

The Community Health Survey, Heart Follow-Up Study

Methodology Report

New York City Department of Health and Mental Hygiene

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Background and Study Objectives

Decreasing population sodium intake is a national public health priority (Healthy People 2010)¹, and reductions in intake prevent and reduce high blood pressure, a leading risk factor for cardiovascular disease (CVD)². CVD is the leading cause of death in the United States³ and in New York City (NYC)⁴ and is thus a public health priority. The NYC Department of Health and Mental Hygiene (DOHMH) conducted a surveillance project, the Heart Follow-Up Study (HFUS), to assess NYC population sodium intake using the gold standard of 24-hour urine collection⁵. The HFUS is a critical component in the evaluation of the National Salt Reduction Initiative (NSRI), which aims to reduce population-level salt intake by 20 percent over five years through gradual reductions in the sodium content of packaged and restaurant food. The NSRI is a partnership of over 80 cities, states and national health organizations, coordinated by DOHMH. Data collected from HFUS 2010 provides a baseline population sodium intake level against which future changes in population intake can be assessed.

The project's primary objective was to provide a baseline population sodium intake estimate for NYC.

Secondary objectives included:

- Determining mean sodium intake for NYC whites, blacks, and Hispanics;
- Determining mean population blood pressure measurement;
- Assessing the relationship between blood pressure and sodium intake;
- Assessing sodium intake for those who are recommended to limit sodium intake to 1,500 mg per day (blacks, persons aged ≥ 51 years, and persons of any age with hypertension, diabetes or chronic kidney disease).

¹ DHHS, ed. Healthy People 2010. 2nd ed. Washington DC: U.S. Government Printing Office; 2007

² IOM (Institute of Medicine). 2010. *Strategies to Reduce Sodium Intake in the United States*. Washington, DC: The National Academies Press.

³ NCHS. Health, United States, 2009. <http://www.cdc.gov/nchs/data/hus/hus09.pdf> Accessed Feb. 8, 2011

⁴ NYCDOHMH. Summary of Vital Statistics, 2009. The City of New York.

<http://www.nyc.gov/html/doh/downloads/pdf/vs/2009sum.pdf>. Accessed Feb. 8, 2011

⁵ Bentley, B. A Review of Methods to Measure Dietary Sodium Intake. *Journal of Cardiovascular Nursing* 2006; 21(1): 63-67.

Overview of Methodology

To obtain a representative sample of adult New Yorkers, HFUS used the 2010 NYC Community Health Survey (CHS) to recruit participants. The CHS is an annual Random Digit Dialing (RDD) telephone survey of approximately 10,000 adults designed to provide estimates at the city, borough, and neighborhood levels. The CHS uses a landline and cell phone sample frame to contact residential households (i.e., not institutional or group quarters) in the five boroughs of New York. Households without a landline telephone or cell phones are not included in the sample⁶. The CHS interview (see the **2010 CHS Questionnaire** in the Study Materials section) is approximately 25 minutes long, covering multiple aspects of health conditions and risk behaviors. Interviews are conducted in English, Spanish, Russian, and Chinese.

HFUS recruits were asked to complete a brief follow-up interview to the CHS, collect urine for a 24-hour period to measure sodium intake, and consent to a brief in-home medical exam. Instructions and materials for urine collection were mailed to participants, and once the collection was complete, medical technicians visited participant homes to aliquot a sample of the urine. At the home visit the technician also took three seated blood pressure readings and anthropometric measurements (height, weight, and waist circumference). Following the home visit, the 24-hour urine samples were mailed to a contracted laboratory for analysis.

Additional funding was secured to add a spot urine component to the study. A spot urine sample is a sample provided by the participant from a single urination. A randomly selected subsample of participants was asked to give a spot urine sample during the home visit appointment in addition to their 24-hour urine collection. The spot urine component was included to provide information on the correlation between sodium in the spot urine sample and the 24-hour collection, and to allow for potential comparisons with national data where spot urine samples were also collected.

The advantages of using the established CHS as a recruitment vehicle for HFUS included:

- Linking the comprehensive health information available in the CHS with additional follow-up questions and laboratory data collected from HFUS recruits;
- Cost savings, as the CHS provided a representative cross-sectional sample of the adult NYC population.
- Higher recruitment, as those who completed the CHS were thought to be more likely to participate in HFUS than using a separate RDD sample of respondents who were cold-called.

One challenge of this study was that study interviewers recruited participants by telephone with no clinical or in-person contact before the participant completed their 24-hour urine collection.

⁶ In the CHS landline sample, once a household is reached and identified as eligible, a randomly selected adult is asked to participate in the survey. In the CHS cell phone sample, the interview is conducted with the person who owns the cell phone. Random adult selection within the household is not done for cell phone interviews.

Therefore, the development of user-friendly instructions, reminder calls, a substantial incentive and a helpline were essential to the study's success.

Project Team and Study Timeline

Within the DOHMH, the HFUS was a collaborative effort between the Bureau of Epidemiology Services (BES), Survey Unit and the Bureau of Chronic Disease Prevention and Control, CVD Prevention and Control Program. Together, these programs developed study materials including a **questionnaire**, **recruitment scripts**, an informational website, a **frequently asked questions** sheet (**FAQ's**), a detailed **instruction booklet**, and **consent forms**. These materials can be found in the study materials and appendices section.

Abt-SRBI, a national survey research organization, was contracted to collect data for the CHS and HFUS. Abt-SRBI also coordinated the work done by two sub-contractors on HFUS: Examination Management Services Incorporated (EMSI) and The Mount Sinai Hospital and Medical School. EMSI scheduled participants' urine collection dates, sent collection kits to participants, collected urine samples and in-person anthropometric measures, and sent aliquoted urine samples via FedEx to the subcontracting laboratory for analysis. EMSI staff attended a full training on all study methods and materials prior to the start of the study. All **laboratory assays** (see Appendix C) - measures of sodium, potassium, albumin, and creatinine levels - were conducted by the laboratory at Mount Sinai Hospital and Medical School.

Recruitment for HFUS began April 1, 2010, and concluded on August 18, 2010. All laboratory analyses were completed by September 22, 2010.

Sample Design and Calculation of Needed HFUS Sample Size

As mentioned above, one major objective of this study was to estimate population-level change in sodium consumption over time. Prior to study and materials development, study researchers performed sample size calculations to determine the optimal HFUS sample size needed to detect a 5% reduction in mean sodium consumption levels between two cross-sectional samples. This percentage was determined based on the prior study design used in the United Kingdom, where a reduction in 24-hour sodium intake between two study waves, 3 years apart was 4.4%.⁷ The sample size needed to detect this change at 80% power was determined to be 1,586 participants. Assuming increased sample variance of $DEff = 1.75$ due to post-stratification weighting, that 4% of participants would drop out of the study, and that 12.5% of participants would not provide usable urine samples, study researchers calculated that 1,856 participants needed to be recruited in both the baseline and follow-up studies.

⁷ An assessment of dietary sodium levels among adults (aged 19-64) in the UK general population in 2008, based on analysis of dietary sodium in 24 hour urine samples. <http://www.food.gov.uk/multimedia/pdfs/08sodiumreport.pdf>.

Pilot Test of HFUS

A pilot test was conducted before data collection began to identify problems in urine collection kit delivery, the **clinical protocol** (see Study Materials), and to test the coordination between DOHMH, Abt-SRBI and the two subcontractors. Before the pilot test, project staff conducted cognitive pretesting of the study materials with other DOHMH employees unconnected to the project. Based on the results of reviewing the materials with other DOHMH staff, project staff made minor changes to the layout and terminology used in an **instruction booklet** (Appendix B) developed for the project.

A total of ten participants were recruited from local District Public Health Offices by DOHMH staff to participate in the pilot test.

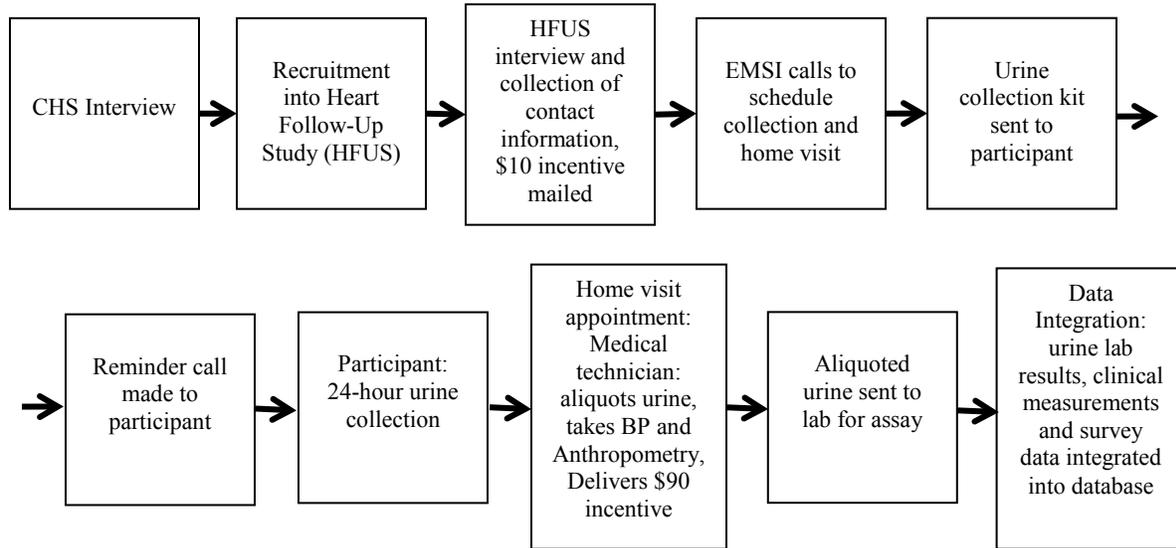
Once recruited, DOHMH staff conducted an abbreviated CHS interview and the brief follow-up interview in person. Staff collected contact information from pilot test participants and delivered the contact data over a secure network to Abt-SRBI. From that point, Abt-SRBI was responsible for coordinating with the subcontractors to schedule a day for urine collection and a home visit, and for delivery of the urine collection kit to the participant. EMSI staff followed the HFUS **clinical protocol**, which included everything up through the delivery of urine samples to the laboratory. For the purposes of the pretest, the laboratory did not analyze urine samples, but they did receive and account for each sample to test timing and mailing procedures.

DOHMH staff also called participants after the 24-hour urine collection and home visit and conducted debriefing interviews. Staff asked participants questions about the written materials included in the package and about their experiences collecting their urine for 24-hours. Pilot test participants were given an incentive of \$100, which was part of the study protocol for all participants.

The pilot test revealed that some participants had difficulties receiving the urine collection kit. These difficulties were due in part to the unique nature of housing units in NYC and differences in neighborhoods and buildings. Some buildings have doormen who routinely collect packages for tenants when they are not home, whereas many buildings do not, and the postal service may not leave unsigned packages for security reasons. Based on these findings, the study team made the decision to include a round trip metro card with an initial study letter, which could be used to take the bus or subway to the local post office to retrieve the collection kit.

Data Collection Protocol: 24-hour Urine Sample

Figure 1: Flow diagram of the overall study process.



Eligibility and Recruitment

A total of 6,342 CHS respondents were screened for eligibility, of which 512 (8.1%) were deemed ineligible⁸. This resulted in a pool of 5,830 eligible respondents. Based on prior experience conducting studies with clinical measures, the research team anticipated that approximately 30% of CHS respondents would be willing to participate, but ultimately 39.5% (or 2,305 respondents) agreed to participate. A total of 1,787 (out of 5,830 eligible) participants provided a 24-hour urine collection. There were 515 participants that also provided spot urine samples. The final participation rate was 30.7%. A more comprehensive description of study participation rates as well as a demographic description of participants follows (see Figures 2 and 3).

⁸ A total of 196 individuals were deemed ineligible because they answered ‘yes’ to one or more screening questions about being pregnant, lactating, or undergoing kidney dialysis. Four were ineligible because they refused to answer the gender question in the CHS interview and an additional 284 answered ‘don’t know’ or ‘refused’ to questions about being pregnant, lactating or undergoing dialysis.

Recruitment into HFUS and HFUS Interview

Upon completion of the CHS interview, respondents were asked three questions to determine eligibility to participate in HFUS:

- 1) If they were pregnant (asked of females only);
- 2) If they were currently breastfeeding or lactating (asked of females only); and
- 3) If they were on current or had received kidney dialysis in the past 12 months.

If the respondent answered “yes” or refused to answer any of the above questions, they were considered to be ineligible for participation in HFUS.

Eligible participants were given a detailed explanation of the study and invited to participate. CHS respondents who agreed to participate in HFUS were asked to do the following:

- Complete a six minute follow-up interview;
- Provide contact information including name, mailing address, home address (if different from mailing address), and phone numbers for re-contact and for scheduling the urine collection and home visit;
- Accept calls from EMSI to schedule a urine collection day;
- Receive a urine collection kit (sent via USPS or FedEx based on participant preference);
- Collect all urine over the scheduled 24-hour period; and
- Allow an EMSI medical technician to come to their home to take a sample of the 24-hour urine collection, ask questions about their urine collection, and take seated blood pressure measurements and anthropometric measurements (height, weight and waist circumference).

After agreeing to participate, the interviewer administered the six-minute follow-up interview with additional questions on nutrition, hypertension, family history of stroke, heart attack, and coronary heart disease and personal history of CVD and chronic kidney disease. This interview was supplemental to the more comprehensive health information collected with the CHS, which included questions about cardiovascular disease, physical activity, nutrition, chronic illnesses, insurance coverage and demographics. Whenever possible, the HFUS interview was conducted directly after the CHS interview. If the participant could not complete the additional six-minute interview at the time of the CHS interview, they were scheduled for a call back (see the **calling protocol** in the Study Materials section for more information). Participants were also asked if they would be able to collect their urine on a randomly selected weekday or weekend day to help control for variations in diet across the week⁹.

⁹ Participants who could not collect urine on the randomly selected weekday or weekend day were scheduled to collect their urine at their convenience.

Abt-SRBI transmitted participant contact information daily to EMSI over a secured network with the goal of re-contacting participants within 48 hour of their CHS interview to schedule the urine collection.

Abt-SRBI offered participants a total incentive of \$100 for completion of 24-hour urine collection. A \$10 check was sent to participants at the conclusion of the six-minute follow-up interview with a separate study letter that included more information about the study. The remaining \$90 check was delivered by an EMSI technician at the time of the home appointment.

EMSI Calls to Schedule Collection and Home Visit

Within a few days of the initial CHS and HFUS interviews, EMSI contacted HFUS participants by telephone to schedule the day that the participants would be collecting their urine and a home visit on the day following the urine collection day using the **home visit scheduling call script** (Appendix A). Technicians tried to schedule participants for a randomly selected weekday or weekend day. Female participants were asked to pick a day when they were unlikely to be menstruating. Participants also had the option of an in-home visit from an EMSI medical technician prior to urine collection to review the instructions for urine collection, but this was rarely requested.

Urine Collection Kit Sent to Participant

Upon scheduling the day that the participant would be collecting their urine, EMSI sent the collection kit via Express Mail using the U.S. Postal Service or via FedEx. Abt-SRBI also included a metro card (valid for two rides) with the study letter that the participant could use if he or she needed to take a bus or a subway to the local post office to pick up the urine collection kit.

Collection kits included all of the items needed to collect urine over a 24 hour period and keep it cool, including a detailed **instruction booklet** with photographs to provide clear directions about how to properly collect their urine. Other materials in the kit (which can be found in Appendix B) included:

- A **kit letter** with the scheduled date of urine collection and the home visit appointment date and time, and additional instructions on how to prepare for the urine collection and home visit;
- A **consent form** requiring the participant's signature to participate in the study;
- A **FAQs sheet**;
- A **study time log** on which participants were instructed to write down the time they started and stopped urine collection, and
- An examiner kit in a separate small box labeled “DO NOT OPEN. Examiner use only.” which contained the materials needed by the examiner at the home visit.

The research team set up a toll-free telephone helpline and the number was printed on the instruction booklet and other written materials for respondents to use if they had additional questions or needed to reschedule collection and pickup. For a complete list of urine collection materials, please see the **clinical protocol**. For a complete list of study materials, please see the study materials and appendices section.

Reminder Calls Made to Participants

EMSI called participants forty-eight hours before the scheduled day for urine collection to remind them of their start date and answer any additional questions. If participants were not home, a voicemail message was left. (The **home visit reminder call script** and **answering machine script** can be found in Appendix A.)

During the reminder call, EMSI confirmed that participants had received the collection kit and confirmed the date and time of the home visit and the participant's home address for the home visit.

The medical technician reviewed the instructions for collecting urine with the participant and answered any additional questions the participant had. To help the participant better prepare for the home visit, the technician asked the participant to wear a short sleeve shirt and to abstain from caffeine, exercise, or smoking 30 minutes before the scheduled home visit (to assure the most accurate blood pressure measurement). EMSI also asked female participants to wear pants or a skirt, and not a dress, to aid in the waist circumference measurement.

Participant 24-Hour Urine Collection

On the designated start day, participants were instructed to wake up and urinate as usual ("first void") into the toilet, and not to collect this first urine of the day in the storage container provided in the collection kit. They were instructed to write down the date and time of their first urine on the **study time log** provided in the kit.

Starting at the second void of the start day, participants were asked to collect all of their urine for the next 24 hours and to keep the urine cool by either using the cooler bag with ice packs provided in the collection kit, or putting the storage container in the large biohazard bag and placing it in the refrigerator.

On the second day, participants were instructed to wake up around the same time as the day before, collect their first urine of the day, and write down the date and time of this last urine on the **study time log**. This concluded their 24-hour urine collection.

Home Visit Appointment

With few exceptions, the home visit occurred on the same day that participants concluded their 24-hour urine collection. If the home visit took place after the day the collection was concluded, participants were instructed to keep the urine cold until the appointment. When the medical technician arrived for the scheduled appointment, he or she presented proper identification and asked for the signed informed **consent form**. Technicians did not continue the home visit if they did not have a signed **consent form** and brought additional copies with them in case participants needed a new form.

The medical technicians used a standardized form called the **site contact report form (SCRFF)** found in Appendix A) to collect data and record participant responses at the home visit.

Collected urine was not usable and participants were asked to redo the urine collection if:

- The total urine volume was less than 0.5 liters (500 ml); or
- Female participants reported they were menstruating at any time during the collection; or
- Participants reported collecting their first urine at their start time.

If these participants declined to redo the collection their samples were discarded, but blood pressure and anthropometry were taken and the technician distributed the remaining \$90 incentive check.

EMSI technicians also asked participants to redo their urine collection if their total collection time was less than 22 hours or more than 26 hours. However, if these participants declined redoing the urine collection, their urine sample was still sent to the laboratory with clear documentation. The inclusion of these urine specimens in the final sample was considered during the analysis stage.

If respondents agreed to redo their urine collection, the technician arranged to deliver a new collection kit, and a new urine collection day and home visit were scheduled. In any case where a redo was needed, the technician completed a **redo form** (Appendix A). The **redo form** was used to record the reason for requiring a new collection or to document why the participant was unwilling to redo the collection. Only a small number of participants were asked to redo the urine collection (n=50 or 3.1% of all participants). Among those who were asked to redo the urine collection, n=32 or 64% agreed, although this did not always result in a usable sample.

The technician confirmed and recorded the start and stop date and times on the **SCRFF** form from the **study time log**. Technicians also asked participants for additional information, which was recorded on the **SCRFF** including:

- The number of times, if any, that urine was not collected;
- Any missing urine due to spillage, and if so, whether it was just a few drops or more;

- If the participant was able to keep the urine containers cold, and if not, how long the urine was not kept cool;
- Whether or not the collection was performed on a day on which the participant also went to work;
- The number of alcoholic drinks consumed during the collection period, if any; and
- Whether or not the participant had any caffeine, smoked or exercised 30 minutes prior to the appointment.

Measuring blood pressure

Technicians took blood pressure measurements from the participant after completion of the **SCRF** questions if the participant answered they had *not* had caffeine, smoked or exercised in the prior 30 minutes. Blood pressure measurements were taken at the end of the appointment for participants who answered they had caffeine, smoked or exercised in the 30 minutes prior to the home visit. Clinic-quality validated blood pressure monitors were used for measurements (Model: Omron HEM 907) and these models have been shown to perform relatively well in comparison to the gold standard of the mercury sphygmomanometer.¹⁰

The technician asked the participant to find a firm chair and sit with feet flat on the floor and back supported, and the right arm resting at heart level. The technician then measured the participant's right arm with a tape measure for the proper blood pressure monitor cuff size. The technicians had a total of 4 cuff sizes, which they would select accordingly. Technicians then instructed the participant to sit quietly for five minutes.

After the five-minute rest period, the technician took three blood pressure and pulse measurements with a one minute rest between measurements. Blood pressure and pulse were measured using the same automated blood pressure monitor model for all participants. The technician recorded the three individual measurements as well as the average value on the **SCRF**. If for some reason the participant became visibly anxious, disturbed or otherwise was not relaxed right before or during the blood pressure measurements, the measurements were taken again, after another five-minute resting period. More detail on the measurement of blood pressure can be found in the **clinical protocol**.

After blood pressure was measured and recorded, the technician wrote the average blood pressure on two copies of a form called "**Understanding Your Blood Pressure Today**"(Appendix A).

- Participants with an average blood pressure less than 140/90 were informed that their blood pressure was in the normal range.
- Participants with an average blood pressure between 140/90 to 179/109 were informed that their blood pressure was above the normal range and to see or call a doctor as soon as possible to discuss the reading.

¹⁰Osthega Y, Nwankwo T, Sorlie PD, Wolz M, Zipf G. Assessing the validity of the Omron HEM-907XL oscillometric blood pressure measurement device in a National Survey environment. *J Clin Hypertens (Greenwich)*;12:22-8.

- Participants with an average blood pressure of 180/110 or higher, were informed their blood pressure was above the normal range and very high according to national guidelines and encouraged to see their doctor or get medical care that day.

Technicians gave one copy of the form to the participant and asked the participant to sign the other copy which was retained for study purposes.

Anthropometry: Weight, Height, and Waist Circumference

After blood pressure was measured and recorded on the **SCRF**, the technician took anthropometric measurements and recorded them on the **SCRF**:

- Participants were weighed without shoes and results were rounded to the nearest pound.¹¹
- Height was measured without shoes and rounded to the nearest hundredth of an inch.
- Waist circumference was also measured and rounded to the nearest hundredth of an inch.

More detail on the protocol for measuring anthropometry can be found in the **clinical protocol**.

Aliquoting the 24-Hour Urine Collection and Preparation for Mailing to Lab

The technician asked for the examiner kit labeled "DO NOT OPEN: Examiner use only." that was included in the collection kit. Whenever possible, the urine was aliquoted in the participant's bathroom in the bathtub. If the participant did not want the technician to use the bathroom, any flat surface such as a table or hard wood floor was used. Technicians assembled the following materials from the examiner kit on an absorbent mat:

- 2 aliquot tubes (8 ml), labeled with the participant ID number
- 1 Vacutainer urine transfer unit
- 1 small beaker
- Pair of gloves
- 1 frozen icepack
- Small biohazard bag
- Small absorbent pad
- Mini thermal bag
- A laboratory requisition form¹² labeled with the participant ID number
- A shipping box – labeled "Exempt – Human Specimens"
- A FedEx shipping label

First, the technician recorded the total volume of urine on the **SCRF** and the laboratory requisition form. If both urine collection containers were used to store the urine, the technician combined the urine from the two containers and recorded the total volume. The technician inverted the collection container several times to ensure a uniform urine sample. The technician then poured the urine into the beaker and used the Vacutainer transfer unit, to extract the urine

¹¹ Medical technicians used EMSI scales and measuring tape for measuring weight and height.

¹² Form sent to the lab with aliquoted urine samples. The form is specific to the laboratory conducting the analysis.

into each of two aliquot tubes. The remaining urine was discarded in the participant's toilet, and the technician gathered all other collection materials for removal from the home.

The subsample of participants selected to provide a spot urine sample were asked to do so after the technician completed the 24-hour urine aliquot procedure. The participants were asked to urinate in the privacy of their own bathroom during the technician visit and to provide a sample in small collection cup. The technician transferred this urine to an aliquot tube. Any remaining urine was discarded in the participant's toilet. The additional materials needed to collect the spot urine samples were included in the examiner kit, and were only sent to participants who had been selected to provide a spot sample. Both aliquoted urine specimen tubes¹³, and the aliquoted spot urine tube when applicable, were sealed in a plastic bag with a small absorbent sheet. The plastic bag and a frozen icepack were inserted into the mini thermal bag. The technician placed the mini thermal bag with the Lab Requisition Form in the original examiner box and placed the box into a FedEx package with the shipping label for shipment to the laboratory.

Incentive Payment

At the end of the home visit, the technician gave the participant the remaining \$90 incentive check for participating in the study. If for some reason the technician did not have the check with them at the home visit, they told the participant that it would be mailed to them that day.

Data Entry and Record Keeping

The **SCRF** forms were faxed and sent electronically by the technician to Abt-SRBI for data entry. Paper copies of the **SCRF**, signed informed **consent forms**, and blood pressure notifications were sent individually by technicians via USPS to Abt-SRBI for internal record keeping and data entry.

Aliquoted Urine Sent to Laboratory for Assays

Technicians delivered the urine samples to a local FedEx express box for overnight delivery to the laboratory at Mount Sinai for appointments conducted Monday through Thursday. For appointments on Friday through Sunday, the urine samples were refrigerated by the technicians and shipped the following Monday.

Laboratory staff registered each received sample by a unique ID number, which was assigned to individual cases at the time of recruitment, and conducted laboratory analysis within 12 hours of arrival. Laboratory staff measured the samples for sodium, potassium, albumin, and creatinine¹⁴

¹³ Two specimen tubes of aliquoted urine were included in case the first tube was damaged during shipment or the lab needed to redo the urinalysis.

¹⁴ Sodium and potassium content of 24 hour urine samples was determined using the ion-selective electrode potentiometric method on the Roche DPP Modular analyzer. Albumin in urine is measured by immunoturbidimetry using the Tina-quant methodology on the Roche DPP Modular analyzer. Creatinine was determined using the Jaffe kinetic colorimetric method on the Roche DPP modular analyzer.

and calculated the ratio of albumin to creatinine. Once analysis of the samples was completed, the laboratory discarded any additional urine. Results from the analyses were sent by the laboratory once a week to the DOHMH CVD Program in a spreadsheet that contained the participant ID number, date the sample was received by the lab, date of the urinalysis, urine sodium, urine potassium, urine albumin, urine creatinine, calculated albumin/creatinine ratio, whether the participant was selected to perform a spot collection, the condition of the samples, and which of the two samples was analyzed. For participants who also collected a spot sample, results for the same analytes using the spot urine sample were included. The original laboratory reports were also sent to the CVD Program to double-check the data entry of the laboratory values.

Individual Participant Results

Because sodium levels are highly variable from day to day, participants were not offered their individual sodium measurement results. However, those HFUS participants with an elevated albumin to creatinine ratio, an indicator of possible impaired kidney function, were flagged and sent a notification letter by Abt-SRBI. The **chronic kidney disease notification letter** informed participants that their test results were above the normal range and they should seek medical care from their doctor.

Quality Control, Data Integration and Processing

Quality Control

To help assure data quality and assess achievement of recruitment targets, data collection for HFUS was closely monitored on a regular basis. Abt-SRBI sent weekly recruitment reports to DOHMH staff to monitor:

- The number of CHS interviews conducted (both landline and cell)
- The number of participants recruited
- The number of scheduled home visits
- The number of completed home visit appointments
- The number of samples sent to the lab, and
- The number of samples analyzed at the lab

In addition, the CHS and follow-up interviews were monitored remotely by DOHMH staff to assure that survey data collection protocols were followed. When problems were encountered, DOHMH staff worked closely with Abt-SRBI and EMSI to resolve them.

Processing of the data occurred throughout data collection and involved several components, including the development of SAS code for cleaning and recoding the data (based on preliminary data sets posted to a DOHMH secure ftp site), and double data entry of **SCRF** data (by Abt-SRBI) and laboratory data (by the CVD Program). At the conclusion of data collection, a unique identifier assigned to participants at recruitment was used to merge all processed data components into a comprehensive analytic data set that included:

- CHS survey data with demographic variables and relevant CVD-related questions
- The **HFUS follow-up questionnaire** (Study Materials section) with additional questions
- **SCRF** data collected at the home visit with data on urine volume and quality as well as blood pressure measurements and anthropometry (weight, height and waist)
- Laboratory data results

Urine Collection Completeness Criteria

There were 4 major steps we took to assess completeness of a urine sample.

The first step involved criteria for assessing the 24 hour urine collection that were built into the protocol. If a urine collection was <0.5L (500 ml) or if the participant reported having included the first void of the day in the collection, the participant was asked to redo the collection.

NOTE: Previous studies¹⁵ have utilized two additional criteria for asking a participant to redo a collection: hours spanned by the collection period (22-26 hours acceptable) and if the participant report of missing a urine void. Because our study was population based, we wanted to minimize the samples that we rejected and the number of redos requested. If the participant fell outside of the 22-26 hour range, they were asked but not required to redo the collection. We also opted to collect the 24 hour sample of participants who reported having missed a void during their 24 hour period to be assessed during the analysis phase.

The second step was during the laboratory analysis. Researchers at the laboratory assessed the volume of urine and sodium levels and would flag any participants where these values seemed incongruous.

The third step was to adjust all laboratory values to 24 hours. For example if a person had a 23-hour collection, their sodium excretion was multiplied by 24/23. Cases that did not have a collection time were removed from the analysis at this step (n=3).

The fourth step was during the analytic phase of the project. At the completion of laboratory analysis, the study team developed additional criteria to determine whether or not a sample was valid and would be kept in the final data set for analysis. There were a total of three additional criteria:

1. Normalized Volume Levels: As described above all urine samples were adjusted or normalized to 24-hours. If the normalized urine volume was less than 0.5 L (500 ml), the case was excluded from the final data set (n=16).
2. Low Creatinine Levels: Creatinine was one of four laboratory assays measured. Low creatinine was defined using the United States creatinine distribution from the INTERMAP study. Sex-specific cutoffs were determined as three standard deviations below the mean. If a sample from a male participant was below 6.05 mmol creatinine, or below 3.78 mmol creatinine for females, the case was excluded from the final data set (n=50).
3. Self-reported having missed a collection: Finally, if individuals reported not collecting their urine one or more times the case was excluded from the final data set (n=55)

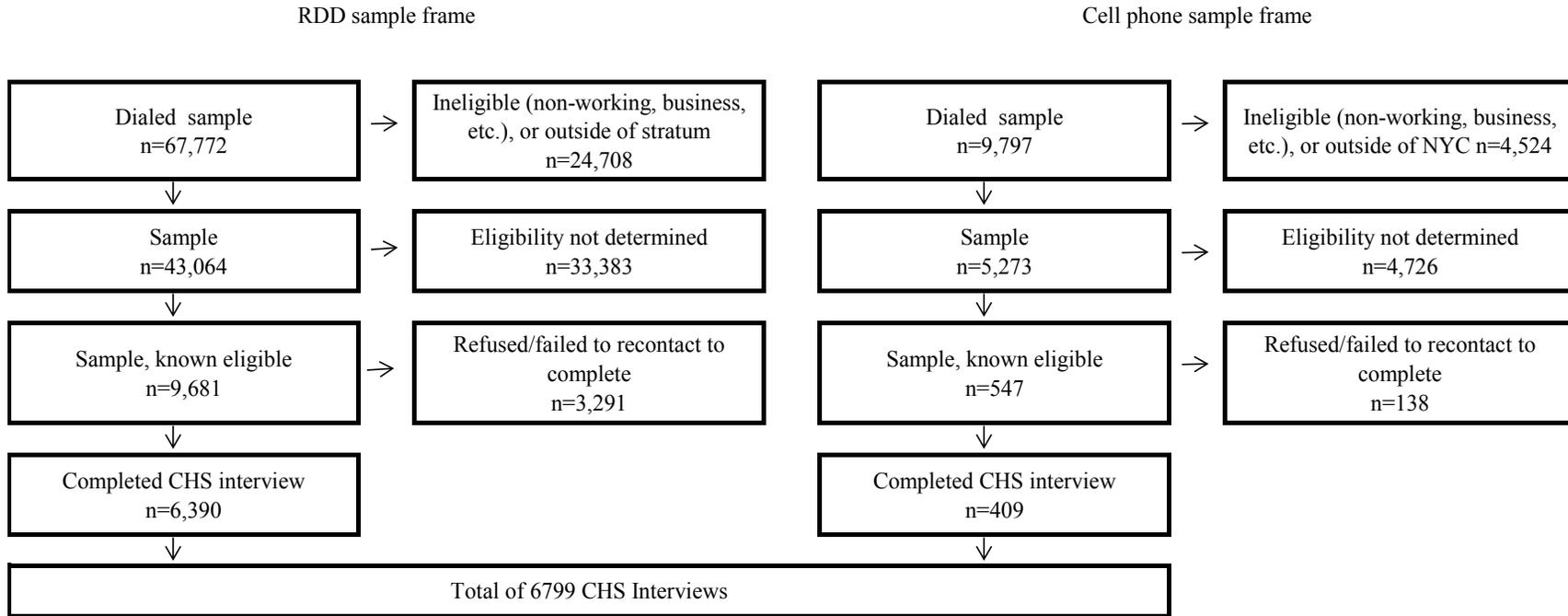
¹⁵ Elliott P, Stamler R. Manual of operations for "INTERSALT", an international cooperative study on the relation of sodium and potassium to blood pressure. *Controlled Clinical Trials*. 1988. 9(2 Suppl): 1S-117S.

After the study team applied the completeness criteria, a total of 116 cases¹⁶ were removed from the final data set, resulting in a final sample size of 1,656 cases that provided usable 24-hour urine samples (see Figure 3).

¹⁶ Some cases had more than one reason for being excluded from the final data set.

Study Participation Diagrams

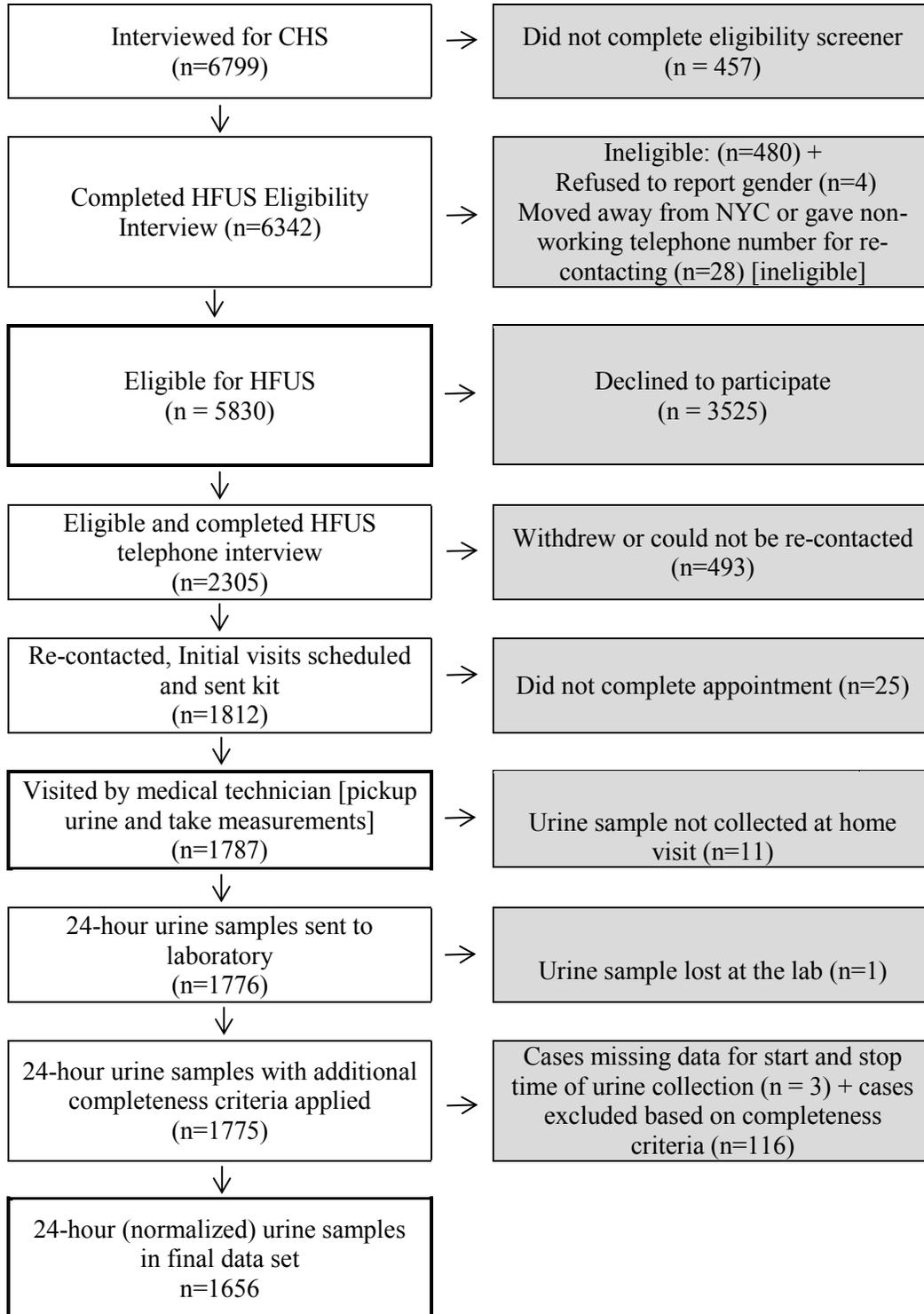
Figure 2
2010 CHS Sample to Contact HFUS Participants (RDD)



Note: The not dialed numbers included both listed and unlisted business numbers that were excluded because they were called and determined to be business numbers.

Figure 3

HFUS 24-hour Urine Collection Study Participation Diagram



Calculation of Study Participation Rates

The CHS HFUS required participation in two phases. In the first phase, an interview was administered to a randomly selected adult in each sample household in NYC. In the second phase eligible adults were asked to participate in the 24-hour urine collection. We report the response rate for each phase of data collection: the household survey response rate and the percent of eligible adults participating in the 24-hour urine collection¹⁷.

AAPOR has published standards for the calculation of response rates in random-digit dialing telephone surveys¹⁸. Following the approach used in the Behavioral Risk Factor Surveillance System (BRFSS), we selected AAPOR response rate 4 which includes partial interviews in the numerator of the response rate calculation. The response rate for the combined landline and cellular sample is 37.5%. In calculating the response rate we omitted the last 20 landline replicates which were released close to the end of the field period. Telephone numbers in these replicates had an average of 3.7 calls made when recruitment ended versus an average of 9.2 calls for telephone numbers in earlier replicates. In excluding these replicates, we removed only 211 completed interviews from the numerator of the response rate calculation.

Participation in the 24-hour urine collection required that the sampled adult complete the supplemental six-minute follow up interview on additional cardiovascular risk factors. From the 6,799 adults who completing the CHS interview, 5,830 cases were identified as eligible for the study. Of these, 1,787 provided 24-hour urine samples, yielding a participation rate of 30.7% for this phase of the study.

Participant Demographics

Table 1 (page 22) presents un-weighted demographic frequencies for eligible respondents, those who declined participation, those who completed urine collection and those who initially agreed to participate, but did not provide a 24-hour urine sample. Because the data in Table 1 is not weighted, it does not accurately represent the population of NYC; however, the samples size is large enough to provide reliable information and accurately weight the data.

Overall, those completing the collection compared to the eligible population were more likely to be Hispanic, younger than 65 years, and have a lower income; no differences were observed with sex or with nativity (U.S. born, foreign born).

Percent Agreeing to Participate

¹⁷ For the two phases of data collection, the overall response rate is the product of the RDD response rate and the 24 hour urine collection participation rate. The overall response rate for the two phases of data collection is 11.5%.

¹⁸ *Standard Definitions* Final Dispositions of Case Codes and Outcome Rates for Surveys. American Association of Public Opinion Research, 7th Edition, Revised 2011.

The percent agreeing to participate can be found in the second to last column of Table 1. Among whites, blacks, Hispanics, Asians, and other race category, Hispanics were the group most likely to agree to participate, with 50.7% initially agreeing. Those aged 18 to 24 years old were more likely to agree to participate than older age groups. The likelihood of agreeing to participate decreased with increasing income. Among those living in households below 100% of the federal poverty level, 50.1% agreed to participate compared to 36.1% of those living in households with incomes at 200% to 700% of the federal poverty level. Additionally, New Yorkers were equally likely to agree to participate regardless of sex or nativity.

Percent Completing Urine Collection

The percentage of each subgroup completing the urine collection can be found in the last column of Table 1. Hispanics and 18-24 year olds were less likely to complete the urine collection than other groups. Those living in households at 200% to 700% of poverty and U.S. born participants were more likely than others to complete the urine collection.

Table 1 - Demographics of Eligible Sodium Participants, by completed status (N=5830)

	<u>All Eligible</u>		<u>Declined</u>		<u>Completed</u>		<u>Incomplete</u>		<u>Percent</u>	<u>Percent</u>	<u>Percent</u>
	<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>	<u>Declined</u>	<u>Agreed</u>	<u>Completed</u>
Overall	5830	100.0%	3525	100.0%	1787	100.0%	518	100.0%	60.5%	39.5%	77.5%
Sex											
Male	2342	40.2%	1383	39.2%	749	41.9%	210	40.5%	59.1%	40.9%	78.1%
Female	3488	59.8%	2142	60.8%	1038	58.1%	308	59.5%	61.4%	38.6%	77.1%
Race											
White	2491	42.7%	1664	47.2%	646	36.2%	181	34.9%	66.8%	33.2%	78.1%
Black	1384	23.7%	777	22.0%	488	27.3%	119	23.0%	56.1%	43.9%	80.4%
Hispanic	1401	24.0%	690	19.6%	526	29.4%	185	35.7%	49.3%	50.7%	74.0%
Asian	451	7.7%	340	9.7%	90	5.0%	21	4.1%	75.4%	24.6%	81.1%
Other	103	1.8%	54	1.5%	37	2.1%	12	2.3%	52.4%	47.6%	75.5%
Age											
18-24	328	5.6%	174	4.9%	112	6.3%	42	8.1%	53.0%	47.0%	72.7%
25-44	1588	27.3%	885	25.1%	548	30.7%	155	29.9%	55.7%	44.3%	78.0%
45-64	2320	39.8%	1385	39.3%	742	41.6%	193	37.3%	59.7%	40.3%	79.4%
65+	1591	27.3%	1080	30.7%	383	21.5%	128	24.7%	67.9%	32.1%	75.0%
Income											
Below 100% Poverty	1105	22.5%	551	17.3%	410	26.1%	144	31.9%	49.9%	50.1%	74.0%
100-200% Poverty	952	19.3%	518	16.3%	330	21.0%	104	23.0%	54.4%	45.6%	76.0%
200-700% Poverty	2863	58.2%	1829	66.6%	830	52.9%	204	45.1%	63.9%	36.1%	80.3%
Missing/Refused	910	(15.6%)	627	(17.8%)	217	(12.1%)	66	(12.7%)	68.9%	28.8%	73.9%
Foreign Born Status											
US Born	3686	63.4%	2245	58.3%	1133	63.8%	308	59.6%	60.9%	39.1%	78.6%
Foreign Born	2129	36.6%	1267	41.3%	653	36.8%	209	40.4%	59.5%	40.5%	75.8%

Note: Declined: Individuals who completed the CHS interview and were eligible to participate in HFUS but declined
 Completed: Individuals who completed the CHS interview and provided a 24-hour urine sample for HFUS
 Incomplete: Individuals who completed the CHS interview and initially agreed to participate in HFUS, but who did not complete the 24-hour urine collection.

Post-survey Weighting

The HFUS data was weighted to account for probability of selection, calculation of a design weight and the calculation of a final weight by raking to population control totals. Weights were calculated for three different samples or sub-samples:

- a) Valid 24-hour urine samples (n=1656)
- b) Spot urine samples with valid 24-hour urine samples (n=482)
- c) All spot urine samples (n=515)

Input weights

Input weights were calculated for RDD interviews to adjust for the household's probability of selection (number of residential phone lines) and for the probability of selection for the CHS respondents (number of adults in the household), along with an adjustment for landline non-coverage that gives additional weight to respondents in households that have experienced more than one week's interruption in landline service in the past 12 months.¹⁹

Imputation of missing data

Deductive imputation and hot-deck imputation (both using SUDAAN) were used to fill in missing values on variables used in the weighting. Borough, age group, and race/ethnicity were used to form the hot-deck imputation cells.

Post-stratification weighting

Post-stratification weights to adjust for differential nonresponse were calculated for the 24-hour urine sample by simultaneously raking along the following dimensions: geographic distribution to account for the disproportionate stratum design of the CHS, gender by age at both the borough and citywide levels, race/ethnicity at the borough and citywide levels, marital status at the citywide level, educational attainment at the citywide level, and telephone usage group. (Where the sample had fewer than 10 cases in a gender/age category, this category was collapsed into the largest adjacent age category within gender.) Raking was constrained to prevent extreme case-level weights and resulting sample variance.

Similar weighting was conducted for both spot urine samples (n=482 and n=515) with the addition of quartile ranking similar to the 24-hour sodium sample.

All weights sum to the 2006-2008 American Community Survey Public Use Microdata Sample (ACS) population estimate of 6,222,961 adults living in households in NYC. ACS data provided all gender, age, race/ethnicity, education, and marital status population totals used for weighting.

¹⁹ Martin R Frankel, KP Srinath, David C Hoaglin, Michael P Battaglia, Philip J Smith, Robert A Wright, and Meena Khare. 2003. Adjustments for non-telephone bias in random-digit-dialing surveys. *Statistics in Medicine* 22:1611-1626

Study Challenges

During the design and development phase of HFUS, it was critical to identify potential obstacles that participants might encounter and develop solutions tailored to the NYC population. Previous studies involving 24-hour urine collection have focused primarily on specialized populations (e.g. those with high blood pressure or other chronic illness), with urine collection beginning with in-person instruction in a clinic. HFUS was unique, as recruitment was done using an RDD telephone survey and urine collection was initiated by participants in the home after receiving verbal instruction over the phone and reading an **instruction booklet** included in the collection kit.

While developing study materials, the project team paid special attention to developing an easy to understand and comprehensive **instruction booklet** with pictures and a **FAQs** sheet. The project team sought to develop study materials that would convey complex information with consideration for low literacy and all materials were translated into Spanish, Russian and Chinese. Development of the toll-free helpline was also important for participants who did not have all of their questions answered through written materials.

However, no matter how much planning was done for the HFUS, there were unanticipated obstacles. DOHMH and vendor staff was careful to monitor the progress of the study on a regular basis and were vigilant in identifying obstacles to participation.

One specific obstacle, identified early in the study, was the delay between the recruitment of participants and the actual completion of urine collection and the home visit. Part of this delay was due to the lag time between recruiting individual participants and reaching them again to schedule the urine collection and home visit. For future studies, if it is possible, participants should be scheduled to collect their urine and schedule a home visit at the time of recruitment. There were also a greater number of participants than expected who needed to reschedule their urine collection and home visit after initially being scheduled in the early phases of the study.

The project team worked closely with the contractors to resolve these issues. In particular, the subcontractor, EMSI, increased staffing to reach participants and schedule the urine collection and home visit in a timely manner. **Recruitment and scheduling call scripts** were also modified to convey the importance of scheduling the urine collection and home visit as soon as possible. Additional field staff with higher credentials and more training were added to the project to provide greater flexibility to schedule and reschedule home visits. In cases where participants had difficulty receiving the collection kit, they were offered an alternative shipment method for the collection kit (e.g. FedEx). Because of the increased number of reschedules, when an individual was rescheduled it was often a different examiner assigned to the home and sometimes this examiner did not have the \$90 incentive check with them at the home visit. In these cases, participants were notified ahead of time that they would not receive their \$90 check at the home visit, but that it would be mailed to them.

Conclusions

Overall, the implementation of the study faced multiple challenges including the fast paced development and data collection schedule and modest resources to launch such an effort. Conducting a population-based study of sodium intake utilizing a 24-hour urine collection in the United States for the first time from an RDD telephone survey was an undertaking with some risk. However, it was a success, exceeding predicted participation rates and participant compliance. Some of the lessons learned include:

- A user-friendly instruction booklet with diagrams and/or photographs.
- A well-tested set of materials and procedures, informed by a pilot with a group of respondents
- A substantial incentive to reimburse the respondent for the demands of the participation. Reminder calls and a call-in helpline.
- Flexibility in shipping options for sending the collection kit.
- Well-trained medical staff to visit participant homes to aliquot the urine and do the physical measurements.
- Flexible scheduling to meet participants' needs, including rescheduling when necessary.
- Supplementation of staff by consultants who can troubleshoot unexpected problems related to the urine collection and processing.
- A realistic schedule which includes time for pretesting and adapting these procedures to any local area.
- A detailed alternative plan for urine pick up when established procedures do not work.

The HFUS study has provided a methodology, clinical protocols, and study materials that can be used by other institutions conducting 24-hour urinary studies in the future. However, other localities should tailor the procedures and incentives to meet the unique needs of their local environment.

Study Materials and Appendices

These study materials and appendices provide a list of all documents for HFUS.

Study Materials:

HFUS Clinical Protocol

Questionnaires, recruitment, incentive, and chronic kidney disease notification

1. **2010 CHS Questionnaire (ENGLISH)**
2. **2010 HFUS Recruitment Script and Follow-up Questionnaire**
3. **Incentive Letter** – sent to participants after completion of the HFUS follow-up interview with first incentive check for \$10. This letter also informed participants that someone from EMSI would be contacting them to schedule a day for urine collection and the home visit.
4. **Abt-SRBI FAQ**- used by interviewers at Abt-SRBI to answer participant questions at the time of recruitment.
5. **Chronic Kidney Disease Notification Letter** – Letter sent to participants after urine was analyzed at the laboratory if they had an elevated albumin to creatinine ratio, a possible indicator of kidney problems.

Appendix A:

Subcontractor Clinical Protocol Written Materials

1. **EMSI FAQ** – used by EMSI to answer participant questions at the time of scheduling and reminder calls.
2. **Home Visit Scheduling Call Script** – used to schedule participants for 24-hour urine collection and home visit.
3. **Home Visit Reminder Call Script** – used to confirm 24-hour urine collection date and home visit 48 hours before the beginning of collection.
4. **Answering Machine Script**- used to remind participant of 24-hour urine collection date and home visit via answering machine if the participant cannot be reached.
5. **SCRF**- Site Contact Report Form used by EMSI technicians at the home visit to record data from the home appointment including: urine volume, blood pressure, height, weight and waist measurements.
6. **Redo Form**- Used to record the reason for asking the participant to redo the urine collection [when needed] and whether or not the participant consented. If a participant did not agree to redo the urine collection, this form was used to record the reason why.
7. **Understanding Your Blood Pressure**- medical technicians wrote down the average blood pressure and pulse of participants at the home visit and gave a copy to the participant for their records, and a second copy which was signed by the participant for study purposes.

Appendix B:

Participant materials included in the collection kit:

1. **Kit Letter**- sent to participants after scheduling a urine collection day and included in the collection kit. Included basic information on HFUS and the participants scheduled urine collection day and home visit.
2. **Consent Form**
3. **Participant FAQ**- included in collection kit and provided answers to frequently asked questions.
4. **Instruction Booklet**- included in collection kit and provided detailed instructions for 24-hour urine collection with photographs of kit contents.
5. **Study Time Log**- included in collection kit. Participants were instructed to record their start date and time and stop date and time on this log.