

**Title of Project:** Asthma Control Initiative Communication Messaging & Materials Development

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**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 understand the current knowledge, perceptions, and attitudes related to self-management of asthma symptoms in adolescents and their caregivers, particularly focusing on perceived facilitators and barriers.

**Methods and Study Population**

The study will be conducted using a mix of focus groups. In each of three locations (see Table 1. Focus Group Locations), two 90-minute focus groups will be held with adolescents suffering from asthma and two 90-minute focus groups will be conducted with caregivers of adolescents with asthma (12 total focus groups). Each focus group will have four participants (total  $n = 48$ ). 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 effective messaging and communication for this target audience.

The moderator 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 themes relevant to current knowledge, attitudes, and behavior, learning styles, media usage habits, structural/personal barriers as well as facilitators of self-management, and levers for behavior change.

Focus groups will be held across three geographic regions—South, Mid-Atlantic, and Midwest—as outlined in Table 1.

Table 1. Focus Group Locations

LOCATION #	REGION	LOCATION
1	South	Atlanta, GA
2	Mid-Atlantic	Arlington, VA (Washington, DC metro area)
3	Midwest	Detroit, MI

**Recruitment Plan and Screening Procedure**

Recruiting will be overseen by Fors Marsh Group (FMG). FMG will conduct recruiting for the groups in Arlington, VA and will work with sub-contractor focus group facilities in Atlanta and Detroit 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 Office of Management and Budget (OMB)- and Institutional Review Board (IRB)-approved screeners (Attachment 1), which will detail eligibility criteria and the recruiting script. For the focus groups, FMG and sub-contracting facilities will use the same screener. The panel databases comprise previous participants and individuals who have expressed interesting in participating in research studies with the respective facility.

Participants for the focus groups will be screened for participation by either FMG or the local focus group facilities in Atlanta and Detroit 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). Child 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 7 and 8 for confirmation and reminder emails).

### **Incentives**

Eligible participants who participate in a focus group will receive \$75 for their time. Adolescents who participate will receive a \$45 token of appreciation for their time, while their parents/caregivers will receive a \$30 token of appreciation to cover costs associated with transporting the adolescent to the focus group facility. The proposed amount 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.

Table 2. Recommended Focus Group Incentive Rates

Location	Proposed Market-Rate Incentive
Washington, DC (Arlington)	\$75
Atlanta, GA	\$75
Detroit, MI	\$75

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 in line with the market rate 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.

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**

In the focus groups, participants will be led through a short introduction followed by a brief ice breaker and warm-up exercise (see Attachment 2). In Section B, participants will be asked segment-specific questions to ease them into the discussion about asthma and provide context on their personal experience for subsequent discussion. This information will be used to give deeper

context to the qualitative data. In Section C, participants will be presented with an asthma attack scenario. They will complete a worksheet in response to the scenario and then discuss their responses as a group. This activity will provide insight into their action steps and set the tone for the next section of discussion. In Section D, participants will brainstorm and discuss in-depth barriers and facilitators to asthma self-management. In Section E, participants will discuss sources of information for asthma management as well as the usefulness of information, desired type and channel of information, and the ability to easily understand information. This information will inform the development of messaging and asthma education 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.

### **Assurance of Privacy Provided to Participants**

The following procedures will be used to ensure confidentiality 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.

All data will be collected with an assurance that participants' responses will remain private to the extent allowable by law. The consent form contains the following statement: "Everything you share will be kept private to the extent allowed by law. This means that we will not share anything you provide with anyone outside the study unless it is required to protect you, or if required by law." The consent form also contains a statement that no one will be able to link the respondent's identity to his or her responses.

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 confidentiality, 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.

### **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 4-6).

### **Data Analysis**

The goal of qualitative research studies such as this one is for researchers to develop a comprehensive understanding of the research topic; as such, they are not intended to yield results that are statistically projectable.

The focus group data will be analyzed following a standard iterative approach to identify emergent themes and patterns related to impressions among current smokers of each proposed strategic concept. 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. Sarah Evans from Fors Marsh Group, who will oversee all activities related to protocol development, recruiting, and fielding. As the transcripts are being coded, Dr. Evans 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 and interpret 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 Protocol Deviations and Adverse Events**

The Principal Investigator (PI) will ensure that appropriate oversight systems are in place to monitor all research activities and identify any adverse events or deviations from the study protocol. Because this is a low-risk study, researchers do not anticipate any adverse events or unintended consequences. All protocol deviations will be reviewed by the PI to assess whether participant safety or study integrity has been affected by the deviation and to what extent the deviation has affected the project. If the deviation is a protocol violation, appropriate measures will be taken to address the occurrence, which may include the development of a corrective action plan. All protocol violations and corrective action plans will be reported to IRB.

Subject privacy and data confidentiality breaches are serious risks and will be reported **within one hour of discovery to Sarah Evans at [sevans@forsmarshgroup.com](mailto:sevans@forsmarshgroup.com), 571-858-3752.**

The following will be **communicated as at least a brief notice to the CDC Sponsor, Linda Thomas-Houston ([hyy5@cdc.gov](mailto:hyy5@cdc.gov)), as soon as possible (generally within 24 hours) with a full report submitted within 10 days.**

- **Serious Adverse Event:** An adverse health event that is life-threatening or results in death, initial or prolonged hospitalization, disability or permanent damage, congenital anomaly or birth defect, or requires medical or surgical intervention to prevent one of the other outcomes.
- **Unexpected Adverse Event:** adverse health events that were not identified in nature, severity, or frequency in the research protocol/informed consent documents.
- **Unanticipated Problem:** Any incident, experience, or outcome that meets all of the following criteria:
  - 1) Unexpected (in terms of nature, severity, or frequency) given a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and b) the characteristics of the subject population being studied;
  - 2) Related or possibly related to the subject's participation in the research; and
  - 3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.
- **Protocol Violation:** Any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB, the results of which do impact on the subjects' rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

The following will be **communicated on a routine non-urgent basis** but no less than annually:

- **Expected adverse events:** Those health effects and other risks that are listed in the protocol and informed consent forms as being likely to occur or as a result of participation in the study.
- **Protocol deviation:** any minor change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB, the results of which do not impact on the subjects' rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

#### **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 Worksheet
4. Focus Group Caregiver for Youth Consent Form
5. Focus Group Youth Assent Form
6. Focus Group Caregiver Consent Form
7. Focus Group Confirmation Email
8. Focus Group Reminder Email