
National Health and Nutrition Examination Survey (NHANES)

24-Hour Urine Pilot Study

Study Protocol

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National Center for Health Statistics, CDC

3311 Toledo Road

Hyattsville, MD 20782

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PROJECT OVERVIEW

Title

National Health and Nutrition Examination Survey (NHANES) 24-Hour Urine Pilot Study

Protocol Summary

This proposed pilot study is designed to assess the feasibility and test all procedures related to the 24-hour urine collection and laboratory analysis. This pilot study is conducted to gain information that will be useful in planning to implement a 24-hour urine collection as part of NHANES in 2014.

The pilot study will be conducted with a half sample of NHANES participants, ages 20-69 years, who were examined in the mobile exam center (MEC) (n=250). Participants will be asked to collect urine samples over a 24-hour period. Half of those who were asked to participate in the 24-hour urine collection pilot (n=125) will be asked to collect a second 24-hour urine 3-10 days later. The addition of 24-hour urine collection to NHANES will allow us to estimate the prevalence of the U.S. adults who meet the recommendations for sodium reduction based on the Dietary Guidelines for Americans 2010 which indicate all Americans should reduce their sodium intake to <2300 mg daily and specific subpopulations to <1500 mg daily to prevent Cardiovascular Disease (CVD). These specific subpopulations include African-Americans, individuals with hypertension, diabetes, and chronic kidney disease, and older aged individuals. Please see Attachment A for the detailed randomization protocol.

Investigators and Collaborators

Ana Terry, M.S., R.D. is the Principal Investigator of this proposed pilot study with Vicki L. Burt, Sc.M. as the Co-Investigator. Collaborators for the study include researchers from CDC's National Center for Chronic Disease Prevention and Health Promotion (Mary E. Cogswell, Dr. P.H. and Robert Merritt, MSPH), and National Center for Environmental Health (Christine Pfeiffer, Ph.D.) NIH's National Heart Lung and Blood Institute (Catherine Loria, Ph.D.).

INTRODUCTION

There is compelling evidence indicating that excess dietary sodium intake is detrimental to cardiovascular health (e.g., hypertension, left ventricular hypertrophy, congestive heart failure, excess risk of coronary heart disease, stroke) for almost all population groups regardless of age, ethnicity, sex, or health status. It is important to obtain population baseline data on sodium intake prior to any population based efforts to reduce sodium in the food supply and to monitor trends in intake at the national level subsequent to changes in the food supply.

Background and Justification

The Institute of Medicine, the Pan American Health Organization, and a recently convened National Heart Lung and Blood Institute (NHLBI) expert work group all strongly recommended measurement of 24-hour urinary sodium excretion as the most accurate means of monitoring mean sodium intake in the U.S. population. In addition, NHLBI recommended collecting a second 24-hour urine sample in a subsample of those with one 24-hour urine sample to estimate the population distribution (e.g., proportion of the population who exceeds recommended limits) accounting for day-to-day variation in sodium intake and excretion.

Sodium reduction plays a crucial role in the treatment of hypertension and CVD. Existing NHANES data on prescription medication data, blood pressure, diabetes, CVD and chronic kidney disease in combination with the currently proposed data on 24-hour urine collections can be used to assess whether those with diagnosed hypertension or other chronic diseases have obtained appropriate treatment at the population level.

This proposed pilot study is designed to assess the feasibility and test all procedures related to the 24-hour urine collection within NHANES. This pilot study is conducted to gain information that will be useful in planning to implement a 24-hour urine collection as part of NHANES in 2014. The major objectives of the pilot study are as follows:

Objectives

- To assess the feasibility and test all procedures related to the 24-hour urine collection
 - Including the weighing, aliquoting, and shipping procedures for the collected urine
- To estimate response rates
- To evaluate completeness of the urine collection

PROCEDURES AND METHODS

This proposed study is planned to be conducted beginning in February, 2013.

Study Protocol

We propose to randomly select half of NHANES non-pregnant participants examined in the MEC in three survey locations, ages 20-69 years (n=250). Of those who collected a 24-hour urine specimen, half will be randomly selected for participation in a follow-up 24-hour urine collection 3-10 days after the first 24-hour urine collection is completed. The second urine collection is proposed to account for day-to-day variation within individuals.

During their MEC examination, participants will be asked to participate in the 24-hour urine pilot (Attachment B). He/she will be scheduled to return on a different day to a Urine Pilot Study MEC (UMEC) to start the urine collection. Upon arriving for their appointment, a urine collection kit will be given to the participant to use for collecting urine samples over a 24-hour period (Attachment C). The kit will contain instructions on how to collect and return the urine specimen. Study staff will open the kit, explain the contents, and provide verbal (Attachment D) and written instructions (Attachment E). To start collection, the participant will be asked to empty his or her bladder. Drinking water will be available to help individuals void, if needed. The time of the void is recorded, the urine sample discarded, and the participant is asked to collect all urine from that moment for a period of 24 hours.

Each participant will be randomly assigned to collect the 24-urine samples either on a weekday or on a weekend day. When the day after the MEC examination is consistent with the randomly assign period of the week (weekday or weekend) we will ask the participant to begin his/her urine collection the following day if possible. If in the course of scheduling the 24-hour urine

start appointment the participant indicates it is impossible for him/her to collect the specimen during the assigned period of the week (weekday or weekend), he/she will not be excluded from participation but will be allowed to schedule urine collection at his/her convenience.

In addition to starting the 24-hour urine collection in the UMEC, participants will be asked to complete the urine collection in the UMEC that is, return 24 hours later. This return visit appointment will be scheduled at the same time the start collection appointment is made. If the participant can't come back in 24 hours they must schedule a time within 48 hours of the start of collection to return the urine. It is preferred that participants begin and end the collection in the UMEC, however, individuals' schedules may not always allow for this. Thus, we have allowed for flexibility by providing instructions on starting and/or ending collection at the UMEC or in the home, depending on participants' availability.

A set of completion questions will be used to assess the completeness of the urine collection (Attachment F).

A remuneration of \$100 will be given to the participant at the end of the questionnaire.

One-half of the participants (n=125) who successfully completed the first collection will be invited to collect a second 24-hour urine. If the participant agrees, the second 24-hour urine collection will be scheduled 3-10 days later, but not on the same day of the week as the first 24-hour urine collection. If the participant indicates it is impossible to collect the second urine on a different day of the week from the first they will be allowed to collect on the same day of the week as the first collection. Verbal consent will be obtained. The same follow-up questions will be asked upon the completion of the second 24-hour urine collection.

Of those participants selected for the second 24-hour urine collection, half (n=63) will be randomly selected to begin the second urine collection at home and half will be asked to return on another day to begin collection at the UMEC to test the feasibility of either protocol.

Please see attachments D and E for specific instructions for each protocol.

A remuneration of \$100 will be given to the participant at the end of second urine collection.

All 24-hour urine collections will be processed as described in Attachment G. The 24-hour urine collection will be assessed for completeness using the Completion Questionnaire. The urine specimen will be considered “Incomplete” and will not be processed if:

- The start and end time of the collection was not recorded and cannot be ascertained
- The length of collection time is <20 hours
- The total volume of urine is less than 500 ml
- A female participant was menstruating during the urine collection (Item FQ1, Completion Questionnaire, Attachment F)
- More than a few drops of urine were missed during collection (items FQ2-FQ8 on Completion Questionnaire, Attachment F)

All urine specimens collected over a period of at least 20 hours which meet other criteria for completeness will be processed (weighed, aliquoted and shipped). NCHS will determine whether specimens collected over a 26+ hour time frame will be included in the analytic sample.

After completing the 24-hour urine collection, all participants will be asked to participate in the Home Urine Collection (HUC) component which is currently part of the 2013 NHANES examination protocol. This existing protocol is scheduled after the 24 hour urine to prevent any deleterious effect on the response rate to the 24-hour urine collection during the pilot study. During their MEC examination, participants selected for the 24-hour urine pilot study will be not be assigned to the HUC component, but will instead be asked to participate in and scheduled for the 24-hour urine pilot study.

Data about time to complete the first and second visit to the UMEC, patterns and frequency of broken appointments and time to process the urine specimens will be tracked within the NHANES computer system. Data on appointment times for the urine pilot study (including broken and re-scheduled appointments) and reminder calls made to participants will automatically be generated. The system will also record the time at which the reminder calls were made. Participants will receive a phone call to remind them of their appointment to start the urine collection (unless their start date is the following day). If a participant does not have a phone where he/she can be reached, an NHANES staff member will make a personal visit to remind them of their appointment to start urine collection.

Participant Burden for Respondents

The respondent burden is estimated to be 90 minutes for the first 24-hour urine collection. Additional 90 minutes of respondent burden is estimated for the second 24-hour urine collection.

Consent

The possibility of the 24-hour urine collection will be explained during the household interview to participants aged 20-69 years as part of the informed consent procedures for the MEC.

Justification for Using Vulnerable Populations

No minors, pregnant women, or participants who do not respond for themselves will be included in this proposed pilot study.

Risks

There is no more than minimal risk associated with this study protocol.

Laboratory Tests

Urine sodium (Na), urine potassium (K), urine chloride (Cl), and urine creatinine.

Report of Findings

Results from the 24-hour urine collection(s) will not be routinely reported to participants. Urine levels of sodium, potassium, and chloride reflect dietary intakes. A participant's kidney function has relevance to his/her health, and the following blood and urine test results showing kidney function are already in the NHANES protocol to be reported to the participant: serum creatinine, BUM, estimated glomerular filtration rate and the albumin creatine ratio.

Participants will be given a toll-free number to call if they want to know any of their results.

Attachment A

Randomization Process

Randomization Process

The selection of the one half sample of NHANES examinees for the initial collection will be done with the existing NHANES subsamples mechanism. That mechanism is based on dividing the Sample Person ID by 12 and selecting one-half of the integer remainders between 0 and 11. Participants whose Sample Person ID has one of those remainders is asked to participate in the 24 hour urine collection. The remainders for the 24-hour subsample collection are: 1, 4, 6, 7, 9, and 11.

The second subsample is carried out on the one-half subsample above and will indicate which participants will be subsampled to do a weekday collection and which of them will be subsampled to do a weekend collection. Those with remainders 1, 6, and 7 will be asked to collect the urine on a weekend. Those with remainders of 4, 9 and 11 will be asked to collect the urine on a weekday.

The selection of participants to do the second 24-Hour urine collection will not utilize the standard NHANES subsampling because of the desire to select half of the participants that are compliant with the first 24-Hour urine collection. Since NHANES subsamples are determined by the Sample Person ID, there is no way to ensure that half of the compliant participants are selected. Instead of the standard NHANES subsampling, the application will use a random number between 1 and 100, to determine the half sample.

Also, the selection of which participants that are doing the second 24-Hour urine collection will be given their kit at the UMEC to start collection at home and which participants will be scheduled to return to the UMEC to get their kit will not use the standard NHANES subsample. This is because those that participate in the second 24-Hour urine collection are not using the standard NHANES subsampling. So, to ensure a 50% distribution, the application will use a random number between 1 and 100 to determine how the participant will receive their second kit.

Attachment B

Suggested Recruitment and Reminder Scripts

Suggested Recruitment Script

Scientists can learn about people's nutrition by examining their urine. We are conducting a urine study to learn more about the nutrition of people living in the U.S. We would like you to participate in this study. If you agree to take part in this study, we will ask you to collect all your urine over a 24-hour period. We will ask you to collect your urine for the entire 24 hours, including any time when you are away from home during those 24 hours. You will need to come to our urine study mobile exam center, parked next to this one, for two short visits. The first visit will take about 20 minutes to receive instructions and materials. We will ask you to empty your bladder during your appointment and give you a urine collection kit to take home. Once you complete the 24-hour urine collection, you will take the urine back to the same place. This second visit will take about 20 minutes and you will be asked to answer some questions. You will receive \$100 as a thank you for your time and effort when you return your sample. You may choose to stop participating in this study at any time. Would you like to participate in this study?

If No: Thank the person and end the conversation.

If Yes:

Let's schedule your first visit.

We will need you to be prepared to collect your urine on the day of this first visit, and so at this first visit we will be asking you to schedule your second visit, 24 to 48 hours later, to return with your urine.

I will read you some times I have available and you can choose the time that is best for you.
(Schedule the respondent)

If you have any questions or need to change your appointment, please call 1-XXX-XXX-XXXX.

Suggested Script for Appointment Reminder Call

Hello Mr. /Ms. _____. My name is _____. I am calling from the NHANES survey to remind you of your appointment at our urine study mobile exam center to start the 24-hour urine study. Your appointment is on _____ (DAY, DATE) at _____ (TIME).

During this appointment, we will ask you to urinate (pee) at our center to start the study, so do not urinate (pee) right before you come to our mobile exam center.

Do you have any questions? Thank you.

Suggested Script for Reminder to Start Collection

(Starting collection at home)

Hello Mr. /Ms. _____. My name is _____. I am calling from the NHANES survey to remind you about your appointment to start the 24-hour urine study. You are scheduled to start collecting your urine tomorrow, _____ (DAY, DATE) at _____(TIME) and stop at about _____(TIME) on _____ (DAY, DATE).

Please review the instructions we gave you at the urine study mobile exam center before you start. Also, be sure to put the ice packs in the freezer tonight, if you haven't already, so they will be ready for you to use tomorrow.

If you have any questions about the instructions, or are unable to start the urine collection tomorrow, please call the helpline as soon as possible at 1-800-XXX-XXXX. Thank you.

Suggested Script for Inviting a Second Urine Collection

We appreciate the time you spent collecting your urine. With this study we will learn about people's nutrition. However, research has shown that food intakes change day to day and the changes can be measured in the urine. A second day of information can give us a more complete picture of people's nutrition. Would you be willing to repeat the collection? You will receive an additional \$100 for your time when you return your urine sample.

Attachment C

Description of Urine Collection Kit

The Urine Collection Kit

(Flesch-Kincaid Grade Level 5.3)

Below is a brief description of the items included in the urine collection kit:

Urine Hat (for women) <picture to be inserted>	Women can use the urine hat to help collect their urine. The urine hat sits under the toilet seat.
Urine Collection Cup (for men) <picture to be inserted>	Men will use this cup to collect their urine.
Storage Containers <picture to be inserted>	The urine collected in the urine hat or the collection cup will be poured into and stored in containers. Containers are provided. All urine should be stored in the container.
Storage Container Label <picture to be inserted>	A label to record the start and end time will be applied to one storage container.
Ziploc bags (2 sizes) <picture to be inserted>	<ul style="list-style-type: none">• The medium Ziploc bag is to store the hat or men's collection cup.• The large Ziploc bag is to store the containers to put in the cooler.
Cooler Bags and Ice Packs <picture to be inserted>	<ul style="list-style-type: none">• The cooler bag is to be used to store the urine containers.• You should keep two frozen ice packs in the bag with the collected urine at all times.

If you have any questions, please call the helpline at **1-888-XXX-XXXX**.

Attachment D

Verbal Urine Collection Instructions

Talking Points: start collection in the Urine Study MEC

You will collect all your urine for 24 hours. To help us learn about people's nutrition by studying their urine, it is very important that you collect every drop of urine and try not to spill any.

INSTRUCTIONS:

1. We will ask you to empty your bladder today before you leave the mobile exam center. You will receive a urine collection kit to take home with you.
2. We will write down the date and time of this first urine on the label, under the line "Start Time".
3. When you arrive at home, place all the ice packs from your urine kit in your refrigerator freezer.
4. Have the urine collection kit near the toilet so that you can use it every time you urinate (pee). Store every urine (pee) in a container. –
5. Every time you put urine in, close the lid tightly.
6. Put the storage container into a Ziploc bag and seal the bag.
7. Keep your collected urine cold either by storing the filled containers in the cooler bag with frozen ice packs or by keeping them in the large Ziploc bag in the refrigerator.

HOW TO COLLECT THE URINE

Females

- Place the urine hat under the toilet seat. Urinate (pee) into the hat to collect your urine.
- Open the storage container. Put the funnel in the container and carefully pour the urine from the hat into the container.
- Close the lid tightly.
- Store the urine hat in the medium size Ziploc bag.

Males

- You may pee directly into the storage container or into the collection cup.
- To transfer the urine from the collection cup to the storage container, use the funnel to carefully pour the urine into the container.
- Close the lid tightly.
- Store the urine hat in the medium size Ziploc bag

IMPORTANT THINGS TO REMEMBER

1. Collect all your urine each time you urinate during the 24 hour study period, from _____ (day of week) to _____ (day of week). If you get up during the night, be sure to collect your urine.
2. When the urine is up to this “full” line (show line on container), use a new container the next time you urinate. This is to avoid over filling the container.
3. If you need to pass stool (poop), urinate and collect your urine first.

WHEN YOU ARE AWAY FROM HOME

If you will be away from home during the 24-hour collection time, take the following items with you and continue to collect all your urine:

- 1 cooler bag
 - 2 Frozen ice packs
 - 1 urine storage container
 - Funnel
 - Females - urine hat in a Ziplock bag
 - Males - collection cup in a Ziplock bag
1. Follow instructions on how to collect the urine.
 2. Put the storage container into a Ziplock bag, seal the bag.
 3. Keep your urine cold by storing the container in the cooler bag with ice packs.
 4. Store the urine hat (FEMALES)/collection cup (MALES) in the medium Ziplock bag and put it in the cooler bag.

ENDING THE URINE COLLECTION

Ending collection at the UMEC:

On _____ (DAY of WEEK) at _____ (TIME):

1. Plan to return to the urine mobile exam center at the time of your appointment to return your urine sample.
2. Do not urinate (pee) right before your appointment because we will ask you to empty your bladder at the urine mobile exam center to end the 24-hour urine study.
3. If you have any questions, please call the helpline at 1-XXX-XXX-XXXX.

Ending collection at home:

On _____ (DAY of WEEK):

1. Collect your urine until _____ (time and day of week). This is the last urine you will collect. Write down the date and time of your last urine collection on the label under "End Time".
2. Return your containers with urine at the time of your appointment: _____.
3. If you have any questions, please call the helpline at 1-XXX-XXX-XXXX.

Talking Points: start collection in the home

Please start your collection on _____ (day of week and date). You will collect all your urine for 24 hours. To help us learn about people's nutrition by studying their urine, it is very important that you collect every drop of urine and try not to spill any.

INSTRUCTIONS

The night before collecting

1. Place all the ice packs in your refrigerator freezer overnight (or at least 6 hours) **before** collecting the urine.
2. Have the urine collection kit near the toilet to be ready to be used the next morning.

On _____ (DAY of WEEK):

1. When you wake up, urinate (pee) in the toilet as usual. DO NOT collect this urine, WRITE down the date and time of this first urine of the day on the label, under the line "Start Time".
2. Begin to collect your urine the second time you urinate (pee).
3. Store every urine (pee) in a container. Every time you put urine in, close the lid tightly.
4. Put the storage container into a Ziploc bag, seal the bag.
5. Keep your collected urine cold either by storing the containers in the cooler bag with frozen ice packs or by keeping it in the large Ziploc bag in the refrigerator.

HOW TO COLLECT THE URINE

Females

- Place the urine hat under the toilet seat. Urinate (pee) into the hat to collect your urine.
- Open the storage container. Put the funnel in the container and carefully pour the urine from the hat into the container.
- Close the lid tightly.

- Store the urine hat in the medium Ziploc bag.

Males

- You may pee directly into the storage container or into the collection cup.
- To transfer the urine from the collection cup to the storage container, use the funnel to carefully pour the urine into the container.
- Close the lid tightly.
- Store the collection cup in the medium Ziploc bag.

IMPORTANT THINGS TO REMEMBER

1. Collect all your urine each time you urinate during the 24-hour study time period.
2. Plan to get up at the same time each morning.
3. If you get up during the night, be sure to collect your urine.
4. When the urine is up to the “full” line (show the full line), use another container the next time you urinate. This is to avoid over filling the container.
5. If you need to pass stool (poop), urinate and collect your urine first.

WHEN YOU ARE AWAY FROM HOME

If you will be away from home during the 24-hour collection time, take the following items with you and continue to collect **all** your urine:

- 1 cooler bag
- 2 Frozen ice packs
- 1 urine storage container
- Funnel
- Females - urine hat in a Ziplock bag
- Males - collection cup in a Ziplock bag

1. Follow instructions on how to collect the urine.
2. Put the container into a Ziplock bag, seal the bag.

3. Keep your urine cold by storing the container in the cooler bag with ice packs.
4. Store the urine hat (FEMALES)/collection cup (MALES) in the medium Ziplock bag and put it in the cooler bag.

ENDING THE URINE COLLECTION

On _____ (DAY of WEEK):

1. Plan to wake up at about the same time you did the day before on _____.
2. **Collect your urine the first time you urinate.** This is the last urine you will collect. Write down the date and time of this last urine on the label under "End Time".
3. Return your containers with urine at the time of your appointment: _____ (DAY) at _____(TIME).
4. If you have any questions, please call the helpline at 1-XXX-XXX-XXXX.

Attachment E

Written Urine Collection Instructions

Directions to start and end collection in Urine Study MEC

(Flesch-Kincaid Grade Level 7.0)

You will collect all your urine for 24 hours. To help us learn about people's nutrition by studying their urine, it is very important that you collect every drop of urine and try not to spill any.

How to collect your urine at home

- When you arrive at home, place all the ice packs from your urine kit in your refrigerator freezer. (include picture of ice packs)
- Have the urine collection kit near the toilet so that you can use it every time you urinate (pee). Store every urine (pee) in a container. Every time you put urine in close the container tightly. (include picture of collection kit)
- Put the storage container with urine into a Ziploc bag and seal the bag. (include picture of the container and Ziploc bag)
- Keep all urine cold. Store the containers in the cooler bag with frozen ice packs or keep it in the large Ziploc bag in the refrigerator. (include picture of two options)
- Continue to collect all your urine each time you urinate during the 24-hour study time period. If you get up during the night, be sure to collect your urine.
- When the urine is up to the "full" line, use another container the next time you urinate (pee). (Include photo of line and level of filling)
- If you need to pass stool (poop), urinate and collect your urine first.

How to collect the urine

Women

- Place the urine hat under the toilet seat. Urinate (pee) into the hat to collect your urine. (include picture of urine hat on toilet)
- Open the storage container. Put the funnel in the container and carefully pour the urine from the hat into the container. (include picture of funnel in container)
- Close the lid tightly. (include picture of container with lid)
- Store the urine hat in the medium Ziploc bag. (include picture of urine hat and Ziploc bag)

Men

- You may pee directly into the storage container or into the collection cup. (include picture of storage container and collection cup)
- To transfer the urine from the collection cup to the storage container, use the funnel to carefully pour the urine into the container. (include picture of funnel in container)
- Close the lid tightly. (include picture of container with lid)
- Store the collection cup in the medium Ziploc bag. (include picture of collection cup and Ziploc bag)

When you are away from home

If you will be away from home during the 24-hour collection time, take the following items with you and continue to collect **all** your urine:

- 1 cooler bag
 - 2 Frozen ice packs
 - 1 urine storage container
 - Funnel
 - Women - urine hat in a Ziploc bag
 - Men - collection cup in a Ziploc bag
1. Follow instructions on how to collect the urine.
 2. Put the container into a Ziploc bag, seal the bag.
 3. Keep your urine cold by storing the container in the cooler bag with ice packs.
 4. Store the urine hat (women) or collection cup (men) in the medium Ziploc bag and put it in the cooler bag.

Ending your urine collection

On _____ (DAY of WEEK) at _____ (TIME):

Plan to return to the urine study mobile exam center at the time of your appointment to return your urine sample.

Do not urinate (pee) right before your appointment because we will ask you to empty your bladder at the urine mobile exam center to end the 24-hour urine study.

If you have any questions, please call the helpline at 1-800-XXX-XXXX.

Directions to start collection in Urine Study MEC and end at home

(Flesch-Kincaid Grade Level 6.3)

You will collect all your urine for 24 hours. To help us learn about people's nutrition by studying their urine, it is very important that you collect every drop of urine and try not to spill any.

How to collect your urine at home

- When you arrive at home, place all the ice packs from your urine kit in your refrigerator freezer. (include picture of ice packs)
- Have the urine collection kit near the toilet so that you can use it every time you urinate (pee). Store every urine (pee) in a container. Every time you put urine in close the container tightly. (include picture of collection kit)
- Put the container with urine into a Ziploc bag and seal the bag. (include picture of the container and ziploc bag)
- Keep all urine cold. Store the containers in the cooler bag with frozen ice packs or keep it in the large ziploc bag in the refrigerator. (include picture of two options)
- Continue to collect all your urine each time you urinate during the 24-hour study time period. If you get up during the night, be sure to collect your urine.
- When the urine is up to the "full" line, use another container the next time you urinate (pee). (Include photo of line and level of filling)
- If you need to pass stool (poop), urinate and collect your urine first.

How to collect the urine

Women

- Place the urine hat under the toilet seat. Urinate (pee) into the hat to collect your urine. (include picture of urine hat on toilet)
- Open the storage container. Put the funnel in the container and carefully pour the urine from the hat into the container. (include picture of funnel in container)
- Close the lid tightly. (include picture of container with lid)
- Store the urine hat in the medium Ziploc bag. (include picture of urine hat and bag)

Men

- You may pee directly into the storage container or into the collection cup. (include picture of collection cup)
- To transfer the urine from the collection cup to the storage container, use the funnel to carefully pour the urine into the container. (include picture of funnel in container)
- Close the lid tightly. (include picture of container with lid)
- Store the collection cup in the medium Ziploc bag. (include picture of collection cup and bag)

When you are away from home

If you will be away from home during the 24-hour collection time, take the following items with you and continue to collect **all** your urine: (include pictures of items)

- 1 cooler bag
 - 2 Frozen ice packs
 - 1 urine storage container
 - Funnel
 - Women - urine hat in a Ziploc bag
 - Men - collection cup in a Ziploc bag
1. Follow instructions on how to collect the urine.
 2. Put the container into a Ziploc bag, seal the bag. (include picture of container in bag)
 3. Keep your urine cold by storing the container in the cooler bag with ice packs. (include picture of ice packs)
 4. Store the urine hat (women) or collection cup (men) in the medium Ziploc bag and put it in the cooler bag. (include picture of urine hat and collection cup in bag)

Ending your urine collection

On (day after started collection) (**DAY of WEEK**):

- Keep collecting your urine until (24 hours after start) (TIME and DAY). This is the last urine you will collect.
- Write down the date and time of your last urine collection on the label under “End Time”. (include picture of label)
- Return your containers with urine at the urine study mobile exam center at the time of your appointment: _____ (DAY; DATE; TIME).

**If you have any questions, please call the helpline at 1-800-XXX-XXXX.
Directions to start and end collection at home**

(Flesch-Kincaid Grade Level 5.6)

You will collect all your urine for 24 hours. To help us learn about people's nutrition by studying the urine, it is very important that you collect every drop of urine and try not to spill any.

How to collect your urine at home

The night before you begin to collect your urine:

- Place all the ice packs in your refrigerator freezer overnight (or at least 6 hours) before collecting the urine (include picture of ice packs)
- Place the urine collection kit near the toilet to be ready for the next morning. (include picture of urine collection kit)

On _____ (DAY of WEEK):

- When you wake up, urinate (pee) in the toilet as usual. DO NOT collect this urine, WRITE down the date and time of this first urine on the label, under "Start Time". (include picture of label)
- Collect ALL your urine every time you urinate (pee) (include picture of container with lid)
- Put the storage container into a Ziploc bag and seal the bag. (include picture of the container and ziploc bag)
- Keep all urine cold. Store the containers in the cooler bag with frozen ice packs or keep it in the large ziploc bag in the refrigerator. (include picture of two options)
- Continue to collect all your urine each time you urinate during the 24-hour study time period. If you get up during the night, be sure to collect your urine.
- When the urine is up to the "full" line, use another container the next time you urinate (pee). (Include photo of line and level of filling)
- If you need to pass stool (poop), urinate and collect your urine first.
- Set your alarm to get up at the same time on _____ (day of week), as you did on _____. (Include photo of alarm clock.)

How to collect the urine

Women

- Place the urine hat under the toilet seat. Urinate (pee) into the hat to collect your urine. (include picture of urine hat on toilet)
- Open the storage container. Put the funnel in the container and carefully pour the urine from the hat into the container. (include picture of funnel in container)
- Close the lid tightly. (include picture of container with lid)
- Store the urine hat in the medium Ziploc bag. (include picture of urine hat and bag)

Men

- You may pee directly into the storage container or into the collection cup. (include picture of collection cup)
- To transfer the urine from the collection cup to the storage container, use the funnel to carefully pour the urine into the container. (include picture of funnel in container)
- Close the lid tightly. (include picture of container with lid)
- Store the urine hat in the medium Ziploc bag. (include picture of urine hat and bag)

When you are away from home

If you will be away from home during the 24-hour collection time, take the following items with you and continue to collect **all** your urine:

- 1 cooler bag
 - 2 Frozen ice packs
 - 1 urine storage container
 - Funnel
 - Women - urine hat in a Ziploc bag
 - Men - collection cup in a Ziploc bag
1. Follow instructions on how to collect the urine.
 2. Put the container into a Ziploc bag, seal the bag.
 3. Keep your urine cold by storing the container in the cooler bag with ice packs.
 4. Store the urine hat (women) or collection cup (men) in the medium Ziploc bag and put it in the cooler bag.

Ending your urine collection

On _____ (DAY of WEEK):

- Plan to wake up at about the same time you did the day before on _____.
- Collect your urine the first time you urinate. Try to pee at the same time you wrote down yesterday when you started collecting your urine. This is the last urine you will collect.
- Write down the date and time of this last urine on the label under “End Time”. (include picture of label)
- Return your storage containers with urine at the urine study mobile exam center at the time of your appointment: _____(DAY; DATE; TIME).

If you have any questions, please call the helpline at 1-800-XXX-XXXX.

Attachment F

Completion Questionnaire

Completion Questionnaire

FQP1-FQP3 are completed based on Technician's observation. Do not read the questions to the participants.

FQP1. WAS THE TIME OF URINE COLLECTION RECORDED?

YES..... 1
NO..... 2 (Go to end of section)

FQP2. WAS THE LENGTH OF THE COLLECTION TIME MORE THAN 20 HOURS?

YES..... 1
NO..... 2 (Go to end of section)

FQP3. WAS THE TOTAL AMOUNT OF URINE COLLECTION MORE THAN 500 ML?

YES..... 1
NO..... 2 (Go to end of section)

We would like to ask you several questions about your experience in collecting the urine for a 24 hour period. Your answers to these questions will not affect your payment.

FQ1. (FOR FEMALES ONLY) Were you having your period at any time in the last 24 hours?

YES..... 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

FQ2. During the 24-hour period, did you collect your urine every time you used the bathroom to urinate?

YES..... 1 (FQ4)
NO..... 2
REFUSED..... 7 (FQ4)
DON'T KNOW..... 9 (FQ4)

FQ3. How many times did you miss?

Interviewer instruction: Probe the amount of the void. Do not count as “miss” if the missed void was only a few drops.

___ times

REFUSED.....77
DON'T KNOW.....99

FQ4. Is there any urine missing from the storage containers for any other reason such as spilling?

YES..... 1
NO..... 2 (FQ7)
REFUSED..... 7 (FQ7)
DON'T KNOW..... 9 (FQ7)

FQ5. Were more than a few drops of urine lost?

YES..... 1
NO..... 2 (FQ7)
REFUSED..... 7
DON'T KNOW..... 9

FQ6. How many times did this happen?

___ times

REFUSED.....77
DON'T KNOW.....99

FQ7. Many people when having a bowel movement also urinate. Was there any time when you were not able to collect the complete urine sample because of a bowel movement?

Interviewer instruction: Probe the amount of the void. Do not count as “miss” if the missed void was only a few drops.

YES..... 1
NO..... 2 (FQ9)
REFUSED..... 7 (FQ9)
DON'T KNOW..... 9 (FQ9)

FQ8. How many times did this happen?

||| times

REFUSED.....77
DON'T KNOW.....99

FQ9. Were you able to keep the storage containers cold in the cooler with ice packs or in the refrigerator until this appointment?

YES..... 1 (FQ11)
NO..... 2
REFUSED..... 7 (FQ11)
DON'T KNOW..... 9 (FQ11)

FQ10. How long was the sample not kept cold?

||| minutes/hour

REFUSED..... 7
DON'T KNOW..... 9

FQ11. Did you perform this collection on a day that you also went to work?

YES..... 1
NO..... 2
DO NOT WORK..... 3
REFUSED..... 7
DON'T KNOW..... 9

FQ12. When collecting the sample, did you have any difficulty in remembering or carrying out the instructions?

YES (specify_____). 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

FQ13. Did you have any other problem when collecting the 24 hour urine sample?

YES (specify_____). 1
NO..... 2
REFUSED..... 7
DON'T KNOW..... 9

Attachment G

Urine Sample Processing Procedure

Urine Sample Processing Procedure at the Urine Study MEC

Participants are asked to return to the UMEC to complete the urine collection, but if not possible, they are asked to bring the urine samples back to the UMEC within 48 hours of the start of collection. When the urine sample is returned to the UMEC, the following procedure will be used to process the urine:

1. Enter participant ID into the Completion Questionnaire application
 - If the start time and end time of the 24-hour collection was not recorded and cannot be ascertained, mark “2 – No” for FQP1 in the Completion Questionnaire application. The system will mark the case as “Not Done” with comment “Participant failed to follow protocol”. The urine sample will not be processed or used.
 - If the length of collection time is <20 hours, mark “2 – No” for FQP2 in Completion Questionnaire application. The system will mark the case as “Not Done” with comment “Participant failed to follow protocol”. The urine sample will not be processed or used.
 - If the total urine volume is less than 500 ml, the urine sample will not be processed or used. Mark “2 – No” in FQP3. The system will mark the case as “Not Done” with comment “Participant failed to follow protocol”.
 - If FQP1, FQP2, and FQP3 all = 1, continue with the Completion Questionnaire.
2. Enter participant ID, start date/time and end date/time of the 24-hour collection into the lab application.
3. The application system will calculate the length of collection. Confirm the length of collection time to be at least 20 hours.
4. Label the individual containers numerically.
 - If the collection ended at the UMEC, remember that the final sample of urine voided is to be included in the 24-hour collection.
5. Record the weight of each container into the lab application.
 - Place each urine container on the scale to obtain the weight.
 - The weight reading will be entered into the lab application system.

- The system will deduct the container weight from the recorded weight and calculate the actual weight of the urine. It will then convert the weight into the volume of the urine, using 1 gm = 1 ml, for the record.
 - The system will calculate the total volume for the 24-hour urine sample.
 - The application will include a drop down list of comment codes (same codes as used for the MEC urine collection module) for the urine sample.
6. Aliquot five vials of urine samples from the 24-hour urine collection.
 - Pool all the urine from the containers into one large container.
 - Before taking sample from the urine container, thoroughly and gently mix the urine sample for at least 15 seconds.
 - Aliquot 2 ml of urine into the first 2-ml cryovial (for sodium, potassium, chloride and creatinine).
 - Aliquot 4 vials of 5-ml urine into the 5-ml cryovials. These vials will be stored for additional tests.
 7. Discard the remaining urine.
 8. Store the aliquots in freezer.
 9. Process the urine samples the same day they were received. Urine samples can be kept refrigerated at 4°C or less for no more than 24 hours.
 10. All aliquots need to be shipped to the lab within 7 days. The aliquots need to be shipped frozen on dry ice.

Attachment H

NHANES Health Measurements List



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics



NHANES Health Measurements List

Below is a list of tests you will receive on the day of your examination.

You will only have the test if your age falls within the ages shown in parenthesis.

You will receive the results of health measures shown with a black diamond (◆). Two diamonds (◆◆) means you will receive the test result only if high or abnormal.

Health Measurements

You will be weighed and measured (all) ◆

The doctor will take your blood pressure (8+) ◆

We will look at the condition of your teeth and gums (1+) ◆

Dental imaging for fluorosis (6-19)

You will have body composition tests that involve low-dosage x-rays (*Pregnant women will not have this test*)

Total body scan (8-59) ◆

Hip and spine bone density scans (40+) ◆

You will have a taste and smell test (40+) ◆

You will have a grip strength test (6+) ◆

Private Interviews

You will be asked questions about your eating habits (all)

You will be asked to answer questions about:

Weight history (8-15)

Reproductive history (females 12+)

Drug use (12-69), alcohol and tobacco use (12-19), self-identified stage of puberty (8-19) and sexual history (14-69)

(You will do these by yourself using a touch-screen computer in privacy)

You will be asked to take short tests to assess your learning and memory (60+)

Lab Tests on Urine (6+)

You will be given a clean empty cup when you arrive at the exam center. When you change into the exam clothes in a private rest room, you will provide a urine sample. The urine will be tested for:

Exposure to environmental chemicals and metals (all) [arsenic ◆◆]

Kidney function tests (all) ◆

Sexually transmitted diseases:

Chlamydia (14-39) ◆

Trichomonas (14-59) ◆

(Urine is not tested for drug use)



Please turn over to see the next page.

2013 NHANES Health Measurements, cont.

Lab Tests on Blood (1+)

You will have your blood drawn. The blood will be tested for:

- Anemia (all) ♦
- Nutrition status (all) ♦
- Lead, cadmium, mercury, manganese (all under 12, selected participants 12+) ♦
- Selenium (6-11, selected participants 12+) ♦
- Copper and zinc (6+) ♦
- Infectious diseases (2+) ♦♦ Total Cholesterol/HDL (6+) ♦
- Triglycerides/LDL (Morning session participants only, 12+) ♦
- Exposure to environmental chemicals (selected participants 6+)
- Kidney and liver function (12+) ♦
- Markers of celiac disease (6+) ♦
- Marker of muscle damage (12+) ♦
- Caffeine (6+)
- Testosterone (6+) ♦
- Estradiol (6+)
- Sex hormone binding globulin (6+)
- Sexually transmitted diseases (STD):
 - Genital herpes (14-49) ♦
 - Human immunodeficiency virus (HIV) (18-59) ♦
 - Human Papillomavirus (HPV) (14-59)
- Glucose (12+) ♦
 - Persons examined in the morning will have their blood drawn a second time to check for prediabetes
- Fluoride (3-19) ♦

Lab Tests on Saliva

Human Papillomavirus (HPV) (14-69)

Women and girls only:

You will be asked to self-administer a vaginal swab in complete privacy. The swab will be tested for the presence of Human Papillomavirus (14-59) ♦

Females 12 years and older will have a urine pregnancy test, as well as girls 8-11 who have started their periods. Our physician will tell you if you are pregnant if you did not already know it. Parents of girls younger than 14 years of age who are pregnant will also be informed of the test result ♦♦

Men and boys only:

You will be asked to self-administer a penile swab in complete privacy. The swab will be tested for the presence of Human Papillomavirus (14-59).

Lab Tests on Water:

The interviewer will collect a sample of household tap water if participants are under 20 years of age. The water will be tested for fluoride. ♦

After your visit to the NHANES mobile center:

If you had a dietary interview as part of your exam, you will get a phone call 4-11 days after the exam to be asked similar questions.

You will be asked to provide two additional urine samples (ages 20 - 69). Before leaving the center, you will be given instructions, two clean empty cups, and a prepaid, addressed box for shipment to our lab.

You will be asked to wear a physical activity monitor for 7 days after your exam (ages 3 years and older). A prepaid envelope will be provided for mailing the monitor back to our headquarters.

Select persons (ages 20-69) may be asked to collect their urine for 24 hours.

Taking part in these interviews and health measures after your visit to the mobile center is voluntary.

If you have questions about getting your results, please call 1-800-452-6115