Operational Implementation of the Healthy Communities Study

How Communities Shape Children's Health

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The Healthy Communities Study (HCS) is examining how characteristics of community programs and policies targeting childhood obesity are related to childhood diet, physical activity, and obesity outcomes. The study involves selected districts and public schools in 130 communities; families recruited through schools; and data collected at the community, school, household, and child levels. Data collection took place in two waves—Wave 1 in Spring 2012 and Wave 2 from 2013 to 2015—with analysis to be completed by August 2016. This paper describes operational elements of the HCS, including recruitment activities, field operations, training of data collectors, human subjects protection, and quality assurance and quality control procedures. Experienced trainers oversaw and conducted all training, including training of (1) district and school recruitment staff; (2) telephone interviewers for household screening and recruitment; (3) field data collectors for conducting household data collection; and (4) community liaisons for conducting key informant interviews, document abstraction, and community observations. The study team developed quality assurance and quality control procedures that were implemented for all aspects of the study. Planning and operationalizing a study of this complexity and magnitude, with multiple functional teams, required frequent communication and strong collaboration among all study partners to ensure timely and effective decision making.

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Introduction

The Healthy Communities Study (HCS) is designed to assess whether characteristics of community programs and policies targeting childhood obesity are associated with diet, physical activity, or obesity outcomes in children. The HCS is being implemented in a diverse sample of 130 communities across the U.S. This paper describes the operational elements of the HCS, including recruitment activities, field operations and data collection, training of recruitment and data collection staff, human subjects protection, and quality assurance (QA) and quality control (QC) procedures. The other papers in this supplement provide detailed information on study design and rationale (Arteaga et al.[1]); statistical design (Strauss and colleagues[2]); weight status measures (Sroka et al.[3]); dietary measures (Ritchie and colleagues[4]); physical activity measures (Pate et al.[5]); and community measurement of programs and policies (Fawcett and colleagues[6]).

The NIH leads the HCS. Battelle Memorial Institute and its university subcontractors at the University of California at Berkeley, University of South Carolina, and University of Kansas worked with NIH staff and partners at CDC and the Robert Wood Johnson Foundation to

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design the study and develop the measures and protocol. The Steering Committee consists of the Battelle study team, the three University partners, NIH staff, and staff from CDC and the Robert Wood Johnson Foundation. Battelle contracted with NORC to recruit the school districts and schools and distribute recruitment materials to families through the schools.

Methods

The study design involves recruiting districts and public schools in 130 communities and recruiting families through the schools for household data collection. In each community, select schools within the targeted public high school catchment area were recruited, and school personnel were asked to provide information on programs and policies related to nutrition and physical activity. Local field data collectors (FDCs) conducted structured interviews with recruited families on diet, physical activity, and related information; obtained anthropometric measurements; and gathered medical record release forms to enable the team to gather child height and weight data for up to 10 prior years. Additionally, trained project staff served as community liaisons (CLs) who conducted school observations and recruited and interviewed key informants (KIs)—community leaders knowledgeable about community programs and policies (CPPs) related to diet and physical activity. Data on the evolution of these CPPs over the past 10 years were documented, and project staff used these data to characterize CPPs and calculate intensity scores (i.e., an index composed of the sum of CPPs weighted for intervention strategy, duration, and estimated reach). Fawcett et al.[6] describes how CPPs were characterized and intensity scores were calculated. Data collection took place in two waves—Wave 1 in Spring 2012 and Wave 2 from 2013 to 2015—with analysis to be completed by August 2016.

Recruitment

Recruitment was conducted in two waves, with Wave 1 (Spring/Summer 2012) designed as an opportunity to test and refine protocols before the launch of full data collection (Wave 2, Fall 2013 through Summer 2015). Recruitment of families for Wave 1 involved obtaining a list of contacts (names, addresses, and phone numbers) through InfoUSA for a random sample of households with landline phones that were expected to have children living within a public high school catchment area. Wave 1 results indicated that this approach was not particularly effective in identifying households with children in the target age range who were willing to participate, and that the sample of participants was not always representative of the selected community with respect to race and ethnicity. Therefore, for Wave 2, an alternate approach was designed with the intent to produce a more representative sample within communities, including families without landlines, and create a more efficient and less burdensome approach to recruiting families. Public elementary and middle schools within the community were sampled, with probability of selection based on how well the student population matched the demographic profile of the strata that the community was representing. Families were then recruited via these schools to sample up to 81 children from kindergarten through eighth grade (K–8) per community. This approach also enabled the study to associate more directly the observations of the school physical and nutrition environments with the study population results, as the sampled children attended the recruited schools.

The first step in the recruitment process was to obtain school district-level approval in each community. An introductory letter was sent to each district superintendent, with telephone and e-mail follow-up as needed. A research package was submitted to each district to request approval for study personnel to recruit specific schools. Additionally, the superintendent was asked to indicate the appropriate person at the district level to complete an online School Foodservice Questionnaire for each recruited school (a description of the questionnaire is provided in Ritchie and colleagues[4]). The goal was to obtain district approval in approximately 150 communities to ensure that data collection could be launched in approximately 125 communities within the study period, allowing for attrition of communities due to incomplete recruitment.

Upon receipt of district approval, up to two elementary and two middle schools (or K–8 schools) were recruited in each community. Introductory letters were sent to principals, with telephone and e-mail follow-up. In a few cases, in-person follow-up was also required. Principals were asked to identify a school liaison (e.g., a teacher, administrative assistant, or other staff member) to serve as a champion for the study; complete the online School Policies and Practices Questionnaire (described in Ritchie et al.[4]); and distribute and collect Participant Interest Forms (PIFs) from families. Principals also were asked to participate in a semi-structured KI interview. Each participating school was provided with a $150 incentive for its participation, and each school liaison was offered a $50 incentive.

Electronic recruitment materials (the "toolkit") and hardcopy PIFs, study brochures, and letters inviting households to participate were sent to each school. The toolkit included suggested text for school liaisons to include in newsletters, announcements, parent e-mails, and social media to encourage parents to respond. The PIFs were colorful, printed forms requesting parent contact information and child's first name, grade, gender, race, and ethnicity. The PIFs were sent home with the children along with a letter and brochure describing the study. All materials were provided in English and Spanish. Each student who returned a completed form received a small gift (e.g., pencils, stickers), whether the family agreed or declined to be contacted by the study. The goal was to obtain sufficient PIFs to recruit $>5{,}000$ families. The Battelle call center contacted households by telephone to complete an eligibility screener and schedule an appointment for the data collection visit. In communities where sufficient households could not be scheduled by phone, additional efforts were made to contact them, including local call attempts by an FDC in the community, letters, and in-person visit attempts.

KIs initially were identified through web-based searches (using program descriptors, types of organizations, and geographic terms) and screened by phone to determine eligibility and invite participation. An appointment for an in-person or telephone interview was scheduled at a convenient time, and documentation on CPPs was requested. During the screening call, the CLs also asked prospective KIs to identify additional KIs from other sectors to contact; this snowball sampling method assisted the CLs in identifying KIs from multiple sectors (including schools, health organizations/coalitions, government, and non-profit/community organizations/service agencies) to obtain a comprehensive overview of the CPPs. For a more detailed description of the interview, see Fawcett and colleagues.[6]

Data Collection

In each community, CLs conducted semi-structured interviews with KIs to document how childhood obesity programs and policies evolved within the community over the previous 10 years and to characterize the current state of these programs and policies. Interviews were supplemented by abstraction of documents provided by the KI. The protocol called for conducting between ten and 14 KI interviews in each community. The interview was designed to require approximately 75 minutes, and KIs were offered a $10 gift card for their participation.

Observational assessments of the nutritional and physical activity environment were conducted in participating schools. A CL observed the school's lunch period and completed the Lunch and Competitive Foods Observation Form during the school visit, interviewed a member of the physical education staff, and observed physical activity resources using the Physical Activity Resource Assessment form. The school liaison was asked to complete a brief, online questionnaire requesting information about wellness policy implementation and physical activity policies and practices. At the district level, the food service administrator/manager was asked to complete an online questionnaire on the lunch programs of each recruited school. To assess community factors at the child level, the FDCs recorded observations of the immediate neighborhood around recruited households using a Modified Windshield Survey and collected information from participating families on their perceptions of their community, school, and home environments.

Parents/caregivers and children completed the HCS standard protocol assessment during an in-home visit by an FDC. The standard protocol baseline visit included height, weight, and waist circumference measurements of the child; height and weight measurements or reported height and weight of the parents or caregivers; completion of sociodemographic questions; brief diet and physical activity behavior questionnaires; and a permission form to abstract the child's medical records. The standard protocol was designed to average 75 minutes in the home. A random subset of participants (approximately 10% of child participants) also completed more detailed measures of diet (two 24-hour recalls) and physical activity (use of an accelerometer over a 1-week period and a previous-day physical activity recall). This enhanced protocol was designed to average 180 minutes over two visits and will allow the study to both (1) characterize the relationship between the standard and enhanced measures and (2) make appropriate statistical adjustments for bias and error to assess relationships. Both protocols were administered in English or Spanish based on participant preference. Medical records for child participants were requested from medical providers after the household data collection visit.

Data collection staff included telephone center staff who screened families for eligibility and scheduled appointments, local FDCs hired in each community to conduct household data collection and supervised by Battelle field supervisors, and CLs who collected key informant and school observation data and conducted QC of FDC activities. Telephone center staff and CLs were selected from among existing Battelle staff based on experience and availability. Applicants for the FDC positions were required to meet extensive eligibility criteria (assessed through an online screener); provide a resume; complete a video interview, telephone screener, and in-depth telephone interview; and pass a thorough background check. In addition, bilingual applicants completed an online language assessment and a portion of the video interview in Spanish. The video was reviewed by a native Spanish speaker to assess fluency, and a follow-up telephone interview was conducted in Spanish when needed.

Experienced trainers from Battelle and its university partners oversaw and conducted the training of the telephone interviewers on screening and recruitment, FDCs on household data collection, and CLs on conducting KI interviews, document abstraction, and community observations. Training sessions were conducted using a number of modalities, including in-person one-to-one and group sessions, online individual coursework, videos, field practice, quizzes, and live webinars. NORC project staff provided training to the staff assigned to recruit districts and schools. As part of the training and quality assurance protocol, all data collection staff also received a training and reference manual and completed human subjects research ethics and confidentiality trainings.

FDCs were trained in groups prior to the launch of data collection in each batch of new communities. FDCs completed approximately 16 hours of online pre-training (materials, videos, quizzes) with field supervisors monitoring completion and quiz scores. Upon successful completion of the pre-training, FDCs completed a 4-day, in-person training that included practice and certification. Refresher trainings were deployed weekly throughout the field period to reinforce protocol. Figure 1 depicts the FDC training process.

Training for CLs included in-person training with field practice, webinars, and certification for each component of the community data collection, with periodic refresher training provided via webinar.

Staging of Operations

Communities were assigned to geographic clusters to increase the efficiency of field operations, allowing FDCs assigned to clusters to collect data in multiple study communities either sequentially or simultaneously, depending on each community's timeline. Similarly, CLs traveled to multiple communities within a cluster when possible to maximize travel efficiency. Communities were assigned to a CL to begin community-level data collection at the point when at least one elementary and one middle school, or at least one K–8 school, was recruited (in a few communities, the schools that agreed only included grades K–6). At that point, CLs began identifying potential KIs and scheduling and conducting telephone KI interviews. Communities were put on hold for KI data collection if PIF response was low and resumed later if PIF response increased. School visits and household data collection began when PIFs had been collected from each of three grade groups (K–2, 3–5, 6–8). When possible, travel to conduct in-person KI interviews and school visits was scheduled during the first 2 weeks of household data collection to facilitate QC of FDCs while the CL was in the community.

Human Subjects Protection

The study was approved by the Battelle IRB. Parents provided written informed consent for their children's participation, and children aged $\geq$8 years provided written assent. Signed medical record release forms also were obtained from parents. Consent information was included in the web surveys completed by school personnel, and verbal consent was obtained prior to each key

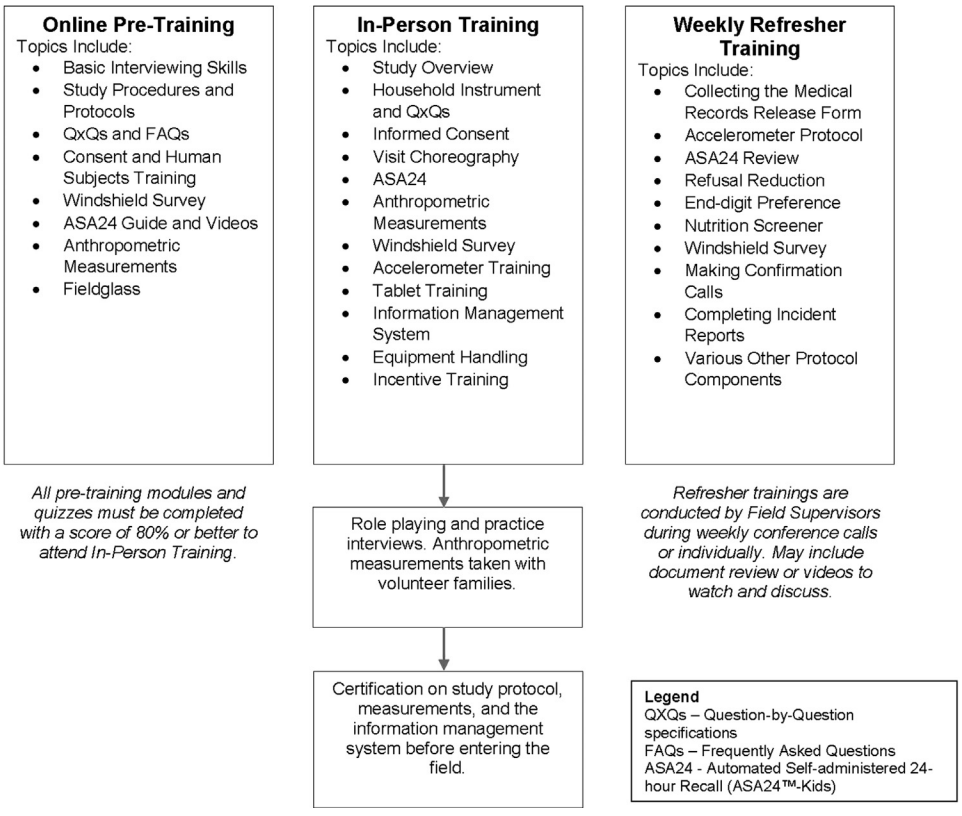

Figure 1. Healthy Communities Study training protocol: field data collectors.

informant and physical education teacher interview. Protocol changes and annual review documents were submitted to the Battelle IRB for approval as required.

Quality Assurance/Quality Control Procedures

Successful implementation of the HCS required a strong focus on QA/QC owing to the complex, geographically dispersed nature of the data collection. The HCS team developed a QA/QC manual and implemented QA/QC procedures for all aspects of the study. A QA/QC subcommittee composed of National Heart, Lung, and Blood Institute (NHLBI), Battelle, and university partner representatives met weekly throughout the data collection period to review quality indicator reports and address any quality-related issues promptly. QC procedures for KI interviews included real-time monitoring by University of Kansas personnel and callbacks by QC technicians (staff hired specifically to conduct QC activities, including field visits); refresher training; and multistep review processes for CPP data. For school data, experts on the study team accompanied CLs periodically to monitor and rate their performance and reviewed the school liaison and district food service manager survey completion and data quality. QA/QC procedures for the household data collection included FDC debriefing with field supervisors following initial data collection visits to reinforce adherence to protocol and in-home observations by CLs, university partners, or QC technicians at least once for each FDC, with feedback and remediation training as needed. In addition, QC technicians called families to assess the professionalism of the FDCs and verify that data were collected correctly, and university partners reviewed anthropometric, dietary recall, accelerometer, and home interview data regularly and quality indicator reports weekly, with any questions identified and resolutions incorporated into the analytic data set and documented in a tracking log. QA/QC for the medical records component included an independent review of 10% of records for accuracy by a second abstractor.

Discussion

Planning and operationalizing a study of the complexity and magnitude of the HCS benefitted from a phased approach to study implementation, a clear communication protocol, and a collaborative leadership team.

The pilot phase was instrumental in setting the groundwork for full study implementation. In particular, results of Wave 1 pilot testing were instrumental in refining recruitment strategies for families and schools. Wave 1 allowed the study to develop a more efficient recruitment approach that combined the efforts needed to recruit schools for observations with the recruitment of families. Wave 1 also afforded the opportunity to develop templates and prototypes of research application packages for recruiting schools and highlighted the importance of adequate lead time to request school involvement.

The HCS involved multiple functional teams and required frequent, regular inter-team communication, and strong collaboration among the study partners to ensure timely and effective decision making. The HCS governance structure (described in Arteaga et al.[1]) established processes to ensure collaboration across the study team throughout all phases of the process, from development of the study design and data collection instruments and protocols, through monitoring and providing input on field operations, to conducting QC of both the field staff and the collected data, to conducting analyses and preparing manuscripts. Team members participated in subcommittees that focused on specific areas of the study,[a] meeting frequently during the initial protocol development period, and as needed thereafter to provide input on suggested study changes and on development of analysis plans. An Executive Committee also met frequently throughout the study to share study updates and review and approve major subcommittee recommendations and operational decisions. Lastly, weekly operations calls between the study team and NHLBI Project Office were held to monitor progress and address issues as they arose.

Through this collaborative approach, which enabled the study to benefit from the diverse expertise of the study team members, the project team was able to implement the study's measurement protocols in communities across the country, collecting essential data on the relationship between programs and policies and child health outcomes nationwide.

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[a]Subcommittees included Design and Analysis; Physical Activity Data Collection; Nutrition Behavior Data Collection; Community Measurement Data Collection; BMI Data Collection; Public Image and Relations; QA/QC; Training; Recruitment and Retention; and Publications, Presentations, and Ancillary Studies.