

***Attachment 13***  
***Results of 24-Hour Urine Pilot Study***

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**National Health and Nutrition Examination Survey 24-Hour Urine Pilot Study**

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## Summary

A 24-hour urine pilot study was conducted as part of the NHANES to test the feasibility of implementing a 24-hour urine collection as part of NHANES in 2014. The pilot study was conducted March - June 2013 in three NHANES locations, including suburban, urban and rural populations.

Between March-June 2013, 282 adults aged 20-69 years were subsampled for the 24-hour urine pilot. Of those who were sampled, 75% (n=212) successfully completed the first 24-hour urine collection. Another 85% (n=92) successfully completed a second 24-hour urine collection. Based on the criteria outlined in the OMB submission the pilot would be considered successful if 70 percent of eligible participants agreed to participate and successfully completed the first 24-hour urine collection and if 70 percent of those asked to collect a second 24-hour urine sample did so successfully. Based on the pre-specified response rate criteria, the pilot was a success.

Additionally, it was desirable that the non-respondents not be highly over represented in any particular major demographic group. As noted in Attachment 1 there was little difference in respondents and non-respondents by age, gender, race, education or employment status.

Finally, it was required that the physical activity monitor (PAM) and Dietary Recall (DR) components that also occur after the NHANES examination not experience a decrease of more than 10 percentage points for the pilot to be considered successful. Participation in the 24-hour urine pilot study had no adverse effect on response rates to the PAM or DR. To date, 87-90% of those who were selected to collect their urine returned their PAM compared to 79-86% who were not selected to collect a urine sample (see MEC Follow-Up Components, page 7). Response rates for the dietary recall are 91-93% among those who were selected to collect a urine sample compared to 85-87% among those who were not selected to collect a urine sample. Results are preliminary as PAMs continue to be received and the DRs are ongoing in the three pilot locations.

Based on the results of the pilot test the DHANES program would like to include a 24-hour urine on a one-half sample of NHANES examinees ages 20-69 in the 2014 NHANES.

## **Detailed Description of Pilot Results**

## Introduction

A 24-hour urine pilot study was conducted as part of the NHANES to test the feasibility of implementing a 24-hour urine collection as part of NHANES in 2014. The pilot study was conducted March - June 2013 in three NHANES locations, including suburban, urban and rural populations. The major objectives of the pilot study were:

- 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

## Overview of Study Protocol

282 individuals ages 20-69 years who were examined in the NHANES mobile exam center (MEC) were randomly subsampled for the urine pilot. Individuals who agreed to the pilot study were asked to return to the Urine Pilot Study MEC (UMEC) for instructions and a urine collection kit. Upon the return of the urine specimen, a set of questions was used to determine the completeness of the urine collection.

One half of participants who returned a complete sample were randomly selected and invited to collect a second urine collection. The second collection was scheduled 3-10 days later, but not on the same day of the week as the first urine collection. Of those participants selected for the second 24-hour urine collection, half were randomly selected to begin the collection at home and half were asked to return on another day to begin collection at the UMEC. This allowed us to test either protocol. It also helped us assess whether a protocol for 2014 that involves three visits to the UMEC would be as successful in obtaining a high rate of complete urine collections as four visits to the UMEC.

The urine specimen was considered “incomplete” if:

- The start or end time of the collection could not be ascertained
- The length of collection time was <22 hours
- The total volume of urine was less than 500 ml
- A female participant was menstruating during the urine collection
- More than a few drops of urine were missed during collection

Because sodium intake varies from day to day, we aimed to obtain data from urines collected on all days of the week. It has also been observed that in studies where participants are not encouraged to collect urines on weekdays most opt to collect the urine on a weekend day. To increase week day collections, a random one-half of the pilot participants were asked to collect on a week day. Participants who stated it was impossible to collect during the assigned interval, were not excluded from participation but were allowed to schedule during the alternative time interval.

We monitored the effect the 24-hour urine collection might have on other NHANES post-examination content: a physical activity monitor (PAM) given during the MEC examination that is worn and mailed back 8 days after examination and a second dietary recall (DR) conducted over the telephone that occurs 3-10 days after the examination.

## Criteria for evaluating pilot test success

The following are the pre-established criteria for evaluating the success of the pilot for possible inclusion in the 2014 NHANES.

Response rates (completion rates) for the 24-hour urine collection

The pilot will be considered successful if:

- 70 percent of eligible participants agree to participate and successfully complete the first 24-hour urine collection
- 70 percent response rate for those asked to collect a second 24-hour urine sample
- Willingness to collect the first and second 24-hour urine and successful collection of a complete urine sample will be looked at by location, gender, age and race and Hispanic origin.

If the response rate meets the success standard above and the pattern of non-response is highly skewed within one or more subgroups defined by age, gender, or race ethnicity this information would be taken into account in making a decision to implement the component in 2014.

PAM and DR

- If either the PAM or DR response rate decreases more than 15 percentage points at the first location the pilot will be stopped during the second location. If the response rate decreases between 10 and 15 points for the first 2 locations we will end the pilot during the third location.
- If the response rate for the entire duration of the pilot (3 locations) for either of these components decreases by more than 10 percentage points (e.g. from 88 to less than 78 percent) the pilot will be considered unsuccessful. If the response rate for both of these components decreases by 5 or fewer percentage points, the pilot will be considered a success. A reduction of greater than 5 up to 10 percentage points in response rate for one or both components will require further evaluation of the impact of the pilot on the post-examination components.

The comparison group to evaluate changes in response rates to post-examination components is the random sample of NHANES examinees not asked to participate in the 24-hour urine collection.

## Results

Response Rates

Between March-June 2013, 282 adults aged 20-69 years were subsampled for the 24-hour urine pilot. Of those who were sampled, 75% (n=212) successfully completed the first 24-hour urine collection and 85% (n=92) successfully completed a second 24-hour urine collection.

First 24-Hour Urine Collection (n=282 eligible)

91% (n=258) agreed to participate

75% (n=212) successfully collected a complete sample

Second 24-hour Urine Collection (n=108 eligible)

108 participants were eligible for a second 24-hour urine collection

85% (n=92) successfully collected a complete sample

Why the Collected Sample was Incomplete

The majority of participants who returned an incomplete sample missed more than a few drops of urine. Below are reasons an incomplete sample was collected.

First collection (n=26)

18 missed more than a few drops of urine during collection

1 collected urine specimen over a period less than 22 hours

4 returned less than 500 ml of urine specimen

3 females were menstruating during collection.

Second collection (n=8)

5 missed more than a few drops of urine during collection

2 were unclear about the start time of collection

1 female was menstruating during collection

Non-Response

The response rate to the examination at the three NHANES locations was 75% (suburban southern city), 66% (mid-western city), and 71% (mid-western rural).

Tables 1 and 2 in Attachment 1 show overall completion rates and willingness to participate at various levels of the study for a complete first and second urine collection. For days 1 and 2, 67 and 59 percent of participants, respectively, who returned a urine sample completed an appointment during the period of the week they were randomly assigned to (weekday or weekend). There was no systematic variation attributable to the characteristics presented in these tables. Statistical significance was not determined.

For the first collection, there was no observed trend in the completion rate by age of the participant. Men had a higher completion rate than women—81% versus 70%. Women were much more likely to miss more than a few drops of urine during the collection procedure which is likely due to differences in anatomy and the collection protocol. Some women were unable to provide a complete collection due to commencement of their menstrual periods during the day they were scheduled to collect the urine. The completion rate for non-Hispanic whites and others was 75%; for non-Hispanic blacks it was 77%. Surprisingly the completion rate steadily decreased with increasing education. Those who were employed had a completion rate of 73% in contrast to 78% among those not employed. For day 2 the variation showed similar patterns.

For the second collection, participants aged 40-59 years had lower completion rates (84% for 40-59 years; 80% for 50-59 years) than those in the 20-39 and 60-69 groups (90% and 88%, respectively). There was no observed difference in completion rates among men and women. The completion rate for non-Hispanic whites and others was 86%; for non-Hispanic blacks it was 85%. The completion rate was higher for those with less than a high school education (93%) and lowest for those with a high school education or GED equivalent (78%). Those who were employed had a completion rate of 83% in contrast to 89% among those not employed.

## Weekend versus Weekday Collection

### First Collection

Of the 258 who agreed to collect a 24-hour urine sample, 56% were randomly assigned to collect their first urine sample on a weekend. This resulted in 55% of the scheduled 24-hour urines being on a weekday and 45% scheduled on a weekend. Below is the distribution for the period of the week they were randomly assigned to and when they agreed to be scheduled.

	WeekEND		WeekDAY	
Assigned	144 (56%)		114 (44%)	
	WeekEND	WeekDAY	WeekEND	WeekDAY
Scheduled	96 (67%)	48 (33%)	19 (17%)	95 (83%)

### Second Collection

Of the 102 who agreed to a second collection, 43% were randomly assigned to start their urine collection on a weekend. This resulted in 61% of the scheduled second collection urines being on a weekday and 39% scheduled on a weekend. Below is the distribution for the period of the week they were randomly assigned to and when they agreed to be scheduled.

	WeekEND		WeekDAY	
Assigned	44 (43%)		58 (57%)	
	WeekEND	WeekDAY	WeekEND	WeekDAY
Scheduled	24 (55%)	20 (45%)	16 (28%)	42 (72%)

#### Starting and Ending Collection at the UMEC versus at home

The gold standard in collecting 24-hour urine samples is to start and end the collection at the UMEC to encourage a complete collection. However, it is not always possible for individuals with a long commute to travel to the UMEC for both occasions. To address this issue, we assessed completion rates for participants who started and ended their collection at the UMEC versus those who started and ended collection at home. Half of participants selected for a second collection were asked to return to the UMEC to start and end collection. Results from the two protocols are as follows:

82% (n=57) of those who started and ended their second urine collection at the UMEC returned a complete sample.

88% (n=51) of those who started and ended their second urine collection at their home returned a complete sample.

#### MEC Follow-Up Components

Participation in the 24-hour urine pilot study had no adverse effect on response rates for the post-exam components, PAM and the telephone DR. Results are preliminary as PAMs continue to be received and the DRs are ongoing. The table below shows the response rate for participants 20-69 years who are eligible for PAM and DR. For example, at location 1, 90% of PAMS were returned among those who were selected for the 24 hour urine sample in contrast to only 86% being returned by NHANES participants not in the 24 hour urine subsample.



	24-Hour Urine Pilot Study	
	Selected	Not Selected
	% (n)	% (n)
PAM		
Location 1	90 (87)	86 (64)
Location 2	87 (110)	79 (57)
Location 3	88 (85)	80 (73)
Telephone dietary recall		
Location 1	91 (81)	87 (60)
Location 2	91 (109)	85 (53)
Location 3	93 (80)	85 (66)

#### Laboratory

Preliminary results of sodium excretion from 123 individuals in the 24-hour urine pilot were similar to results from a urine calibration study of timed-spot urine conducted in the Washington DC area in 2012 among 18-39 year old volunteers (1).

	Sodium, <i>mg</i>				Total Urine Volume, <i>mL</i>
	Males		Females		
	N	Mean	N	Mean	
Calibration study	186	3540	221	3088	1397
24-hour urine pilot first collection	67	3831	56	2931	1770
second collection	25	3481	16	3235	1798

#### Limitations

The three locations selected for the pilot study needed to occur in the first half of 2013 without disrupting new content in the NHANES introduced at the beginning of 2013. The racial and Hispanic origin of these three locations was almost entirely non-Hispanic white and non-Hispanic black. Thus, the number of Hispanic and Asian persons was insufficient to assess participation among these groups and the instructions developed for other languages or with the use of interpreter.

These three locations did not have extreme travel times (1 hour or more each way) to get to UMEC.

The tight schedule of having the pilot test at three consecutive locations with overlap limited the ability to fine tune the scheduling system for appointments and to modify instructions to participants during the pilot study.

### **Recommendations Based on Pilot Results**

Half of the participants selected for a second collection started the urine collection at home. The completion rates for those specimens were comparable to the other half who started in the UMEC. To maximize response rates in the 2014 NHANES 24-hour urine collection we will offer this option to participants who indicate participation may depend on the travel requirements to and from the UMEC or if the day they can start is not consistent with the UMEC schedule.

The NHANES MEC has 60% of its exam sessions occur on weekdays. Because of our success in scheduling participants to weekdays we are changing the random assignment from 50% to 60% of participants to collect on weekdays to curtail heavy weekend schedules.

### **Reference**

1. Wang CY, Cogswell ME, Loria CM, Chen TC, Pfeiffer CM, Swanson CA, Caldwell KL, Perrine CG, Carriquiry AL, Liu K, Sempos CT, Gillespie CD, Burt VL. Urinary excretion of sodium, potassium, and chloride, but not iodine, varies by timing of collection in a 24-hour calibration study. *J Nutr*, in press.

**Attachment 1: Characteristics of respondents to the first and second 24-hour urine collection, tables 1 and 2**

Table 1. Characteristics of respondents to the first 24-hour urine collection.

	Total individuals sampled for 24-hour urine collection		Returned complete urine sample*			Returned incomplete urine sample*		Made appointment but did not show*		Refused pilot*		Returned a urine sample: complete or incomplete		Returned a urine sample and collected on assigned weekday/ weekend		
	N	Col %	N	Row %	Col %	N	Row %	N	Row %	N	Row %	N	Row %	N	Row %	Col %
<b>First 24-hour urine collection</b>																
Age, years																
20-39	103	37%	78	76%	37%	9	9%	8	8%	8	8%	87	85%	68	78	36
40-49	73	26%	53	73%	25%	5	7%	5	7%	10	14%	58	80%	46	79	24
50-59	60	21%	48	80%	23%	7	12%	4	7%	1	2%	55	92%	47	86	25
60-69	46	16%	33	72%	15%	5	11%	3	7%	5	11%	38	83%	28	74	15
Gender																
Male	139	49%	112	81%	53%	7	5%	9	7%	11	8%	119	86%	92	77	49
Female	143	51%	100	70%	47%	19	13%	11	8%	13	9%	119	83%	97	82	51
Race/Ethnicity																
Non-Hispanic white/other	193	68%	144	75%	68%	18	9%	14	7%	17	9%	162	84%	122	75	65
Non-Hispanic black	83	29%	64	77%	30%	8	10%	5	6%	6	7%	72	87%	63	88	33
Hispanic	6	2%	4	67%	2%	0	0	1	17%	1	17%	4	67%	4	100	2
Education																
Less than high school	42	15%	34	81%	16%	2	5%	3	7%	3	7%	36	86%	30	83	16
High school grad/GED/ Equiv	82	29%	60	73%	28%	8	10%	5	6%	9	11%	68	83%	56	82	30
Some college or AA degree	86	30%	65	76%	31%	9	11%	5	6%	7	8%	74	86%	54	73	29
College grad or above	72	26%	53	74%	25%	7	10%	7	10%	5	7%	60	83%	49	82	26
Employment status																
Employed	177	63%	130	73%	61%	16	9%	15	9%	16	9%	146	83%	115	79	61
Not Employed	105	37%	82	78%	39%	10	10%	5	5%	8	8%	92	88%	74	80	39
<b>Total</b>	<b>282</b>		<b>212</b>			<b>26</b>		<b>20</b>		<b>24</b>		<b>238</b>		<b>189</b>		

\*The row percent for the second through fifth columns (returned complete urine sample, returned incomplete urine sample, made appointment but did not show, and refused pilot) add up to 100%.

Table 2. Characteristics of respondents to the second 24-hour urine collection.

	Total individuals sampled for second 24-hour urine collection		Returned complete urine sample*			Returned incomplete urine sample*		Made appointment but did not show*		Refused second collection*		Returned urine sample: complete or incomplete		Returned a sample and collected on assigned weekday/ weekend		
	N	Col %	N	Row %	Col %	N	%	N	%	N	%	N	%	N	Row %	Col %
<b>Second 24-hour urine collection</b>																
Age, years																
20-39	31	29	28	90%	30%	0	0	1	3%	2	7%	28	90%	19	68	30
40-49	31	29	26	84%	28%	2	7%	1	3%	2	7%	28	90%	12	43	19
50-59	30	28	24	80%	26%	5	17%	0	0	1	3%	29	97%	20	69	31
60-69	16	15	14	88%	15%	1	6%	0	0	1	6%	15	94%	13	87	20
Gender																
Male	54	50	47	87%	51%	4	7%	1	2%	2	4%	51	94%	34	67	53
Female	54	50	45	83%	49%	4	7%	1	2%	4	7%	49	91%	30	61	47
Race/Ethnicity																
Non-Hispanic white/other	73	68	63	86%	68%	4	6%	2	3%	4	6%	67	92%	40	60	63
Non-Hispanic black	33	30	28	85%	30%	4	12%	0	0	1	3%	32	97%	24	75	38
Hispanic	2	2	1	50%	1%	0	0	0	0	1	50%	1	50%	0	0	0
Education																
Less than high school	15	14	14	93%	15%	1	7%	0	0	0	0	15	100%	10	67	16
High school grad/GED/Equiv	27	25	21	78%	23%	4	15%	2	7%	0	0	25	93%	16	64	25
Some college or AA degree	37	34	32	87%	35%	2	5%	0	0	3	8%	34	92%	21	62	33
College grad or above	29	27	25	86%	27%	1	3%	0	0	3	10%	26	90%	17	65	27
Employment status																
Employed	64	59	53	83%	58%	5	8%	2	3%	4	6%	58	91%	37	64	58
Not Employed	44	41	39	89%	42%	3	7%	0	0	2	5%	42	96%	27	64	42
Total	108		92			8		2		6		100		64		

\*The row percent for the second through fifth columns (returned complete urine sample, returned incomplete urine sample, made appointment but did not show, and refused pilot) add up to 100%.