

Section B: Statistical Methods

OMB control # 0920-07AC

*Formative Research to Develop Social Marketing Campaigns: Routine HIV Testing for
Emergency Medicine Physicians, Prevention Is Care (PIC), and Partner Services*

PROJECT OFFICER:

Donata R. Green, Ph.D.

Centers for Disease Control and Prevention

Division of HIV/AIDS Prevention

8 Corporate Blvd.

Mail Stop E-49, Room 5020

Atlanta, GA 30329

(404) 639-3869 office

(404) 639-2007 fax

dqg7@CDC.GOV

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The purpose of this study is to conduct formative research (one-on-one interviews¹) that will be used to develop campaign materials for three CDC-sponsored social marketing campaigns:

- Routine HIV Testing,
- PIC, and
- Partner Services.

Activities will be conducted in three phases over a three year period. For Routine HIV Testing, draft materials will be tested in three cities in Phase 1, revised materials will be tested in three cities in Phase 2, and a final materials check will be conducted in two cities in Phase 3. For PIC, draft materials will be tested in three cities in Phase 1, revised materials will be tested in three cities in Phase 2, and a final materials check will be conducted in three cities in Phase 3. For Partner Services, exploratory research will be conducted in two cities in Phase 1, concepts will be tested in two cities in Phase 2, and materials will be tested in two cities in Phase 3. The project design is summarized below.

Campaign Name	Phase 1	Phase 2	Phase 3
Routine HIV Testing	Cities* 1, 2, and 3	Cities 4, 5, and 6	Cities 7 and 8
PIC	Cities 1, 2, and 3	Cities 4, 5, and 6	Cities 7, 8, and 9
Partner Services	Cities 1 and 2	Cities 3 and 4	Cities 5 and 6

* The nine participating cities will be selected after OMB approval.

Qualitative methods provide flexible in-depth exploration of the participants' perceptions and experience; and the interviews yield descriptions in the participants' own words. It also allows the interviewer flexibility to pursue relevant and important issues as they arise during the discussion. Furthermore, a qualitative approach will allow us to capture subtle nuances in participants' attitudes, beliefs, and feelings related to the campaign materials. Our interview discussion guides include probes to ensure that we obtain input on specific items of interest, while open-ended questions ensure that participants' responses and perceptions are fully addressed and captured.

We plan to supplement the qualitative data collected during the interviews with a brief paper and pencil questionnaire that will be administered to participants either immediately before (while they are waiting to begin their interview) or at the end of the interview while the moderator is checking with observers about whether there are additional questions. The brief questionnaire will collect basic background information about the participants and some general characteristics of their patient populations to enable us to more fully describe the participants. These questions could be asked as warm-up questions during the interview, but we feel that using the brief questionnaire provides the opportunity to ask these items consistently across all participants and will not take time away from the interview discussions. The paper and pencil questionnaires are included in **Attachments 16 to 18**.

¹ We may use a combination of individual interviews and small group discussions (such as dyads or triads). However, our total estimated number of participants will be the same thus the burden hours we included in Section A will also be the same.

We will use a convenience sample. Therefore, the results are not generalizable to the general population. The annual estimated formative research sample size for each of the three campaigns is as follows:

- Routine HIV Testing: 72 participants across eight cities
- *PIC* : 162 participants across nine cities.
- Partner Services: 174 participants across six cities.

Statistical power is not applicable because this is a qualitative study.

Study Population

Routine HIV Testing. The target audience for the campaign is practicing emergency medicine physicians. Therefore, if a physician is not post-residency, he/she will be excluded from the study. Additionally, participants must be currently working full-time in an emergency department and order at least two HIV tests per month.

PIC. The *PIC* campaign is aimed at providers who treat a significant number of patients who are living with HIV. Therefore, IDS' who currently treat fewer than 50 patients who are living with HIV and PCPs who treat fewer than 20 patients who are living with HIV will be excluded from the study. PCPs who see their largest patient loads in private practice settings are the main target audience of the campaign. Therefore, PCPs who see less than 50% of their patients in a private practice setting will be excluded from the study.

Partner Services. The Partner Services campaign is aimed at IDS providers who treat a significant number of patients who are living with HIV. Therefore, IDS who currently treat fewer than 50 patients who are living with HIV will be excluded from the study. PCPs who see their largest patient loads in private practice settings are the main target audience of the campaign. Therefore, PCPs who see less than 50% of their patients in a private practice setting will be excluded from the study.

2. Procedures for the Collection of Information

RTI will select and reserve focus group facilities (with CDC's approval) in each city for each of the three campaigns. RTI will oversee the local focus group facilities' recruitment of participants. RTI staff may also recruit participants for the research. The professional focus group facilities as well as RTI will use the screeners (**Attachments 13 to 15**) to identify eligible participants.

As participants are recruited, recruitment grids will be prepared to keep track of recruitment. The recruitment grids will list the participants' first name and some demographic information obtained from the screener. The grids will not contain any identifying information. The recruitment grids will be stored in a locked file cabinet or on a password protected project share drive at RTI and at each focus group facility. The focus group facilities will destroy their copies of the recruitment grids after data collection is completed in that city. RTI and CDC will have copies of the recruitment grids in order to describe the study sample. These copies of the recruitment grids will be kept in locked file cabinets or on a password protected project share drive at RTI and CDC for the duration of the study.

Recruitment will begin at least four weeks before the interviews are scheduled. RTI will closely communicate with each focus group facility to monitor the recruitment and troubleshoot any problems. RTI will keep CDC apprised of the recruitment progress and will make any necessary adjustments during the recruitment process. Identification of recruitment facilities and recruitment will begin once IRB and

OMB clearance is received. Typically, recruitment takes about 1 month and we will begin recruitment for the first 2 cities within a week of receiving clearance. Recruitment for the first city in phase 2 (third city overall) will occur while conducting research in the last city of phase 1 (second city overall). This overlapping process will continue until all phases have been completed. Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearance.

Personal information from the potential participants will be maintained and protected to the extent allowable by law. At each facility, recruitment staff will sign a letter of agreement with RTI agreement (see **Attachment 19**). At each facility and at RTI, the screeners will be kept in locked file cabinets. All identifying information (name, address, telephone number) will be recorded on the last page of the screener, which will enable the facility and/or RTI to send reminder letters/e-mails and make reminder phone calls. The last page of the screener will be torn off and destroyed after the interviews are conducted. Local focus group facilities will send the screeners (without the last page) to RTI. The screeners will be stored in a locked file cabinet at RTI throughout the duration of the project. Once the project ends, the screeners will be transferred into a locked RTI storage facility for three years. The screeners will be kept for three years in the event additional data verification is needed at a later date. RTI staff will destroy the screeners after three years. No identifying information about participants will be kept at the focus group facilities after the interviews are completed and the focus group facilities will not send any identifying information to RTI or CDC.

Reminder letters/e-mails will be sent to potential participants prior to the interview giving them directions to the facility. Confirmation calls will also be made 1–2 days prior to the interview to assure that all recruits are confirmed.

Once the potential participant comes to the study site and checks in, he/she will be given a consent form (see **Attachments 10 to 12**). The individual will be given time to read the consent form on his/her own and a trained RTI staff member will be available to answer any questions. If the participant agrees to be in the study, he/she will sign the consent form. The participant will be given a copy of the consent form to keep for his/her records. Participants will be reminded that they can refuse to answer any question and they can stop being in the study at any time, without penalty. RTI staff will FedEx or personally take these forms back to RTI after the interviews are completed in a particular city. The consent forms will be stored in a locked file cabinet at RTI for the duration of the project. Once the project ends, the forms will be transferred to a locked RTI storage facility for three years. After three years, RTI staff will destroy the forms.

All interviews for each of the campaigns will be conducted over the course of one year. The interviews for all campaigns will be conducted in-person at focus group facilities by a professionally trained moderator. Each interview will last for one hour. In addition to the interviewer, an additional RTI staff member will attend the interviews to take notes on a laptop computer from behind a one-way mirror and to coordinate logistics of checking in participants and obtaining informed consent. CDC staff member(s) may also attend and observe the interviews from behind a one-way mirror. All interviews will be audio taped.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The following procedures will be used to maximize cooperation and to achieve the desired participation rates:

- Recruitment through professional focus group facility recruitment firms. Participants will be contacted at their practices and screened for eligibility via telephone. Reminder letters/e-mails will be sent with directions to the research site and reminder phone calls

placed 1-2 days prior to the scheduled interview. Participants will not be contacted again after the interview is over.

- Provision of honoraria to thank participants for their time and effort in the study (please see Section A-9 for more information about the honoraria).

4. Test of Procedures or Methods to Be Undertaken

To estimate the burden for administering the screening questionnaire, two different project team members were consulted. The project team members conducted mock screening interviews and provided affirmative responses to most or all questions that branched to further follow-up questions. In this way, the burden estimate most closely resembles a maximum average burden, since almost all screening questions were presented in the interview. In addition, the project team members deliberately read each item at a slow rate of speed. The project team members estimated the maximum average burden to be 10 minutes for the screening instrument. The screening instruments is shown in **Attachments 13 to 15**.

Prior to implementing the formative research described in this OMB submission, RTI will pilot test the recruitment and data collection protocol for Routine Testing and Partner Services. The pilot testing will include screening and interviewing a small sample of no more than nine participants for Routine Testing and nine participants for Partner Services who meet the screening criteria for the two studies. When the participant arrives at the interview site, the RTI interviewer will read the participant an introduction to the activity and obtain the participant's informed consent. After obtaining informed consent, the RTI interviewer will continue through the interview process with the participant. The main objective of the pilot test will be to assess the discussion guide to ensure adequate flow, clarity, and level of detail throughout the 1-hour interview.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Jennifer D. Uhrig
RTI Task Leader
RTI International
3040 Cornwallis Rd.
Research Triangle Park, NC 27709
uhrig@rti.org
919-316-3311

Julia Kish Doto
RTI Deputy Task Leader
701 13th Street, NW, Suite 750
Washington, DC 20005-3967
jkdoto@rti.org
(202) 974-7850

References

- Abreu, D.A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.
- Alpert PL, Shuter J, De Shaw MG, et al. Factors associated with unrecognized HIV-1 infection in an inner-city emergency department. *Annals of Emergency Medicine*. 1996;28:159-164.
- Centers for Disease Control and Prevention (CDC). 2003. Advancing HIV Prevention: The Science Behind the New Initiative." <http://www.cdc.gov/hiv/partners/AHP/AdvancingFS.pdf>. As obtained on November 11, 2005.
- Fleming, P., R.H. Byers, P.A. Sweeney, D. Daniels, J.M. Karon, and R.S. Janssen. 2002. HIV Prevalence in the United States, 2000 (Abstract). In *Program and Abstracts of the 9th Conference on Retroviruses and Opportunistic Infections*.
- Glynn, M. and P. Rhodes. June 2005. Estimated HIV Prevalence in the United States at the End of 2003." Presented at National HIV Prevention Conference, Atlanta, GA. Abstract 595.
- Greenbaum, T. L. (2000). *Moderating focus groups: A practical guide for group facilitation*. Thousand Oaks, CA: Sage Publications, Inc.
- Holtgrave, D.R. and T. Anderson. 2004. Utilizing HIV Transmission Rates to Assist in Prioritizing HIV Prevention Services. *International Journal of STD and AIDS*, 15(12): 789-792.
- Fenton, Kevin A., and Peterman, Thomas A. "HIV Partner Notification: Taking a New Look." *AIDS*, Vol. 11, No. 13, November 1, 1997, pp. 1535-1546.
- Kaiser Family Foundation (KFF). 2005. HIV/AIDS Policy Fact Sheet: HIV Testing in the United States. <http://www.kff.org/hivaids/upload/Updated-Fact-Sheet-HIV-Testing-in-the-United-States.pdf>. As obtained on November 11, 2005.
- Kilmarx, P.H., F.F. Hamers, and T.A. Peterman. 1998. Living with HIV: Experiences and Perspectives of HIV-Infected Sexually Transmitted Disease Clinic Patients After Posttest Counseling. *Sexually Transmitted Diseases*, 25: 28-37.
- Kreps, G.L., & Thornton, B.C. *Health Communication Theory and Practice*. 2nd ed. Prospect Heights, Illinois: Waveland Press; 1992.
- Maibach, E.W., Rothschild, M.R., & Novelli, W.D. Social Marketing. In: Glanz, K., Rimer, B., & Marcus, Lewis F., eds., *Health Behavior and Health Education*, 3rd ed. San Francisco, CA: Jossey-Bass; 2002:437-461.
- Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics*, 15, 231-250.
- Slater, M.D. Choosing audience segmentation strategies and methods for health communication. In: Maibach, E., & Parrott, R.L., eds., *Designing Health Messages: Approaches from Communication Theory and Public Health Practice*. Thousand Oaks, CA: Sage Publications; 1995:186-198.

Slaughter, P., P. Pinfold, V. Flintoft, E. Gort, E. Thiel, P. Blackstien-Hirsch, T. Axcell, M. Paterson, C. Cameron, C. Estabrooks, S. Mercer, V. Goel, and J. I. Williams. (May 1999). Focus groups in health services research at the Institute for Clinical Evaluative Sciences. Pub. No. 99-02-TR. Ontario, Canada: Institute for Clinical Evaluative Sciences.

Wenger, N.S., F.S. Kussling, K. Beck, and M.F. Shapiro. 1994. Sexual Behavior of Individuals Infected with the Human Immunodeficiency Virus: The Need for Intervention. *A.M.A. Archives of Internal Medicine*, 154: 1849-1854.