Title of Project: Asthma Control Communication Materials Field Testing

February 16, 2018

Introduction

The Centers for Disease Control and Prevention (CDC) identified chronic disease as the "public health challenge of the 21st century." Chronic conditions (e.g., heart disease and stroke, cancer, diabetes, arthritis, obesity, respiratory diseases, oral conditions) are the leading causes of death and disability in the U.S. and more than 75% of U.S. health care spending is on people with these conditions. Asthma—a disease that affects the lungs and causes repeated episodes of wheezing, breathlessness, chest tightness, and nighttime or early morning coughing—is one of the most common lifelong chronic diseases. Approximately 17.7 million adults currently have asthma (7.4% of adults 18 years or older), and 6.3 million children suffer from asthma (8.6% of children 18 years or younger).

Background and Objectives

Although asthma cannot be cured, it can be controlled by knowing the warning signs of an attack, avoiding environmental triggers, and following health care provider recommendations. Current literature points to variation in identification of such triggers, offering an opportunity for interventions to increase knowledge and awareness of asthma triggers. It is also recommended that children 10 and younger take an active role in their asthma care, if they are able. Action plans offer guidance about taking medications properly, avoiding asthma triggers, tracking level of asthma control, responding to worsening symptoms, and seeking emergency care when needed. Despite recommendations, an estimated 1.8 million asthma-related emergency department visits occur annually. Similarly, an estimated 439,435 asthma patients are admitted to the hospital annually, averaging hospital stays longer than three days. There is also evidence that current self-management asthma programs are ineffective at reducing morbidity, and behavioral interventions are a more effective solution to enhancing asthma outcomes. As such, the Air Pollution and Respiratory Health Branch (APRHB) of the National Center for Environmental Health, in support of its mission to reduce the burden of non-infectious respiratory diseases, is conducting focus groups with adolescents and their parent/caregivers to test and refine key messages aimed at encouraging and helping with self-management of asthma symptoms in adolescents and their caregivers, particularly focusing on perceived facilitators and barriers. This project is a continuation of the Asthma Control Initiative Communication Messaging and Materials Development project. During the first phase of this project, two 90-minute focus groups (n=4 participants per focus group) with adolescents suffering from asthma and two 90-minute focus groups with caregivers of adolescents with asthma, were conducted across three geographic regions in Atlanta, GA; Arlington, VA; and Detroit, MI. The focus groups were conducted to understand the current knowledge, perceptions, and attitudes related to self-management of asthma symptoms in adolescents and their caregivers (Health Message Testing System, OMB Approval No. 0920-0572, Expiration Date: 3/31/2018).

Methods and Study Population

The study will be conducted using a mix of focus groups. In each of four locations (see Table 1. Focus Group Locations), to test key messages, CDC and Fors Marsh Group (FMG) will hold three 90-minute focus groups with adolescents suffering from asthma (aged 12–18 years) and one 90-minute group with caregivers of adolescents with asthma in each location (16 total focus groups). Each focus group will have four participants (total $N = 64$). To further facilitate group cohesion and comfort level in sharing, the youth groups will be separated so that groups in each

location comprise youth in grades 6 to 8 (i.e., middle school-aged) and youth in grades 9 to 12 (i.e., high school-aged). In order to obtain accurate feedback, it is necessary to speak directly with adolescents who are disparately affected by asthma. If we are unable to speak with the target audience and only with influencer groups (e.g., caregivers), CDC will be unable to develop and test effective messaging and communication for this target audience.

The moderator's guide across the focus groups will share core content while some sections of the guide will be segment-specific. The guide includes questions to address barriers and facilitators of self-management, and specific questions to gauge reactions to key messages aimed at facilitating asthma management. These questions will address initial reactions, understanding or comprehension of message, and engagement with message. An additional important objective will be to ensure there are no unintended consequences underlying the message.

Focus groups will be held across four states as outlined in Table 1.

Table 1. Focus Group Locations

LOCATION #	REGION	LOCATION
1	South	Birmingham, AL
2	South	Raleigh, NC
3	Mid-Atlantic	Baltimore, MD
4	South	Atlanta, GA

Recruitment Plan and Screening Procedure

Recruiting will be overseen by FMG. FMG will work with sub-contractor focus group facilities in Birmingham, Raleigh, Baltimore, and Atlanta to recruit locally for focus groups in these locations as detailed below. Potential participants for focus groups will be recruited from existing participant panel databases and screened following the attached screeners (Attachment 1), which will detail eligibility criteria and the recruiting script. For the focus groups, sub-contracting facilities will use the same screener. The panel databases comprise previous participants and individuals who have expressed interest in participating in research studies with the respective facility.

Participants for the focus groups will be screened for participation by the local focus group facilities from their existing panel databases and through other methods that FMG and the facilities use to expand their database (e.g., networking, social media posting). Adolescents participants must be between the age of 12 and 18, in middle school or high school, and be disparately affected by asthma (i.e., have visited the emergency room or had a hospital stay in the past year and have missed at least one day of school/work due to asthma). Parents of adolescents with asthma fitting these eligibility criteria will also participate in separate focus groups.

Eligible participants will be asked to schedule a time to participate upon completing the screener and will receive multiple confirmation and reminder emails (please refer to Attachments 10 and 11 for confirmation and reminder emails).

Incentives

Eligible caregivers who participate in a focus group will receive a maximum of $75 as a token of appreciation for their time. Adolescent participants will receive a $45 token of appreciation and

caregivers will receive a $30 token of appreciation to cover costs associated with transporting the adolescents to the focus group facility. The proposed amounts will be provided to participants for their entire burden time, which includes screening time (5 minutes), obtaining informed consent (5 minutes), and participating in the 90-minute focus group session.

The Contractor notes that, because there are more youth groups per location than caregiver groups, the instances where youth and caregivers would be paired are very low (a maximum of 2 – 4 participants per location). If youth and caregivers do arrive together and participate on the same day, the caregiver would still be waiting approximately 90 minutes for the youth to participate, in which the $30 extra token of appreciation may alleviate the extra time spent. Therefore, the increased burden on participants to make this change may outweigh the benefits.

The target population is very unique in that they are youth disparately affected by asthma and caregivers of youth disparately affected by asthma; specifically, they must have (1) visited an emergency room or urgent care center in the past 12 months because of their asthma, and (2) stayed overnight in the hospital because of their asthma over the past 12 months.

As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives treat participants justly and with respect and are an approach that acknowledges respondents for their participation by recognizing and acknowledging the time and effort they expend to participate. In FMG's experience, providing incentives encourages participation in a manner that reduces the likelihood of no-shows and increased recruiting efforts and costs. Incentives must be high enough to equalize the burden placed on respondents in respect to their time and cost of participation, as well as provide enough incentive to participate in the study rather than another activity (Russell, 2000). If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with recruitment, facility fees, and moderator and observer time (Morgan, 1998). Incentives are also necessary to ensure adequate representation among harder-to-recruit populations (Groth, 2010). In the context of this study, the target population is considered a harder-to-recruit population because of the screening criteria (i.e., adolescents disparately affected by asthma) and absence of an existing research panel from where potential participants could be recruited. It should also be noted that message testing is a marketing technique, and it is standard practice among commercial market researchers to offer incentives as part of respondent recruitment.

The participation incentive will be distributed directly to the participant at the conclusion of the focus group in a form preferred by the facility, anticipated to be cash or a non-retailer specific gift card. In the event a gift card is used, participants will not be required to pay any potential fees associated with activating the card.

Procedure

The Focus Group Discussion guide consists of six different sections – Section A: Introduction and Icebreaker; Section B: Asthma Background; Section C: Key Message Testing; Section D: Comparison of Key Messages; Section E: Comparison of Message Strategies; and Section F: Conclusion (see Attachment 2. Focus Group Discussion Guide). In the Birmingham and Raleigh focus groups, participants will be led through a short introduction followed by a brief ice breaker (Section A). In Section B, participants will be asked about barrier and facilitators to asthma management. This information will be used as background information on the target audience and to introduce the topic of key messages, setting the tone for the next section of discussion. In

Section C, participants will be asked to view and react to key messages aimed at helping adolescents manage asthma. They will complete a worksheet in response to the messages and then discuss their responses as a group. In Section D, participants will discuss and compare the key messages and complete worksheet to assess which message is most effective. In Section E, participants will see and compare the key messages applied to communication strategies (e.g., narrative message encouraging an adolescent to "own their asthma" or a narrative providing tips and tricks for managing asthma). This section will inform the development of educational materials. Lastly, Section F includes the wrap-up and closing of the focus group. If time permits, the moderator will implement a false close during which he/she will regroup with the observing research team to determine if there are any additional questions for the group.

After key messages are tested in Birmingham and Raleigh, the most effective key message and key message strategy will be developed into communication/education materials (e.g., poster, pamphlet). The materials will be tested in Baltimore and Atlanta. The materials testing will use the same discussion guide as message testing, with some flexibility to ensure that reactions to communication materials are adequately assessed.

Protection of Privacy of Information Provided by Participants

The following procedures will be used to ensure security for focus groups: (1) scheduling information, such as last name, email, and phone number(s) will be held by the respective recruiting teams only and not transferred to the research team; (2) full names of the participants will not be used on any interview materials (typed lists of participants, transcripts, reports, or during the audio recorded discussion); instead, each participant will be assigned a unique ID by which they will be referred. The research team at FMG will have access to the key that links the participants (by first name only, not the scheduling information described above) to their unique ID and this information will not be passed to CDC; (3) transcripts and reports will not contain any personal identifying information and will be stored securely on a password-protected computer and/or in locked file cabinets only accessible by members of the research team; and (4) quotes that might be used in the final report to illustrate a discussion-derived theme will not be attributed to specific participants.

Researchers will not tie respondents' personal information to their answers. Additionally, moderators will not ask participants to provide identifying information as part of their responses, and no identifying information will be included in the data files delivered by FMG to CDC. All analyses will be done in the aggregate and respondent information will not be appended to the data file used.

Sessions will be audio recorded. Participants will be informed of the audio recording during the screening process and in the consent form. Any report or transcript delivered to the CDC will not include identifying information. De-identified transcripts will be used by the CDC to assist in material development and to provide CDC with a record of the sessions. All identifying information, including information collected during screening, will be kept on a separate password-protected computer and/or in locked cabinets for a period of three years only accessible by FMG, after which they will be destroyed by shredding and/or permanently deleted from the password-protected computer. In the case of a breach of security, appropriate steps will be taken to notify participants.

Justification for Sensitive Questions

We will ask potential participants a series of screening questions as part of the recruitment process (see Attachment 1). In order to reach a wide range of participants, this may require

asking questions about race/ethnicity. Respondents will be assured that providing this information is completely voluntary and will be treated as private to the extent allowed by law.

In addition, given the nature of this research effort, focus group participants may be asked about their perceptions of personal health risks related to asthma. This information is necessary in order to gain insight into which types of messages, strategies, and materials will be most effective among the target audience. Though not as personal as questions about sexual behavior or religious beliefs, for instance, questions of this nature still require some sensitivity in how they are worded and approached. Participants will be informed prior to actual participation about the nature of the project and the moderator will emphasize that their participation is completely voluntary prior to the session start. To avoid fear of disclosure of potentially sensitive information, respondents will be told that all data provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

Procedures for Obtaining Informed Consent and Assent

Focus group participants will be directed to read and sign the appropriate consent/assent forms upon arrival at the focus group facility. Eligible adult participants will be directed to read and sign an informed consent form. Adolescent participants will provide assent by reading and signing an assent form and their parent/guardian will provide permission via a consent form for youth. The research team will be available to review the informed consent with qualifying participants, answer any questions, and ensure each participant understands all the ground rules for recording and reporting his/her responses. Upon request, the research team will provide participants a copy of the consent and/or assent form.

All consent forms were assessed for their readability level and were found to be approximately at the eighth to ninth grade level across the documents, which corresponds with ages 13 to 15. Specific reading grade levels according to the Flesch-Kincaid were: 9.6 for the Caregiver for Youth Consent; 9.7 for Caregiver Consent; and 8.4 for the Youth Assent forms.

The various informed consent and assent forms are included in the attachments for reference (see Attachments 7-9).

Data Analysis

The focus group data will be analyzed following a standard iterative approach to identify emergent themes and patterns related to impressions among adolescents with asthma of each proposed strategic message. Following the focus groups, members of the research team will meet and discuss any initial themes that may have emerged during the interview process. These initial insights will be further refined through group discussion and a thorough review of a sample of the focus group transcripts in order to develop a set of codes for data analysis. The focus group transcripts will be imported into a qualitative data analysis software program, such as NVivo, and systematically coded by a research team overseen by Dr. Brian Griepentrog from Fors Marsh Group, who will oversee all activities related to message testing,recruiting, and fielding. As the transcripts are being coded, Dr. Griepentrog will conduct regular briefings with the coding team to review and make any necessary refinements or changes to the master code list or coded interviews. After the coding is complete, more detailed analyses will be conducted of the coded transcripts to identify aninterpret intersections among key themes.

A trained notetaker/analyst will take notes during each interview session. The notetaker will use a structured template that follows the discussion guide. These notes will be compiled and analyzed iteratively by CDC and FMG for emergent/key themes to inform reporting. FMG will

conduct analysis and deliver a draft report to CDC. CDC will provide feedback prior to FMG delivering a final report.

Assessment and Reporting of Adverse Events

The Principal Investigator (PI) will ensure that appropriate oversight systems are in place to monitor all project activities and identify any adverse events. Because this is a low-risk project, researchers do not anticipate any adverse events or unintended consequences. Participant contact information will be maintained in the contractor's proprietary recruitment system and will not be disclosed to CDC.

Subject privacy and data security breaches are serious risks and will be reported **within one hour of discovery to Brian Griepentrog at pi@forsmarshgroup.com, 571-858-3757.**

References:

Groth, SW. (2010). Honorarium or coercion: use of incentives for participants in clinical research. Journal of the New York State Nurses Association.

Morgan, DL., Scannell, AU. (1998). Planning Focus Groups. Thousand Oaks, CA: Sage.

Russell, ML., Moralejo, DG., Burgess, ED. (2000). Paying research subjects: Participants' perspectives. *Journal of Medical Ethics, 26*(2), 126–130.

List of Study Material Attachments:

1. Focus Group Screener
2. Focus Group Discussion Guide
3. Focus Group Rating Worksheet (Youth)
4. Focus Group Rating Worksheet (Caregiver)
5. Focus Group Comparison Worksheet (Youth)
6. Focus Group Comparison Worksheet (Caregiver)
7. Focus Group Caregiver for Youth Permission Form
8. Focus Group Youth Assent Form
9. Focus Group Caregiver Consent Form
10. Focus Group Confirmation Email
11. Focus Group Reminder Email
12. Focus Group Message Stimuli