

III. How to Get Started

Once the data collection model, including the survey design and content, has been finalized it is time to begin planning the study implementation. The first area discussed below – writing the survey protocol – is an opportunity to think through many of the details of data collection, management of the day-to-day operations of the survey, and development of a more detailed budget.

A. Write the Survey Protocol and Obtain Approvals

Careful documentation is the key to organizing the study and ensuring that all procedures are standardized. The first step toward standardization is development of a clear and detailed protocol. The writing process will shed light on many issues that are best thought through at this early stage. The development of the survey protocol is also a critical piece in gaining Institutional Review Board (IRB) approval for your study. While getting IRB approvals is not unique to a community HANES, there are several issues that may require particular attention.

[View: NYC HANES Protocol & Attachments:

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_protocol.pdf

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_protocolatta.pdf

1. Informed consent procedures and materials

All studies will require that participants recruited into the study give informed consent. In developing informed consent procedures for a community HANES, planners should give special attention to the burden placed on the participant due to the potentially lengthy interview and exam. Also consider any potential risks due to invasive procedures, as well as potential benefits (e.g., provision of exam results and remuneration). Finally, consider any future uses of data (e.g., specimen storage).

NYC HANES Informed Consent

NYC HANES produced and distributed to all eligible participants a brochure that included the informed consent form, and explained the purpose, procedures, potential risks and benefits, and voluntary nature of the study.

All materials were written for comprehension at a sixth grade reading level. In addition to English, the consent form was translated into seven major languages (Arabic, Cantonese, French Creole, Italian, Korean, Russian, and Spanish). Because NYC HANES involved a specimen repository, separate consent for future storage had to be given by each participant.

The informational brochure and consent information were provided to eligible survey participants during recruitment. Upon arrival at the NYC HANES clinic, the clinic coordinator explained all components of the survey and obtained written consent for both the survey and specimen repository.

[View: NYC HANES consent & future specimen informed consent:

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_consentform.pdf

http://www.nyc.gov/html/doh/downloads/pdf/hanes/hanes_start_speccconsent.pdf

The NYC HANES Confidentiality Statement

The NYC HANES confidentiality statement informed participants that their data would be de-identified and combined with that of other study participants for both analysis and publication. All NYC HANES staff attended a mandatory training, conducted by study coordinators, on confidentiality protocols and penalties for breaching protocol. To further ensure protection against requests, subpoenas and other demands for data, NYC HANES obtained a Certificate of Confidentiality from the National Institutes of Health [42 USC 241(d)].

[View: Confidentiality statement:

http://www.nyc.gov/html/doh/download/pdf/hanes/HANES_start_confid.pdf

NYC HANES Report of Findings Procedures

At the Clinic:

Preliminary reports on body mass index and blood pressure were provided at the conclusion of each clinic visit. Participants also received targeted, personalized referrals in response to abnormal or unhealthy test results, and proactive age- and gender-specific health care referrals for clinical preventive services.

Results from Laboratory Testing:

If a participant's laboratory tests indicated the presence of disease, the participant was notified (either by letter or phone call) of the condition. If results indicated highly abnormal levels or an emergent health condition, a phone call was placed to the participant upon receiving the findings from the laboratory. All participants received a cover letter and a final report of findings by mail, once all the laboratory test results were available. These were sent to participants on a rolling basis.

Referral System:

It was expected that some survey participants would have questions about their test results ranging from basic health concerns, to options for further testing, to the availability of medical care in their area. To answer these questions, a dedicated phone referral hotline, staffed by DOHMH nurses, was established. Hotline staff received specialized training on conditions covered by NYC HANES. The staff was also equipped to provide participants with information regarding free or low cost health care facilities in their borough.

[View: Report of findings protocol, and referral website

http://www.nyc.gov/html/doh/downloads/hanes/HANES_plan_report.pdf

<http://www.nyc.gov/html/doh/html/downloads/hanes/refdirectory.shtml>

2. Developing a confidentiality statement

Documenting the procedures that are in place to protect the confidentiality of participant information is essential for a community HANES. A confidentiality statement should be developed and provided to potential participants to specifically address how the data will be used. Organizers should also clearly acknowledge if any state or local regulations require that personal information be disclosed to health authorities for reportable conditions.

3. Recruitment Procedures

Due to the effort and expense involved in conducting a community HANES, repeated contact will likely be necessary with households that may not initially be interested in order to achieve a high response rate. Refusal conversion procedures (methods to convince reluctant participants to enroll) and the number of times that a household can be contacted will need to be carefully considered and outlined in your protocol. In the NYC HANES protocol, “hard” and “soft” refusals were defined and the maximum allowable number of contacts per household was specified.

4. Report of Findings & Referrals

Because a community HANES will involve the measurement of health indicators, organizers will need to consider if any test results should be reported back to participants. If so, decisions about what will be reported (all results or only abnormalities), and where and when reports will be provided (immediately after the clinic or home exam, or through mailed notification after the study) will need to be made. Study planners should also consider:

- Protocols for handling abnormal results
- Additional resources to be provided to participants

- How participants’ questions or concerns will be answered
- Whether abnormal individual results are reportable to state or local health departments

B. Create a Detailed Budget & Develop Contracts

Budgets are rarely fixed objects. While the initial budget plan provides a good outline for overall budgeting, a more detailed budget will need to include confirmed cost figures from contractors and suppliers. Prior to purchasing supplies and equipment, or paying salaries, clear procedures for tracking purchasing and spending should be developed with the agency’s fiscal office.

Once contracting needs have been determined, organizers should begin the contracting process. It can take weeks or even months to find the right contractor, negotiate the price, and execute a final contract. Some of the more time-consuming aspects of negotiating the terms of contracts may involve data ownership, publicity and publication rights. It is important that your agency go into the selection and negotiation processes with a clear idea of how these issues should be handled. Looking at similar agency contracts executed with the vendors under consideration, or similar vendors, can inform this process. Key issues to consider when developing a contract are the exact task to be performed, the deliverables expected and the time schedule for the submission of reports and other deliverables.

[View: Lab contract check list

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_contractcheck.pdf]

NYC HANES Major Budget Areas

Sample Design: Contracted services required to design a population sampling scheme and to draw the sample.

Central Office: Labor costs for the staff supervising data collection.

Publicity and Communication: Costs associated with press-related activities and production of recruitment materials.

Screening and Interviewing: Labor costs to approach and screen selected households.

Facilities and Exams: Labor, equipment and supply costs required to operate fixed-site clinics.

Information Technology: Labor, hardware and software needed to collect the study data.

Training: Costs to conduct training sessions with all interviewers, central office and exam staff.

Remuneration: Compensation for all survey participants for their participation in the study, including study incentives (\$100 per participant) and transportation.

Laboratory: Costs of conducting laboratory tests, including analysis kits, materials, specimen storage and shipping, and labor.

Weighting: Costs associated with computing survey weights that are used in the analysis of the data to account for the sample design and ensure that data findings are representative of the NYC population.

[View: Percentage cost of major budget items

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_budget.pdf

C. Obtain Physical Facilities, Equipment and Supplies

An examination study requires particular attention to facilities, equipment and supply needs. For example, conducting a physical examination may require appropriate examining rooms, patient gowns and specialized equipment such as blood pressure cuffs and scales for weight and height measurements.

If specimens are being collected, specialized laboratory supplies will be needed for collection, processing and storage. A step-by-step review of processing procedures will be required to determine the number and types of specimen collection tubes needed, the transportation requirements, and the necessary processing procedures and equipment. In determining this process, study planners will want to include agency or outside staff responsible for transporting, processing, and analyzing specimens.

NYC HANES: Use of Outside Contractors

NYC HANES organizers decided to use outside contractors for data systems design, laboratory analysis, and other services. All contracts specified requirements including timeliness, reporting protocols and confidentiality.

National Center for Health Statistics provided:

- Adaptation/development of data collection software
- Staff training assistance

Westat provided:

- Sample design
- Calculation of analytic weights

State, federal and private laboratories performed:

- Analysis of blood and urine specimens

Car services provided:

- Transportation for selected survey participants

Language interpretation services provided:

- Interpretation assistance in the field and at NYC HANES clinics

NYC HANES Facilities/Equipment/Supplies

Facilities

Each of the four NYC HANES clinics included:

- Three private interview rooms
- A phlebotomy room used for blood draw, processing and storage
- A bathroom
- A waiting area

Exam Equipment

- Desktop manometers
- Blood pressure cuffs
- Digital floor scales
- Telescopic stadiometers
- Adult stethoscopes
- Metal tape measures
- Paper gowns

Information Technology Equipment

- Laptop computers
- Touch screen monitors
- Headphones

Laboratory Supplies

- Barcode scanners
- Dymo label writers
- Datamax printers
- Datamax labels
- Transport coolers
- Refrigerators/freezers
- Cryovials (various sizes)
- Centrifuge & centrifuge tubes
- Safety goggles
- Mercury spill control kits
- Urine container cups with lids
- Tubes (10 ml, 15 ml, 25 ml)
- Transfer pipettes
- Racks

[View: NYC HANES equipment and supplies

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start equip.pdf

NYC HANES Specimen Processing

The NYC HANES staff developed detailed flow charts that outlined all procedures for collecting and processing specimens at the clinic, transporting the specimens to the central DOHMH laboratory for additional processing, and shipment of the processed specimens to the contracted testing laboratories.

In developing these procedures, NYC staff worked closely with NCHS, the DOHMH staff responsible for the transport of specimens, and the contracted laboratories to ensure compatibility with NHANES and compliance with quality assurance and quality control procedures.

[View: Specimen processing flow chart

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_specflow.pdf]

NYC HANES Overall Survey Schedule

NYC HANES opted to undertake field recruitment in a sequential manner. Therefore, exam site operations were started and finished in one area before moving to another area. This decision was based primarily on budgetary and staff restraints, and a desire to target public relations and outreach efforts in support of participant recruitment. Because so many New Yorkers work in the borough of Manhattan, regardless of their borough of residence, the Manhattan clinic operated throughout the survey.

June & July 2004

- Field recruitment in the Bronx, Brooklyn and Staten Island
- Clinics operating in the Bronx, Brooklyn and Manhattan

August & September 2004

- Field recruitment in Manhattan and Queens
- Clinics operating in Manhattan and Queens

Study Extension through December 2004

- Limited field recruitment in all communities (clean up)
- Clinic operating in Manhattan only

D. Develop the HANES Schedule

Planners will need to determine the survey schedule; this will include the time period for the entire survey, as well as the day-to-day operational schedules.

1. The survey schedule

The overall schedule will most likely be based on several factors including the survey budget, the data collection model, the geographic area to be covered, and the laboratory capacity for specimen processing. In planning the overall schedule, consider the following:

- How long will it take to interview and examine the survey sample to achieve the targeted response rate?
- How will the rollout of the survey occur?
- How will staff recruit participants, sequentially through neighborhoods, or in all areas simultaneously?

- How will decisions about recruitment times and operations affect the schedule of exam sites?

2. The operational schedule

Decisions about the schedule of daily data collection activities will depend upon both the survey schedule and the staffing model. Some issues to be considered in developing the operational schedule are described below.

Exam Schedule: Determine when survey participants are most likely to be available for the interview and exam – daytime, evenings or weekends. This information will be helpful in constructing the best schedule to recruit and examine participants. Key questions include:

- How many appointments need to be offered in total?
- How many appointments need to be offered per day/per week?

NYC HANES Clinic, Field, and Central Office Schedules

Clinic

- Monday through Friday daytime appointments – 7:30 am to 5:00 pm
- Monday and Wednesday evening appointments – 5:00 pm to 9:30 pm
- Saturday appointments – 8:30 am to 5:00 pm
- Sunday appointments were added during the last month of data collection

Field Recruitment

- Weekday hours – 11:30 am to 8:30 pm
- Saturday hours – 8:30 am to 4:30 pm
- Sunday hours – 10:00 am to 4:00 pm

Central Office

- A staff person was available in the central office at all times field or exam site operations were scheduled (see above)
- Additionally, a senior staff person was available evenings and weekends via a rotating manager-on-duty system

[View: NYC HANES operational survey schedule

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_opsched.pdf]

- What is the timeframe needed to conduct all of the exams - weeks, months, etc?

Recruitment Schedule: If participants are recruited from their homes, be sure to consider the following:

- When are interviewers most likely to find people at home?
- How often should staff recruit – 5, 6 or 7 days per week?
- What time of year will the survey be conducted?
- How late in the day can recruitment occur?

Central Office Schedule: The role played by the central office will impact its operational schedule. In NYC HANES, the central office served as an information hub, and thus operated during all recruitment and examination hours.

E. Assess Logistical Needs

Planning also involves a critical assessment of the operational resources necessary to manage the staff and schedule. Two major logistical concerns will include transportation and communication.

1. Transportation

Any community HANES will involve challenges related to transportation, both for staff members and survey participants. Though NYC HANES encompassed the five NYC boroughs, a community HANES that covers a wide geographic area may face even larger, more complex challenges than those described here.

Staff: If recruitment staff will be going door-to-door, you will need to determine how they will travel to each neighborhood, and how examination staff will travel to examination sites. Depending upon the geographic area, public transportation networks may cover

many of the selected neighborhoods; however organizers should verify that bus and train schedules match field recruitment hours. Because staff may not be familiar with all the selected areas, providing detailed maps and directions is advisable. Study planners will also want to consider transportation safety issues for staff traveling at night.

Survey participants: Survey participant travel to examination sites is another important consideration. Planners will need to gauge whether most participants will be able to travel on their own or if the study will need to provide transportation. This will largely be dependent on vehicle ownership rates among the sample population, the distance participants will need to travel, and the availability of public transportation. Special thought will need to be given to elderly or infirmed survey participants. Planners may also want to prepare detailed directions to clinic locations that can be provided to participants during recruitment.

Supplies & Specimens: If the data collection model involves multiple examination sites, a system for transporting supplies to and between the sites may become critical. If blood and urine specimens are to be collected, specialized transportation (equipped with dry ice or other temperature controls) may need to be arranged between the sites and the lab, or at the labs where processing will occur.

2. Communication

Recruitment and examination staff will need to communicate frequently with survey organizers and the central office staff. Survey organizers will also need to communicate routinely with all staff members, in order to provide assistance and troubleshoot problems. Having the appropriate mechanisms and technology in place will be critical to good communication.

NYC HANES Transportation

New York City has an excellent and extensive public transportation system. Clinic locations were selected for their proximity to public transportation, allowing many staff members and survey participants to use trains and buses. However, because of the breadth of the survey area, other arrangements were needed for staff, participants and supply movement in some neighborhoods.

Staff:

- Field recruiters used a combination of public transportation, department-owned cars, and personal cars (with reimbursement for mileage).

Study participants:

- Most participants used public transportation to reach clinic sites.
- Taxi service companies were contracted to provide transportation for elderly and infirmed participants, and to participants who refused to travel otherwise.

Supplies:

- A transportation system was developed to pick-up blood and urine specimens from the exam sites for delivery to the processing laboratory.
- Transportation systems were also developed for periodic delivery of supplies to the exam sites.

NYC HANES Communication

With nearly 50 NYC HANES staff members spread across numerous neighborhoods and in various clinics on a typical day, maintaining on-going communication was a critical issue. NYC HANES organizers designated the central office as the communication hub for all survey operations, serving as the collection and dissemination point for all field and clinic staff. Senior study staff worked from the central office (when not in the field or at a clinic). All senior staff, field staff and clinic coordinators were issued pre-programmed cell phones with two-way walkie-talkie and conference features. These formed the backbone of the day-to-day communication system. Additionally, standard meeting times were scheduled for clinic, field and central office staff. A weekly newsletter kept all personnel informed of study news and events.

[View: NYC HANES sample weekly newsletter

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_work_newsletter.pdf]

F. Data Management: Systems for Capturing Important Data Elements

1. Identify Important Data Elements

The data collection model you choose will largely determine how survey results will be collected, captured, delivered and stored. Many system options and combinations exist, including manual paper data gathering, electronic recording and electronic transmission. Factors to consider include:

- Budget
- Existing data infrastructure
- Collaborating institutions' contributions and needs
- Field, clinic and central office logistics
- Staff skills
- Timeliness of data needs

Whatever system or combination of systems is adopted, data collection will need to include:

1. Tracking of recruitment efforts and outcomes at the household level (e.g., no response, participant enrolled).
2. Tracking all identified survey participants and their enrollment status (all participant information should be linked to household information).

3. Scheduling and noting any special circumstances of selected participants.
4. Recording interview responses and exam measurement information.
5. Specimen tracking of blood and urine samples.
6. Quality control monitoring, including the aggregating and comparing of survey data from multiple examination sites, calculating response rates, report generation and bench-marking status against goals.

2. Pilot Test Data Collection Systems

After the data collection systems have been designed and developed it is important to test each system to be sure that the correct information is being collected, the information being collected is consistent with operational procedures at each collection point, and data collection systems are integrated (e.g. the necessary information is being transferred from one system to another). Pilot testing of data collection systems is important regardless of the media on which data are being collected. For example, if the household contact information that is critical to recruitment efforts is being collected on paper, planners will want to consider when and how that data will be stored and supplied to those who use this information.

NYC HANES Data Collection Components

- Tracking Household Visit Outcomes
- Tracking Identified Study Participants
- Appointment Scheduling
- Clinic Flow Management
- Interview and Exam Data Collection
- Specimen Tracking
- Electronic Laboratory Reporting

[View: NYC HANES data collection architecture

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_dataarch.pdf]

Additionally, if specimens are being sent to laboratories for testing, planners will have to determine how those data will be captured and linked to participant information. Extensive testing of the data collection systems will need to occur well in advance of the staff training and dress rehearsal, so as to identify and solve major system problems prior to study implementation.

G. Thinking Ahead About Outreach

Before beginning a community HANES it is important to gain the support of key stakeholders in the community, and to think through communication strategies for reaching potential survey participants. As the survey progresses, community and media contacts may prove critical in disseminating information about the survey and its importance. Outreach efforts during the survey are described in more detail in Section VI.

Getting the word out about a community HANES survey (or any population-based survey) presents interesting challenges. Unlike other public health media campaigns, the goal of outreach during a community HANES is not to reach everyone with your message. While it is important to raise the general level of awareness about the

survey, outreach efforts and resources are best targeted to neighborhoods selected for the survey.

1. Key stakeholders

Key stakeholders are community leaders and elected officials who have the most relevance and influence within the geographic area covered by the survey, specifically the neighborhoods where potential survey participants live. In New York City, we contacted members of congress, and state and local elected officials to inform them about NYC HANES and ask for letters of support. Influential community and religious leaders were also briefed on the importance of the survey for their constituents and for the city as a whole.

2. The media

The agency's community relations or press offices will have experience in transmitting important information to residents through the media and community organizations. Their expertise and connections can be crucial to the success of your survey. They can also help study planners shape their messages, as well as anticipate any negative attitudes or sentiments toward the project.

NYC HANES Makes the News

For NYC HANES, the DOHMH press office used its contacts with local television, radio stations and city newspapers to get the word out about NYC HANES.

Headlines from NYC HANES-related newspaper articles included:

"Health Workers Go Door to Door in Attempt to Take the City's Pulse"

"Say 'Aaaah,' New Yorkers, It's a Citywide Health Checkup"

"City to Conduct Comprehensive Health Study"

"Big Apple Wants Your Health Stats"

"Mediran Salud de Neoyorquinos"

[View: Press coverage articles, and outreach documents

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_samplepress.pdf

http://www.nyc.gov/html/doh/downloads/pdf/hanes/HANES_start_outreach.pdf

The press office may be able to plan a press conference or other informational events, as well as identify important local and ethnic media outlets to generate articles and gain cooperation in specific neighborhoods or among particular groups.

3. Potential Survey Participants

The most important outreach efforts should be directed at potential survey participants – individuals who live in households selected for inclusion in the survey. While these

individuals may be positively influenced by media coverage and letters of support from prominent government and community leaders, the most direct influence that study planners will have is through well-prepared staff and effective recruitment materials.

In the early stages, organizers should brainstorm about the types of participant recruitment materials they will need. Once a list is constructed, planners should develop a production schedule, allowing time for approvals and translations, if necessary.

NYC HANES Outreach and Recruitment Plan

Three months prior to survey kickoff, senior staff:

- Made presentations to elected officials at the borough and neighborhood levels.
- Solicited letters of support from elected officials and community organizations.
- Planned a kickoff press conference with the DOHMH press office.

One week prior to survey kickoff, senior staff:

- Held a press conference and issued a press release.
- Offered the press an opportunity to “ride along” with field recruitment staff.

NYC HANES Recruitment Materials

Three months prior to survey kickoff:

NYC HANES staff prepared the following materials:

- Advance letter
- NYC HANES flyer
- NYC HANES informational brochure
- NYC HANES confidentiality statement

All materials were translated into Arabic, Chinese, French Creole, Italian, Korean Russian and Spanish.

Two weeks prior to survey kickoff:

Advance letters and flyers were sent to selected households in the first neighborhoods to be visited.

[View: Recruitment materials

<http://www.nyc.gov/html/doh/html/hanes/section3.shtml>

(Note: When accessing this link, please scroll down to the bottom of the webpage)