

B. SURVEY APPROACH

INTRODUCTION

This study approach is designed such that it includes the entire population of beachgoers at each study site. This includes swimmers and nonswimmers of all ages with the exception of unaccompanied minors (since an adult is necessary to provide informed consent).

1. Survey Objectives and Key Variables

The objective of this study is to conduct health effects studies to evaluate exposure to water quality indicators in recreational waters and their subsequent relationship to health effects. The beaches will be chosen to consider a range of exposures. There are four key variables considered in this study; health status, water quality measures, environmental exposures and potential confounders. Each of these variables is considered in the development of the study objectives.

Health status of the respondents includes health symptoms experienced prior, during, and after the beach visit (10-12 days after). Such symptoms include: diarrhea, vomiting, sore throat earache, eye infection, rash, sunburn, and fever.

Water quality measures will be collected in the same beach areas on the same days as the health data collection.

Environmental exposures include activities in the designated beach area. These include digging in the sand, swimming in the water, snorkeling, collecting seashells, or length of time in the water.

Potential confounders are possible other symptom determinants that are not related to the environmental exposure of interest (coastal recreational water). These include demographic factors such as age, sex, race, and specific behaviors such as contact with animals, consumption of specific foods and contact with other types of water.

2. Survey Design

The health survey is administered by bilingual interviewers (English-Spanish) in three parts: enrollment, exit interview, and telephone interview. Both the enrollment and the exit interviews are completed at the beach. A second interview is completed by calling the family at home.

Beach Interview: The enrollment (Part A) is done shortly after the family settles in the beach area. This part of the questionnaire provides the EPA with information about household health status and it also limits the amount of time the participants must spend on the interview as they are leaving the beach. Part A of the questionnaire obtains individual-level information on health status and potential confounders such as age, sex, race, ethnicity, housing characteristics, family characteristics, and behaviors. Part B (exit beach interview) captures data about potential exposures. The information collected includes the day's activities, food and water consumption, potential water exposure (extent, time, duration, and location), and other potential confounders.

Telephone interview: Study participants are contacted by phone 10 to 12 days after visiting the beach. An adult caregiver, preferably the same one interviewed at the beach, is asked a series of questions about family members' swimming activities, other exposures, health status, and the severity of any illnesses reported since the initial beach visit. Questions cover enteric and nonenteric illness (GI, respiratory, ear, eye, skin irritations, and urinary tract infections).

3. Pretests, Pilot Tests

The beach interview is based on previous questionnaires used in the studies conducted by EPA in the 1970s and 1980s. These questions have been compared to and when possible modifications made to be compatible with the Centers for Disease Control and Prevention, National Center for Infectious Diseases FoodNet survey. In addition, similar questions have been used in drinking water studies (ref Payment 1, Payment 2, Calderon, Colford).

Respiratory symptoms have been adapted from the Epidemiology Standardization Project of the American Thoracic Society and the Division of Lung Diseases. Also, the questionnaire was evaluated after the beach pilot study in 2002. Modifications of the questionnaire wording were made based on that experience. Between the years of 2003 and 2007, the questions were minimally altered to resolve participation comprehension due to language culture. Other questionnaire changes are submitted each year the study is conducted to the Office of Management and Budget (OMB). It is anticipated that questionnaire modifications after this date will not vary from the current format.

4. Collection Methods

The study is a prospective cohort study. Trained interviewers disperse on the beach and visually identify households eligible to participate. The goal is to approach and offer enrollment to **all** beach-goers between 11:00 a.m. and 5:00 p.m. Interviewers approach beach-goers on weekends and holidays during the recreational season (Generally April to mid September depending on the geographic location). An adult (age 18 or older; 19 in Alabama) answers questions for other household members. All contacts on the beach are given either a flag or colored tape to signify they have been approached to avoid repeatedly disturbing them. Respondents are given an inexpensive gift (cooler or tote bag) following completion of the exit interview.

Consent process: The study protocol and questionnaire were reviewed by the Institutional Review Board (IRB) for the Centers for Disease Control and Prevention and approved by the EPA Human Subjects Review Official. A waiver of written informed consent for the enrollment process was obtained.

Consent brochure: This document serves as the verbal consent form and included information about the benefits of participation (incentives and public health improvements for beach users), potential disadvantages of participation (time), absence of health risk, confidentiality, information dissemination, contact information for investigators, IRB, and contractor (email address, telephone number, and a website for the project). Study participation is completely voluntary and the participant may withdraw at any time and refuse to answer any individual questions.

Incentives: Incentives are provided to participants to encourage completion of the beach questionnaire on enrollment day (e.g., tote bag, cooler, or beach-related item). Upon completion of the follow-up telephone interviews, a \$25 check is issued to each household.

Eligibility criteria: Potential enrollees had to meet the following criteria:

- 1) have a household member legal age to participate (generally at least age 18),
- 2) participate in the study and complete the telephone interview,
- 3) have not participated in the study within the prior 28 days.

Quality control: EPA developed and implements a Quality Assurance Project Plan prior to the conduct of any data collection. In addition, EPA sends a Quality Assurance Team to perform a Technical Systems Review at each beach to assure the plan was being adhered to and also to review procedures carried out at the beach.

Data entry, management, and security: A computer-assisted personal interview device (CAPI) equipped with a template of the questionnaire is used to collect the information at the enrollment and exit interviews. This device is a lightweight, hand-held tablet computer tolerant of extreme environmental conditions. The CAPI program flags missing items prior to terminating the interview and also flags erroneous responses to allow the interviewer to obtain the correct information while interviewing the household. All data are kept in locked cabinets or in password-protected computers. All data is removed from the computers daily and they are always secured at the beach site. Networks are protected with a firewall to prevent unauthorized access to agency networks. Personal identifying information is stored separately from questionnaire and telephone survey information, and all personal information was removed from analytical databases. Following completion of the final follow-up survey at the end of the study, participant personal identifiers were unlinked from the data.

The phone interview is conducted using a similar program and a computer-assisted telephone interview (CATI) system. The CATI system automatically flags missing or erroneous data prior to termination of the interview. Telephone interviews are conducted from secured research facilities. Each of these devices reduces data entry errors that result from data transfer in traditional paper-based studies.

Paper Reduction Act: The questionnaires and study protocol were published in the Federal Register and public comment was requested. The comments and the estimated burden of the questionnaire were reviewed and approved by the Office of Management and Budget. The OMB number for this study is 2080.0068.

5. Analyzing Survey Results

The primary goal of the data analysis is to evaluate the relationship between novel and rapid measures of water quality and health effects and determine whether the new approaches to measuring water quality would be useful in protecting beach-goers health. If these methods prove to be useful, then they have potential to be used in criteria and guideline development. A second goal is to conduct subgroup analysis on particular sensitive subpopulations such as children and the elderly.

Analyses will be conducted by comparing gastrointestinal and other health symptoms by swimming and non-swimming status and by exposure to varying levels of water quality measures.

At the completion of the entire program, an overall report will be produced that synthesizes all the information. An EPA report will be produced for Agency and public use. A manuscript for each recreational season will be submitted for publication in a peer-reviewed scientific journal.