2.0 Data Collection Preparations

Preparations for the 1999 NLTCS Supplemental Studies involved Duke's CDS and several RTI units. The Kin and NOK questionnaires were adapted by RTI project staff from the 1994 NLTCS questionnaire. Manuals and training programs were prepared by RTI staff to guide and standardize all NLTCS data collection operations. Telephone Survey Department (TSD) staff and supervisors were trained to make phlebotomy appointment calls, reminder calls for the return of specimens to the lab, and KIN and NOK interview calls. Data Preparation Unit (DP) staff and supervisors were trained on the appropriate procedures for the phlebotomy supply mailouts, venipuncture participant packet preparation, and buccal cell collection kit mailouts. The RTI computing staff developed programs and applications that enabled the other project staff to track and complete their tasks.

This chapter reviews our preparations for the 1999 NLTCS Supplemental Studies. These preparations included the development of procedures, manuals, and various data collection forms. We also discuss recruitment and training of phlebotomy nurses for the venipuncture study as well as telephone interviewer (TI) training for all four Supplemental Studies.

2.1 The 1999 NLTCS Questionnaires

The Duke Senior Investigator assumed primary responsibility for the content of the Kin and NOK questionnaires. Both questionnaires were modified versions of the 1994 NLTCS instrument. The 1994 NLTCS cognitive interview was used because it was readily adaptable to a telephone interview format, while the 1999 NLTCS instrument was not. The Kin questionnaire was based on the health and cognitive functioning portion of the NLTCS community interview, and the NOK questionnaire was based on the caregiver's survey. RTI staff assisted the Duke Senior Investigator in making adjustments to the Kin questionnaire in the fall of 2000. The questionnaire was shortened to 25 minutes in order to conduct the study over the telephone.

In addition to biospecimen collection for the Venipuncture and Buccal Cell studies, Duke requested RTI staff collect participant data on places of residence up to the age of twelve, date of birth for both parents, date of death for both parents, and parents' ages at death. The RTI Telephone Survey Manager drafted the questionnaire and submitted it to the Duke Senior Investigator for approval. The questionnaire was included in all buccal cell collection kits for the Venipuncture, Buccal Cell, and Kin studies. Telephone Interviewers (TIs) administered the questionnaire to Venipuncture participants during the phlebotomy appointment call. A copy of the *Questionnaire regarding Childhood and Parents* is displayed in ***Appendix A***.

2.2 Development of Manuals and Other Data Collection Materials

To prepare for the 1999 NLTCS Supplemental Studies, RTI project staff developed several Telephone Interviewer Manuals and a Phlebotomy Manual to provide step-by-step directions for performing

specific tasks for the supplemental studies. Each manual provided an overview of the NLTCS, emphasized the importance of confidentiality, and outlined specific tasks to be completed to conduct the particular supplemental study. The manuals were used in training and as a reference by TSD and nursing staff.

The 1999 NLTCS Supplemental Studies Telephone Interviewer Manuals described the computer-assisted telephone interview (CATI) procedures that were used for the various calls made to NLTCS participants and their siblings and children. The manuals displayed each CATI screen, showing the questions to be asked by the TI during a specific call. The manuals were annotated to guide the TI through possible scenarios they might encounter when calling the elderly and their caregivers, particularly if the participant was a resident of a skilled nursing facility. To better equip the TI to interact with staff at these facilities, the manuals contained information about the characteristics of the treatment centers, answers to frequently asked questions, and a list of common terms and definitions. General telephone interviewing techniques and tips for successful calls were outlined as well. Finally, the Telephone Interviewer Manuals contained step-by-step instructions for conducting the Kin and NOK interviews, setting the venipuncture appointments, reminding participants to submit their specimens to the lab at the University of Washington, and performing assessments of participants coded as incapable in order to determine their eligibility.

The Venipuncture Study Phlebotomy Manual outlined each step that was followed to prepare for and conduct each phlebotomy appointment, as well as instructions for packing, labeling, and shipping the blood to the lab. This manual also provided precise directions on receipt of participant packets and incentive money, obtaining informed consent from the participants, and returning the appropriate forms to RTI. For each participant, nurses returned the phlebotomy control card and a copy of the consent, incentive receipt, and shipping manifest forms. Copies of the shipping manifests were then used to track blood shipments to the lab.

2.3 Mailout Materials

Items included in the 1999 NLTCS Supplemental Studies mailouts were created by project staff and approved by the Duke Senior Investigator before the studies were implemented. Ten different lead letters were written and approved by the IRB for the four Supplemental Studies. Each study sent respondents an introductory lead letter and brochure describing the study and inviting them to participate. A toll-free number was included for subjects to call with any questions about the research projects. Four additional lead letters were written for the Venipuncture and Buccal Cell Studies. In order to increase the response rate, sample members that declined venipuncture were invited to submit buccal cell specimens. One of the four additional lead letters was sent to venipuncture sample members who either refused venipuncture, claimed not to have participated in the 1999 NLTCS, lived in an area not covered by the subcontracting phlebotomy agency, or were a “short stick” (e.g., venipuncture that results in little or no blood). Additional lead letters were also sent for follow-up to refusal conversion and for invitation of participation to incapables in the Buccal Cell Study. Copies of these letters are provided in ***Appendix B***.

Initially, the decision was made to use money orders for incentives for the Buccal Cell Study. Unlike checks, the money orders did not require the recipient to have a checking account and could be cashed by anyone who received the buccal cell collection kit. Money orders in the amount of $10 were ordered and included in the pilot study buccal cell collection kits. Some elderly participants were unfamiliar with money orders, so for the main study, buccal cell incentive money was distributed in cash. For the Venipuncture Study, nurses also distributed $50 cash incentive money.

Several items were ordered and printed for use as return materials for all four Supplemental Studies. These items included pre-addressed Tyvek return envelopes, business envelopes, and bubble mailers labeled with Priority Mail stickers for delivery of buccal cell specimens to the lab. Supplies of the *Questionnaire regarding Childhood and Parents*, consent forms for the Venipuncture, Buccal Cell, and Kin studies, and other written and visual instructions for collecting the buccal cell specimen were printed and stored in the Data Preparation Unit in anticipation of the 1999 NLTCS Venipuncture, Buccal Cell, and Kin mailouts.

2.4 TSD and Data Preparation Training

Once the 1999 NLTCS Supplemental Studies procedures and documents were finalized, TSD staff were trained by the RTI Telephone Survey Manager. Study specific training sessions were held for TSD staff, and sequential training formats were used. Each study was explained thoroughly during a training session, but each session covered only the procedures for the study activity that was to be completed next. For example, the initial Venipuncture TSD training covered only setting phlebotomy appointments. An additional training session was conducted to address refusal conversion to buccal cell collection and the assessment of incapacity to determine eligibility. ***Exhibit 2-1*** lists the TSD training dates by task for the 1999 NLTCS Supplemental Studies.

Exhibit 2-1. TSD Trainings by Date and Task

Study	Task	Date	Number of Interviewers Trained
Venipuncture	Schedule Appointment - Pilot	July 24, 2000	5
	Schedule Appointment - Main	January 16 & 19, 2001	10
Venipuncture/Buccal Cell	Refusal Conversion Incapable Assessment	September 17, 2001	6
Buccal Cell	Reminder Call - Pilot	July 24, 2000	5
	Reminder Call - Main	October 2000	7
Kin	Conduct Interview - Pilot	March 30 & April 3, 2001	11
	Conduct Interview - Main	April 30, 2001	11
NOK	Conduct Interview	October 27, 2000 March 1, 2001	5 5

Data Prep staff were trained by the Biospecimen Collection Manager and additional project staff. Data Prep staff were trained for a wide range of assembly tasks across the supplemental studies. For the Venipuncture Study, Data Prep staff were trained to assemble the boxes of phlebotomy supplies, including compiling the items for the phlebotomy kit, participant paperwork packets, and the training packets for the nurses. Data Prep staff also assembled and mailed out all buccal cell collection kits for the Venipuncture, Buccal Cell, and Kin studies. The first training of Data Preparation staff was conducted in October of 2000. In total, seven Data Prep staff, one supervisor, and three project support staff were trained to complete the assembly tasks for the supplemental studies.

2.5 Nurse Recruitment and Training

RTI contracted for phlebotomy services from HealthForce for the pilot study and Interim HealthCare for the main study. HealthForce was selected for the pilot study because the organization was local to North Carolina, and the per draw rate was the least expensive. HealthForce did not have the capabilities to provide national coverage for the main study, so RTI investigated a variety of home health care companies including Gentiva and Interim HealthCare. After a thorough comparison, Interim HealthCare was selected to complete the main study. Interim was selected because their nurses could provide complete coverage of the US through the franchise and subcontracting offices and distribute the cash incentive money. Gentiva policy prohibited the nurses from carrying money in any form. Interim did not incorporate a set-up charge into their fee, and their hourly rates for phlebotomy services were less than those quoted by Gentiva by more than thirty dollars per draw.

RTI trained the majority of the nurses and their supervisors at one of six regional trainings held in Fort Lauderdale, Los Angeles, New York, Houston, Chicago, and Atlanta. ***Exhibit 2-2*** lists the date, location, and number of nurses trained at each site. The training sessions lasted four hours and consisted of lecture-style presentations, question and answer sessions, hands-on forms and blood shipping practicum, and training and a test on human subjects protection. The training sessions covered all project procedures and requirements for obtaining informed consent, paying the incentive money, completing the appropriate forms, and packing and shipping the blood. RTI trainers reinforced protocol components with demonstrations and classroom practice. During training, each form was projected on the large screen while the trainees practiced filling it out correctly. RTI trainers also demonstrated the proper method to pack the blood and passed around a sample shipper for nurses to view. A sample training agenda is displayed in ***Exhibit 2-3***.

Exhibit 2-2. Phlebotomy Training by Location

Location	Date	Number of Nurses Trained	Number of Supervisors Trained
Fort Lauderdale, FL	January 12, 2001	33	4
Los Angeles, CA	January 19, 2001	17	1
New York, NY	February 16, 2001	34	
Houston, TX	February 23, 2001	15	
Chicago, IL	March 16, 2001	33	
Atlanta, GA	March 23, 2001	5	

Exhibit 2-3. Phlebotomy Training Agenda

Phlebotomist Training
Functional and Health Changes of the Elderly

January 12, 2001
9:00 a.m. - 12:00 p.m.

Interim HealthCare

9:00 - 9:10	Registration	
9:10 - 9:15	Welcome and Introductions	Rebecca Martin
9:15 - 9:30	The National Long Term Care Survey	Amy Ladner
9:30 - 10:15	Internal Review Process	Rebecca Martin
10:15 - 10:25	Break	
10:25 - 10:45	Preparing for Specimen Collection	Amy Ladner
10:45 - 11:00	Blood Collection	Amy Ladner
11:00 - 11:20	Data Collection Forms	Amy Ladner
11:20 - 11:35	Specimen Shipment	Amy Ladner
11:35 - 11:45	Supplies	Amy Ladner
11:45 - 11:55	Practical	Rebecca Martin
11:55 - 12:00	Summary	Rebecca Martin

Not all nurses attended one of the six regional phlebotomy trainings. In some instances, contracts with nurses in rural areas were not in place prior to the trainings or a nurse could not attend a specific training. For these nurses and for nurses added to combat attrition, training was conducted over the telephone. Telephone trainings were conducted as needed for groups of up to five nurses. Prior to these training sessions, the nurses received the phlebotomy manual, a packet summarizing respondent rights and ethics in research, a packet of sample forms, and a box of materials and supplies. This enabled the nurses to follow along and practice completing the data collection forms as the trainer explained the procedures. RTI trained 32 nurses via teleconference.