purpose of the overall communication effort into which this health message/s will fit: (Please provide 2-3 sentences below.)

CDC requests OMB approval to collect information related to assessing exposure to the BAA effort and testing perceptions/reactions to the BAA messages and materials. Information collected will inform modifications and/or enhancements to the BAA effort for continued, future implementation. In addition, results of the survey will allow CDC to assess the effectiveness of the messages and materials on raising knowledge/awareness among key consumer audiences relative to the general population of adults.

6. Category of time sensitivity: (Please check one below)

- Health emergency: _____
- Time-limited congressional/administrative mandate: __ __
- Press coverage correction: _____
- Time-limited audience access: X
- Ineffective existing materials due to historical event/social trends: _____
- Trend tracking: _____

7. Describe nature of time sensitivity: (Please provide 2-3 sentences below.)

In November 2017, CDC launched the *Be Antibiotics Aware* messages/materials to raise awareness and knowledge among healthcare professionals and consumers about appropriate antibiotic use and prescribing. It is critical to rapidly assess these messages/materials (within 12 weeks) to determine whether they resonate with target audiences and to identify areas for improvement for continued implementation.

8. Number of burden hours requested: 359 BURDEN HOURS*

Category of Respondent	Form Name	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hours
Consumers (ineligible)	BAACS screener	250	2/60	8
Consumers (eligible)	BAACS	1054	20/60	351
Total		1304		359

9. Are you using questions from the approved question bank? If yes, please list the item number(s) for questions used from the question bank.

- Yes: _____
- No: X

*** Items Below to be completed by Office of Associate Director for Communication (OADC)***

1. Number of burden hours remaining in current year's allocation: _____

2. OADC confirmation of time-sensitivity:

Yes: _____

No: _____

Project Officer Signature