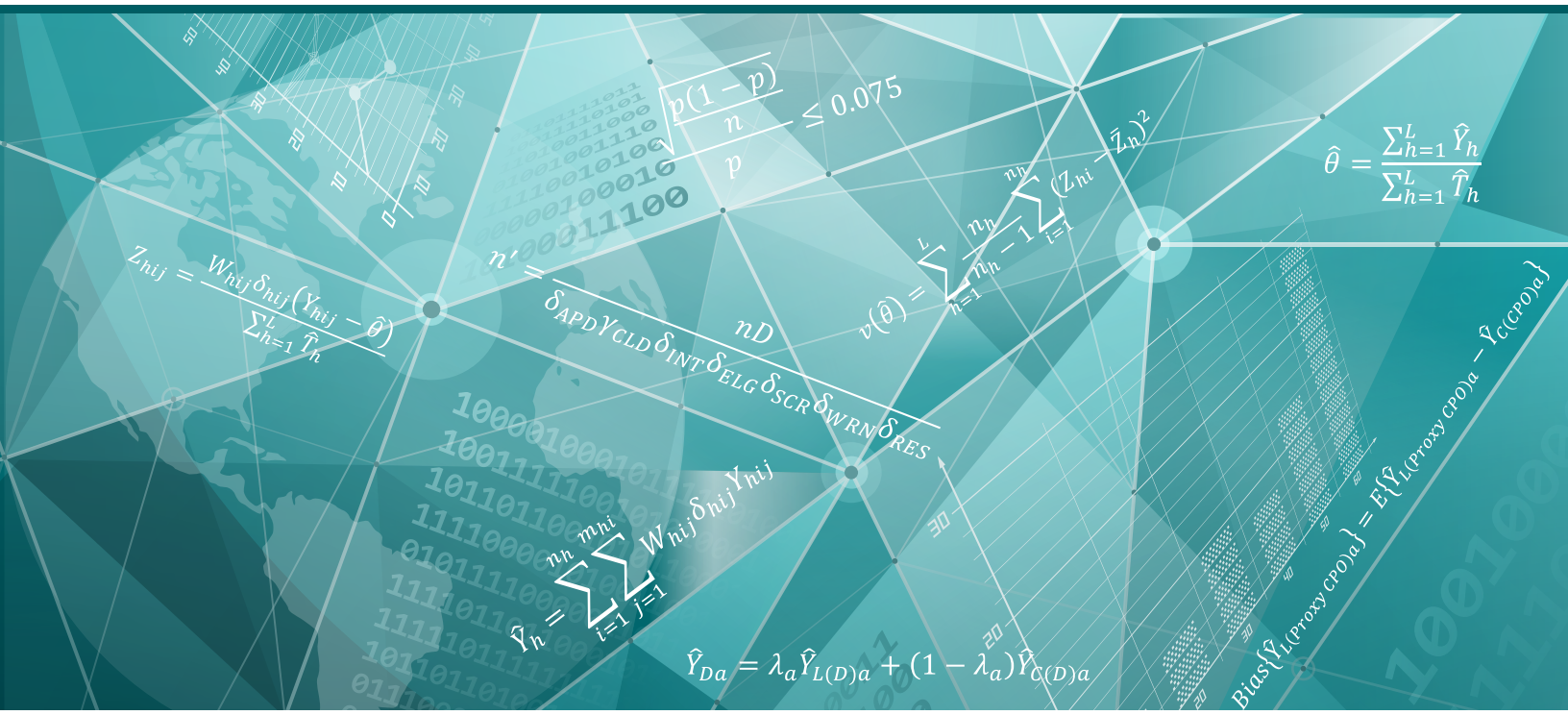
NATIONAL CENTER FOR HEALTH STATISTICS

Vital and Health Statistics

Series 2, Number 210

December 2024



National Health Interview Survey Follow-up Health Study: Feasibility Evaluation of Adding an In-home Physical Examination to a National Health Survey

Data Evaluation and Methods Research

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

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Suggested citation

Galinsky AM, Medley GE, Nguyen DT, Villarroel MA, Warren A, Zablotsky B, et al. National Health Interview Survey Follow-up Health Study: Feasibility evaluation of adding an in-home physical examination to a national health survey. Vital Health Stat 2(210). 2024. DOI: https://dx.doi.org/10.15620/cdc/159283.

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Mail Stop: SSOP
Washington, DC 20401–0001
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Data Evaluation and Methods Research

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

Hyattsville, Maryland
December 2024

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National Health Interview Survey Follow-up Health Study: Feasibility Evaluation of Adding an In-home Physical Examination to a National Health Survey

by Adena M. Galinsky, Ph.D., Grace E. Medley, M.A., Duong T. Nguyen, D.O., Maria A. Villarroel, Ph.D., Antonia Warren, Ph.D., Benjamin Zablotsky, Ph.D., Eric Leadbetter, M.S., and Aaron Maitland, Ph.D.

Abstract

Background

Adding biological measure collection to a household survey can increase the usefulness of the survey data. Between 2020 and 2021, two major federal household health surveys, both conducted by the National Center for Health Statistics—the National Health Interview Survey (NHIS) and the National Health and Nutrition Examination Survey—planned and conducted a pilot study to examine the feasibility of adding physical measurements and biological measure collection to NHIS. NHIS's large nationally representative sample can be used to calculate national and subnational estimates of health conditions and healthcare access and use, but it does not collect physical measurements or biospecimens. The National Health and Nutrition Examination Survey, in addition to an in-person survey, also includes a comprehensive physical examination that collects both physical measurements and biospecimens but does so with a smaller sample.

Objective

This report describes the study design and field operations in addition to presenting cooperation and response rates at each stage. It also offers insight into the challenges of gaining cooperation; scheduling home examination appointments; conducting home physical examinations; and shipping and analyzing biospecimens during COVID-19, as well as lessons learned and implications for the future of physical measurements and biological measure collection on NHIS and other large household surveys.

Methods

The pilot study was fielded between June and October 2021. Adult NHIS respondents who completed their survey interview in English and lived in the selected sample areas were eligible to participate. Eligible respondents were introduced to the study at the end of their NHIS interview and those who agreed to be contacted could schedule their home health examination in the weeks following their interview. The examinations, conducted by phlebotomists, included a urine sample and a venous blood sample collection, and measurement of respondents' height, weight, waist circumference, blood pressure, and resting heart rate. Participants received a $75 prepaid card and the results of all measures that were collected.

Keywords: biomarkers • gaining cooperation • scheduling • National Health Interview Survey (NHIS) • National Health and Nutrition Examination Survey (NHANES)

Introduction

There has long been interest in combining the strengths of the National Center for Health Statistics's (NCHS) flagship household health data collection systems, the National Health Interview Survey (NHIS) and the National Health and Nutrition Examination Survey (NHANES). The goals of both surveys are to track national health status, healthcare access, and progress toward achieving national health objectives. Both surveys collect survey data through household interviews from nationally representative samples of the U.S. civilian noninstitutionalized population. The NHIS sample size (about 28,000 households a year) is large enough to calculate reliable annual estimates and subnational estimates for detailed geographic and sociodemographic groups. However, it does not include any physical measurements or collection of biospecimens. NHANES, in contrast, collects the nation's gold standard nationally representative health data using physical examinations and laboratory measurements in a standardized environment, in addition to survey data.

However, its sample is currently too small to produce statistically reliable annual estimates, and its ability to make subnational estimates is more limited compared with NHIS.

The NHANES sample size limitation is a direct consequence of the infrastructure, staffing, and cost logistics that enable NHANES to produce its gold standard estimates. Specifically, the physical examination and biospecimen collection is conducted following the home survey interview, in specially designed and equipped mobile examination centers (MECs) that travel the country with a dedicated, full-time staff of health professionals, offering standardized environments for data collection. Although it would not be feasible, or easily affordable, to expand this system so it could collect data from the full dispersed NHIS sample, it would conceivably be possible to send trained health professionals to visit the homes of NHIS respondents and conduct health examinations. The addition of physical measurements and biospecimen analytic results to the NHIS data set could enable the release of annual estimates based on these data for detailed geographic, demographic, and socioeconomic groups. Even though the data would not be as precise as the measured biological data collected by NHANES, it would still enable NCHS to produce more timely estimates of national health status and progress toward achieving national health objectives, like increased health equity between detailed population groups.

In 2012, NHANES and NHIS collaborated on a pilot study designed to assess the possibility of collecting high-quality physical measurements and biospecimens in the homes of survey participants. Specifically, the Health Measures at Home Study compared health measurements of height, weight, blood pressure, and results from assays of blood collected by NHANES staff (health technicians, physicians, and phlebotomists) from the same NHANES participants in the MEC to measurements collected in the participants' homes. In the home, the blood and measurements were collected twice, once by a field interviewer and once by a health technician hired specifically for the pilot study (1–3). The equipment used in the home differed from that used in the MEC, and the blood collection differed substantially: venous blood in the MEC and dried blood spots in the home. That study found that both the field interviewers and health technicians were able to collect height, weight, and blood pressure from at least 98% of participants and dried blood spots from at least 96% of participants. Additionally, the correlations between all height and weight measurements were higher than 99% (1). The blood pressure measurements were also close, and although measurements obtained by the field interviewer in the home were higher on average than those obtained by the health technician, the magnitude of the differences was less than 5 mmHg, which is within the range of acceptable differences between blood pressure measurements according to standards of the Association for the Advancement of Medical Instrumentation (3). In contrast, while hemoglobin A1c from dried blood spots collected by field interviewers and health technicians in the home were comparable to results from assays of venous blood, the same was not true for measurements of total and high-density lipoprotein (HDL) cholesterol (2).

Although the Health Measures at Home Study demonstrated that physical measures like height, weight, and blood pressure could be measured successfully in the home, it did not evaluate the feasibility of collecting urine or venous blood in the home, although both can provide important health insights. The latter is of particular interest because of the greater accuracy of venous blood assays and the increased number of assays that can be completed with the larger quantity of blood collected through venous methods compared with dried blood spots. Also, the Health Measures at Home Study, which used a convenience sample of NHANES participants who had already completed their MEC examination when invited to participate in the Health Measures at Home Study, could not evaluate respondents' willingness to participate in, or the specific challenges of adding, a physical examination to a survey like NHIS that does not currently ask anything extra from respondents. Although up to three adult respondents are allowed per NHIS household, the NHIS respondent of interest for this purpose is the Sample Adult. The Sample Adult is the adult household resident who is randomly selected by the NHIS instrument to answer detailed health questions about themselves. More information on NHIS respondents is provided in "Methods."

In 2019, NHIS asked about Sample Adults' willingness to participate in a hypothetical study in which a nurse would come to their home and measure their height, weight, and blood pressure, collect a blood sample, and provide an unspecified incentive. About 35% of NHIS Sample Adults were somewhat or very willing to participate in such a hypothetical in-home examination (4). However, this information was collected before the COVID-19 pandemic, and it was unknown how the pandemic might impact respondents' willingness to agree to in-home measurements.

In 2021, NHIS and NHANES collaborated on the 2021 NHIS Follow-up Health Study (FHS) to learn more about the feasibility of adding an in-home health examination, including physical measures, venous blood, and urine collection, to NHIS.

Goals and Research Questions

NHIS FHS had two goals. The first was to learn if NHIS Sample Adults who completed the Sample Adult interview would be willing to participate in an in-home physical examination conducted by a health professional in the weeks following their NHIS interviews, consisting of measurement of height, weight, waist circumference, and blood pressure, and collection of a blood and urine sample. The second was to determine the feasibility of, and potential challenges to, implementing such pilot examination procedures among

NHIS's large-scale, geographically dispersed national sample. This study had the following research questions:

- What percentage of NHIS adult respondents who have completed their Sample Adult interview will participate in each stage of the in-home health examination process?
  - What percentage introduced to the study will give permission for their contact information to be given to a private, nonfederal company scheduling the appointments and conducting the examinations on behalf of NCHS?
  - What percentage who give permission to share their contact information will schedule an appointment?
  - What percentage who schedule appointments will start the in-home examination?
  - What percentage who start the in-home examination will complete each examination component?
  - What percentage of the blood and urine specimens provided by Sample Adults will be of sufficient quantity for analysis?
  - What concerns will Sample Adults have at each stage, what reasons will they give for refusing, and what reasons will examination participants give for participating?
- What are the operational challenges of each step of the in-home health examination process?
  - Gaining initial agreement to participate
  - Scheduling the home health visit appointments
  - Conducting the in-home examinations
  - Packaging, shipping, and analyzing the biospecimens from, and reporting the results of, these home health examinations

Report Organization

This report is organized into seven main sections. The first section provides an overview of the study methods, including the constraints that determined many of the operational parameters. The second through sixth sections provide results answering the research questions. The final section discusses the feasibility of implementing these procedures among the full NHIS sample. This section includes a summary of the challenges encountered in the pilot study that would be minimized or eliminated if the procedures were implemented with the full sample.

Methods

NHIS

NHIS collects survey data annually on a broad array of health and sociodemographic topics from a large, nationally representative sample of the U.S. civilian noninstitutionalized population. The U.S. Census Bureau is the data collection agent for NHIS. A U.S. Census Bureau field representative (FR) visits the sampled addresses and attempts to gain cooperation from the household residents. Because this task has become more difficult in recent years, additional training to address doorstep concerns has been added to FR NHIS training. However, FRs have always been provided with suggested language and approaches, and then instructed to use their judgement to choose the appropriate language for each case. Most NHIS FRs are highly experienced at gaining cooperation; they are usually members of the communities they work in and have worked on the survey for years (5). This unscripted approach to gaining cooperation is used by many other surveys, including NHANES. This is worth noting because the NHIS FHS took a different approach to the process of gaining cooperation.

Once the household resident agrees to participate, the FR collects a household roster including basic demographic information for all household members. Next, the instrument randomly selects one adult (the Sample Adult) and one child, if applicable (the Sample Child), per household. The Sample Adult answers for themselves unless they are physically or mentally unable to do so, in which case a knowledgeable adult proxy may answer on their behalf. An adult knowledgeable about the Sample Child's health answers on behalf of the child. NHIS interviews are typically conducted in person, with telephone follow-up when necessary. However, the COVID-19 pandemic impacted typical interviewing procedures and, as a result, a higher percentage of Sample Adult interviews were conducted in part or entirely by telephone after March 2020 compared with before that time. Specifically, during the period when FRs were introducing Sample Adults to the NHIS FHS during June through September 2021, 56.8% of all Sample Adult interviews were conducted in part or entirely by telephone. In contrast, in 2019, 34.3% of Sample Adult interviews were conducted at least partially by telephone (6).

The NHIS interview is about 1 hour long. NHIS respondents do not receive an incentive for participating.

NHIS and NHANES Collaboration

Although NHIS took the lead in planning the NHIS FHS, including coordinating with the U.S. Census Bureau and selecting the primary contractor who scheduled the appointments and conducted the examinations, NHANES contributed key infrastructure and expertise, primarily but not exclusively for the physical examination, laboratory work, and results reporting aspects of the project.

IT Security Boundary

The NHIS FHS used the NHANES IT security authorization boundary, which included several components adapted for this pilot study. The foundational component was the information technology infrastructure, such as the database that included Sample Adult information, results

of contact attempts, home examination appointment information, examination results, and laboratory results. The next component was the internal web application that schedulers and recruitment specialists used to interact with the study scheduling system, and that they and the health representatives used to interact with the electronic record of contacts system. Along with this, health representatives used a separate application to enter the results from the home examination. The staff completed these tasks using smart phones, tablets, and laptops dedicated to this project and configured to keep all information secure within the security authorization boundary. The last components included the VPN (virtual private network) gateway, which ensured secure encryption for transmitting home examination results from the field instrument to the database, as well as the secure File Transfer Protocol "mailbox" used for receiving laboratory results from the Quest Diagnostics laboratory.

Medical Officer

The NHANES medical officer advised the planning team on all clinical aspects of the study design and served as the public-facing medical officer for the project, as needed. In the results report that participants received after their examination, the medical officer was listed as the contact person for questions about their results. The medical officer also called participants whose biospecimen test results required expedited reporting because the results were significantly outside of the normal range, indicating a potentially life-threatening condition, referred to in this report as critical results. See "Preliminary Report of Findings" and "Critical Laboratory Test Value Reporting" for more information.

NHIS FHS Interagency Agreement

To understand the reasons for many of the study design decisions, it is necessary to understand the other non-NCHS groups that worked on the study. First, was the U.S. Census Bureau. The Sample Adult was introduced to the study by the Census FR at the end of the NHIS Sample Adult interview. FRs' experience at gaining cooperation and the rapport they build during NHIS interviews was expected to make them ideal recruiters. However, because the U.S. Census Bureau's authorizing legislation includes conducting surveys but does not include conducting health examinations, NHIS FRs could not take a substantive role in the NHIS FHS. A substantive role was defined by the U.S. Census Bureau as anything other than the activity that the FRs already perform, namely reading NHIS instrument text and inputting respondent answers. Specifically, FRs could inform the Sample Adult about the study by reading text from the NHIS instrument screen, answer questions about the study using a Frequently Asked Questions (FAQ) form provided in the instrument, and record the contact information that the Sample Adult shared with the study schedulers through NHIS instrument questions. Because these activities were defined by the U.S. Census Bureau as separate from the study, the FRs could perform them.

The restriction of FRs to the activities they already perform when administering the NHIS instrument had a cascading impact on NHIS FHS study methods and FR training. Because this process was required to be scripted, FRs could not use their full cooperation-gaining skills when introducing the study to the Sample Adults and asking about their willingness to be contacted to schedule an appointment. Also, there were restrictions on the wording of that script, as well as on the training that the FRs received in reading it. For example, the introduction was required to include the information that the U.S. Census Bureau played no role in the study. Also, the instrument text that the FRs read about NHIS FHS could not be described in the training as an "invitation" to participate because that suggested that the FRs played a role in the study. The section "Successes and Challenges of Informing Sample Adult About Study and Related FR Tasks" discusses how these restrictions may have impacted the percentage of NHIS Sample Adults who agreed to be contacted.

External Contractors

Because NHIS does not include a home examination, it was necessary to contract with a company who could handle the appointment scheduling, home examinations, biospecimen analysis, and results reporting. Because the study involved data covered by the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), the law that governs the collection and protection of data collected by federal statistical agencies, the contractor needed to meet the strict requirements of this authorization. Only a limited number of contractors were able to meet the CIPSEA requirements in time for the start of the study.

Westat, which collected NHANES data at the time, was selected as the FHS contractor. Westat managed all field operations, including appointment scheduling, noncontact and refusal follow-up, refusal conversion, home examinations including participant incentive provision, and biospecimen analysis and results reporting. Westat also developed and provided the training for the schedulers, recruitment specialists, and phlebotomists; prepared the staff competency assessments; and provided the data collection systems and information technology for all but one step of the process. (That step was identifying study-trained ExamOne phlebotomists available at the appointment time requested by the participant. More information on this topic is provided in "COVID-19 Screening and Setting the Appointment.") Westat also supplied each project staff member with an encrypted laptop, tablet, and smart phone, configured to keep the data safe within the security authorization boundary, for their use during the pilot study. Finally, Westat reported the results to participants, reported results requiring priority reporting to the medical officer, and delivered a data file and documentation to NCHS.

Westat also subcontracted with ExamOne, which administered staff competency assessments, attempted to contact the Sample Adults, scheduled participant appointments, and completed the home health examinations. The ExamOne staff who were trained and passed the competency assessment for NHIS FHS scheduling protocols are referred to in this report as schedulers. ExamOne phlebotomists who were trained and passed the competency assessment for NHIS FHS scheduling and home visit protocols are referred to in this report as health representatives.

Certain ExamOne business practices and policies impacted how appointment scheduling responsibilities were distributed between Westat and ExamOne staff. Specifically, ExamOne phlebotomists were not used to gaining cooperation from study participants, so ExamOne expressed doubt they would be able to recruit adequate phlebotomists to work on the study if recruitment was part of their responsibilities. Furthermore, ExamOne was concerned that any recruited phlebotomists might have trouble following the study's scheduling contact attempt protocol and convincing reluctant Sample Adults to participate. Lastly, only ExamOne staff had access to the proprietary ExamOne portal and calendar where the ExamOne phlebotomists document their availability; Westat staff could not access it. As a result, ExamOne's standard scheduling staffing model was implemented. ExamOne schedulers made the contact attempts and assigned phlebotomists to cases when scheduling the initial appointment with the participant.

ExamOne subcontracted with Quest Diagnostics, a national provider of diagnostic testing certified by the Clinical Laboratory Improvement Amendments (CLIA), to receive the blood and urine specimens and conduct the biospecimen analyses. Quest Diagnostics' main goal is to complete biospecimen testing for healthcare systems, physicians, and hospitals, but it also provides biospecimen testing services for research studies. Most of these are clinical research studies.

NHIS FHS Study Design

Overview

FRs told a small, purposeful sample of Sample Adults at the end of their interview that NCHS was inviting them to participate in a follow-up health study and asked if NCHS could provide the contractor hired to collect the study data, ExamOne, with the Sample Adult's contact information so the contractor could contact them to schedule an appointment. If the Sample Adult agreed, their information was collected and shared, through NCHS, to Westat. Westat then entered the information into the system where it could be accessed by ExamOne staff. ExamOne and Westat attempted to contact the Sample Adults by phone and, if necessary, followed up with letters, text messages, and e-mails, following a specific protocol for all contact attempts. If an ExamOne scheduler was able to schedule an appointment, the scheduler then assigned a study-trained ExamOne phlebotomist to conduct the home visit. That health representative then attempted to confirm and keep the appointment, obtain informed consent, and complete the home visit. After each successful home visit, the health representative packaged and shipped the blood and urine samples to Quest Diagnostics, ExamOne's subcontractor. Quest Diagnostics laboratory technicians tested the urine samples for glucose, hemoglobin, and analytes related to kidney function (protein, microalbumin, and creatinine). They also tested the blood samples for analytes related to diabetes, liver and kidney function, cholesterol, and anemia. After concluding the testing, they returned the test results to Westat, which then prepared and mailed reports of findings to participants and prepared a final data file for NCHS.

NHIS FHS Sample

The NHIS FHS initial sample included all NHIS housing units in selected primary sampling units (PSUs) in nine states in June–September of 2021. The nine states spanned two Census regional offices and included both rural and urban PSUs. The NHIS FHS sample was a purposeful sample based on the location of the FRs and ExamOne's phlebotomists. All Sample Adults in households selected for NHIS FHS who completed the Sample Adult interview in English and for themselves were eligible. Resources for the pilot study did not allow for inclusion of respondents who did not speak English or whose physical or mental condition prevented them from responding directly.

NCHS's intention was to include enough households in the initial sample to ensure that ultimately at least 900 Sample Adults would agree to be contacted to schedule an appointment. This was the number of households given in the "Statement of Work" in the "Request for Quotation" issued by the Centers for Disease Control and Prevention, through which NCHS hired Westat, and what Westat used to plan their staffing. The PSUs selected for NHIS FHS contained 3,057 housing units. Budget and geographical constraints were the key drivers of this initial sample size. This starting sample of 3,057 households yielded 1,148 Sample Adults who met the eligibility criteria: they completed the Sample Adult interview in English for themselves. These 1,148 were asked about NHIS FHS. The percentage and number of those 1,148 Sample Adults who agreed to be contacted to schedule an appointment is presented in "Results."

Invitation to Study and Collection of Permission to Be Contacted

At the end of the NHIS Sample Adult interview, FRs informed eligible Sample Adults about NHIS FHS. The FR read the script from the NHIS instrument screen (Appendix I), which was programmed to display the text about NHIS FHS only if the Sample Adult met all the eligibility criteria. This script explained the goal of the study, what participants would be

asked to do, and that after completing the home examination participants would receive their test results and $75. The $75 incentive was provided as a prepaid Visa gift card. The amount on the card was selected to roughly correspond with the incentive offered in a 2018 NHANES follow-back study. That study was somewhat similar in scope to NHIS FHS but also differed in many key ways. See "Feasibility of Implementing Protocols With Full NHIS Sample." The script explicitly stated, "The Census Bureau does not have a role in this study." The FR then read a question asking for permission to pass the Sample Adult's contact information to the contractor: "ExamOne, a Quest Diagnostics company, is collecting the study data for NCHS. May NCHS provide them with your name, age, and gender, along with your address and phone number so they may contact you to schedule an appointment?" The name of the contractor was included so the Sample Adult would understand why that company was calling when it appeared on their phone's caller ID screen. If the Sample Adult agreed and provided a phone number, the FR then asked what days and time of day they preferred to be contacted and were then asked for permission to be contacted with text messages or e-mails. This information was then passed on to Westat.

If the Sample Adult refused the request or refused to provide a phone number, the FR asked for their main reason for not wanting to participate. Shortly after the FR left the home, they completed the section of the NHIS instrument designed to collect paradata about the interview. For the NHIS FHS, two additional questions were added to that section (Appendix II). Specifically, the FR first entered whether or not they gave the Sample Adult a copy of the study brochure. If the Sample Adult refused to participate and refused to explain why, the FR was asked to enter their impression of the Sample Adult's reasons for refusing. If the Sample Adult agreed to participate and gave a valid phone number, the FR was asked to enter the reasons the Sample Adult gave, if any, for agreeing to be contacted by a study scheduler. Coding the Sample Adult's verbatim responses to the question about their reason for refusing occurred in stages. After the first weeks of data collection were completed, NCHS staff reviewed the verbatim responses and created an initial list of refusal categories. Responses were then routinely coded into those categories during the remainder of the field period in which FRs read these questions. Two coders separately coded all the responses then compared their results and resolved any differences. Also during this coding process, the coders would occasionally add a new category when needed. After the initial coding was completed, reason-for-refusal categories were collapsed to form nine major categories.

Coding the FRs' responses to the question about the reason the Sample Adult refused also occurred in stages and followed the same pattern. Two NCHS staff members coded these answers, compared their results, and resolved any differences. After the initial coding was completed, reason for agreement categories were collapsed to form seven major categories.

Case data transfer

NHIS FRs were trained to transmit all completed cases to the U.S. Census Bureau at the end of each workday. When the FR transmitted the completed case, the NHIS FHS information was transmitted with the rest of that case's NHIS responses. Each Monday, Census staff created a file including only the NHIS FHS-relevant data and sent that file to NCHS staff. NCHS created a subset of that data file, including only age, sex, and contact information for NHIS FHS Sample Adults and sent that file to Westat each Monday or Tuesday. Within 24 hours of receipt, Westat uploaded the information to the study's secure computer system so ExamOne could then begin scheduling those appointments. NCHS was required to be the intermediary; Census staff could not pass the Sample Adult's information directly to Westat because the U.S. Census Bureau and Westat did not have an agreement or contract with each other. This restriction affected scheduling operations, which are discussed in "Appointment Scheduling Delays" and "Participant Suggestions for Improving Appointment Scheduling Procedures." All files were passed using secure methods. NCHS did not provide any Sample Adult health data to the contractors.

Study Materials

NHIS FHS initial brochure

NCHS created a study brochure in collaboration with the U.S. Census Bureau (Appendix III). The study brochure described reasons why the Sample Adult might want to participate, safety measures and privacy protections, what to expect as a participant, and what participants would receive, including a list of the laboratory measures and health tests included in the results report. The study brochure emphasized that the study appointment would be scheduled at a convenient time for the participant. It included a toll-free number, answered by NHIS FHS study staff at NCHS, with an invitation to call for more information about the study. If the interview was in person, the FR offered the Sample Adult a copy of the study brochure when reading the NHIS FHS script. If the interview was conducted over the phone, the FR mailed the brochure to the Sample Adult in a stamped envelope provided by NCHS after the interview was completed.

NHIS FHS "why participate" brochure

NCHS also created a second study brochure in collaboration with the U.S. Census Bureau (Appendix IV) to convince reluctant Sample Adults to participate. In contrast with the initial brochure, the "why participate" brochure had more pictures, less text, and included a full-page spread with brief reasons for participating. Because this brochure was sent after the Sample Adult's contact information had been loaded into the NHIS FHS system, this brochure included the ExamOne scheduling phone number instead of the NCHS number.

NHIS advance letter

The NHIS advance letter (available from: https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2021/advance-letter-2021.pdf) mailed to respondents ahead of the FR's first home visit was not modified for NHIS FHS respondents, primarily to avoid influencing the household's decision to participate in NHIS. Additionally, it was not possible to know in advance if the Sample Adult's interview in a selected household would be conducted in English and not through a proxy, which were eligibility requirements. Although it would have been possible to create an NHIS–FHS version of the NHIS advance letter for the FRs to give to the Sample Adult during the introduction, the NHIS FHS initial brochure was considered sufficient.

Scheduling Protocol

ExamOne scheduling staff attempted to contact Sample Adults following a scripted, study-specific protocol in which the next step was determined by the Sample Adult's response or lack of response (Appendixes V–VII). The ExamOne scheduler recorded the results of each contact attempt in the system. If the scheduler reached a willing Sample Adult, the scheduler screened the participant for COVID-19 (Appendix VI) and, if the participant passed, the scheduler attempted to schedule the appointment. If a study-trained ExamOne phlebotomist was available when the Sample Adult was available, the scheduler scheduled the appointment. If ExamOne schedulers could not reach the Sample Adult, or reached the Sample Adult but they initially gave a soft refusal (refused in a manner that indicated, in the scheduler's judgement, that the Sample Adult could potentially be converted), then Westat sent a letter encouraging them to call the scheduling number (Appendix VII) and two study brochures (Appendixes III and IV) via FedEx. The language in the letter for noncontacts differed appropriately from the language in the letter for refusals. Westat recruitment specialists attempted to contact and gain the cooperation of the Sample Adults who did not respond to the refusal letter. When successful, they brought an ExamOne scheduler into the call to complete the rest of the steps for scheduling the appointment. If the scheduler spoke to the Sample Adult and the Sample Adult did not refuse but also did not schedule an appointment, no phlebotomist was yet available at a convenient time for the Sample Adult, or an appointment needed to be rescheduled, the case was returned to the schedulers so they could try calling again in the next call cycle. When the Sample Adult gave a hard refusal, which meant refusing in a way the scheduler judged to be hostile or final, whether before or after scheduling an appointment, the case was given a final outcome code of refused.

Phone calls

The ExamOne schedulers were authorized to schedule the home visits immediately after Westat uploaded Sample Adult information to the system. They were expected to schedule as soon as possible and required to do so no more than 24 hours after the case was loaded into the system. However, the time between the Sample Adult agreeing to be contacted and the scheduler placing the first phone call could be as much as a week and sometimes longer, if the FR was delayed in transmitting the case. The schedulers placed calls and were available to answer incoming calls Monday through Friday, 8:00 a.m.–9:00 p.m. CT; Saturday, 9:00 a.m.–6:00 p.m. CT; and Sunday, 1:00 p.m.–6:00 p.m. CT. The schedulers recorded the results of each contact attempt and received phone call, including any reasons the Sample Adult gave for refusing or agreeing to participate, using the web application that connected to the NHIS FHS scheduling system. The schedulers made calls following the study's recruitment protocol, which included using scripts (Appendixes V–VII) for all contacts with the potential study participants to ensure consistency and compliance with the study protocol.

If the scheduler could not reach a willing Sample Adult in the initial call, schedulers made up to two more phone attempts over 5 days to schedule the appointment. They took the respondents' preferred contact days and times into account when making subsequent calls, although this was not always feasible depending on when the 5-day call window was set to close. The scheduler left a message if they reached a voice mailbox or answering machine (Appendix V).

If the scheduler reached the Sample Adult and they gave a soft refusal (refused in a manner that indicated, in the scheduler's judgment, that the Sample Adult could potentially be converted), Westat sent that Sample Adult a refusal mailing; see "Follow-up mailings." If the scheduler reached the Sample Adult and they gave a hard refusal (a refusal that sounded firm or hostile in the judgement of the scheduler), that case was closed out with a final outcome code of "refused," and no further refusal conversion efforts were made.

COVID-19 screening and setting appointment

If the scheduler reached a willing Sample Adult, the scheduler screened the participant for COVID-19 symptoms (Appendix VI) to determine when an appointment could be scheduled. The screener included a slightly modified version of the COVID-19 screening questions recommended by the Centers for Disease Control and Prevention when the pilot package amendment was submitted to the NCHS Ethics Review Board (ERB) the first time. The questions were edited for clarity and brevity. If the study participant answered "yes" to any of the screening questions, the scheduler made an appointment for at least 2 weeks into the future. Otherwise, the scheduler made the appointment for the earliest possible date that was both convenient for the participant and on which an ExamOne study-trained phlebotomist was available. To identify such a date, the scheduler used ExamOne's established protocol for assigning phlebotomists. Specifically, to identify an available health representative, the scheduler consulted the ExamOne portal and calendar where the ExamOne phlebotomists

documented their availability for all ExamOne studies they work on. There was no interaction between the calendar that ExamOne maintained and the NHIS FHS systems, and, as stated previously, Westat staff were unable to access this system.

Phlebotomists usually, but not always, kept their information current, so schedulers were sometimes unaware when their availability changed. ExamOne's requirement that their schedulers—and only their schedulers—use this restricted-access system for viewing and scheduling phlebotomists, and calendar inaccuracies of phlebotomist availability, impacted operations (see "Difficulty Finding an Available Health Representative") and may have impacted participation (see "Inability of Recruitment Specialists to Schedule Appointments" and "Participant Suggestions for Improving Appointment Scheduling Procedures"). After identifying a mutually agreeable date and time and scheduling the appointment in the NHIS FHS system, the scheduler then provided the Sample Adult with instructions about how to prepare for the home visit (Appendix VII). This included information noting that some of the laboratory tests would be more accurate if the participant did not eat for 8 hours before the appointment, but that the Sample Adult could still participate no matter when they last ate.

Although the participant's home was the recommended location for the examination, the participant could request a different location, such as their porch or workplace. Ultimately, the health representative and participant had to agree on the location.

E-mails and text messages

If the scheduler did not speak to the Sample Adult, the system sent the Sample Adult a text message, e-mail, both, or neither (Appendix V), as determined by which permissions the Sample Adult had given when asked by the FR in the introduction to the study at the end of the Sample Adult NHIS interview. The e-mail and text message asked the respondent to call ExamOne's toll-free number to schedule the appointment. The system sent these automated messages up to two times, each immediately after the scheduler documented the unsuccessful phone contact in the system.

Follow-up mailings

After the ExamOne scheduler made three phone call contact attempts within the 5-day call window, if none of those attempts resulted in speaking with the Sample Adult, Westat staff sent the respondent a noncontact letter (Appendix VIII) via FedEx encouraging them to participate, with instructions about calling the toll-free number to make the appointment. If during that 5-day call window a respondent gave a soft refusal, Westat staff sent the respondent a refusal letter (Appendix VIII) via FedEx acknowledging their reluctance and encouraging them to reconsider. Both the noncontact and refusal mailings included a copy of the study brochure used during the initial contact (Appendix III) and a separate brochure (Appendix IV) listing reasons why some might choose to participate. Cases were eligible to receive only one letter—either the noncontact or refusal letter. If the scheduler successfully contacted the participant during the initial call cycle and the participant did not refuse (that is, neither mailing was sent) but also did not schedule an appointment, the case was returned to the schedulers for another call cycle and was eligible to receive a mailing during that subsequent call cycle. Westat staff reviewed cases in the NHIS FHS system each weekday to identify those that needed a follow-up letter and sent the appropriate material the same day.

Refusal conversion calls

Westat recruitment specialists began calling potential participants who had given soft refusals 2 days after the refusal mailing was sent, if the Sample Adult had not called ExamOne by that time, to schedule the examination or conduct refusal conversion efforts as needed. The recruitment specialists called up to two times in a 3-day period. Before making calls, they reviewed the participant's preferred contact days and times and previous contact history to determine when to call. No further attempts were made if the recruitment specialists were unable to reach the Sample Adult after two attempts or the Sample Adult declined to participate. If a recruitment specialist reached a Sample Adult who was willing to schedule a visit, they called an ExamOne scheduler who could schedule the actual appointment. Recruitment specialists, like the schedulers, documented the results of each call in the system as well as any reasons given by the Sample Adult for agreeing or refusing.

Timing of scheduling protocol stages

As noted previously in "Case Data Transfer," NCHS typically provided Westat with the weekly file of respondents who agreed to be contacted on Monday or Tuesday, and Westat released the cases for the schedulers to begin making calls the day the file was received or the following day. This flow meant that the 5-day call window for the batch of released cases ended on the weekend. On the following Monday, Westat identified cases without a scheduled appointment from the previous week's batch of cases that should receive the noncontact mailing. Westat prepared and sent the follow-up packages on Monday or Tuesday, with the call window for the Westat recruitment specialists starting on Wednesday or Thursday and ending on Saturday or Sunday.

Extra call cycles

Cases were returned to the schedulers for another cycle of calls for the following reasons: (1) the Sample Adult asked to be called back within a specific time frame, (2) the scheduler had spoken with the Sample Adult previously and was actively working to identify an appointment date and time that worked for both the health representative and Sample Adult, and (3) the Sample Adult answered "yes" to one of the COVID-19 screening questions (Appendix VI)

and was flagged for another cycle of calls 2 weeks later. In some instances, ExamOne supervisors and Westat managers placed cases on hold before returning them to the scheduler for another cycle of calls. They did this when, for example, the Sample Adult was out of town for an extended period and requested a callback weeks later, or ExamOne needed to arrange for a health representative to travel outside of their assigned location to conduct the study visit.

Appointment reminder and rescheduling appointments

Three days before the scheduled visit, the ExamOne supervisor sent a reminder to the assigned health representatives to remind the participant of the appointment using the participant's preferred contact mode: e-mail, phone, or text message. One or 2 days before the appointment, the health representative e-mailed, called, or text messaged, as requested, to provide an appointment reminder (Appendix IX). Midway through the field period, health representatives requested to use phone reminders because they could administer the COVID-19 screening questions if they reached the participant. In mid-August, the reminder protocol changed to Sample Adult-preferred mode, followed by a phone call.

The appointment reminder also included the information about fasting. If the health representative was able to reach the participant by phone, they answered any questions the participant had and readministered the COVID-19 screener. If the participant did not pass the screening, the visit was rescheduled at least 14 days into the future.

The visit could also be rescheduled if the participant requested it. If the participant and health representative knew their availability and were able to agree on a date and time for the rescheduled appointment, the health representative rescheduled the home visit immediately. Otherwise, the schedulers would call later to reschedule. If the health representative could not reach the respondent, they left a message if possible and still visited the home at the appointed date and time.

Home Visit COVID-19 Safety Protocol

Health representatives used a four-step COVID safety protocol on the day of each home examination appointment. First, they completed a COVID-19 self-assessment each workday, using the same screening questions asked of study participants (Appendix VI). If the health representatives did not pass, they could not work that day and the visit was rescheduled. Second, they wore wear full personal protective equipment, including a face shield, surgical mask, laboratory coat or long sleeves under scrubs, gloves, and closed-toe shoes before approaching the participant's home. This was for their safety and the safety of study participants. Third, they screened the participant for COVID-19 before entering the home to conduct the examination (Appendix VI). If the participant did not pass the screening, the visit was rescheduled as described in the previous section. Fourth, the health representative covered the signature pad used to obtain informed consent with a sheet of clear barrier film before each participant signed. The participants signed using an individually wrapped, single-use, disposable wooden stylus.

ExamOne reported no known instances of the health representatives contracting COVID-19 from a study participant, or of study participants contracting the illness from a health representative.

Biospecimen Collection Kits

Westat developed a collection kit specific to the needs of this study in collaboration with ExamOne and Quest Diagnostics (Appendix X). The kits included the consent documents, COVID-19 safety supplies, the prepaid Visa gift card, a blank initial report of findings, and all supplies needed to safely collect, label, package, and ship the blood and urine samples, including the laboratory requisition form. The COVID-19 safety supplies included surgical face masks, hand sanitizer, and sanitizing wipes.

Each participant was assigned a single four-digit identifier, which was preprinted on labels included in the kit. The health representative attached these labels to the biospecimen containers and to the laboratory requisition form. The health representative also entered this identifier into the instrument during the checkout phase of the home examination protocol. Westat worked with Quest Diagnostics to create and print the laboratory test requisition forms, which only listed the study-specific blood and urine tests.

The shipping supplies included the boxes used to send the samples via FedEx, with all 13 required International Air Transport Association markings and a shipping label to eliminate errors by the health representatives. Westat assembled the kits before the start of data collection, in time for the health representative training.

Westat and ExamOne also developed a system to provide kits to health representatives as needed, to ensure a sufficient supply chain. Each health representative received three kits before the start of biospecimen collection. One kit was for training, and two were for use with participants. As cases were assigned to health representatives, they informed the ExamOne scheduler of the number of kits they needed. An ExamOne manager provided a consolidated list to Westat at regular intervals, and the Westat warehouse sent the resupplied kits to the health representatives through overnight shipping. The warehouse staff also provided tracking information to ExamOne.

Anthropometric and Blood Pressure Equipment

In addition to the kit, the health representatives carried a digital scale to measure weight; a hard tape measure, straight-edge ruler, and sticky note to measure height; and a soft tape measure to measure waist circumference. They also carried a sphygmomanometer, regular and large

blood pressure cuffs, and a stethoscope to measure blood pressure. This equipment was provided by ExamOne. The next section and Appendix XI explain how this equipment was used.

Home Examination Protocol

Protocol summary

If the participant passed the COVID-19 screening, the health representative began the home examination protocols. These were approved by the NCHS ERB, as described in the following section, and were similar to life insurance examination protocols (Appendix XI). The protocols included obtaining informed consent (Appendix XII), collecting body measurements and biospecimen samples (Appendix XIII), administering a survey about the participant's study experience (Appendix XIV), entering the examination and survey data into the instrument on their laptops, attaching the participant's specific 4-digit specimen identifier labels to the biospecimen containers, providing the participant with a paper copy of their initial results and the $75 prepaid Visa gift card, and entering the Visa card proxy ID into the laptop. Taking body measurements and biospecimen samples consisted of measuring the participant's height, weight, waist circumference, and blood pressure; collecting a urine sample; and collecting a venous blood sample. To complete this protocol, the health representative used the biospecimen collection kit and anthropometric and blood pressure equipment described in the previous section. The following sections provide more detail on the protocol components.

Informed consent

To obtain informed consent, the health representative gave the participant a hard copy of the informed consent form and the Measurement and Laboratory Test Explanation handout (Appendixes XII and XIII) and asked the participant to read them. Then they asked the participant to sign their name on an electronic signature pad that was attached to the health representative's laptop, to document their consent.

Urine collection

To collect the urine, the health representative provided the participant with a sterile 4-ounce collection cup and instructions for collecting about 20 mL of urine in the cup. After the participant returned the urine cup, the health representative transferred a portion of urine from the sterile cup into two transport vessels and labeled all three containers with unique specimen IDs using preprinted labels provided by Westat. After dividing the sample, the sterile collection cup contained enough urine for the urine hemoglobin test. One of the transport vessels contained about 10 mL of urine for total protein, microalbumin, and creatinine testing. The second vessel contained about 10 mL for urine glucose testing. These methods were designated by Quest Diagnostics; see "Biospecimen Processing and Testing."

Anthropometry, blood pressure, and pulse

Before measuring the participant's height, weight, and waist circumference, the health representative asked the participant to remove their shoes and any heavy outer clothing. Height was measured in inches using a steel measuring tape, sticky note, and straight edge. Complete details of how the health representative used the equipment to measure height are provided in Appendix XI. Weight was measured in pounds using a digital scale placed on a hard surface. Waist circumference was measured at the umbilicus, with the abdomen relaxed and the soft measuring tape at the same level front and back. Weight and waist measurements were not collected from pregnant women.

The health representative used a sphygmomanometer and stethoscope to take three blood pressure readings (systolic and diastolic) at 30-second intervals on the same arm after an initial 5-minute rest period. During the rest period, the participant sat with their back supported and legs uncrossed and was asked to remain still and not talk. The health representative took a single pulse measurement manually at the participant's wrist.

Blood collection

The health representative collected the venous blood into two 10 mL serum separator tubes and one lavender tube using a 21-gauge butterfly needle and following standard phlebotomy protocols. The health representative labeled all three tubes with unique specimen IDs using preprinted labels provided by Westat. Blood was not collected if the participant had hemophilia or had received cancer chemotherapy in the past 4 weeks. After collecting the blood, the health representative mixed it by gently inverting the tubes 8 to 10 times, which is standard laboratory practice and ensures the blood is thoroughly mixed with any of the additives in the tubes.

The health representatives centrifuged the serum separator tubes using Quest Diagnostics protocols within an hour after leaving the home. Centrifuging the samples separates the whole blood into its individual components, red blood cells, and serum. This is necessary when only red cells, serum, or plasma is required for testing, or if certain biological processes will affect the results, such as red blood cells using the glucose when in the collection tube. For the blood glucose testing in this study, the serum was tested, and separating the serum from the red cells within 1 hour of collection was a priority for accurate results. Only the hemoglobin and hemoglobin A1c tests used whole blood. The other tests required serum for testing.

Visit checkout and post-examination survey

After collecting the venous blood, the health representative administered a survey about the participant's study experience (Appendix XIV). This survey included questions about how easy or difficult it was to complete various steps

of the process, ideas for improving the process, concerns about participating, and reasons for participating.

As the health representatives completed the protocol, they entered the examination data, paradata, post-examination survey data, and unique 4-digit specimen identifier into the instrument on their laptops. The examination instrument on the laptop displayed limited on-screen reminders about the protocol, primarily data entry instructions on the correct unit or format (for example, enter height in inches to the nearest half-inch; enter time as HH:MM a.m. or p.m.; if the participant says 12 "midnight," code as 12:00 a.m.). Additionally, for some items the instrument displayed an error message if the health representative entered an unusual or invalid entry.

After administering the post-examination survey, the health representative completed and provided the participant with the preliminary report, along with the prepaid Visa gift card and instructions for using the card before leaving the home. An example paper report showing participant height, weight, waist circumference, blood pressure, and resting heart rate is shown in Appendix XV. Participants received the prepaid card if they completed at least one of the following components: urine collection, anthropometry, blood pressure measurement, or blood draw. At the end of that day, the health representative logged into the secure VPN within the NHANES IT security authorization boundary and transmitted the results of the examination.

Packaging and Shipping Biospecimens

After leaving the home, and within 1 hour of collection, the health representative centrifuged the serum venous blood tubes to separate the red blood cells from the serum in the blood.

The health representative also completed the Quest Diagnostics laboratory sample requisition forms for the blood and urine samples, including entering the participant's unique 4-digit identifier. By recording the sample identification number from the labels on the tubes and vessels in both the instrument on the secure laptop and the laboratory requisition form, Westat was able to match each set of laboratory results to the correct participant when the results were transmitted from Quest Diagnostics, while protecting the actual identity of the participant. Westat maintained the link between the specimen ID and the study participant's data within a secure IT environment hosted at Westat to ensure Quest Diagnostics did not have any of the participant's personally identifiable information.

To help ensure the samples arrived at the laboratory in time and at the correct temperature for all planned tests, the samples were shipped via FedEx overnight to the Quest Diagnostics laboratory in Lenexa, Kansas, on the day of collection. This was necessary because the stability window of the urine sample in the tube for glucose testing was 72 hours after collection, while the stability window of the blood sample for blood hemoglobin testing was only 48 hours after collection. The overnight shipping also helped ensure that the urine sample in the sterile urine cup, which was packaged with two gel ice packs at the bottom of the transport container, remained at 2–8 degrees Celsius so it could be tested for urine hemoglobin. The health representative added absorbent material on top of the ice packs, and then the remaining biospecimens: the two centrifuged serum separator tubes, the lavender blood tube, and the urine vessels. After closing the lid and putting both the transport container and the laboratory requisition form in a cardboard container, the health representative added appropriate labels and dropped off the box at a FedEx shipping center or an authorized FedEx drop-off location. In a few cases, health representatives requested a home pickup.

Biospecimen Processing and Testing

Quest Diagnostics tested the urine sample for creatinine, glucose, hemoglobin, microalbumin, protein, and protein–creatinine ratio. The blood samples were additionally tested for diabetes (hemoglobin A1c and glucose), liver and kidney function (albumin, albumin-to-globulin ratio, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, bilirubin, blood urea nitrogen, calcium, chloride, creatinine, globulin, glomerular filtration rate [estimated], potassium, protein, and sodium), cholesterol (total cholesterol, total cholesterol-to-HDL ratio, HDL, LDL, non-HDL cholesterol, and triglycerides), and anemia (hemoglobin). See Appendix XIII for more information on these tests.

As previously noted, Quest Diagnostics did not have access to any of the participant's personally identifiable information. Quest Diagnostics stored the samples for 7 days after processing and then destroyed the samples. The results, stripped of personally identifiable information, were retained by Quest Diagnostics because of regulatory requirements for clinical laboratories. The 1988 CLIA regulations and College of American Pathologists accreditation standards require Quest Diagnostics to keep the results at least 2 years before destruction.

Re-collection

When the laboratory encountered a problem testing a blood or urine specimen, the participant was notified and given the opportunity to repeat the urine collection or blood draw. Repeat blood draws were limited to collecting only the blood tubes needed to perform the missing tests from the initial collection. If the participant agreed to the re-collection and scheduled an appointment for it, the health representative returned to the participant's home, completed the relevant protocol, and then labeled, packaged, and shipped the specimens. Westat provided the health representative with written instructions for performing the re-collection, including documenting the specimen ID and FedEx tracking number. Once Westat received the re-collected sample

results from Quest Diagnostics, the specimen ID was updated to match the original specimen ID used during the primary collection.

Reporting Results to Participant and NCHS

All participants received two reports about the results from their examination: a preliminary report of findings and a mailed final report. For the few participants whose blood or urine analysis yielded critical results, NCHS also provided critical laboratory test value reporting. The laboratory test results were delivered weekly to Westat, in batches to NCHS, and at the end of the project, Westat delivered a final data file and report.

Preliminary report of findings

At the end of the home visit, the health representative provided the participant with a handwritten report of their height, weight, waist circumference, calculated body mass index, body mass index and waist circumference risk statement, blood pressure, resting heart rate, and blood pressure risk statement. The form used is shown in Appendix XV.

Critical laboratory test value reporting

Westat and NCHS established a process for relaying critical values identified by Quest Diagnostics's analysis of participant samples to the participant in a timely manner. This process was modeled on the critical value reporting process used by NHANES, which, as explained previously, used the NHANES medical officer as the point of contact. Before data collection began, Westat provided Quest Diagnostics with contact information for a Westat staff member who would serve as the point of contact for all critical values. When Quest Diagnostics identified a critical value, they notified the Westat point of contact immediately after the result was detected, as required by 1988 CLIA regulations. Westat then used the specimen ID of the critical value provided by Quest Diagnostics to identify the participant whose ID was linked in Westat's secure database to that specimen ID. Westat relayed that participant's contact information and critical value result to the medical officer within 1 hour of receiving the notification. Then the medical officer attempted to contact the participant. Of the 27 lab tests performed on study participant samples, 6 tests had established critical values: hemoglobin, glucose, calcium, creatinine, potassium, and sodium. Biospecimen analysis yielded at least one critical value for three participants.

Weekly laboratory test results delivery, mailed final reports, and final data file delivery

Quest Diagnostics sent Westat a weekly data file of the test results from the previous week through Westat's study-specific secure FTP site. Westat merged these test results with the information from the preliminary report of findings, performed several quality control checks, and then populated the final report template with the results (Appendix XVI). The biospecimen test results were reported with reference ranges, as is standard. The reference ranges for a given test result sometimes varied by one or more demographic characteristics. The final report of findings filled in the appropriate reference range, given a particular participant's age and sex. Westat then reviewed these reports to detect any irregularities in results that would normally get identified by the testing laboratory. Westat mailed reports to participants in weekly batches, typically within 4 weeks of the home visit. Before mailing the reports, Westat provided electronic copies to the medical officer, who was listed in the report as the person participants should call if they had questions about their results.

After receiving the last test results delivery from Quest Diagnostics, Westat prepared the final data files and documentation for NCHS.

IT Systems Testing

Before the field period began, NCHS conducted end-to-end tests of the NHIS instrument, including the sample eligibility logic, the introduction to the study questions read by the FR to the Sample Adult, and the FR paradata questions. This testing ensured that all and only the correct Sample Adults were read the NHIS FHS questions, their responses to those questions were captured accurately, and the FR's information about the process of asking and recording answers to those questions was recorded accurately. The U.S. Census Bureau and NCHS collaborated to test the process for sending NCHS the file with only the data from the NHIS FHS section and contact information for all Sample Adults who agreed to be contacted for FHS. NCHS tested the process for transforming this file into a new file that only contained data for Sample Adults who agreed to participate and sending the new file to Westat. Westat tested their procedures for uploading the data into their system but did not fully test that all data were loaded and displayed correctly. The consequences of this lack of testing are discussed in "Preferred Contact Times Not Initially Displaying Correctly." Westat tested their systems for recording contact attempts and examination results.

Quality Assurance

All study staff received training on the study procedures, as detailed in "NHIS FHS Staff Training." NCHS monitored the time FRs spent on the NHIS FHS questions in the NHIS instrument to check whether they were reading the complete text on these screens or speeding through them. Timing was recorded in the instrument during each visit to a question. That information was used to calculate the FR's longest visit and the total amount of time spent on a question across all visits. This was then compared with an expected timing, calculated as the average time it took five members of the study team to read the NHIS FHS questions out loud at a slow pace.

Westat monitored scheduling and home visit activity and sent daily e-mails to the ExamOne supervisors describing any issues identified, corrective action required, and retraining of field staff.

In the second month of data collection, Westat learned of and was granted access to Quest Diagnostics's electronic reporting application, Quanum for Healthcare Professionals. This application allowed Westat to access laboratory results and identify potential sample concerns in near-real time, which enabled faster problem resolution. Westat used this application to monitor processing of the biospecimens for the remainder of the field period.

After Westat received the weekly laboratory test results data from Quest Diagnostics, Westat performed several quality control checks to identify and correct any errors the ExamOne health representatives made on the hard-copy requisition form and to reconcile the sample IDs in the laboratory data against those recorded in the blood and urine collection instruments. Westat provided NCHS with weekly participation rate reports and updates on problems identified and solutions implemented.

NHIS FHS Contractor Staffing

Westat and their subcontractor ExamOne assembled the study staff team of schedulers, recruitment specialists, and health representatives. The schedulers attempted to contact Sample Adults, attempted to convince them to participate in the study when they were reluctant to do so, and scheduled appointments. The recruitment specialists attempted to contact and convince the Sample Adults, when needed. The health representatives reminded Sample Adults of their appointments and conducted the home examinations.

Westat identified two recruitment specialists for the study, both of whom had experience in gaining cooperation for venous blood draws on Westat studies. Both recruitment specialists completed the study training and worked on the pilot study.

ExamOne used their existing group of seven schedulers to support the pilot study. These schedulers had no known experience in recruiting for other research studies. Seven schedulers completed the study training and passed the competency assessment, and six of them called study participants.

ExamOne initially recruited 37 certified phlebotomists with insurance examination experience from their existing national network to work as health representatives for the study, and subsequently hired 2 new phlebotomists to ensure coverage in all the geographic locations included in the study. The number of phlebotomists recruited from each location varied depending on the size of the expected NHIS sample in the area and the success of ExamOne's recruitment efforts. Slightly more than one-half of the phlebotomists recruited for the study had previous experience on other ExamOne research studies, but that experience was clinical and did not include study recruitment. Of the 39 phlebotomists initially identified by ExamOne as pilot study staff, 32 attended training and passed the competency assessment. None of the phlebotomists failed the competency assessment, although three needed additional practice before the ExamOne supervisor signed off on their assessment. Once ExamOne phlebotomists passed the competency assessment, they became eligible to serve as health representatives for NHIS FHS. Ultimately, only 21 health representatives completed home visits, of which 15 had previous experience with other ExamOne research studies.

Of the 21 health representatives who were assigned and completed at least one home visit, 6 completed two-thirds of all study visits; 8 health representatives each completed three visits or fewer. This uneven distribution of study visits across health representatives was due to a number of factors. Health representatives differed in their availability, the degree to which their availability overlapped with participants' preferred appointment times, and their physical proximity to Sample Adults willing to make appointments. When possible, ExamOne schedulers assigned the nearest health representative to the visit, so health representatives closer to willing Sample Adults were assigned more visits.

The number of health representatives hired for the pilot study was based on the expectation that NCHS would send Westat 900 NHIS Sample Adults who agreed to be contacted for the follow-up study, and that a high percentage of those Sample Adults would schedule appointments. When the lower-than-planned pilot recruitment numbers provided them with minimal work, some health representatives left the project early or took another job, because ExamOne phlebotomists were paid only for completed visits. Among those who stayed, some staff had limited availability to work on this project due to other commitments, both personal and work-related.

NHIS FHS Staff Training

FR training I and II

In May 2021, just before the field period began, NHIS FRs whose caseload included addresses in the NHIS FHS sample took a computer-based training about the study. The training began with the statement that "The Census Bureau's only role in the NHIS Follow-up Health Study is to inform Sample Adults about the study, answer general questions, and ask if they are willing to be contacted about this study." This training then provided an overview of the purpose and methods of the study; a review of the NHIS FHS questions they would ask the respondent and the questions FRs would answer about that Sample Adult's responses to the NHIS FHS questions; and answers to questions that Sample Adults might ask about the study. These answers to potential Sample Adult questions covered the study's purpose, U.S. Census Bureau's role, safety, COVID-19, privacy precautions, what the blood and urine samples would and would not be tested for, staff training, and home visit procedures. This

information was also included in the instrument so they were available to FRs in the NHIS FHS section of the instrument. FRs were encouraged to end any answers they gave with a reminder that study staff could provide more information.

Midway through July 2021, NCHS drafted, and the U.S. Census Bureau distributed, a short training update to the FRs working on the study. This update was distributed as an electronic memo containing a set of talking points FRs could use to respond to each type of reason for refusal. This memo represented a small but significant shift in the U.S. Census Bureau's position regarding FR's role in the study: FRs now had permission and encouragement to provide additional information to respondents who initially refused, if those respondents seemed open to conversion. The reasons for this change are discussed in "FR Role Restrictions and Training Delays." In late August, FRs working on the study also received a follow-up memo that answered questions raised during the FR focus groups, which is described in the next section.

Westat and ExamOne staff training and competency assessment

Westat led the training for the study schedulers, recruitment specialists, and health representatives in the 2 1/2 weeks immediately preceding Westat's receipt of the first Sample Adult contact information, from the end of May through the first week of June 2021. Westat supplied all the content and materials and gave the lectures; ExamOne staff assisted during breakout sessions. The health representatives and schedulers received a role-based, 2-day training with their peers, while the recruitment specialists participated in both the scheduler training and a separate hands-on practice session on a third day.

Although the original plan was to hold the Westat and ExamOne training in person, it was instead conducted virtually as a result of COVID-19 pandemic restrictions, which included no use of conference rooms and no air travel without special permission. Each trainee participated in the training by watching presentations, practicing using the project data entry applications, and interacting during breakout discussion groups using the Westat-configured laptop each trainee received before training. The trainees then used those laptops to collect the data during the field period as well.

All ExamOne study staff, including schedulers, recruitment specialists, and health representatives, were trained on the core project content. It included the pilot study's purpose, goals, and basic logistics; methods for gaining cooperation and avoiding refusals; maintaining accurate records of all contacts and contact attempts; screening for COVID-19 and providing pre-examination instructions; and using the components of the project computer applications specific to their assigned tasks. It also included a brief section on strategies for addressing participant questions and concerns and how to document participant concerns and reasons for refusal. In addition to this content, the health representatives' training also covered all procedures related to the home visit, including making contact, sending reminders, obtaining consent, conducting the home examination, entering the examination data and paradata into the study computer application, and packaging and shipping the biospecimens.

Thirty-two phlebotomists attended training. To accommodate health representatives based in three different time zones and limit the number of trainees per session, the phlebotomists were split into two groups, and each group had 2 separate days of training. The class sizes were relatively large for an online training of this kind, with each group ranging from 11 to 21 trainees.

Seven schedulers completed training. To ensure coverage on ExamOne's scheduling number, which is used by multiple projects, each training module was held twice. This allowed one-half of the schedulers to attend the session while the rest of the schedulers covered the phones. A high trainer-to-trainee ratio allowed trainers to provide targeted assistance if trainees were having difficulty during hands-on practice sessions.

The two Westat recruitment specialists responsible for the follow-up calls attended the scheduler training and a separate hands-on practice session to learn how to document their contacts with participants who did not respond to the mailing.

Westat developed separate competency assessments for the schedulers and health representatives. The assessments included a series of scripted scenarios and role plays intended to evaluate trainees' ability to implement the study protocols, including using the data system. The ExamOne supervisors were responsible for completing individual assessments with each of the health representatives and schedulers and documenting their performance using checklists developed by Westat. In most cases, ExamOne conducted the assessments using a video-calling application available on the project smart phones. Some assessments were conducted using a video conference service, and one in person. All assessments were concluded before Westat received their first set of cases in early June.

NHIS FHS FR Feedback Collection

NCHS collected feedback from FRs with NHIS FHS cases about their experience working on the study at three time points, from successively larger groups of FRs. First, halfway through the 4-month period during which FRs read the NHIS FHS text and questions to Sample Adults, U.S. Census Bureau staff conducted a virtual focus group with four FRs working in each of the two regional offices, for a total of eight FRs. The goals of that focus group were to learn more about Sample Adult privacy concerns; comments about the $75 incentive; differences in challenges between introducing Sample Adults to NHIS FHS over the phone compared with in person; FR efforts, if any, to convince Sample Adults to participate;

the impact of the NHIS FHS questions on respondents' willingness to complete the Sample Child interview; and the helpfulness of the FAQs in the instrument and the NHIS FHS initial brochure.

Next, in October 2021, after the field work was complete, the U.S. Census Bureau's Center for Behavioral Science Methods conducted five focus groups about NHIS FHS on behalf of NCHS, three with FRs from one regional office and two with FRs from the other. Participants were recruited to represent diversity in FR experience level and the type of geographic location worked (urban and rural). Each group had between six and nine participants. The goals of these focus groups were 1) to collect FRs' perceptions of respondent reactions to the NHIS FHS questions, the incentive, and the brochure and 2) to collect FRs' perceptions of respondent concerns regarding participation. NCHS created the guide for moderating the focus groups with input from the U.S. Census Bureau. The full results from those focus groups are available elsewhere (7).

Finally, over the last 3 weeks of November 2021, the Center for Behavioral Science Methods fielded a web survey to collect FRs' feedback on the NHIS FHS. All 99 FRs who introduced the study to at least one NHIS FHS-eligible Sample Adult were invited, and 72% (n = 71) responded. The questionnaire included adapted items from the focus group moderator guide and new items based on preliminary results from the focus groups. NCHS revised and approved the final FR web survey instrument. Some of the results from that survey are available elsewhere (7).

ERB Clearance

The ERB package was submitted in December 2020 and approved by the full NCHS ERB at the end of February 2021 through a full, nonexpedited review. However, the initial project plan called for COVID-19 antibody testing and reporting to the participant, without providing the subcontractor with the Sample Adult's personally identifiable information. Quest Diagnostics informed Westat in February that it could not complete this requirement. As a result, NCHS dropped the COVID-19 antibody testing from the set of laboratory blood tests. This resulted in changes in the project materials, and the necessity of preparing and submitting an ERB amendment to account for those project changes. This amendment was approved through expedited review by the NCHS ERB in April 2021.

Additionally, Quest Diagnostics could not provide blood and urine test results without either signed Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization forms from study participants or a waiver of HIPAA authorization. As a result, NCHS drafted a HIPAA waiver request and submitted it to the NCHS ERB, acting in its authorized capacity as a HIPAA privacy board. The NCHS ERB confirmed NCHS's argument that it would not be possible to conduct the project without the waiver and approved the request through expedited review in early May 2021. Quest Diagnostics approved the waiver in late May 2021, so field work could begin on June 1, 2021.

Planning and Operations Timeline

NCHS's planned development phase for this pilot study was extremely short. According to the "Statement of Work" in the "Request For Quotation" issued by CDC, data collection was expected to begin less than 4 months after the kickoff meeting. NCHS awarded the contract to Westat on September 28, 2020, and NCHS and Westat held the kickoff meeting for the study on October 14, 2020. Although the project team worked steadily and intensely through the fall, preparing the ERB package for submission in less than 11 weeks, the project was unavoidably delayed due to a range of factors. These included the COVID-19 pandemic, the initial ERB submission's ineligibility for expedited review, and two subsequent challenges that delayed the ERB clearance process, which are described previously. Consequently, the NHIS FHS section of the NHIS instrument did not go live until June 1, 2021. FRs continued to introduce Sample Adults to the study through the end of September 2021. The last home examination was completed on October 31, 2021. Figure 1 shows the study's timeline.

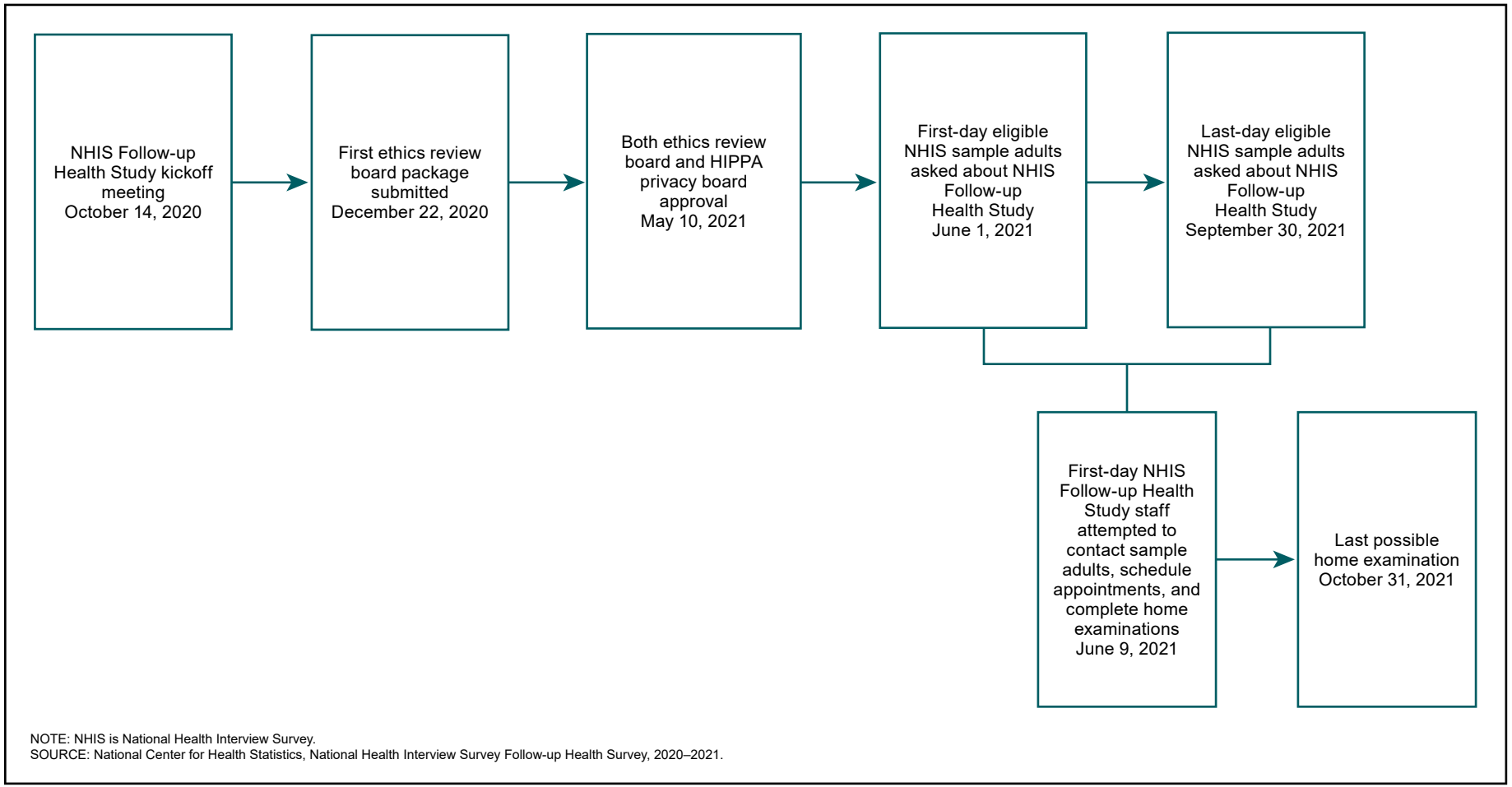
In some ways, the delay in the field period was advantageous. When data collection began in June 2021, COVID-19 case rates were relatively low and remained so through the end of the field period, which ended before the highly transmissible Omicron variant was detected (for more information, see: https://www.cdc.gov/mmwr/volumes/71/wr/mm7106a4.htm). Additionally, one-half of the field period occurred during the summer months, which minimized the potential for school-related exposures affecting either the participants' or health representatives' children, and consequently their ability to schedule the study visit.

Ultimately, only 11 appointments were delayed or rescheduled due to COVID-19-related reasons. Nine appointments were delayed due to COVID-19 exposure, symptoms, or illness in either the participant, a participant's family member, or a health representative's family member. Two appointments were delayed because the participant wanted to get the COVID-19 vaccine or booster before scheduling the visit. Of these 11 participants, 6 ultimately completed the home examination. The first instance of a participant responding "yes" to the COVID-19 screening questions occurred in early August 2021, around the time that the Delta variant was beginning to impact the United States.

COVID-19-period Conditions

The period effects on the planning, implementation, and results of this pilot study should not be underestimated, but they cannot be precisely quantified. The timing of the pilot field period within the pandemic impacted all aspects of planning and implementing the study. It also likely impacted

Figure 1. Timeline of National Health Interview Survey Follow-up Health Study



NOTE: NHIS is National Health Interview Survey.
SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Survey, 2020–2021.

the willingness of Sample Adults to participate, although it is impossible to say exactly how much.

Designing the study and selecting a contractor in the spring and summer of 2020 during the COVID-19 pandemic was challenging. The United States was under a national emergency, several states issued stay-at-home orders and mask mandates, schools were closed, and businesses implemented capacity limits to slow the rate of new infections. During this time, and into the NHIS FHS field period, all NCHS employees were teleworking, NHIS field operations were changed from in-person to telephone, and NHANES stopped data collection. CDC recommended social distancing measures for shared spaces including workplaces. However, other CDC recommendations changed over time as the science evolved, and these recommendations were not always popular. The organization was also frequently competing with misinformation spreading through social media. All of these factors undermined trust in CDC among some segments of the population. During this period, COVID-19 deaths were at their highest so far in the pandemic, and vaccines were not available. Parents whose jobs could not be moved to the home scrambled to find childcare, while those working from home juggled their job responsibilities with supervising and assisting with their children's distance learning. This stressful time was unprecedented in living memory and had wide-ranging negative impacts on population mental health, even among those who stayed physically healthy (8).

The situation and the virus kept evolving, with significant developments occurring even within the short 5-month pilot field period. By the time data collection began in June 2021, the situation had improved in some ways, but only recently and incrementally. People age 16 and older had been eligible for Pfizer vaccines and adults age 18 and older had been eligible for Moderna vaccines in every state for at least a month and a half, but the percentage of people age 16 and older who were vaccinated varied across and within states. Children ages 12–15 years had just become eligible for the Pfizer vaccine through an emergency use authorization from the U.S. Food and Drug Administration in May. Many people were still not hosting family and friends inside their homes, let alone strangers. Midway through collection, in late July 2021 amid the Delta variant surge, CDC released updated masking guidance that everyone in areas with substantial or high transmission should wear a mask indoors. By the time data collection concluded at the end of October 2021, many people older than age 16 in the United States had been vaccinated, as well as many children ages 12–15, but the rates differed by race and Hispanic origin. Some schools had returned to in-person instruction, some were implementing hybrid models, and some were still completely virtual. Children younger than age 12 years were still not yet eligible for COVID-19 vaccines.

These COVID-19-period conditions likely impacted Sample Adults' cost-benefit analysis of the home visit and their willingness and ability to be contacted, schedule appointments, and keep appointments. The factors that connected the period conditions and these outcomes include fear of infection, pandemic-related exhaustion, and time constraints from pandemic-related daily life alterations. Among some population groups, mediators also likely included increased suspicion of and hostility toward the federal government in general and CDC in particular. These period conditions also impacted the ability of the contractors to hire and train staff and the ability of those staff to plan for and keep appointments.

Results

Agreement and Scheduling

Sample characteristics of the Sample Adults are shown in Table 1. Four Sample Adults who gave permission for their contact information to be shared with the NHIS FHS contractor were dropped from the final NHIS sample due to data quality concerns. However, those four cases were retained in the NHIS FHS analysis because the quality of their data in FHS was determined to be adequate. The invited sample was 51.6% female and 48.4% male. By age group, 22.9% were ages 18–34, 51.1% were 35–64, and 26.0% were 65 and older. The invited sample was 13.1% Hispanic or Latino, 65.9% White non-Hispanic, 12.8% Black non-Hispanic, and 8.2% other. By education level, 5.2% of the sample had less than a high school diploma or GED; 20.2% had a high school diploma or GED; 25.0% had some college or an associate degree, 28.2% had a bachelor's degree, 21.0% had a master's, professional, or doctoral degree; and education was missing for 0.4%. Most of the sample, 62.5%, reported excellent or very good health status, 24.6% reported being in good health, 12.8% reported being in fair or poor health, and 0.1% was missing self-reported health status. Most of the sample, 77.7%, reported having had a wellness check in the past year. The NHIS interview was conducted in part or entirely by phone for 64.8% of the sample and entirely in person for 34.9% of the sample.

The percentage of the sample who completed each step of the NHIS FHS protocol is shown in Table 2. The first column shows unconditional percentages, which are based on the number of Sample Adults invited to participate (n = 1,164). The second column shows the conditional percentages, which are based on the number of the relevant participants in the previous row of the table. Of the 1,164 Sample Adults who were told about the study and asked if they would be willing to be contacted about it, 30.4% (n = 354) gave permission for their contact information to be shared with the schedulers. Of those, 253 (71.5%) spoke with study staff on the phone, and 81.8% (n = 207) of those who spoke with study staff scheduled an appointment for a home visit. The final result was that 176 Sample Adults completed the home

examination, representing 85.0% of Sample Adults who scheduled an appointment and 15.1% of the initial 1,164 Sample Adults who were asked about NHIS FHS. The flow of Sample Adults through each step of the NHIS FHS protocol is shown in Figure 2.

Home Visit and Examination

Participants who completed any of the components of the examination were considered to have completed it. Most Sample Adults who completed the examination completed all components (conditional percentage shown: 91.5%, *n* = 161). Of those who completed the examination, 100.0% (*n* = 176) completed the waist circumference measurement, blood pressure, and checkout components; 98.9% (*n* = 174) completed the height measurement; 99.4% (*n* = 175) completed the weight measurement; 99.4% (*n* = 175) provided a venous blood sample adequate to send to the laboratory; and 97.2% (*n* = 171) provided a urine sample adequate to send to the laboratory. Only two participants who completed the examination refused any component.

Sample Adults were reminded that some laboratory tests would be more accurate if they fasted for 8 hours before the appointment. Of the 175 participants who provided a partial or complete blood sample, 45.1% (*n* = 79) fasted for at least 8 hours before the examination.

Blood and Urine Processing

The status of collected blood and urine with test results reported to the Sample Adult are shown in Table 2. Of the 175 Sample Adults who provided a blood sample, 86.3% (*n* = 151) received complete blood test results, 12.0% (*n* = 21) received partial blood test results, and 1.7% (*n* = 3) received no blood test results. Of the 171 Sample Adults who provided a urine sample, 90.1% (*n* = 154) received complete urine test results, 5.8% (*n* = 10) received partial urine test results, and 4.1% (*n* = 7) received no urine test results.

In nearly all instances, the reason that results were not reported to Sample Adults who provided urine or blood sample was because of errors in the laboratory requisition forms. More details about these problems are provided in "Biospecimen Packaging, Shipping, Handling, Analysis, and Results Reporting."

All blood and urine tests were completed for 11.9% (*n* = 138) of the Sample Adults initially asked if they would like to be contacted about participating.

Types of Nonresponse

The distribution of types of nonparticipation (not completing an examination) among all Sample Adults who agreed to be contacted (unconditional) and all Sample Adults who did not participate (conditional) are shown in Table 3. This text reports the conditional percentages. Of the 178 Sample Adults who gave permission to be contacted by a scheduler but never completed a home examination, 52.2% (*n* = 93) never spoke to an ExamOne scheduler or Westat recruitment specialist. Another 23.6% (*n* = 42) spoke to a scheduler but never scheduled an appointment before the maximum number of contacts were reached, could not be reached after an appointment did not occur, or called in and left a message or sent an e-mail but never spoke to a scheduler or recruitment specialist. Fourteen percent (*n* = 25) of Sample Adults refused the study after speaking with a scheduler, and 5.6% (*n* = 10) did not keep an initial or rescheduled appointment and did not reschedule (again). The remaining 4.5% (*n* = 8) provided a variety of reasons for not completing the examination: an examiner was not available (*n* = 2), they moved or would be out of town (*n* = 4), a family member refused for the Sample Adult (*n* =1), or the Sample Adult requested a Spanish-speaking health representative, but no such health representative was available (*n* = 1).

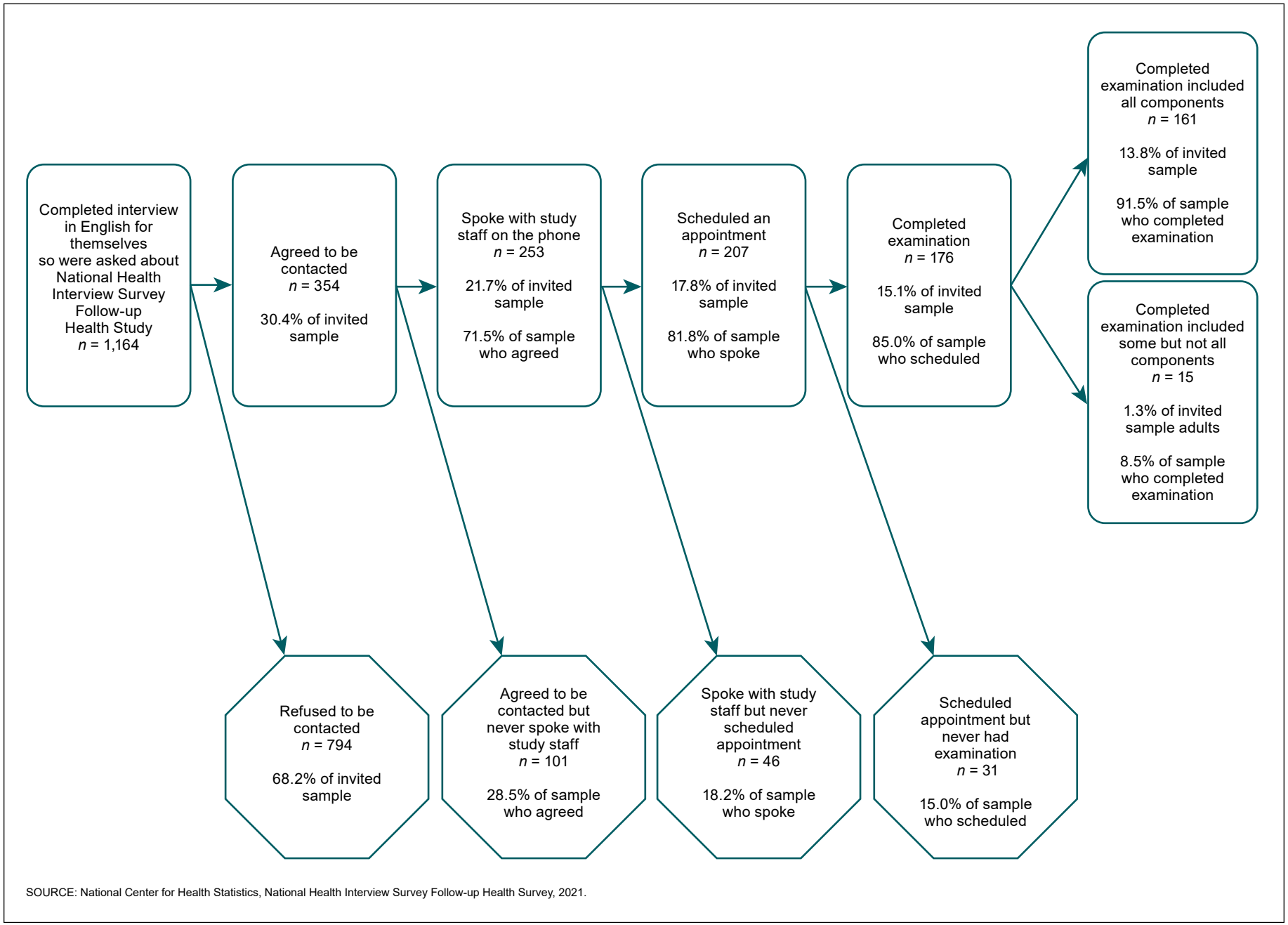
Sample Adult Reasons for Refusal and Agreement to Participate and Sample Adult Concerns About Participation

Reasons for Refusal and Concerns at Introduction Stage

The percentage of all Sample Adults who gave a reason for refusing among those who mentioned a concern are shown in Table 4. Of the 806 Sample Adults who refused to be contacted for FHS when asked by the FR, 80.5% (*n* = 649) responded to the question, "Please tell me the main reason why you don't want to take part in this study." The nine categories identified in the Sample Adult verbatim refusal reason coding (Appendix XVII) were: lack of interest, lack of time, privacy concerns, don't want someone in the home, study collects too much information, government distrust, other family members had concerns, and the respondent had family obligations, a needle or blood phobia, or some other reason. The most common reasons mentioned were lack of interest (44.7%), lack of time (26.0%), and privacy concerns (16.5%).

The lack of interest category included subcategories such as "My doctor will do or did those tests," "I already get enough tests," and "I'm healthy and don't need these tests." The lack of time category included "Too much trouble," "Not home," and "Inconvenient or difficult to schedule." Privacy concerns included a mention that the study was too intrusive. However, most respondents who gave each of these three reasons did not provide any further details about their reason. Fewer Sample Adults gave a reason in any of the other six categories: 5.2% said they didn't want someone in their home; 6.5% said the study collects too much information; 3.2% said they distrust the government; 2.2% mentioned a needle or blood phobia; and 1.5% mentioned family member concerns or obligations.

Figure 2. Number and percentage of Sample Adults at each stage of National Health Interview Survey Follow-up Health Study protocol



SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Survey, 2021.

Many of these results were reported in the FR focus groups that were conducted with FRs with NHIS FHS cases, in which they discussed their experience working on the study. Sample Adult privacy concerns about NHIS FHS mentioned in the July 2021 focus group included concerns about a stranger in their home and related-COVID-19 concerns, and mistrust that the government would responsibly handle their blood and urine. Some Sample Adults did not believe that the government would not test their blood for DNA or that the government could protect their results from foreign hackers.

FRs in the October focus groups reported that Sample Adults felt that having their physical measurements and biospecimens collected was physically and personally invasive, and they were suspicious to share this additional information after already answering the long NHIS survey instrument (7). FRs in both focus groups reported that some Sample Adults said they would be willing to participate if they could go to a laboratory instead of having someone come to their home, to reduce the invasiveness, while others offered their results from a recent physical examination, to reduce burden (7).

Sample Adult time concerns mentioned in the July 2021 FR focus group included a reluctance to spend an additional hour on the home visit after already spending an hour on the interview, and concern that the home visit would take longer than an hour. Also, although they may result from different causes, FRs reported that time concerns were common across socioeconomic groups. For example, one FR reported, "Time is valued by people for different reasons—affluent people say $75 isn't enough money, [while] people working from dawn 'til dark really value their weekends."

Reasons for Agreement at Introduction Stage

As described in the Methods section, if the Sample Adult agreed, the instrument asked the FR to provide the Sample Adult's reason for agreeing. If the Sample Adult did not give one, the FR could enter that information as well or leave the field blank. Of the 354 Sample Adults who agreed to be contacted for NHIS FHS when asked by the FR, 47.2% (n = 167) gave a reason for participating (Table 4). The seven categories identified via the reasons for agreeing coding were: monetary incentive, interest in or expectation of enjoying the study, free examination or test results, belief that the study is important, helping people or contributing to the public good, no reason not to, and other.

Of those who gave a reason, 7.2% (n = 12) gave more than one reason. Among the 167 participants who provided a reason for agreeing to be recorded by the FR, the most common answers were the monetary incentive (18.6%), interest in or expectation of enjoying the study (18.6%), and free examination or test results (16.8%) (Table 4). The next three most commonly mentioned reasons were belief that the study is important (14.4%), a desire to help people or serve the public good (13.8%), and didn't see any reason not to because it was not inconvenient (10.2%). Among the 15% of Sample Adults who reported other reasons for participating, six mentioned their healthcare background, five agreed after learning there was scheduling flexibility, three Sample Adults agreed because it supported their identity (for example, as a nice person), three agreed because a family member gave them permission to participate, two agreed after learning they could skip parts, and six gave other reasons.

Reasons for Refusal During Scheduling

As described in the Methods section, if the Sample Adult refused, the schedulers recorded their reason, if provided. As shown in Table 3, 25 Sample Adults gave permission to be contacted but refused when contacted by a scheduler. This refusal could have been either a refusal to schedule an appointment or a refusal to reschedule an appointment. Results are presented as counts, rather than percentages, because the total number of refusals at the scheduling stage of the protocol was small. Of the 25 participants who refused during the scheduling stage, 9 indicated that they were not interested; 7 indicated that they were too busy; 3 were reluctant to provide biological samples; 1 reported that they were reluctant to allow a health representative into their home due to risk of COVID-19 exposure; 3 reported health issues of their own or of a close family member; 3 reported being uncomfortable allowing a stranger in their house; and 1 needed to travel due to a recent death in the family. (Note that 2 participants each provided 2 reasons, resulting in a total of 27 reasons given for refusal.) Eight of the 25 cases scheduled an appointment that did not occur and subsequently refused during an attempt to reschedule. In two cases it was not possible to identify a location for the home examination acceptable to both the Sample Adult and the health representative (as noted previously, while inside the participant's home was the recommended location, the participant could request a different location, such as their porch or workplace), one Sample Adult did not provide a reason, one Sample Adult said they thought it was a scam and also had "too much going on," one Sample Adult lost interest after learning more about what the visit included, one mentioned an arthritis flare-up, one did not have time, and one would be traveling.

Participant Concerns Assessed in Post-examination Survey

About 23% (22.7%, n = 40) of study participants who completed an examination reported in the post-examination survey that they had concerns. The nine categories of reasons coded by Westat staff were privacy or confidentiality, legitimacy of the study, specimen collection, making time for the home visit, stranger in the home or personal safety, unclear about what visit includes, cleaning home before the visit, dogs in home, and other. Concerns only mentioned by one participant were grouped into the other category.

As shown in Table 5, privacy issues and the confidentiality of their information was mentioned by about one-quarter of participants (27.5%), followed by the legitimacy of the study and specimen collection (15.0% each). Concerns surrounding specimen collection included that they would faint during the blood draw, reluctance to have the tests for liver and kidney function, and the success of the blood collection because the participant could be a difficult draw. Fewer participants reported concerns about making time in their schedule, safety concerns associated with allowing a stranger in their home, confusion about what the visit included, concerns about having to clean their home before the visit, and dogs in the home. Concerns mentioned by a single participant were categorized as "Other" and included the participant forgetting about the scheduled appointment, ensuring that the health representative had been vaccinated against COVID-19, and the participant's low blood pressure.

Participant Motivation Assessed in Post-examination Survey

At the end of the examination, participants were asked, as shown in Appendix XIV, "Please tell me yes or no, whether you took part in this study for any of the following reasons: free test results, the $75 prepaid card, help with health efforts in the United States, improve information used by policymakers, some other reason."

The top panel of Table 6 shows the percentage of participants who completed an examination (n = 176) who answered "yes" to each of these reasons for participating. To help with health efforts in the United States was the reason most frequently indicated (88.6%), followed by improving information used by policymakers (72.7%). Slightly less than 60% each said that the free test results (58.0%) and the $75 prepaid card (58.5%) motivated their participation.

Of the 30 participants (17.0%) who provided some other reason, 6 provided reasons related to monitoring their health, and 6 expressed a desire to support research studies because they worked in research or a science-related field, had personally benefited from research studies, or liked participating in research. Civic duty and wanting to help others were mentioned by four participants each. Three participants said it sounded interesting, it gave them something to do, or they were curious about the study. Three participants agreed because they were asked or because the U.S. Census Bureau field representative was nice. The remaining four participants offered responses ranging from "Curious why I was asked," "Chose me because of my nationality," "Haven't done it in so long," and "None."

After being asked about each possible reason individually, participants were then asked to identify their main reason for participating. Specifically, they were asked, "What was your main reason for taking part in this follow-up study?" The distribution of the main reason for participating is shown in the bottom panel of Table 6. About 40% of participants reported that helping with health efforts was the main reason. Free test results and the prepaid card were each listed as the main motivator by one-fifth of participants. Improving information used by policymakers was the main reason for 8.0%, 6.3% said some other reason, and 9.1% did not provide a main reason.

Successes and Challenges of Informing Sample Adult About Study and Related FR Tasks

Operational Successes

The mean amount of time FRs spent reading the text describing NHIS FHS to the Sample Adult (121 seconds) was mostly higher than the expected duration (101 seconds). This indicates that FRs were not speeding through the NHIS FHS questions but reading them fully.

FRs were well prepared for their role, as defined by the U.S. Census Bureau. In the post-study survey of the FRs, 42.5% felt "very prepared to ask Sample Adults about the NHIS FHS" after their computer-based training, and 10.0% felt either "somewhat or very underprepared." In the July focus group, FRs reported that they did not refer to the FAQs in the instrument because they already knew the answers from the training. They also reported that the brochure clearly explained the purpose and procedures of the study and answered the questions of respondents who had questions, although few did. FRs reported in both focus groups and the FR survey that the training was appropriate, thorough, clear, helpful, and high quality (7).

The instrument functioned as intended, and all Sample Adult demographic and contact preference information was shared with the contractor accurately, securely, and on schedule throughout the study period.

Operational Challenges

As noted in the Methods section, the U.S. Census Bureau policy prevented FRs from taking any "substantive role" in this study. This introduced three key challenges. The first challenge was that the process of introducing the Sample Adult to the study and asking about their willingness to be contacted about it had to be embedded in the FR's existing job of reading the text from the NHIS instrument and entering the Sample Adult's answers. Second, that script had to include particular language that may have discouraged response. Third, FRs only received limited and late training in converting reluctant participants, and gaining cooperation for this study was never defined as part of their job, nor did they receive any incentive for gaining cooperation. Consequently, while FRs were well prepared for their defined role, their role limitations created challenges.

Operational challenges also arose from the pilot nature of the project: the delay between the FR obtaining the Sample Adult's permission to be contacted and the opportunity to schedule the home visit, the credibility gap created by not mentioning FHS in the advance letter and on the NHIS website (see "Credibility and Integration With NHIS"), and limitations on the information that could be included in the brochure.

Two operational challenges arose as a result of the timing of the pilot study during the COVID-19 pandemic: the unusually high phone interview rate of NHIS in summer 2021 (9) and the unusually high rate of mental health difficulties and daily stress in the U.S. population (10). The second may have made the monetary incentive less effective than it would have been otherwise.

Preprogramed Introduction Script

The U.S. Census Bureau's requirements to script the process of asking the respondent if they would be willing to give permission to pass their information to the contractor and to include the sentence "The Census Bureau does not have a role in this study" may have contributed to the low response rate, individually or in combination. In addition, the mention of ExamOne in that script may also have also discouraged response. The requirement to script the interaction undermined a major advantage of timing the introduction to the study to coincide with the end of the Sample Adult interview—the chance to capitalize on the FR's rapport with the respondent and their expertise in reading respondent cues and customizing the language accordingly. Even after FRs were allowed to use their expertise in converting reluctant participants, starting in the second month of the field period, they still could not use it until after they had read the prepared script in its entirety. The agreement rate increased from 29.6% in June to 38.9% in July, though it dipped again to 33.3% in August before rising to 37.7% in September. The rise between June and July may have been due at least partly to the new procedure but was likely also due to increased FR familiarity with the text and the increased in-person interview rate that month (see "High NHIS Phone Interview Rate in Summer 2021").

In the first focus group, FRs suggested creative ways for revising the script, giving examples of how they would have used their skills and expertise to customize the introduction, had they been allowed to do so. In addition, FRs in the July focus group suggested that the introduction might have been more successful if it was shorter, got to the question sooner, and referenced the rest of the interview process (such as by acknowledging that it had already been long, and saying "we're almost done"). They also suggested that the introduction should emphasize the information that the participant can refuse to do any part.

In the post-study survey, FRs also indicated that they felt the scripted introduction was too abrupt and did not adequately explain why the respondent should participate (7). In the post-study survey, only 39.4% of responding FRs said they never needed to rephrase the questions about being contacted for the study, while 50.7% of responding FRs said they sometimes needed to do so (7). More than one-quarter of responding FRs said they only sometimes could get through the introduction screens without being interrupted by the Sample Adult (7).

In addition, the inclusion of the sentence "The Census Bureau does not have a role in this study" and the explicit mention of ExamOne created a break between NHIS and FHS that contrasted the FR's usual technique of maintaining momentum through the entire interaction to reduce breakoffs. By deliberately defining FHS as a separate project, participation became an "extra task" instead of an intrinsic part of NHIS. FRs mentioned this problem in the second set of focus groups (7).

The explicit mention of ExamOne had an uneven impact on privacy concerns among Sample Adults. In the first FR focus group, some noted that some Sample Adults were concerned about their data going to an external company, even though no respondent's personally identifiable information ever left the systems and hardware within the NCHS IT security authorization boundary. In contrast, in the second round of focus groups, some FRs reported that the mention of the subcontractor's name was reassuring to the respondent when the respondent was familiar with and had positive perceptions of ExamOne or Quest Diagnostics (7).

FR Role Restrictions and Training Delays

The U.S. Census Bureau's limits on FR involvement in FHS also negatively impacted the FR's study-specific training. FRs only received permission, and guidance for converting reluctant participants during the second month of the study, and not during the initial computer-based training. This permission and training came through a memo, which did not provide FRs with an opportunity to practice the skills the way computer-based or role play-based training could have. Also, the memo could have been easily overlooked in an e-mail inbox.

In a later survey of FRs asking about their experiences working on NHIS FHS, 33.7% reported that they did not use or remember using this memo. This suggests that they may not have read the memo. Supporting evidence for this interpretation is that FRs rarely read the FAQs, and 29.5% of responding FRs said they did not use or did not remember using the FAQs when asked how helpful they were (7).

In the July focus group, FRs reported that most Sample Adults did not have questions, were not interested in seeing the brochure, and were not swayed by the brochure; they just refused. Also, FRs reported that because they already knew the answers to the questions in the FAQs from the training, they did not use the FAQs embedded in the instrument.

The memo training was also unspecific about the FR's role. Most NHIS FR training is very clear about the FR responsibilities. In contrast, the memo introduction described its contents as "…some additional information that you can use to address respondent concerns about the follow-up study. If you feel that a respondent's initial refusal might be converted using some of this additional information, we encourage you to do so…. Please use your own judgement as to whether additional efforts to convince respondents to participate is appropriate." Gaining cooperation was never explicitly defined as part of the FR's role.

Another possible consequence of the ambiguity about the FR's role, and the absence of any clear instruction or benefit to the FR for gaining agreement, was lack of FR commitment to gaining agreement. When asked if it would have been helpful to have the scheduler available on the phone to answer the Sample Adult's questions and schedule the health visit on the spot, only 16.9% of responding FRs said "yes." Another 32.4% responded "not sure" and 50.7% said "no." The survey question was not clear, however, about who it would have helped to have the scheduler on the phone. As discussed in the next section, there are theoretical and practical reasons to believe that having a scheduler available at the time of the NHIS interview would have been helpful for gaining agreement to be contacted and perhaps for scheduling appointments. However, introducing an extra person and step into the NHIS interview process could have potentially disrupted the FR's main goal of completing the NHIS interview.

Credibility and Integration With NHIS

The absence of the study from the NHIS website also posed a challenge during the introduction stage. To avoid confusing and possibly even alarming most NHIS respondents, who were not included in this small pilot study, no information about NHIS FHS was added to the NHIS website. Also, the advance letter was not modified for this pilot study (see "Study Materials"). As a result, FRs could not refer the Sample Adult to the website or the advance letter for more information about FHS, which may have damaged the FR's credibility, the legitimacy of the study, and the Sample Adult's likelihood to agree to participate. These absences may have contributed to Sample Adults' impressions that FHS was an extra burden, instead of an integral part of the NHIS participant experience.

Limitations on Content in Initial Brochure

Because this was a pilot study with a convenience sample whose purpose was to learn whether NHIS respondents would be willing to participate in a home examination following their interview, the home examination anthropometry and blood pressure measurements and the biospecimen test results had no use beyond the pilot study. This would not be true in a full-scale implementation of the home examination procedures. This created a challenge for the content of the initial brochure, which was resolved by using deliberately vague language about the intended use of the data. Although this was necessary, it may have limited the effectiveness of the brochure. Two of the most frequently endorsed responses to the FR survey question about changes to the materials that would be helpful for convincing reluctant Sample Adults to participate were "Providing more detailed information about how the data will be used" (21.7%) and "Providing more information about how participation will benefit the Sample Adult" (25.1%).

Timing of Introduction Relative to NHIS Interview

A related challenge resulting from the pilot status of this study was the lack of mention of the study in the advance letter. However, FRs were not uniform in their assessment of this timing issue. Some FRs suggested introducing the study earlier in the interview or in the advance letter so it was not unexpected (7). However, some FRs suggested delaying the introduction until a later date, noting that Sample Adults might be more willing to agree to be contacted after they had a break. Many participants considered the near hour-long NHIS interview to be very long already and were tired by the time it finished. This split perspective was reported in the responses of FRs to the post-survey question about whether it would be easier to convince Sample Adults to provide their contact information for FHS if they could have told them in advance about the study. The most frequently endorsed answer was "not sure" (50.0%), and the rest were split between "no" (27.8%) and "yes" (22.2%) (7).

High NHIS Phone Interview Rate in Summer 2021

Two period effects added challenges. The low percentage of Sample Adult interviews completed in person for the main NHIS during the study introduction period (June–September 2021) (43.6%, see "Methods") may also have contributed to the low agreement rate for FHS. FRs reported in the July 2021 focus group that it was easier for respondents to refuse to be contacted for NHIS FHS over the phone, while they were more likely to ask questions and agree to be contacted when the NHIS interview occurred in person. Although the Sample Adult in-person rate for NHIS rose between January and June 2021, it leveled off in June (42.5% in June, 46.4% in July, 42.8% in August, and 42.4% in September) (Table 7).

Compounding this problem was the difference in NHIS in-person interview rates between PSUs selected for the pilot study and PSUs not selected for the pilot study. Within the two regional offices with NHIS FHS sample, the Sample Adult in-person rate in PSUs selected for the NHIS FHS sample (35.0%) was lower than the Sample Adult in-person rate in PSUs not selected for the NHIS FHS sample (51.0%) between June and September 2021 (Table 7). The difference was particularly large in June. That month, the Sample Adult in-person rate in PSUs in the NHIS FHS sample was 29.6%, while

the Sample Adult in-person rate in the non-NHIS FHS PSUs was 51.9%. The difference decreased over the next 3 months of the introduction period, which may have contributed to the higher agreement rate in July–September compared with June.

Inadequate Incentive

Another possible period effect was the insufficient monetary incentive relative to the burden an in-home health examination may have represented to NHIS respondents. FRs in the focus groups reported that the incentive and argument for the value of participation was inadequate to convince reluctant respondents (7). According to the FRs, while some respondents appreciated that the study offered to give back something tangible, unlike NHIS which does not offer an incentive, the dollar amount of the incentive was too low relative to the burden and time of the home examination, particularly for respondents with high incomes and for those with multiple jobs and very limited leisure time with their families. Also, it may not have seemed relevant to respondents who were concerned that a visiting ExamOne health representative would increase their risk of COVID-19 (7). The results report was motivating for a few respondents, but others reported that they already received their health measurements from their annual physical examination (7).

A little more than one-quarter of responding FRs (28.6%) said the incentive was very helpful for convincing reluctant Sample Adults to participate, and an additional 37.1% reported it was somewhat helpful. However, 20.0% reported it was neither helpful nor unhelpful, and 10.0% reported it was unhelpful or very unhelpful. (7). Furthermore, when asked how the incentive could be improved for the future, 46.4% of responding FRs suggested increasing the incentive or adding more benefits.

Also, even with the incentive, 45.8% of responding FRs reported that it was somewhat difficult to convince Sample Adults to participate, and an additional 12.5% reported it was very difficult. Only 1.4% reported it was very easy and only 7.0% reported it was easy.

FR Concerns About Impact on Sample Child Interview Completion

Some FRs in the focus groups expressed concerns that asking the Sample Adult if they would be willing to be contacted for NHIS FHS would reduce their willingness to complete the Sample Child interview (7). This concern was also reported in the responses to the FR survey. About one-third or 23.6% of responding FRs indicated they were concerned, and 9.7% indicated they were very concerned. There was no evidence that this occurred, however. In households with both an eligible Sample Adult who completed a Sample Adult interview and an eligible Sample Child, the percentage of households who completed the Sample Child interview was higher among households whose Sample Adult was asked about FHS compared with those whose Sample Adult was not asked (91.1% compared with 85.2%). In addition, there was no evidence that the rate of completed Sample Child interviews differed by whether the Sample Adult agreed to be contacted (89.6%) or refused (91.7%). However, this concern may have decreased FRs' willingness to try to gain Sample Adult agreement to allow their contact information to be shared.

Successes and Challenges of Scheduling Home Health Visit Appointments

Operational Successes

Although overall participation was relatively low among those initially asked to participate in NHIS FHS, most participants who gave permission for their contact information to be passed to study staff scheduled an appointment (207 of 354, 58.5%), and of those who scheduled a home visit, most completed a home examination (85.0%, *n* = 176) (Figure 2).

As shown in Table 8, the case information for more than three-quarters of the 354 participants who agreed to be contacted (79.4%, *n* = 281) were delivered to study staff within 7 days after the NHIS interview. Nearly all cases (97.2%, *n* = 344) were delivered within 14 days. Only 10 (2.8%) were delivered more than 2 weeks after the NHIS interview, of which, 9 were delivered 15–21 days after and 1 was delivered more than 22 days after (see "Operational Challenges").

Study schedulers spoke with 198 of the 354 Sample Adults (55.9%) who gave permission for their contact information to be shared within 5 days of the initial phone attempt. Of those 198, about one-half scheduled an appointment during the first successful phone contact and completed the home examination without the need for a follow-up mailing.

Regardless of outcome, study staff made the minimum three phone contact attempts for most cases, and more phone contact attempts for some cases. Table 9 shows the percentage of cases that received less than three, three, and more than three phone contact attempts by final status. Among Sample Adults who scheduled a home examination but did not complete it, 100% received more than three contact attempts. Among Sample Adults who completed a home examination, 24.2% (*n* = 43) received less than three contact attempts, 14.2% (*n* = 25) received three, and 61.4% (*n* = 108) received more than three. Among Sample Adults who spoke to study staff but never scheduled a home examination, nearly all (93.5%, *n* = 43) received more than three. Among Sample Adults who never spoke with study staff, 100% received more than three phone contact attempts.

All the telephone numbers provided by Sample Adults were in service (as determined by ringing status), and all answered calls were answered by someone in the home of the Sample Adult. Everyone who was supposed to be mailed a noncontact or refusal packet was mailed one, and everyone who qualified for an e-mail or text message was sent one. Twelve of the 264 e-mail addresses provided returned notification that the message could not be delivered (4.5%).

During the initial weeks of the data collection period, Westat reviewed the contact records to ensure the schedulers had documented contact attempts accurately. Scheduler errors were minimal. Those that occurred were identified and corrected quickly.

As shown in Table 10, while 44.0% of the initially scheduled appointments were eligible for reschedule (91 of the 207), most of these were rescheduled and ultimately completed. One-quarter of the 91 eligible-for-reschedule initial appointments (n = 23) never rescheduled either because the scheduling staff could not reach the Sample Adult, or the Sample Adult refused to reschedule. Most, at 74.7% (n = 68), did reschedule, and most of these, 88.2% (n = 60), ultimately completed their home examination.

As a result of the rescheduling efforts and creative problem solving by the study team, 15 difficult-to-schedule home visits were completed 50 days or more after the interview, instead of not occurring at all. Ten of these outliers were situations where the visit was rescheduled one or more times, including three refusals that were successfully converted and two cases that were a no-show for an appointment. The remaining five cases included a participant who was temporarily living out of state for 3 months and returned shortly before the end of the field period; a participant who said they were very busy and requested a recontact several weeks later; two participants for whom arrangements were made for a health representative to drive more than 500 miles round trip to conduct the examination because the health representative who lived in their location was unavailable; and one participant who required a Sunday appointment but was difficult to schedule due to work travel.

As shown in Table 11, among the 176 Sample Adults who completed a home examination, 62.5% (n = 110) said scheduling their appointment was very easy and 32.4% (n = 57) said it was easy; 4.5% (n = 8) said it was difficult and less than 1.0% (n = 1) said it was very difficult .

Major Operational Challenges

Appointment Scheduling Delays

A delay between introduction and appointment scheduling always occurred because the Sample Adult and FR could not schedule the FHS home examination during the NHIS interview. As described in "Case Data Transfer," the Sample Adult had to give permission to pass their contact information to Westat's subcontractor, and ExamOne could not schedule the appointment until the Sample Adult's contact information was loaded into ExamOne's computer system. This process usually took between a few days and a week, although sometimes longer if the FR was delayed in transmitting their cases. On average, Westat received cases 6 days after the NHIS interview. The schedulers made their first phone attempt 7 days after the interview, it took another 3 days before they actually spoke to the participant, and 3 more days until the phone contact resulted in scheduling an appointment.

As shown in Table 8, Westat received 79.4% of the cases (n = 281) within 1 week of the NHIS interview, 17.8% of the cases (n = 63) between 8 and 14 days after the interview, and 2.8% of the cases (n = 10) 15 or more days after the interview. Cases received within 1 week and between 1 and 2 weeks after the interview had similar likelihoods of scheduling a home examination (58.4% and 60.3%, respectively). While a lower percentage of the cases received more than 2 weeks after the interview (longer than the protocol specified) scheduled an examination (50%, n = 5), this was a minor issue because so few cases fell in this category.

Nudge theory suggests that minimizing the barriers to a desired action is a key to raising the likelihood of response (11). However, this scheduling process did the opposite, by introducing notable barriers. Even if the Sample Adult wanted to call to make an appointment at the time of the NHIS interview, they could not. For this reason, the phone number printed in the study brochure was not the number of the ExamOne scheduling office, but rather a line answered by NCHS staff. In practice, no Sample Adults called this NCHS number to get more information about the study. Only one person called it asking to schedule an appointment (the spouse of the Sample Adult who had given permission to be contacted and who wanted to participate themselves but were ineligible to do so).

Making Contact

The most common type of nonparticipation—"never spoke to study staff"—was the result of the main challenge in scheduling: the inability of the scheduler to contact potential participants. In order to schedule the appointment, the scheduler had to speak with the Sample Adult on the phone. As explained previously, most Sample Adults who gave permission for their contact information to be passed on to the schedulers but who never completed the examination never spoke with a scheduler. This was the case even though the schedulers called multiple times and sent e-mails and text messages to all those who agreed to be contacted by those methods, along with the noncontact letter and brochures. These Sample Adults did not answer the phone when the schedulers called, never sent an e-mail, and never called the scheduling line. The noncontact mailing may have helped some, but of the 197 Sample Adults who were sent a noncontact mailing, nearly one-half (47.2%, n = 93)

never spoke with a study staffer and three-quarters (76.6%, *n* = 151) never had an examination.

Too-short call window

The postrefusal, noncontact-letter, 3-day call window, suggested by Westat during the planning process, was shorter than the initial 5-day call window. The recruitment specialists reported that the 3-day window to complete their calls made it difficult to complete calls during the Sample Adult's preferred days of the week, or to follow up with cases that requested a specific callback time because Westat's computer system removed the case from their call list after the window had closed. This may have contributed to the high no-contact rate.

Maximum Contacts

The second most common type of nonparticipation—"maximum contacts"—was a result of the second challenge: the tendency of some Sample Adults to interact with schedulers by speaking with a scheduler but not scheduling or scheduling but not completing an examination, without ever outright refusing. These respondents often gave evasive answers when schedulers called, until the maximum number of contacts allowed by the protocol was reached, and did not reschedule appointments after they had been canceled by either the Sample Adult or the health representative.

Refusals

The third most common type of nonparticipation—"refusals"—was a result of the third challenge. Some Sample Adults refused before scheduling an appointment, while others refused after scheduling. The refusal letter and refusal converters had limited success with conversion. Of the 25 cases who refused at some point and were sent the refusal mailing, 5 ultimately completed the examination; the rest had a final status of refusal.

Inadequate training in convincing reluctant Sample Adults to participate

As described in previous sections, the segment of the training for the schedulers and recruitment specialists on convincing reluctant respondents to participate was short, with minimal opportunity for practice. This skill was not assessed as part of the post-training assessment of scheduler readiness. This may have played a role in the high rate of maximum contacts and refusals.

Rescheduled appointments

In total, 91 cases were eligible for reschedule. In some cases, only the participant was responsible for the need to reschedule, in some cases only the health representative was responsible, and in some cases both were responsible. The numeric results are shown in Table 10.

Only the participant was responsible for the need to reschedule in 52.7% of the 91 cases eligible for reschedule (*n* = 48). Many participants did not explain why they needed to reschedule, particularly those who called the toll-free number to change their appointment. The health representatives were more likely to obtain a reason if the person canceled in response to the appointment reminder call. Work or other scheduling conflicts were common reasons, and a few participants forgot about the appointment or did not answer the door when the health representative visited, even after confirming with the health representative.

Only the health representative was responsible for the need to reschedule in 30.7% of the 91 cases eligible for reschedule (*n* = 28). An additional 16.5% of the 91 reschedule-eligible cases (*n* =15) were rescheduled more than once, with the health representative and participant each responsible for at least one instance of rescheduling eligibility. These cases are not counted in either the participant-only-initiated or the health representative-only-initiated reschedules. Health representatives rescheduled due to illness, car trouble, and scheduling conflicts that arose after the appointment was scheduled. In a few cases, the health representative was double-booked by mistake, and one of the visits had to be rescheduled. A few visits had to be rescheduled due to computer problems, mainly at the start of data collection. There were also six instances where the health representative was unaware of a scheduled appointment. In one instance, the health representative failed to mark the missed appointment on their personal calendar. One missed appointment was transferred to a different health representative and the scheduler failed to inform the health representative that the case had been reassigned to them. Three of the missed appointments occurred because the case did not download to the health representative's laptop during a data transfer. In another instance, the health representative had been texting back and forth with the scheduler about appointments for two different cases and mixed up the dates.

In the first few weeks of data collection, the contractor instituted procedures to minimize the possibility that visits would have to be rescheduled due to operational factors (health representative unaware of the appointment, case did not download, double-booking, etc.). When the schedulers made an appointment for the participant's home examination visit after confirming the health representative's availability, they sent the health representative a text message or e-mail notifying them that the case had been assigned. Health representatives were instructed to conduct a data transmission to pick up the case within 24 hours and confirm that the case had downloaded to their computer. Additionally, the ExamOne supervisor reviewed the scheduling system to identify upcoming appointments and sent health representatives a reminder text message or e-mail 3 days before their scheduled appointments.

Minor Operational Challenges

Inability of Recruitment Specialists to Schedule Appointments

Because the Westat recruitment specialists did not have access to the ExamOne portal or calendar where ExamOne phlebotomists documented their availability, only ExamOne schedulers could identify an available health representative and schedule the home visit. As a result, if and when a Westat recruitment specialist reached a Sample Adult who was willing to schedule, they had to add the scheduler to the phone call via conference call. They encountered a few instances where the call dropped and they were unable to get the scheduler back on the line, or they were put on hold and eventually transferred to voicemail and had to leave a message. The recruitment specialists reported this experience was frustrating for them and for the Sample Adult. However, it was not a primary reason why refusals did not schedule appointments.

Difficulty Finding Available Health Representative

Health representatives were not always available on the days and at times requested by Sample Adults. If the participant requested specific dates, days of the week, or times of day on which no health representative was available, the scheduler tried to contact and identify one who could accommodate the participant's preferences. Also, when participants wanted appointments further out because of vacation or travel plans, and the health representatives had not yet entered their availability for that time period, the scheduler had to contact health representatives to find one who was available. Even if the scheduler identified a health representative who was available at the selected time, sometimes it took several follow-up calls to finalize the appointment. Occasionally the participant was no longer available on the dates they had requested, and the scheduler had to begin the process again. Of the 44 cases with a final status of maximum contacts, 9 cases (20.5%) included scheduler contact with the participant, an attempt to locate an available health representative, and no subsequent contact with the participant, despite attempts. Of these nine, six were Sample Adults who had called into the scheduling line. While this was not a common problem, it prevented nine willing Sample Adults from participating.

Preferred Contact Times Initially Not Displaying Correctly

Although the preferred contact times were collected and transmitted to study staff accurately, it was discovered 3 weeks into the field period that the computer system was displaying mornings as the preferred contact time for all cases, regardless of the Sample Adult's actual preference. The contractor fixed this issue the same day so that the preferred contact times displayed correctly for all cases and subsequent call attempts were placed at these preferred times whenever possible.

Scheduling Challenges Identified by Participants

Of the 66 participants who responded that scheduling their appointment was anything other than "very easy" (Table 11) and were asked how the appointment scheduling could be improved, one-half did not offer any suggestions.

Among participants who provided feedback, the scheduling challenge identified most often was the lack of alternative scheduling modes. About one-third of those providing a response to this question would have liked an alternative to scheduling by phone. Others suggested the ability to schedule online, through text message, or through e-mail. While it is unknown how many, if any, Sample Adults (among those who ultimately participated and those who did not) would have used these other scheduling methods if they had been available, it is notable that the most common suggestion for improving the scheduling process was an alternative to scheduling by phone.

Other challenges identified by participants included the initially unidirectional scheduling process, difficulties rescheduling, poor communication about rescheduling, and limited appointment options. Some participants suggested including the scheduling number on the initial brochure so they could call to make an appointment instead of waiting for the scheduler to contact them. Other participants indicated they did not know which number to call if they had to reschedule or reported having difficulty reaching the health representative to reschedule. One participant expressed frustration that the health representative failed to keep the appointment and they were not contacted in advance that the visit needed to be rescheduled, and another participant would have liked better communication about why a visit was rescheduled twice. Others noted that health representative availability was limited, and they would have preferred more options for appointment dates or times.

Unexpectedly, answers to the question on the post-examination survey about suggestions for making the home visit easier and more convenient were also all about scheduling challenges. Of the 44 participants asked this question (see "Conducting the Home Health Examination, Operational Successes"), only a few offered suggestions, but all those suggestions related to appointment scheduling. They suggested having more weekend appointment slots, reducing the amount of time on hold when calling the scheduling number, and having the option to schedule via text messaging.

Successes and Challenges of Conducting Home Health Examination

Operational Successes

Once the participants gave consent for the examination, nearly all finished all parts of the examination protocol. As shown in Table 2, between 97% and 100% of participants who gave consent completed each of the blood pressure, height, weight, and waist circumference measurements, and provided adequate urine and venous blood samples to send to the laboratory.

For all but two of the incomplete components, the participants who did not complete a component were prevented from doing so by physical limitations. In only one case did a participant refuse the blood component partway through, and in only one case did a participant refuse the urine component. Three participants were unable to void, and six participants could only provide a partial urine sample. Of the 173 participants who provided a blood sample, 1.7% provided a partial sample (*n* = 3), and of the 171 participants who provided a urine sample, 4% provided a partial sample (*n* = 6).

The examinations were conducted according to protocol with little or no documented problems. No components were incomplete due to communication problems or equipment failure. The battery on the scale never ran out without a spare, and the blood pressure equipment functioned as intended in all examinations. Because the biospecimen collection kits supplied by Westat were all complete, health representatives had all needed supplies for each home examination's blood and urine collection. Health representatives had and used all required personal protective equipment for each examination, and there were no reports of any participant or health representative infecting the other with COVID-19. All the Visa prepaid cards that the health representatives provided to participants worked correctly.

The duration of the examinations was within the promised range, about 1 hour, as stated on the informed consent form (Appendix XII), in nearly all cases (92.0%). About one-third of examinations took less than 30 minutes (34.7%). Examination durations, stratified by sex and age group separately and combined, are shown in Table 12. The median duration for the full examination was 34 minutes for the total sample, women and men. The median duration by age was 33 minutes for adults ages 18–34, 34 minutes for adults ages 35–64, and 36 minutes for adults ages 65 and older. A similar pattern and range were seen when men and women were examined separately.

The schedulers were instructed to schedule the home examination as soon as possible. Table 13 shows the number of days between the NHIS interview and the completed home examination. Most examinations, 62.5% (*n* = 110), were conducted within 1 month following the interview, but 13.1% (*n* = 23) were conducted within 14 days of the NHIS interview. Although 37.5% (*n* = 66) were completed more than 28 days later, most of these (*n* = 51) were conducted within the next 2 weeks (5–7 weeks after the interview).

As described in "Methods," after completing the examination procedures, the health representative asked the Sample Adult a set of questions about their NHIS FHS experience. Most participants reported that the burden of participation was low, and that participation did not negatively impact their expectation of participation in a future similar study (Table 14). Among Sample Adults who completed a home examination, 75.0% (*n* = 132) said it was very easy to participate in the home visit, and 24.4% (*n* = 43) said it was easy. Only one participant said it was difficult; that participant had trouble scheduling an examination due to limited health representative availability. Additionally, 68.2% (*n* = 120) said it was very easy to get their questions answered, 19.3% (*n* = 34) said it was easy, and 12.5% (*n* = 22) said they did not have any questions. No participants said it was difficult or very difficult to get their questions answered. Of the 44 participants who completed the home visit, who reported in the post-examination survey that participating in the home visit was easy or difficult, and who were asked for suggestions for making the home visit easier and more convenient, two-thirds stated that they had no recommendations. Two participants, rather than providing a suggestion for improvement, noted that they appreciated the convenience of having a health representative come to their home. Of the small number of suggestions offered, all were related to scheduling. Nearly all 176 Sample Adults who completed a home examination responded that they would be very likely (64.2%, *n* = 113) or likely (34.7%, *n* = 61) to participate in a similar study in the future. Two participants (1.1%) reported they would be unlikely to participate in the future and none said they would be very unlikely.

In summary, the examination itself had no avoidable problems. A few participants had incomplete components of the examination (*n* = 15), and most of those were unable to complete the omitted components due to physical limitations (*n* = 13). No equipment failures, incomplete kits, faulty Visa prepaid cards, or COVID-19 transmission were reported, and examinations were completed in a timely manner. No problems or complaints were reported by Sample Adults during or after the examination visit concerning the health representatives who visited them.

Minor Operational Challenges

Data Entry Errors

As shown in Table 15, health representatives made data entry errors in a few cases. The health representative entered the incorrect number of urine vials in 5.1% of cases (*n* = 9), the incorrect number of blood tubes collected in 2.3% of cases

(*n* = 4), the incorrect height in 3.4% of cases (*n* = 6), and the incorrect Visa card proxy ID in 2.8% of cases (*n* = 5). After Westat discovered these errors early in the field period and provided feedback, those health representatives did not repeat the error. To prevent these errors from recurring, ExamOne included reminder instructions in the weekly e-mail to the health representatives on these topics. A few of these data entry errors occurred later in the field period among different health representatives who had also, perhaps not coincidentally, completed the fewest examinations.

Short Blood Pressure Rest Period

While monitoring home examination time stamps, Westat project staff discovered early in the field period that some health representatives were either beginning the 5-minute rest period before opening the instrument or failing to observe the full rest period before taking the measurements. The ExamOne supervisor provided feedback to individual health representatives. In most instances, the health representatives reported they had followed the protocol but did not open the instrument before reading the talking points and beginning to time the rest period. Following this discovery, the weekly e-mail to health representatives included reminders to use the project smart phone to time the rest period and open the blood pressure instrument before starting the examination, including reading any talking points. This problem persisted among a minority of health representatives throughout the field period.

Delayed Transmission

In about one-quarter of the cases with completed examinations (25.6%, *n* = 45), the health representative did not transmit their case data within a day after the appointment had occurred, as directed by the protocol. Westat and the ExamOne supervisors discovered these cases when reviewing the transmission report each day against the scheduled appointment list and contact effort reports. If they discovered that health representatives with appointments scheduled for the previous day had neither transmitted nor entered a note to indicate why the visit did not occur, the ExamOne supervisors followed up with the health representatives and provided a transmission reminder or guidance on how to document the incomplete visit, as needed. Even though ExamOne's weekly project e-mail reminded the health representatives to transmit immediately after completing the appointment, and to alert their supervisor and schedule a remote session with Westat's project helpdesk if they encountered any computer problems, the late transmission problem persisted throughout the field period. Health representatives were not paid for time spent working with the helpdesk. Late transmission is undesirable because it increases the chances of data loss, through theft or inadvertent destruction of the laptop.

Successes and Challenges of Biospecimen Packaging, Shipping, Handling, Analysis, and Results Reporting

Operational Successes

Of the 175 participants who submitted a blood sample, 86.3% received complete results (*n* = 151), 12.0% received partial results (*n* = 21), and 1.7% did not receive results because their blood could not be tested (*n* = 3) (Table 2). Of the 171 participants who submitted a urine sample, 90.0% received complete results (*n* = 154), 5.8% received some of the results (*n* = 10), and only 4.1% did not receive any results (*n* = 7). The reasons for incomplete and missing results are discussed in "Minor Operational Challenges."

Because the biospecimen collection kits supplied by Westat were all complete, health representatives had all the labeling and packing supplies they needed to correctly label, package, and ship the blood and urine collected in each home examination.

As shown in Table 16, most of the samples arrived at the laboratory within either 1 day (44.9%, *n* = 79) or 2 days (29.0%, *n* = 51), but 25.0% (*n* = 44) of the samples arrived between 3 and 5 days after collection. One sample was shipped 7 days late and arrived 10 days after collection. When the samples arrived at Quest Diagnostics, the staff did not routinely check the stability window of the samples. It may be that some samples that were tested for blood hemoglobin and urine glucose should not have been tested, and the results, while within the normal range, may not have been accurate. Westat mailed 135 (76.7%) of the final report of findings to the participants within 30 days of the home examination.

The low volume of critical values—only three in three separate participants—matched NCHS and Westat's expectations and were handled according to protocol. Each of the three critical values identified by Quest Diagnostics was relayed to the medical officer on the day it was identified, meeting the requirements of the CLIA regulations. In two of the three cases, the medical officer was able to speak with the participant about the critical value. While the medical officer was unable to reach the third participant even after multiple contact attempts, the participant's final report of findings was generated early and sent to the participant's address on file.

Minor Operational Challenges

Packaging, Shipping, Handling, and Analysis Problems

Five causes were identified for incomplete urine test results received by 17 participants and incomplete blood test results received by 24 participants. Problems with laboratory requisition forms were the cause of most of the missing or incomplete urine (10 of the 17 urine samples) and blood (20 of the 24 blood samples) test results. Specifically, 3 of the 10 incomplete urine test results, all 7 of the missing urine test results, 18 of the 21 incomplete blood results, and 2 of the 3 missing blood results could have been completed had it not been for problems with the lab requisition forms. Completing the paper requisition form was the most challenging aspect of the biospecimen collection for the health representatives. Even so, it did not present a major problem.

The health representatives encountered no other challenge regularly; the other four problems were rare. Packaging problems accounted for three of the partial urine test results, centrifuging problems accounted for three of the partial blood test results, laboratory error accounted for three of the partial urine test results and one of the missing blood test results, and inadequate urine quantity was the cause of one set of incomplete urine test results.

Incomplete or inaccurate laboratory requisition forms

Of the 17 urine samples with partial or missing results and 24 blood samples with partial or missing results, 58.8% (*n* = 10) and 83.3% (*n* = 20), respectively, could have had complete results if the requisition forms had been completed and delivered correctly.

Three of the 10 urine samples with partial test results were incomplete due to missing information on the urine requisition form. Among the seven urine samples with no test results, the laboratory did not receive the urine requisition form with the urine sample in two cases, and the health representative incorrectly filled out the form in five cases. Of these five cases, two had an incorrect sample ID number on the form, and three did not have marked off which tests were to be performed.

Two of the three blood samples with no test results could not be tested because the health representative did not complete the requisition form correctly.

Eighteen of the 21 blood samples with partial results were missing the bilirubin test due to a missing code on the blood requisition form. Quest Diagnostics does not test the blood for direct bilirubin unless that code is listed on the form, even though their pricing for the comprehensive metabolic panel includes direct bilirubin. However, the direct bilirubin test code was not printed on the blood requisition form. This problem was discovered 1 month into the study when the first results were transmitted to Westat, by which time 13 samples had already been delivered to the laboratory. Although new forms were ordered once the problem was identified and the health representatives were instructed to write in the direct bilirubin test code until the new forms arrived, in five additional cases the health representative did not write in the code, so those five blood samples were also missing the direct bilirubin test result.

Packaging problems

Three of the 10 urine samples with incomplete results could only be tested for some analytes because either the urine vial leaked during transport (*n* = 2) or the yellow-top urine vial was not received by the laboratory (*n* = 1).

Problems with centrifuging blood serum

In this study, blood glucose testing was performed on the serum. Separating the serum from the red cells within 1 hour of collection was a priority for accurate results. Three blood samples could only be tested for some analytes because the health representative did not centrifuge the serum separator tubes correctly or at all. As a result, these three samples had prolonged exposure to the red blood cells after collection, so the blood glucose test could not be run.

Laboratory error

Three of the 10 urine samples with incomplete test results were due to laboratory error. The laboratory misplaced one of the three blood samples that could not be tested at all. Three of the blood samples with incomplete test results for other reasons also had no hemoglobin test result because the stability window for hemoglobin was exceeded due to laboratory error. When the samples arrived at Quest Diagnostics, the staff did not routinely check the stability window of the samples. If the laboratory technologist received an abnormal value or had some other reason to investigate the results, the laboratory still did not check the collection time of the sample.

Reporting Problems

Delay in sending final report of findings to NCHS

While 135 of the final reports of findings were mailed to the participants within 30 days of the home examination (76.7%), 41 of the final reports were sent more than 30 days after the home examination (23.3%). About one-half of the delayed reports were due to an unexpected change in the procedure for accessing the reports by the medical officer (*n* = 18). In the original plan, Westat was going to mail a package of paper copies of the reports to the medical officer so they would have them on hand in case a participant called with questions about their results. However, after preparing the first batch of final reports, Westat raised a confidentiality concern and suggested that the copies instead be provided to the medical officer electronically. Because these reports contained personally identifiable information, they needed to be stored on a restricted server, which the medical officer could not access from their telework location. As mentioned in "COVID-19-period Conditions," the entire NCHS workforce

was teleworking during the NHIS FHS field period. After it was decided that Westat would send NCHS the copies of the final reports electronically, it took just over 2 weeks for the medical officer to gain access to the NCHS-restricted server. As a result, the first set of 18 reports were mailed about 15 days later than planned; this was an inconvenience but not a major problem.

Another 18 of the final reports of findings were sent more than 30 days after the initial home examination because the participant was informed of a testing problem with the collected specimen and was offered a re-collect of one or more of their biospecimens, and the delay pushed out the mailing date past the 30 day-post-examination mark (10.2%). The final report of findings for the 29 cases offered a re-collect were only sent after the participant declined the re-collect, did not respond to three phone attempts, or agreed to the re-collect and Westat received the test results for the re-collected samples. A total of 27 cases were offered re-collects because of problems with biospecimen collection due to health representative or laboratory error. Seven of the potential re-collects were for urine only. Nine of the potential re-collects were for blood samples only. Re-collects of both blood and urine samples were offered to the remaining 11 of the 27 participants. Of the 27 re-collects offered, only 8 participants agreed to and provided a second sample. Five of the eight completed re-collects were for blood only, two were for urine only, and one was for blood and urine.

The last five of the final reports of findings were delayed for a variety of unrelated reasons (2.8%). One report was delayed because an ID was incorrectly recorded in the Quest Diagnostics computer system. Another delay was due to a urine sample not being collected but was assumed pending by Westat. That report was mailed 32 days after the home examination. One was an error with mailing the report, resulting in the report being sent 47 days after the examination. The report was recorded in the computer system as mailed although it had not been. Westat discovered the error during a quality control review of the files. One report was mailed initially 19 days after the examination but there was a change in address for the participant, so Westat sent a copy of the report to the new address 34 days after the examination. The most prolonged report delay was 97 days. This occurred because of an error in completing the requisition forms by the health representative that caused a delay in sample testing at Quest Diagnostics. In addition, the participant did not have any blood collected, which was not evident in the health representative's examination documentation. These factors caused pending partial results for an extended time in the weekly laboratory file that Westat received from Quest Diagnostics.

Estimated glomerular filtration rate

The introduction to the NHIS FHS that the FR read to the Sample Adult mentioned sex and age but not race in the list of personal information that would be passed to the contractor if the Sample Adult agreed to participate. Therefore, race could not be passed on to the contractors. However, the formula used to calculate one blood test value, the estimated glomerular filtration rate (eGFR), depended, at the time, on the participant's race. There was one formula for people who are Black or African American and one for people of other races. (More details are available from: https://www.kidney.org/kidney-topics/understanding-african-american-and-non-african-american-egfr-laboratory-results).

While the National Kidney Foundation and the American Society of Nephrology have since published a recommendation to use one equation that does not factor in race, two equations were still in use when the missing race variable problem was discovered on July 2, 2021, a month into the field period. At that point, it was too late to get permission from the NCHS Ethics Review Board to change the instrument to get permission from the participant to provide the contractor with the participant's race. As a result, the value was calculated using both formulas and reported the results for Black or African American and non-Black or African American people on the final report of findings for each participant. This could have caused a problem for critical value reporting, had eGFR been included on the critical value reporting list, but it was not. See Appendix XVI for a sample final report of findings.

Causes of Packaging, Shipping, Handling, Analysis, and Reporting Problems

The problems described in the previous sections were likely at least partially the result of other challenges encountered during the pilot study. Most of these underlying challenges were the result of the short duration and small pilot sample, and some were also the result of COVID-19-related conditions. These challenges were communication difficulties between the laboratory and Westat, the few cases available for some health representatives, health representative training limitations, and laboratory staffing shortages.

Communication difficulties between contractor and subcontractor

The bilirubin code, eGFR, and requisition form problems could have been avoided with more efficient communication between the subcontractor and contractor. Better communication about which tests needed their own code on the form could have ensured that the direct bilirubin code was printed in the forms initially distributed to the health representatives, and then all samples would have been tested for bilirubin. Better communication about the need for the participant's race in order to report a single eGFR reference range for each participant could have enabled proactive planning for eGFR reporting. More prompt communication about requisition form errors (incorrect sample ID number or not all the required tests checked off) could have resulted in more samples being tested within the acceptable window. Also, when Westat learned in the second month of data collection that it could use Quest Diagnostics's Quanum for

Healthcare Professionals to monitor test results in near-real time, Westat was better able to address problems quickly. These problems might have been fixed sooner if Westat had been granted access to the system sooner.

Short timeline and absence of test run

The biospecimen analysis process was not tested before the field period began. A test set of blood and urine samples could have been, but they were not, sent to the laboratory along with the study's requisition form and tested with the results sent electronically following planned study procedures. Had there been such a test run, the missing bilirubin code would have been noticed early and new forms with the correct direct bilirubin code could have been provided to the health representatives before the field period began.

Few cases available for some health representatives

Health representatives had less work than expected because fewer Sample Adults agreed to participate and schedule an appointment than expected. Also, the Sample Adults who scheduled appointments were not evenly distributed across the geographic areas of the pilot sample, so the work was not evenly distributed among the health representatives. As a result, some health representatives had few cases or conducted their home examinations a relatively long time after their training. Both factors could have contributed to their errors with the forms.

In general, health representatives who completed the greatest number of examinations had fewer data entry and procedural errors. The repetition associated with frequent examinations helped to reinforce the study procedures and led to increased proficiency. In contrast, health representatives who were assigned a small number of examinations may not have completed their first examination until weeks or even months after training. In this situation, ExamOne provided the health representative with a brief refresher of the study protocols, emphasizing areas where health representatives were most likely to encounter problems or deviate from the approved procedures, based on the problems encountered in the initial weeks of data collection. However, the health representatives who received this refresher training were not reassessed after receiving it.

Health representative training and assessment limitations

The paper requisition form was the most challenging aspect of the biospecimen collection for the health representatives. Although ExamOne and Quest Diagnostics routinely use paper requisition forms for most of their projects, every project has slightly different forms due to the type of samples being collected. This project's form was very different from most requisitions that the health representatives had worked on previously. The training could have focused more on this aspect of the protocol by providing the health representatives with more opportunities to practice filling out the forms. The virtual format of the training, though not ideal, was not necessarily a barrier to including such practice. The kit could also have included a sample copy of the requisition form with instructions.

However, the virtual format did have other limitations. Because each trainee only had one laptop, and it was difficult to view two windows side by side, trainees could not easily view the trainer's screen and practice entering data at the same time. There were also the unavoidable distractions of virtual training, conducted at a time when childcare options were limited due to the pandemic. In an effort to address the limitations of virtual training, Westat offered additional one-on-one training review and practice, but only four health representatives attended these sessions.

The virtual evaluations, conducted using smart phones or laptop computers that did not allow for an entire field of view, made on-the-spot correction difficult and may also have contributed to the error rate.

Laboratory staffing shortages

Quest Diagnostics staffing shortages, due to COVID-19 and routine staffing problems, may have caused delays in notifications of problems that could have been corrected, and testing accomplished, if Westat had been notified more quickly.

Feasibility of Implementing Protocols With Full NHIS Sample

Bringing Project to Scale: Eliminating Many Identified Problems

If the collection of biological measures was made an integral part of NHIS, many of the challenges encountered in this pilot study would presumably be eliminated. In other words, NCHS knew in advance that certain operational parameters, discussed in the following sections, would be preferable, but it was not possible to implement them in this pilot study because of the constraints inherent in pilot studies.

The first step would be to identify one set of staff members to take primary responsibility for inviting and recruiting the Sample Adults to participate. The primary operational problem encountered in this study was that no contractor and, so, no individual staff member, took primary responsibility for recruitment. If NCHS decided to make biomeasure collection a core element of NHIS, willingness to take full responsibility for, a history of success in, and a robust plan for recruitment for examinations following survey interviews should be a central requirement of all contractors responsible for the parts of the operations that precede the start of the home examination.

With such a contractor(s) in place, many of the operational limitations encountered in this study could be avoided. First, the staff issuing the introduction would be fully invested and integrated into the study, with no limitations on their

involvement due to authorizing legislation, for example. As a result, instead of being required to read a scripted introduction, they would be free to use their best judgement based on their observations of the Sample Adult, experience, and expertise, to craft their own pitch, as many of the FRs suggested during the FR debriefing. Such an approach is the standard for NCHS surveys and would be consistent with the procedures used by NHIS FRs when introducing the NHIS interview, and by NHANES interviewers when introducing the NHANES study (12,13). Second, as an integrated step within the survey participation experience, there would be no need to mention the contractors collecting the biological measures by name, even if they are a separate entity from the NHIS interviewer contractor. This might reduce respondent privacy concerns and increase agreement to be contacted. Third, there would be time for, and no restrictions placed on, the training provided to all study staff on introducing and explaining the purpose and value of the study and the many benefits of participation, and on skills and strategies for convincing reluctant participants. Such training could be extensive and involved, using adult learning best practices including role plays, similar to NHIS's standard initial and refresher training. Incorporating this training into the initial training for the project, instead of sending it as a memo mid-field period, was also suggested by the FRs during the focus groups. NHANES provides robust training for all household operations staff, which includes both field interviewers and phone line staff, at initial and annual trainings, and sometimes at additional midyear trainings. All of these improvements would likely increase the chances of higher agreement rates.

The second step would be to increase the planning period and investment in infrastructure. Having more than 12 weeks to plan would bring a number of advantages besides the extra time to plan and implement the training described previously. First, with more time, and presumably additional funding, it would be possible to create a more extensive IT infrastructure to enable immediate and possibly online appointment scheduling at the time of the interview that can be accessed by all study staff at all times. NHANES has a system with some of this capability. NHANES field interviewers can see the MEC schedule while they are still at the home but must call a scheduler to make the appointment. Given that NHIS FHS scheduling staff were never able to make phone contact with 52.2% of incompletes, making it possible for the FR to schedule the appointment while already speaking to the Sample Adult could substantially raise overall completion rates. Such a system would also eliminate the need for recruitment specialists to bring a separate scheduling staffer into the phone call with the participant who has agreed to schedule an appointment. Such a system might also reduce the delay between the interview and the home examination. Second, with more time and additional funding, it would be possible to implement an online participant portal that Sample Adults could use to schedule and view appointments, view examination results, and communicate with study staff about scheduling or any other concerns. Such a system would eliminate scheduling barriers to participation. In addition, the personalized passcode provided to the Sample Adult during the introduction could be a kind of proxy advance incentive for the results they would obtain by participating. Third, it would be possible to automate the generation of appointment reminders for both health representatives and participants. This might reduce the need for reschedules. Fourth, additional laptops, one for the presenter's display and one for the trainee to practice entering data, could be provided if the health representative training is still virtual. If the assessment is still virtual, the assessor could have multiple views and a full field of vision via a shared health representative application screen and a camera and tripod to observe the health representative's work with the examination equipment.

A longer planning timeline would also offer opportunities for other improvements. It would make it possible to incorporate information about the biological measure collection step into the survey advance materials and the survey website, which would underscore its legitimacy and importance. A longer planning timeline would provide more time to develop and test recruitment strategies and techniques. More time would also be available before data collection began to test planned communication systems between the laboratory and study management, and to test the biospecimen processing and test results reporting procedures with a set of blood and urine samples. This would make it possible to catch any errors, such as missing test codes in the laboratory requisition forms, and to ensure that the laboratory had all the participant information needed to calculate all planned results. Such pretesting would minimize the number of re-collects, and consequent delays in results reporting.

Extending the timeline would also increase the contractor pool to include those without an existing NCHS-approved IT security authorization boundary but the ability, given enough time, to obtain one. As a result, NCHS could choose from a wider selection of contractors. The staff would also presumably be directly employed and managed, rather than subcontracted. This would allow for closer monitoring, management, corrective feedback, and, if needed, termination if the health representative is unable to follow study protocols, meet quality expectations, or is unwilling to meet the hours commitment. This might also enable the requirement that staff enter their availability in the project calendar at least a month in advance, which could make scheduling easier.

Bringing Project to Scale Not During a Public Health Emergency

If this project were brought to scale at a time without a pandemic or other public health emergency, other improvements would be possible. Health representative training and assessment could occur in person, which is preferable for both learning and robust assessment of

skill readiness. In-person training helps ensure that health representatives are fully engaged with the materials, equipment, and systems throughout the entire training process. In-person training also allows the trainers to monitor trainee progress and intervene if they notice that a trainee is having difficulty.

Fewer staffing problems among the health representatives and laboratory staff would also be likely. This increased staffing would likely increase the availability of appointments at times convenient for participants, and reduce laboratory errors. Also, Sample Adults might be more willing to welcome a stranger into their home to conduct the examination.

Lessons Learned

In future similar studies, implementing the following suggestions might make the invitation to participate more effective:

- Add information about the study to the survey respondent website and advance letter, or send a separate letter about the study. Either approach could help legitimize the study.
- Allow interviewers to use their expertise and the rapport they develop with the respondent to customize the introduction. If the introduction must be scripted, shorten it, ask the question sooner, emphasize that the respondent can refuse to do any part, and provide a better explanation of the value of participation.
- Instruct all staff to omit the name of the contractors working on the study, if any. All study staff should instead be referred to as "NHIS staff" or something similar.
- Conduct methodological experiments to determine optimal incentive size. Consider adjusting incentive size to account for differences in period conditions, timing of the follow-up relative to the main study, sample composition, and examination components between such experiments and the study being planned.
- Hire a separate sales or marketing contractor to identify stories and strategies for explaining the value of the study and of participation. Bringing on board such expertise and incorporating their language into the staff training and respondent materials could help motivate respondents who might otherwise refuse.

In future similar studies, implementing the following suggestions might increase the percentage of eligible cases who schedule appointments:

- Expand the calling window and increase the number of mandated phone contact attempts beyond three tries over 5 days and beyond two follow-up contact attempts in 3 days. Besides providing more opportunities for connection, such an expansion will give the schedulers and recruitment specialists greater flexibility in scheduling their contact attempts to coincide with respondents' preferred time slots, increasing the likelihood of reaching the respondent. NHIS interviewers have a month to attempt to schedule the interview. NHANES field interview staff usually schedule MEC appointments immediately after the home interview, but at times may not be able to. NHANES household operations staff work diligently with participants to set up appointments before the end of examinations at that location.
- Provide extensive training in selling the study and refusal conversion to all study staff tasked with contacting Sample Adults to schedule appointments. This training should use modern adult learning modalities, including extensive roleplays, and should provide trainees with extensive language for explaining why participation in the study is exciting and important. The competency assessment should evaluate this skill. Such training may help prevent refusals and motivate participation.
- Assess the skills of recruitment specialists.
- Increase or change the incentive structure to attract those who have been difficult to reach or reluctant to participate. A larger incentive might help, as might including an unloaded gift card with the follow-up (noncontact and refusal) mailings, and a note reminding the participant that $75 would be added to the card after the visit. Alternatively, this card could be included in a separate mailing sent after the first. Having the gift card in hand may motivate some respondents who may be otherwise reluctant to participate. An incentive could also be provided at the time of scheduling in the form of a gift code. However, this recommendation would increase costs.
- Add in-person, nonresponse follow-up to the contact attempt protocol, if cost and staffing allow.

If maximizing the number of participants who fast before their appointment is a goal of future studies—unlike in this study—then implementing the following strategies might increase the percentage of participants who fast:

- Ensure that project health representatives are available to conduct home examinations before 10:00 a.m. because most people will find it easier to fast for 8 hours if the appointment is early in the morning.
- Provide an additional incentive greater than $75 for participants who fast at least 8 hours. It may be helpful to include information in the study brochure about the added benefit to the participant if fasting, but this strategy might also discourage some people from participating entirely.

In future similar studies, implementing the following strategies might decrease problems with biospecimen packaging, shipping, handling, analysis, and results reporting.

Biospecimen collection, processing, and analysis is a highly technical and regulated industry, so a high level of planning, research, and validation is necessary even for a pilot study, even when using a national laboratory that is CLIA-certified. Quest Diagnostics's systems and procedures, which are fine-tuned to support ongoing processing in a healthcare

setting, were not easily modified to support the privacy of participant information required in a research study.

In future studies, to minimize ethics review delays, study planners should consider the following steps:

- Check if any test result requires mandatory reporting to public health authorities, if confidentiality is promised.
- Inquire and determine if the laboratory requires signed HIPAA authorization forms from study participants or if a waiver of HIPAA authorization will meet the laboratory compliance and legal requirements. If a waiver will meet the compliance, obtain the waiver as soon as possible during the development phase.
- Inquire and determine if the laboratory has regulatory or corporate reporting and record retention requirements that conflict with study protocol or legislative requirements. If so, determine if mitigation strategies can be put in place.
- Check the list of all types of demographic participant data required by the laboratory to perform the tests and calculate the results. Ensure that all the information can be passed to the laboratory by gaining all necessary ERB approvals and participant consents.

In future studies, to minimize problems due to late delivery of biosamples to the laboratory, study planners should consider the following:

- Encourage participants to avoid scheduling on Saturday (because there is no Sunday delivery for FedEx shipments collected or sent on Saturday), and in the evening if it will not be possible for the health representative to deliver the package to the FedEx location before it closes. Doing so will maximize the chances that the blood and urine samples will arrive at the laboratory within their stability window (for example, 48 hours after specimen collection for blood hemoglobin). Note that even early evening appointments could be problematic if the participant is late, the examination runs long, or the participant lives in a rural location with limited FedEx service or in an area with heavy evening traffic.
- Inform participants whose availability is limited to these times that they may not receive all of their test results when booking the appointment.

In future studies, to maximize the study staff's ability to monitor the biospecimen results, study planners should consider the following:

- Use a laboratory with a results portal or system that the project staff can access to identify and quickly resolve sample issues to ensure laboratory testing is completed within the stability window.
- Use a laboratory that can provide results electronically.

In future studies, to minimize health technician errors, study planners should consider the following:

- Use electronic, not paper, requisition forms, if possible. Auto-populate the electronic requisition form to minimize health representative input errors. If paper forms must be used, consider providing paper job aids to the health representatives, such as checklists or an annotated version of a completed laboratory requisition form. Provide additional practice during training in completing the requisition forms correctly.
- Provide paper job aids with explanatory photos for tasks that the health representative completes after they have logged out of the computer and left the home, such as biospecimen packing and shipping instructions.
- Require health representatives to review the aspects of the study's examination procedures with a manager, if their first scheduled appointment is many weeks following the training. This could help prevent some of the form and packaging problems that were more common among health representatives who conducted their home examinations a relatively long time after the training.

In future studies, to increase the likelihood that health representatives transmit their cases in a timely manner, consider paying them for hours needed to work with the project helpdesk to resolve issues. In future studies, to minimize delays in mailing the final reports, ensure that the plan for transmitting final reports of findings to the medical officer meets confidentiality requirements and test the system before the beginning of the data period.

Problems That Cannot Be Solved by Scaling Up

Even if this project was brought to scale, it would be very difficult to ensure that NHIS sample sizes in each area were large enough to support 20–30 hours of work per health representative per week. NHANES sampling design enables this staffing model, but NHIS's sampling design cannot. In many sparsely populated areas of the country, identifying such a large NHIS sample would not be feasible. As a result, it would still not be possible to require staff in many areas to commit to working that many hours per week. As a result, it would not be possible to gain the benefits of such a model. Staff working that frequently can conduct home examinations regularly and begin conducting home examinations shortly after training. Such staff are better prepared to follow standardized study protocol, consequently reducing error, and improving data quality. Also, the more health representatives who are able to commit more hours to working on the study in advance, the greater the availability of appointments at times convenient for participants. This would also reduce scheduling conflicts due to health representatives' other projects or jobs and reduce the need for reschedules. Reschedules due to cases not yet loaded on the health representatives' laptop would also likely be reduced, because they would presumably have more availability and scheduled time to meet and review assigned cases each week with their supervisor. In such a

scenario, there would presumably be health representatives able to fill in for health representatives who are unable to keep scheduled appointments.

Limitations

Because Sample Adults who completed the interview in a language other than English or who required a proxy were not eligible, this study provides no information about the best ways to facilitate the participation of such members of the population. Doing so would be vital if these protocols became an integral part of the NHIS, in order to ensure the study results were representative of the full U.S. population.

Information about the concerns or reasons for nonparticipation was not collected for the 52.2% of Sample Adults who gave permission for their contact information to be passed on to the schedulers but never spoke with a scheduler.

Also, there is no information about if or how the characteristics of the FRs who responded to the post-field period FR survey differ from FRs who were invited but did not respond. It is also unknown if or how the Sample Adults who were eligible for NHIS FHS and who were interviewed by those responding and nonresponding FRs differed, and if or how the agreement percentage differed between those two groups of Sample Adults.

It is unclear from this pilot study if eliminating the gap between the introduction and appointment scheduling would increase or decrease participation. Although it would streamline the process because the interviewer is already speaking to the Sample Adult, the interviewer has developed rapport with the Sample Adult, and the Sample Adult is not given a chance to forget why they agreed to schedule an appointment or to avoid the scheduler's calls, the delay between the interview and scheduling might give the Sample Adult time to recover from the exhaustion of the interview, consequently increasing their willingness to participate when asked at that later date. Also, NHIS FRs already reported "satisficing scheduling," also called "ghosting." In these cases, the Sample Adult schedules an appointment just to get the FR to leave, but then does not show up at the scheduled time. Sample Adults displayed this behavior sometimes in this pilot study, and it might happen more frequently if the Sample Adult were pressured to schedule at the time of the NHIS interview.

Because the visit durations were calculated using instrument time stamps, those durations do not include the approximately 5–10 minutes the health representative spent at the household before opening and after closing the instrument. That time was spent greeting, screening, and consenting the participant, and unpacking and repacking the equipment. The visit durations also do not include any time the health representative spent collecting the body measurements or urine before opening the instrument.

NCHS had almost no direct contact with ExamOne, Westat's subcontractor who made the scheduling calls and conducted the home examinations, so NCHS could not learn directly from ExamOne about their capabilities or reasons for decisions. As a result, some factors that may have impacted a Sample Adult's willingness to participate are unknown, as is their impact on the results. For example, NCHS had no ability to provide direct feedback or direction to ExamOne, which would presumably not be the case if NCHS brought this project to scale. The ability to provide direct feedback also could potentially help raise response rates. Also, as mentioned in the sections "NHIS FHS Interagency Agreement" and "External Contractors," ExamOne phlebotomists were not accustomed to gaining cooperation from study participants. In addition, ExamOne schedulers had an unknown degree of experience in recruiting for research studies. Both of these factors may have had a negative impact on participation rates.

The COVID-19 pandemic had period effects whose exact extent is unknown. For example, it is unknown how COVID-induced stress might have reduced the likelihood that Sample Adults agreed to participate at the end of the NHIS interview or when the scheduler called, or even answered the phone when the scheduler called.

Conclusion

Although this pilot study demonstrated the possibility of fielding an in-home biological measures collection study and collecting adequate blood and urine samples from adults who have already completed a major health survey in their homes, even in the middle of a pandemic, some unique challenges were presented. Once participants started the examination, nearly all provided both a blood and urine sample, nearly all those samples were shipped successfully, and most were tested successfully. Using the lessons learned, many, if not most of the problems encountered in this pilot study could be prevented in a scaled-up version of the study. One exception is overcoming the relatively low Sample Adult participation rate. That challenge remains central to this project and will likely remain so in future studies of this kind.

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Table 1. Characteristics of Sample Adults invited to participate in 2021 National Health Interview Survey Follow-up Health Study

Characteristic	Number	Percent
Sex		
Women	601	51.6
Men	563	48.4
Age group		
18–34	266	22.9
35–64	595	51.1
65 and older	303	26.0
Race and Hispanic origin		
Black, non-Hispanic	149	12.8
White, non-Hispanic	767	65.9
Other races, non-Hispanic	96	8.2
Hispanic[1]	152	13.1
Education		
Less than high school	60	5.2
High school diploma or GED	235	20.2
Some college, including associate's degree	291	25.0
Bachelor's degree	328	28.2
Master's, professional, or doctoral degree	245	21.0
Missing	5	0.4
Health status		
Excellent or very good	728	62.5
Good	286	24.6
Fair or poor	149	12.8
Missing	1	0.1
Had a wellness check in the past year		
Yes	905	77.7
No	259	22.3
Mode		
In-person	406	34.9
Phone	754	64.8
Missing	4	0.3

[1]People of Hispanic origin may be of any race.

NOTE: A total of 1,164 Sample Adults were invited to participate in the 2021 National Health Interview Survey Follow-up Health Study.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 2. Unconditional and conditional participation rates among Sample Adults invited to participate in 2021 National Health Interview Survey Follow-up Health Study

Characteristic	Number	Unconditional percent[1]	Conditional percent
SA agreed to be contacted	354	30.4	…
SA spoke with study staff on the phone	253	21.7	[2]71.5
SA scheduled appointment	207	17.8	[2]81.8
SA completed examination	176	15.1	[2]85.0
SA's height measured	174	14.9	[4]98.9
SA's weight measured	175	15.0	[4]99.4
SA's waist circumference measured	176	15.1	[4]100.0
SA's blood pressure taken	176	15.1	[4]100.0
SA completed checkout component	176	15.1	[4]100.0
SA completed all parts of examination[3]	161	13.8	[4]91.5
SA received all blood and urine test results	138	11.9	[4]78.4
SA provided a blood sample	175	15.0	[4]99.4
SA provided a blood sample consisting of 3 vials	172	14.8	[4]97.7
SA provided a blood sample of less than 3 vials	3	0.3	[4]1.7
SA received complete blood test results	151	13.0	[5]86.3
SA received partial blood test results	21	1.8	[5]12.0
SA received no blood test results	3	0.3	[5]1.7
SA provided a urine sample	171	14.7	[4]97.2
SA provided a urine sample consisting of 3 containers	165	14.2	[4]93.8
SA provided a urine sample of less than 3 containers	6	0.5	[4]3.4
SA received complete urine test results	154	13.2	[6]90.1
SA received partial urine test results	10	0.9	[6]5.8
SA received no urine test results	7	0.6	[6]4.1

… Category not applicable.
[1]Denominator of all percentages is total number of invited Sample Adults (SAs).
[2]Denominator is number of SAs in the previous row.
[3]All body measures were taken and enough fluids for at least one blood and at least one urine test were collected.
[4]Denominator is number of SAs who completed the examination (n = 176).
[5]Denominator is number of participants who provided a blood sample (n = 175)
[6]Denominator is number of participants who provided a urine sample (n = 171).

NOTE: A total of 1,164 Sample Adults were invited to participate in the 2021 National Health Interview Survey Follow-up Health Study.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 3. Type of nonparticipation among Sample Adults who agreed to be contacted about 2021 National Health Interview Survey Follow-up Health Study but did not participate

Type of nonparticipation	Number	Unconditional percent[1]	Conditional percent[2]
Did not participate	178	50.3	100.0
Never spoke to study staff	93	26.3	52.2
Maximum contacts[3]	42	12.4	23.6
Refusals[4]	25	7.1	14.0
Scheduled an appointment but did not show up.	10	2.8	5.6
Other	8	2.3	4.5

[1]Denominator of percentages is number of Sample Adults (SAs) who agreed to be contacted (n = 354).
[2]Denominator of percentages is number of SAs who agreed to be contacted but did not participate (n = 178).
[3]Includes SAs who spoke with the scheduler or conversion interviewer during at least one contact attempt but none of the contact attempts resulted in a scheduled appointment; SAs who scheduled an appointment that did not occur and the appointment was eligible for reschedule but all subsequent attempts to reschedule the appointment were unsuccessful; and SAs who sent an e-mail to the project mailbox or called the scheduling line and left a voicemail message but never spoke with a scheduler or conversion interviewer.
[4]Includes SAs who spoke with study staff and refused without scheduling an appointment; and SAs who scheduled an appointment but then refused after the appointment needed to be rescheduled.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 4. Reasons given by Sample Adults for refusing and agreeing permission to pass contact information to National Health Interview Survey Follow-up Health Study staff

Reason	Number	Percent
Refusing (n = 649)		
Lack of interest	290	44.7
Lack of time	169	26.0
Privacy concerns	107	16.5
Don't want someone in home	34	5.2
Study collects too much information	42	6.5
Government mistrust	21	3.2
Phobia of needles or giving blood	14	2.2
Family members in the way (baby, relatives, dog)	10	1.5
Other reason	46	7.1
Agreeing (n = 167)		
Monetary incentive	31	18.6
Interest in or expectation of enjoying the study	31	18.6
Free examination or free test results	28	16.8
Believes study is important	24	14.4
Help people or serve the common good	23	13.8
No reason not to	17	10.2
Other reason	25	15.0

NOTE: Percentages do not add to 100 because some Sample Adults gave more than one reason.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 5. Percentage of National Health Interview Survey Follow-up Health Study examination participants who reported concerns about participating, by type of concern

Concern	Number	Percent
Any concern[1]	40	22.7
Privacy and confidentiality	11	27.5
Legitimacy of the study	6	15.0
Specimen collection	6	15.0
Making time for the home visit	3	7.5
Safety related to having a stranger in home	2	5.0
Confusion about what visit involved	2	5.0
Have to clean home before the visit	2	5.0
Dogs in home	2	5.0
Other	6	15.0

[1]Refers to participants who completed an examination (*n* = 176) who had one or more concerns about participating. Other categories show the percentage of participants with any concern who mentioned a particular concern.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 6. Participant reasons for participating in National Health Interview Survey Follow-up Health Study examination

Reasons for participation[1]	Number	Percent
Free test results	102	58.0
$75 prepaid card	103	58.5
Help with health efforts in the United States	156	88.6
Improve information used by policymakers	128	72.7
Some other reason	30	17.0
Main reason for participation		
Free test results	34	19.3
$75 prepaid card	32	18.0
Help with health efforts in the United States	69	39.0
Improve information used by policymakers	14	8.0
Some other reason	11	6.3
No response	16	9.1

[1]Number of participants who completed an examination and answered yes to each reason for participation (*n* = 176).

NOTES: The post-examination survey asked whether any of four reasons contributed to the participant's decision to participate. Participants could answer yes or no to each one, and could also provide another reason. The post-examination survey then asked participants to identify their main reason for participating. Respondents could only choose one answer.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 7. Percentage of completed Sample Adult interviews conducted in person, by month, geographic area, and inclusion in 2021 National Health Interview Survey Follow-up Health Study sample

Sample characteristic	January	February	March	April	May	June	July	August	September	June–September
Total NHIS sample	21.5	23.1	28.3	34.3	39.9	42.5	46.4	42.8	42.4	43.6
Census regional offices with NHIS FHS sample	25.9	26.7	34.0	37.1	45.2	43.8	49.7	42.1	45.9	45.4
Primary sampling units not selected for NHIS FHS	28.7	30.0	38.5	43.0	50.8	51.9	56.3	47.5	50.8	51.0
Primary sampling units selected for NHIS FHS	22.0	21.5	26.5	28.5	35.6	29.6	38.9	33.3	37.7	35.0

NOTE: NHIS is National Health Interview Survey; FHS is Follow-up Health Study.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 8. Number of days between National Health Interview Survey interview and receipt of case information by study staff, and percentage of cases who ultimately scheduled follow-up home examination

	Scheduled an examination			
Number of days	Number	Percent	Number	Percent
7 or less	281	79.4	164	58.4
8 to 14	63	17.8	38	60.3
15 or more	10	2.8	5	50.0

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 9. Number of phone contact attempts, by type of participation in National Health Interview Survey Follow-up Health Study

Number of contact attempts	Scheduled but did not complete examination (*n* = 31)	Completed home examination (*n* = 176)	Contact made, no examination scheduled (*n* = 46)	Never spoke with study staff (*n* = 101)
Less than three	0 (0%)	43 (24.2%)	1 (2.0%)	0 (0%)
Three	0 (0%)	25 (14.2%)	2 (4.3%)	0 (0%)
More than three	31 (100%)	108 (61.4%)	43 (93.5%)	101 (100%)

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 10. Information about rescheduled National Health Interview Survey Follow-up Health Study home examination appointments

Characteristic	Number	Percent
Percent of initially scheduled appointments (n = 207) eligible for reschedule	91	44.0
Percent of cases eligible for reschedule (n = 91) that rescheduled	68	74.7
Percent of rescheduled cases (n = 68) that completed an examination	60	88.2
Person who initiated the reschedule among initially scheduled appointments eligible for reschedule:		
Participant	48	52.7
Health representative	28	30.7
Participant and health representative	15	16.5

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 11. Burden of scheduling among National Health Interview Survey Follow-up Health Study participants who completed a home examination

Level of difficulty scheduling visit	Number	Percent
Very easy	110	62.5
Easy	57	32.4
Difficult	8	4.5
Very difficult	1	0.6

NOTE: A total of 176 participants completed a home examination.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 12. Duration of National Health Interview Survey Follow-up Health Study home examination components among adults who completed each component, by age and sex

	Total for all examination components		Urine		Body measure		Blood pressure		Blood collection		Check out	
Characteristic	Median	Min, Max	Median	Min, Max	Median	Min, Max	Median	Min, Max	Median	Min, Max	Median	Min, Max
All	34	20,69	5	0,29	3	1,15	9	1,19	7	1,31	5	2,26
Sex												
Women	34	20,66	4	0,14	3	1,15	9	2,16	7	1,21	5	2,22
Men	34	21,69	5	0,29	3	1,14	9	1,19	6	1,31	5	2,26
Age												
18–34	33	20,63	3	0,16	3	1,7	9	2,17	6	1,15	5	2,15
35–64	34	20,69	4	0,22	3	1,14	9	1,19	7	1,28	5	2,26
65 and older	36	21,69	6	0,29	3	1,15	9	2,19	7	1,31	5	2,22
Women												
18–34 (n = 20)	32	20,61	2	1,7	3	2,7	9	2,14	6	1,15	4	3,12
35–64 (n = 39)	34	20,66	4	0,14	3	1,8	9	4,16	7	2,16	5	3,17
65 and older (n = 21)	38	22,59	6	1,12	3	1,15	9	2,14	7	3,21	5	2,22
Men												
18–34 (n = 19)	33	23,63	5	0,16	3	1,6	8	3,17	6	1,14	5	2,15
35–64 (n = 33)	33	22,69	5	0,22	4	1,14	9	1,19	7	1,28	5	2,26
65 and older (n = 31)	36	21,69	6	0,29	3	1,9	9	2,19	7	1,31	5	3,8

NOTE: Duration is measured in minutes.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 13. Number of days between National Health Interview Survey interview and completed Follow-up Health Study home examination

Duration (days) after interview	Number	Percent
1–14	23	13.1
15–28	87	49.4
29–49	51	29.0
50 or more	15	8.5

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 14. Burden of home visit and expectation of participation in future similar study among National Health Interview Survey Follow-up Health Study participants who completed home examination

Characteristic	Number	Percent
How easy or difficult was it for you to take part in this home visit?:		
Very easy	132	75.0
Easy	43	24.4
Difficult	1	0.6
Very difficult	0	0.0
How easy or difficult was it to get your questions answered?:		
Very easy	120	68.2
Easy	34	19.3
Difficult	0	0.0
Very difficult	0	0.0
Didn't have questions	22	12.5
How likely or unlikely are you to participate in a study like this in the future?:		
Very likely	113	64.2
Likely	61	34.7
Unlikely	2	1.1
Very unlikely	0	0.0

NOTE: A total of 176 National Health Interview Survey Follow-up Health Study participants completed a home examination.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 15. Percentage of all completed National Health Interview Survey Follow-up Health Study examinations with data entry errors

Data entry error	Number	Percent
Incorrect number of urine vials	9	5.1
Incorrect number of blood tubes collected	4	2.3
Incorrect height	6	3.4
Incorrect Visa card proxy ID	5	2.8

NOTE: A total of 176 National Health Interview Survey Follow-up Health Study participants completed a home examination.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Table 16. Number of days between home examination and arrival of biospecimens at laboratory

Duration (days)	Number	Percent
1	79	44.9
2	51	29.0
3–5	44	25.0
10	1	0.6

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Appendix I. Follow-up Health Study Introduction Questions in National Health Interview Survey Instrument

Survey Instrument

BIOINT1_A

Before we finish today, the study sponsor, the National Center for Health Statistics, or NCHS, which is part of the CDC, would like to invite you to participate in a follow-up health study. The goal of the study is to develop methods to collect important health data that cannot be obtained from an interview. If you participate you will receive $75. The Census Bureau does not have a role in this study. For this study, a trained health representative will come to your home at a day and time that is convenient for you. The health representative will measure your height, weight, waist, blood pressure, resting heart rate and will collect a blood sample. You will also be asked to provide a urine sample and feedback about your study experience. Your blood and urine will be tested for standard health measures such as liver and kidney function. You will receive your personal results and, as mentioned, $75. At the end of the study, NCHS will combine your results with the results of all other participants. This information will ONLY be used for statistical purposes.

Read if necessary: Strict federal laws prevent NCHS and its contractors from releasing information that could identify you or your family to anyone else without your permission. All identifying information is removed from the data.

If the respondent refuses, go to BIORFWHY_A

BIOINT2_A

This visit will take about an hour and your participation is voluntary. If you choose, you can complete just part of the study.

If the interview is in person: **Here is a brochure that explains in more detail what the study will be about.** *Hand over brochure.

If the interview is over the phone: **I am happy to answer questions and I can also send you a brochure explaining more about the study.** *If the respondent agrees to be contacted, mail study brochure after the end of the interview.

If the respondent refuses, go to BIORFWHY_A

BIONAME_A

ExamOne, a Quest Diagnostics company, is collecting the study data for NCHS. May NCHS provide them with your name, age, and gender, along with your address, and phone number so they may contact you to schedule an appointment?

Read if necessary: ExamOne will ONLY use this information for the purpose of scheduling and completing your home health visit. No other information about your health will be provided to ExamOne. **Read if necessary:** Study staff will use your age and gender to interpret the results from your home health visit.

If the respondent says anything other than yes (no, refuse, don't know), go to BIORFWHY_A

BIOPHONE_A

Your phone number is needed to participate in the follow-up study. Could you please provide a number?

If the respondent does not provide a phone number, go to BIORFWHY_A

BIODAY_A

What are the best days for the study representative to contact you? Would you say weekdays, weekends, or both?

BIOTIME_A

What is the best time of day for the study representative to contact you?

Would you say mornings, afternoons, evenings, or anytime? Enter all that apply

BIOTEXT_A: If they have difficulty reaching you by phone, is it OK for a study representative to text you?

If respondent says phone can't receive texts ("it's a landline"), enter 'no'.

BIOEMAIL_A

If they have difficulty reaching you, the study representative could try contacting you via e-mail. May I have your e-mail address?

Enter e-mail address. If respondent does not want to provide an e-mail address enter 'Refused'. If respondent does not have an e-mail address enter 'N'.

BIORFWHY_A

There are several reasons why someone may not want to take part in a study.

Please tell me the main reason why you don't want to take part in this study?

Read if necessary: The study sponsor wants to understand your concerns so they can plan better versions of this study in the future.

Use your best judgement. If respondent is hostile or agitated, don't ask this question, just enter CTRL-R. There will be an opportunity in the Back section for you to record your impression of the respondent's reason(s) for refusal.

Appendix II. National Health Interview Survey Follow-up Health Study-related Questions for Field Representative

Computer-assisted Personal Interviewing Instrument Completed by Field Representative

The following questions were included in the section of the National Health Interview Survey instrument with questions answered by the field representative. These questions were displayed only when the Sample Adult was selected for the Follow-up Health Study and the interview was conducted in English not via a proxy.

BIOBROCHURE

Did you give the Sample Adult a copy of the Follow-up Health Study brochure?

1. Yes
2. No
3. I offered it but the Sample Adult refused to take it
4. Interview was over the phone

If the Sample Adult refused to participate and then refused to explain why (RF or DK in response to BIORFWHY_A) go to BIORFWHYFR

BIORFWHYFR

What REASON(S), if any, did the Sample Adult give for REFUSING to be contacted to schedule the home health visit?

If the Sample Adult agreed to participate and gave a valid phone number, go to BIOOKWHYFR

BIOOKWHYFR

What REASON(S), if any, did the Sample Adult give for AGREEING to be contacted to schedule the home health visit? Enter 'N' for none.

Appendix III. Study Brochure

Your safety is important to us.
Health representatives working on this study are experienced and highly skilled employees of ExamOne, a Quest Diagnostics Company. They will wear a face shield, surgical mask, lab coat or long sleeves under scrubs, gloves, and closed-toe shoes. The National Center for Health Statistics recommends you wear a facemask during the visit. Study staff will follow standard safety procedures during the visit.

The tests are safe.
Some tests may cause you slight discomfort, such as having a blood sample drawn from a vein in your arm with a needle. We will not ask you to have any test that is wrong for you because of a health condition you have.

We ensure your safety.
For your protection, the ExamOne employee will show you a photo ID that includes the ExamOne logo which is presented below.

ExamOne®
A Quest Diagnostics Company

We guard your privacy.
All study staff took an oath to protect your privacy and are required to follow privacy and protection laws. Anyone who shares information about you can be fined up to $250,000, lose their job, and go to jail for up to 5 years. We will use data from this study only for statistical purposes.

The following federal laws protect your information: Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)), the Privacy Act of 1974 (5 U.S.C. § 552a), and the Confidential Information Protection and Statistical Efficiency Act of 2018 (Title III, Public Law 115-435).

National Health Interview Survey
Follow-Up Health Study
A Healthier America Begins With You

Thank you!

National Health Interview Survey
Since 1957

For more information on the NHIS Follow-Up Health Study, call us toll-free at
1-833-872-0534

The National Health Interview Survey Follow-Up Health Study is conducted by the National Center for Health Statistics, Centers for Disease Control and Prevention,
U.S. Department of Health and Human Services.

FHS-100
(12-2020)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

THE NATIONAL HEALTH INTERVIEW SURVEY
Follow-Up Health Study

Thank you for taking part in the National Health Interview Survey (NHIS). With the help of people like you, the NHIS continues to be the gold standard of health data in the United States.

To make sure we have timely information about the nation's health, we are conducting the NHIS Follow-Up Health Study. You have been chosen to be part of this important study.

Why should I participate?

This study is important. You can help us improve the way we understand and address important public health challenges like cardiovascular and kidney disease, anemia, high blood pressure, and diabetes.

Your participation is vital. Only a few select individuals can participate. No other person can take your place.

What do I have to do?

Answer the call! We will contact you in the next few weeks to schedule your appointment for a time that is convenient for you. The study representative can answer any questions you might have.

Answer the door. A health representative will come to your home at the scheduled time to measure your height, weight, waist, blood pressure, and resting heart rate. We will ask you to provide a blood sample and a urine sample. We will also ask for your feedback about this study to help improve it for future participants. The health visit will take about an hour.

What do I get from this study?

Important information you can use. At the end of the visit, we will give you a written summary of your immediate results. We will mail a second summary of results a few weeks after the visit. It will have the results from your blood and urine tests. These results can help you start important conversations with your health care provider and your family.

A $75 prepaid card to thank you for your time.

What health measures and test results are included?

Health Measures:

- Height and weight
- Waist circumference
- Blood pressure and pulse

Urine Tests:

- Creatinine
- Glucose
- Hemoglobin
- Microalbumin
- Protein
- Protein/Creatinine Ratio

Blood Tests:

Anemia Screen:

- Hemoglobin

Cholesterol Tests:

- Total Cholesterol
- Total Cholesterol: HDL Ratio
- High Density Lipoprotein (HDL)
- Low density Lipoprotein (LDL)
- Non-HDL Cholesterol
- Triglycerides

Diabetes Screen:

- Hemoglobin A1c
- Glucose

Liver and Kidney Function Tests:

- Albumin
- Albumin: Globulin Ratio
- Alanine Aminotransferase (ALT)
- Alkaline Phosphatase
- Aspartate Aminotransferase (AST)
- Bicarbonate
- Bilirubin
- Blood Urea Nitrogen (BUN)
- Calcium
- Chloride
- Creatinine
- Globulin
- Glomerular Filtration Rate (estimated)
- Potassium
- Protein
- Sodium

A Healthier America Begins With You

Appendix IV. Follow-up Brochure

Designed with you in mind

Safe

Staff are highly skilled and trained in all procedures used in this study.

Secure

We take your privacy very seriously. This study is bound by laws to protect your data according to rigorous privacy standards.

This includes the following privacy and protection laws: The Privacy Act of 1974, the Public Health Services Act, and the Confidentiality Information Protection and Statistical Efficiency Act.

Study staff have taken an oath to protect your privacy and are subject to a jail term of up to five years, a fine of up to $250,000, or both if they willfully disclose ANY identifiable information about you.

Convenient

You tell us the day and time that works for you. We will come to you.

Quick

The visit should take about an hour.

Easy

The experienced staff prioritize your comfort and peace of mind.

Call to schedule your appointment today
1-833-996-2771
(toll-free)

National Health Interview Survey
Since 1957

The NHIS Follow-up Health Study is conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention.

CDC

The National Health Interview Survey (NHIS)

Welcome to the NHIS Follow-up Health Study!

NHIS has been the leading national health survey since 1957. The power of NHIS data comes from people like you, who respond when selected. Your participation is important, and you cannot be replaced.

As a participant, you will receive:

A home health visit

An experienced health representative will come to your home to collect your health measures.

Important information you can use

After the home health visit, you will receive an easy-to-read report of your results. This report can help you start conversations about your health with your doctor and your family.

An opportunity to directly support successful health planning

Policymakers and public health professionals rely on NHIS data. By taking part, you will help improve the quality and value of that data. Better data supports better decisions about programs and funding that can impact you, your family, and your community.

A $75 prepaid card

Your participation is gratefully appreciated. You will receive a $75 prepaid card after the home visit. You can use it in stores, restaurants, and to make purchases online.

Here are some reasons why people participate.

It's important to me to give back to my community.

It's important to me to help my country.

I want to help with developing methods to better understand illnesses that affect my family and friends, like heart, liver and kidney disease.

It's important to me to take care of myself and my family. The more information I have to take care of myself, the easier it is to make sure I'm ready to take care of others.

What will YOUR reason be?

Please call our toll-free number today

1-833-996-2771 to schedule your appointment

It's important to me to know my numbers. I really appreciate that I didn't have to leave my home to get important lab tests.

It's important to me to make sure people like myself are included in health studies.

I've already made it this far. Now that I've finished the main survey, all that's left is this last step. I might as well finish it and reap the rewards.

They accommodated my schedule and the $75 prepaid card was really useful.

It's a rare opportunity to help policymakers write informed legislation. By taking part, I'll be making sure policymakers have information to make good decisions about how to spend my tax dollars.

1035747347.0421

Photos are of models and quotes are for illustrative purposes only.

Appendix V. Scheduling Scripts

Voicemail script for scheduler and recruitment specialist:

Hello, my name is ___. I'm calling on behalf of the CDC's National Center forHealth Statistics. I'm trying to reach {participant name} about scheduling a home health visit.Please call our toll-free number (1-833-996-2771) and let us know what time would be convenient for you. That's (1-833-996-2771). Thank you. We look forward to hearing from you!

Phone script for scheduler and recruitment specialist:

Hello, my name is, may I please speak with (PARTICIPANT NAME)?

Participant not home or unavailable:

Can you please ask {him/her} to call me at 1-833-996-2771? When is the best time to reach {participant name}?

Participant is available but person on the phone wants to know who is calling before handing the phone over:

I'm calling on behalf of the CDC's National Center for Health Statistics.

Participant is on the line now but wasn't the person who answered the phone:

Hello, my name is. **[Continue with Speaking to the participant.]**

Speaking to the participant:

I'm calling from the National Health Interview Survey Follow-up Health Study to schedule your home health visit.

Read if necessary: You spoke with an interviewer recently about general health topics like doctor's visits and health conditions and agreed to be contacted for this study.

[Answer any questions the respondent has.]

Before making the appointment, I need to ask about COVID-19 symptoms you may have or possible exposure to someone with COVID-19.

[Read COVID screening questions. (Appendix F)]

[If participant responds "YES" to any COVID screening question, schedule the participant's home health visit for a date more than 14 days after the current date, if the study will still be active at that time.]

[If participant responds "No" to all COVID screening questions, schedule the appointment as soon as is convenient for the participant and possible given health representative schedules.]

There are a few ways you can prepare for the visit.

[Read visit preparation instructions. (Appendix G)]

Your home health visit is scheduled with (NAME OF HEALTH REPRESENTATIVE). How would you prefer {she/he} contact you to remind you of the appointment– phone, text, or email? There may be fees to get a text message, depending on your plan.

Read if necessary: NCHS will not reimburse you for any text message charges.

[Enter preferred contact mode and phone number or email address in the scheduling system.]

[Provide the toll free number to the participant to call if they need to cancel or reschedule the appointment (1-833-996-2771).]

Thank you for agreeing to take part in this study.

Computer generated email and text message template

Email subject line/first line of the text message: Please call to schedule your CDC/NCHS home health visit

Thank you for agreeing to take part in our study.

Please call our toll-free number (1-833-996-2771) to schedule your home health visit at a time that is convenient for you.

We look forward to hearing from you!

National Center for Health Statistics Centers for Disease Control and Prevention

Appendix VI. COVID-19 Screening Questions

Have you experienced any of the following symptoms in the past 48 hours:

fever or chills

cough

shortness of breath or difficulty breathing

fatigue

muscle or body aches

headache

new loss of taste or smell

sore throat

congestion or runny nose

nausea or vomiting

diarrhea

Within the past 14 days, have you been in close physical contact with a person who tested positive for COVID-19 or has any symptoms of COVID-19?

Read if necessary: Close physical contact means being 6 feet or closer for at least 15 minutes

Are you isolating or quarantining because you were diagnosed with COVID-19, you may have been exposed to a person with COVID-19, or are worried that you may be sick with COVID-19?

Are you currently waiting on the results of a COVID-19 test?

Appendix VII. Visit Preparation Instructions

Drink water—it is important that you stay hydrated during the health visit

Wear short sleeves.

Please have photo identification ready to show the health representative. Examples include a driver's license, non-driver's ID, military ID, state ID, or passport.

Some of the tests are more accurate if you do not eat for 8 hours before the appointment. But you can still take part in the study no matter when you last ate. Would you like to know more about this topic?

If the participant says yes: If you choose not to eat for 8 hours before your appointment, you should still drink water and take your prescription medications as instructed by your doctor during that time. But avoid gum, breath mints, vitamins, and non-prescription medicine. Also, if you need to take any of your prescription medications with food, please do so. Remember, if you do eat in the 8 hours before your appointment, you can still take part in the study, and most of your results will be unaffected.

During the home visit, our health representative will need to be close to you in order to take measurements such as height and blood pressure. Therefore, they are required to wear full personal protective equipment including face shields. We recommend you wear a facemask at all times during the visit.

Read if necessary (Answers to possible participant questions)

Which tests are more accurate if I don't eat for 8 hours before the appointment?

The tests for pre-diabetes, diabetes, and cholesterol.

What if I have diabetes and take pills or insulin to treat it?

We will be testing to see how well your medicines are working to treat your diabetes. If your diabetes treatment plan will allow you to wait to take them until after your blood sample is taken, you can do so. Please consult with your medical provider if you have any questions about this. If you need to eat or drink with any of your medications, **please do so**. You can still take part in the study even if you do take your diabetes pills or insulin first.

What is personal protective equipment?

Personal protective equipment includes face shield, surgical mask, lab coat or long sleeves under scrubs, gloves, and close-toed shoes.

Will you provide a mask?

We will offer you a mask to wear during the visit.

Appendix VIII. Noncontact and Refusal Letters

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

{DATE}

Dear {PREFIX} {LAST NAME}:

Thank you for agreeing to take part in the National Health Interview Survey (NHIS) Follow-up Health Study!

Have you received a phone call or email from CDC's National Center for Health Statistics, or a text from 35842? That was us!

We want to make it easy for you to take part.

Please call our toll-free number 1-833-996-2771 to schedule your appointment at the time that works best for you.

If you still have questions, take a look at the enclosed brochures, or give us a call at 1-833-996-2771. We'd be happy to answer any questions you have.

We look forward to hearing from you!

Sincerely,

Director, National Center for Health Statistics
Centers for Disease Control and Prevention

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

{DATE}

Dear {PREFIX} {LAST NAME}:

You recently spoke with our study representative about the National Health Interview Survey (NHIS) Follow-up Health Study. We understand you may not want to take part – but we hope you do!!

By agreeing to participate, you can help us address important public health challenges facing the nation like COVID-19.

Please call our toll-free number 1-833-996-2771 to schedule your appointment at the time that works best for you.

We look forward to hearing from you!

Appendix IX. Appointment Reminder

Voicemail script for health representative:

Hello, this is (NAME) from ExamOne. I'm calling to confirm your home health visit with me on (MONTH, DAY) at (TIME). Please call (PROVIDE YOUR PROJECT CELL PHONE NUMBER) for important reminders about the visit. Thanks and see you soon.

Phone script for health representative:

Hello, my name is _____, may I please speak with (PARTICIPANT NAME)?

Participant not home or unavailable:

Can you please ask {him/her} to call me at <health representative's contractor-provided cell phone number>? When is the best time to reach (PARTICIPANT NAME)?

Participant is available but person on the phone wants to know who is calling before handing the phone over:

I'm calling on behalf of the CDC's National Center for Health Statistics.

Participant is on the line now but wasn't the person who answered the phone*:*

Hello, my name is_____. **[Continue with Speaking to the participant.]**

Speaking to the participant:

I'm calling from the National Health Interview Survey Follow-up Health Study. I'm calling to confirm your home health visit with me on (MONTH, DAY) at (TIME).

Before I come to your home, I need to ask you again about COVID-19 symptoms you may have or possible exposure to someone with COVID-19

[Read COVID screening questions.]

[If participant responds "YES" to any COVID screening question, reschedule the participant's home health visit for a date more than 14 days after the current date, if the study will still be active at that time.]

Before the visit, please be sure to drink plenty of water, wear short sleeves, and have a photo ID ready. We also recommend that you wear a mask. Some of your tests will be more accurate if you do not eat for 8 hours before the appointment. But you can still take part in the study no matter when you last ate. Do you have any questions?

[Answer any questions the respondent has.]

If any of your answers to the COVID-19 questions change before my visit, please call me. My phone number is (PROVIDE YOUR PROJECT CELL PHONE NUMBER). Thank you.

Appendix X. Home Visit Kit Inventory

The Table shows the items included in the National Health Interview Survey Follow-up Health Study home visit kit carried by the health representative.

Table. National Health Interview Survey Follow-up Health Study home visit kit inventory

Item	Quantity
General supplies:	
Disposable 6x6 pad	1
Disposable patient towel	1
Trash bag	1
Sanitizing wipes	2
IATA[1] shipping container	1
Refrigerant pack	1
Cellulose wadding	1
FedEx Air bill (on IATA shipping container)	1
Surgical mask	1
Disposable stylus	1
Tape strips	2
Biohazard bag	1
Exempt human specimen label (on IATA shipping container)	1
Blood collection supplies:	
Alcohol prep pad	2
Disposable tourniquet	1
4 mL EDTA vacutainer	1
10 mL SST[2] vacutainer	2
Bandage	1
Gauze pad	2
21 g needle	1
23 g butterfly needle	1
Vacutainer hub	2
Nitrile gloves	1
Sample ID label	3
Specimen transport bag	1
Urine collection supplies:	
Collection container	1
Transport tube	2
Plastic transfer pipet	1
Nitrile gloves	1
Sample ID label	3
Specimen transport bag	2
Paper supplies:	
Home visit kit inventory sheet	1
Quest Diagnostics requisition form (1 blood, 1 urine)	2
Consent form	1
Test and measurement handout	1
Report of findings	1
Visa card FAQs	1
Visa card and carrier sheet	1

[1]International Air Transport Association.
[2]Serum separator tube.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Appendix XI. Examination Protocol Deviations From Life Insurance Examination Protocols

The blood pressure and body measurement components of the National Health Interview Survey Follow-up Health Study home visit followed the protocols for life insurance paramedical examinations, with slight modifications to the height and waist circumference measurements. The Table describes the nature and reason for those modifications.

Table. Comparison of protocols for measuring height and waist circumference: Life insurance paramedical examination and National Health Interview Survey Follow-up Health Study home visit

Measurement	Life insurance protocol	NHIS Follow-up Health Study protocol	Reason for modifying life insurance protocol
Height	Measurements are taken from the bottom of the participant's foot to the top of the participant's head. The participant remains standing against the wall when recording the measurement. One measurement is recorded in inches, to the nearest inch.	The measurements were taken from the floor to a sticky note that was placed on the wall alongside the straightedge placed on top of the participant's head. The participant stepped away from the wall while the health representative used the tape measure to measure the distance from the floor to the sticky note. One measurement was recorded in inches to the nearest half-inch.	NHIS FHS used the protocol that ExamOne typically uses in their research studies. The height measurement was measured to the nearest half-inch to match the reported body mass index format in the report of findings, which was to the nearest 0.1.
Waist circumference	Body mass index is a poor measurement of true obesity because muscle weight is not considered in the calculation, which includes only height and weight. For this reason, the life insurance industry guideline is to take chest and waist measurements on males only to get a better understanding of body mass index. The waist measurement is taken by the examiner, who wraps the measuring tape around the participant at the level of the umbilicus, with the abdomen relaxed and the measuring tape at the same level front and back. One measurement is taken in inches to the nearest inch.	The measurement was taken on male and female participants. The measurement was taken by having the participant hold the zero end of the tape measure at the umbilicus and turning 360 degrees while the health representative held the other end of the tape measure. The health representative then recorded the measurement where the two ends of the tape measure met. One measurement was taken in inches to the nearest half-inch.	Because the follow-up study required that waist circumference be taken on both males and females, ExamOne recommended that the protocol be modified to avoid having the health representative place their arms around the participant's waist. The weight measurement was measured to the nearest half-inch to match the reported body mass index format in the report of findings, which was to the nearest 0.1.

SOURCE: National Center for Health Statistics, National Health Interview Survey Follow-up Health Study, 2021.

Appendix XII. Informed Consent Form

OMB # 0920-1208
Expiration Date: 8/31/2023

NHIS Follow-up Health Study
HOME VISIT CONSENT

Thank you for participating in the National Health Interview Survey (NHIS). You have been chosen to take part in the NHIS Follow-up Health Study. This study, like the NHIS, is conducted by the National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC).

We will use what we learn from this study to develop methods to measure liver, and kidney health, and better understand public health challenges such as diabetes, at the national level.

You will get: 1. Health test results which you can use to start conversations about your health with your doctor and your family. **2.** A $75 prepaid card that you can use in stores, restaurants, and to make purchases on-line.

The health representative will measure your height, weight, waist, blood pressure, resting heart rate, and collect a blood sample. You will be asked to provide a urine sample and answer some questions about your study experience. The health visit will take about an hour. We may contact you after the visit to check the work of our staff.

Your safety is important to us. The health representatives working on this study are experienced and highly skilled. They are employees of ExamOne, a Quest Diagnostics Company. They will wear a face shield, surgical mask, lab coat or long sleeves under scrubs, gloves, and close-toed shoes. NCHS recommends you wear a facemask during the visit. Study staff will follow standard safety procedures during the visit.

The tests are safe. Some tests may cause you a bit of discomfort. One example is having a blood sample taken. For the blood sample, you will have some blood drawn from a vein in your arm with a needle. We will not ask you to have any test that is wrong for you because of a health condition you have.

You will get some results immediately and some a few weeks later. At the end of the visit, the health representative will give you a written report. That report will contain your height, weight, waist measurement, heart rate and blood pressure findings. If your blood pressure findings indicate an urgent health problem, the health representative will let you know.

Your blood and urine samples will be shipped to a lab. That lab will test your samples for standard health measures. Those measures are explained in the Measures and Tests handout that goes with this form. Seven days after the testing is done, the lab will destroy your samples. Your test results, after all identifying information has been removed, will be retained by NCHS and its contractors.

A second report will be mailed to you several weeks after this visit. That report will have the results from your blood and urine tests, if they were successfully performed. If they were not successfully performed, your report will tell you why. If these results show urgent health problems, we will notify you as soon as possible. NHIS does not cover the cost of any health care you may decide to get after the visit. If you have questions about your results, you can call our Medical Officer, Dr. Duong (Tony) Nguyen, toll-free at **1-833-872-0534**.

OMB # 0920-1208
Expiration Date: 8/31/2023

Your information will be protected. We take your privacy very seriously. The information you give us will be kept confidential and used for statistical purposes only. This means that your information will be combined with other people's information in a way that keeps everyone's identity confidential. As required by federal law, only those NCHS employees, our contractors, and our specially designated agents who must use your personal information for a specific reason can see it. Otherwise, your data will only be shared after all information that could identify you and/or your family has been removed. After that information has been removed, your data might be used by NCHS for future studies. Please refer to the box below for more detailed information on the strict federal laws that protect your privacy.

You may choose to take part in this study. That is your choice. There is no penalty if you refuse. If you choose to participate, you don't have to do every part of the study and you can stop at any time. The more parts you do, the more complete and valuable your results will be.

Do you have more questions about the study? Your health representative can discuss other questions or concerns you might have. You can also make a free call to our Medical Officer Dr. Duong (Tony) Nguyen to discuss any aspect of the study. He can be reached toll-free at **1-833-872-0534**, Monday- Friday, 9:00 AM-4:00 PM ET. If you have questions about your rights as a participant in this study, call the NCHS Ethics Review Board, toll free, at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # 2019-09. Your call will be returned promptly.

I have read the information above and in the accompanying handouts. I freely choose to take part in the study.

_____ _____

Signature of person participating in the study Date

Print:_____

First Middle Last

Assurance of Confidentiality – We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you.

Medical errors and injuries are very rare. The NHIS program cannot provide money or other compensation if they occur. However, if you believe you have been harmed as a result of your participation in NHIS or the NHIS Follow-up Health Study, we want to know about it. Please call us at 1–833-872-0534. You also have a right to file a claim under the Federal Tort Claims Act with the Centers for Disease Control and Prevention. We can provide you with information about how to do so. You must file the claim within two years after the date you became aware of the personal injury, loss of property, or other damage.

Appendix XIII. Measurement and Laboratory Test Explanation

NHIS Follow-Up Health Study

Health Measurements and Laboratory Tests on Blood & Urine

Below are brief descriptions of the health measurements, urine tests, and blood tests included in this health study. Please note that this study does not test blood and urine for drugs, alcohol, pregnancy or genetic ancestry.

Health Measurements

Your **height** and **weight** will be measured to calculate your **Body Mass Index (BMI)**.

Your **waist circumference** will be measured.

Your **blood pressure** and **pulse** will be taken.

Urine Tests

Creatinine: A waste product of normal muscle breakdown filtered by the kidneys out of your blood into your urine. This test shows how well your kidneys are working.

Glucose: A type of sugar. It is your body's main source of energy. If too much glucose gets into the blood, the extra glucose will be eliminated through your urine.

Hemoglobin: The molecule in red blood cells. This test looks for the presence of blood in your urine.

Microalbumin: A test to detect very small levels of albumin in urine. The test is used to detect early signs of kidney damage in people who are at risk of developing kidney disease.

Protein: A test to detect albumin in urine. The test is used to detect kidney damage.

Protein:Creatinine Ratio (Calculated): A test to screen for excess protein in the urine. It can help your doctor evaluate and monitor kidney function, and detect kidney damage.

Blood Tests

Diabetes Screen

Hemoglobin A1c: Gives information about your average blood sugar level during the past 2–3 months. High levels are seen in diabetes.

Glucose: The amount of sugar in your blood. Glucose is an important source of energy for all body organs and functions. High levels are seen in diabetes.

Liver and Kidney Function Tests

Albumin: A protein in your blood. Albumin keeps fluid from leaking out of blood vessels, nourishes tissues, and transports hormones, vitamins, drugs, and substances like calcium throughout the body.

Albumin:Globulin Ratio: This test is used to screen for and help diagnose certain diseases or disorders.

Alanine Aminotransferase (ALT): ALT is an enzyme involved in breakdown of body chemicals and is mostly found in the liver. ALT levels reflect the health of your liver.

Alkaline Phosphatase: A blood enzyme that comes from liver and bone cells.

Aspartate Aminotransferase (AST): AST is an enzyme involved in the breakdown of body chemicals, and AST levels reflect the health of your liver.

Bicarbonate: A molecule in blood that shows the balance between your breathing and chemical systems.

Bilirubin: A chemical produced when hemoglobin breaks down. Bilirubin is broken down by the liver and then it becomes a waste product. It is used as a measure of the health of your liver.

Blood Urea Nitrogen (BUN): Urea is a waste product that your kidneys filter out of your blood. This test helps show how well your kidneys are working.

Calcium: A mineral found mostly in the bones. It is needed for muscle and nerve action, bone strength, and blood clotting.

Chloride: One of the electrolytes found in your body. Chloride plays an important role in the balance of body fluids.

Creatinine: A waste product of normal muscle breakdown filtered by the kidneys out of your blood into your urine. This test shows how well your kidneys are working.

Globulin: A protein in the blood. Globulins play an important role in liver function, blood clotting, and fighting infection.

Glomerular Filtration Rate (estimated): This test is used to detect chronic kidney disease (CKD), as well as monitor CKD progression and response to therapy.

Potassium: A nutrient found in your body's cells. Potassium helps control muscle and nerve actions.

Protein: The total amount of protein (both albumin and globulin) in the fluid part of your blood. Protein is an important part of all your body's cells and tissues.

Sodium: One of the electrolytes found in body fluids. Sodium plays an important role in the balance of body fluids and in muscle and nerve actions.

Cholesterol Tests

Total Cholesterol: A fat substance normally found in the bloodstream and in all your body's cells. Too much cholesterol is a major risk for a heart attack and stroke.

Total Cholesterol:HDL Ratio: Compares the total cholesterol to the HDL, or good, cholesterol. This test can help your doctor determine your risk of heart problems or stroke.

High Density Lipoprotein (HDL) Cholesterol: HDL cholesterol is known as the "good" cholesterol because it helps remove cholesterol from the body cells and helps prevent fatty buildup in blood vessels.

Low Density Lipoprotein (LDL) Cholesterol: LDL cholesterol is known as the "bad" cholesterol because it can lead to cholesterol buildup in your body cells and can lead to fatty buildup in blood vessels.

Non-HDL Cholesterol: A test to measure how much of the "bad" cholesterol you have in your blood. It can help your doctor evaluate your risk for heart disease.

Triglycerides: A fat in the blood. High levels can lead to heart disease and stroke.

Anemia Screen

Hemoglobin: The molecule in red blood cells that carries oxygen to all body tissues.

Appendix XIV. Post-examination Survey

We would like to ask you a few questions about your study experience. Your feedback will help us improve studies like this in the future. Please answer honestly. There are no right or wrong answers.

How easy or difficult was **scheduling your appointment**? Very easy, easy, difficult, or very difficult? (Don't read: Don't know, refused)
(Ask if response to Q1 is easy, difficult, or very difficult): In what ways could **the appointment scheduling be improved**?

How easy or difficult was it to **get your questions answered**? Very easy, easy, difficult, or very difficult? I didn't have any questions (Not read to respondent, code only if volunteered). (Don't read: Don't know, refused)
(Ask if response to Q3 is easy, difficult, or very difficult): In what ways could we **better answer your questions**?

How easy or difficult was it for **you to take part in this home visit**? Very easy, easy, difficult, or very difficult? (Don't read: Don't know, refused)
(Ask if response to Q5 is easy, difficult, or very difficult): In what ways could the **home visit be made easier and more convenient?**

How likely or unlikely are you to participate in a study like this in the future? Very likely, likely, unlikely, or very unlikely? (Don't read: Don't know, refused)

What were your concerns, if any, about participating?

Please tell me yes or no, whether you took part in this study for any of the following reasons:
(Read a through f) (Answer options on the screen: Yes, No Don't read: Don't know, refused)
Free test results
The $75 prepaid card
Help with health efforts in the United States
Improve information used by policymakers
Some other reason_____
(Ask if response to 9f was yes) What was that reason?

(Ask if more than 1 response selected in Q9 a-f) What was your main reason for taking part in this follow-up study? Pick one or specify

Free test results

The $75 prepaid card

Help with health efforts in the United States

Improve information used by policymakers

Other_____

Appendix XV. Preliminary Report of Findings

NHIS Follow-up Health Study
REPORT OF FINDINGS

Date of Home Visit: _____

Participant Name: _____

Participant ID: _____

This report provides you with results from today's body and blood pressure measurements. You will receive your results from the laboratory blood and urine tests in the mail in several weeks.

The NHIS Follow-up Health Study visit is not intended to be a substitute for visits to your medical care provider. Your health care provider can help you understand your study results in the enclosed report.

Please keep this document in a safe place so that you can control who sees it. NCHS can only protect information that is inside NCHS systems.

If you have any questions about your results, you can call our Medical Officer, Dr. Tony Nguyen, toll-free at **1-833-872-0534** between 9:00 AM and 4:00 PM Eastern Time, Monday through Friday.

Body Measurements

Height: ____ ft ____ inches

☐ **This measurement was not done for you during the home visit.**

Weight: _____ lbs.

☐ **This measurement was not done for you during the home visit.**

Waist Circumference: _____inches

☐ **This measurement was not done for you during the home visit.**

Body Mass Index (BMI): ____

The Body Mass Index (BMI) is used to define the categories of underweight, healthy weight, overweight, and obesity. BMI is calculated from measured height and weight using the formula below:

BMI=weight (lbs.) ÷ height (in.) ÷ height (in.) x 703.

1) Your blood pressure today **is within the normal range**.*

2) Your blood pressure today is **elevated**. Based on national guidelines for the treatment of hypertension*, you should take this report to a health care provider within the next 3-6 months to have your blood pressure rechecked.

3) Your blood pressure today is **high**. Based on national guidelines for the treatment of hypertension*, you should take this report to a health care provider within two weeks.

4) Your blood pressure today is **very high**. Based on the national guidelines for the treatment of hypertension*, you should take this report to a health care provider within two weeks.

5) Your blood pressure today is **severely high**. Based on national guidelines for the treatment of hypertension*, this level warrants immediate attention by a health care provider. Our Medical Officer will contact you to answer any questions you may have.

*ACC/AHA Hypertension Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, *American Journal of Hypertension*, 31(2), 2018, p133-35.

These measurements were obtained as part of a health study and do not represent a medical diagnosis. Interpretation of these measurements must be made by your physician.

Appendix XVI. Final Report of Findings

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

John Doe
1111 Main Street
Anywhere, US 11111

Dear John Doe,

We appreciate your participation in the NHIS Follow-up Health study conducted by the National Center for Health Statistics.

Enclosed are your test results from the measurements taken during our visit to your home on 1/1/2021 and from the tests that were run on the blood and urine that you provided during that visit. We have provided you with information about what your height, weight, and blood pressure could mean to your health based on recommended guidelines. In addition, we have provided all laboratory results with reference ranges. Reference ranges are sets of values that can be used by your health care provider to interpret your results. **We reviewed your test results, found that one or more values were abnormal, and want to make you aware of them. These results are flagged in the table.**

The home visit was not intended to be a substitute for visits to your health care provider. Your health care provider can help you understand your study results in the enclosed report.

If you have any questions about your results, you can call our Medical Officer, Dr. Tony Nguyen, toll-free at **1-833-872-0534** between 9:00 AM and 4:00 PM Eastern Time, Monday through Friday.

Sincerely,

Brian C. Moyer, Ph.D.
Director, National Center for Health Statistics
Centers for Disease Control and Prevention

Enclosure

NHIS Follow-Up Health Study

These measurements were obtained as part of a health study and do not represent a medical diagnosis. Interpretation of these measurements must be made by your physician.

Please keep this document in a safe place so that you can control who sees it. NCHS can only protect information that is inside NCHS systems.

Date of Home Visit:	1/1/2021
Participant Name:	John Doe
Participant Age at Home Visit:	50
Participant Gender:	Male
SA ID:	100154

Body Measurements

Height:	5 FT. 9 IN.
Weight:	195 LBS.
Body Mass Index (BMI):	28.8

Based on your height, your BMI is:

Body Mass Index	National Institutes of Health (NIH) Statement
>= 25.0 - < 30.0	**NIH classifies this as overweight.**

Waist circumference: 42 INCHES

Your BMI and waist circumference measurements today indicate you are **at a high risk** for type 2 diabetes, high blood pressure, and cardiovascular disease. This is based on guidelines from NIH's National Heart, Lung and Blood Institute.

Blood Pressure & Heart Rate

		Normal
Systolic Blood Pressure:	114 mm Hg	< 120
Diastolic Blood Pressure:	70 mm Hg	< 80
Resting Heart Rate:	57 BPM	

Your blood pressure today is **within the normal range**.

*ACC/AHA Hypertension Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, *American Journal of Hypertension*, 31(2), 2018, p133-35.

Laboratory Tests - Blood

Number of hours fasted prior to blood draw: (10)

	Result	Units	Flag	Reference Range
Hemoglobin A1c	5.4	%		< 5.7
Glucose	95	mg/dL		65-99
Albumin	3.8	g/dL		3.6-5.1
Albumin:Globulin Ratio	1.6			1.0-2.5
Alanine Aminotransferase (ALT)	18	U/L		9-46
Alkaline Phosphatase	53	U/L		35-144
Aspartate Aminotransferase (AST)	14	U/L		10-35
Bicarbonate	25	mmol/L		20-32
Total Bilirubin	0.7	mg/dL		0.2-1.2
Direct Bilirubin	0.2	mg/dL		=<0.2
Indirect Bilirubin	0.5	mg/dL		0.2-1.2
Blood Urea Nitrogen (BUN)	17	mg/dL		7-25
Calcium	9.2	mg/dL		8.6-10.3
Chloride	106	mmol/L		98-110
Creatinine	0.97	mg/dL		0.70-1.18
Globulin	2.4	g/dL (calculated)		1.9-3.7
eGFR if non-African American	>=60	mL/min/1.73m^2		> =60
eGFR if African American	>=60	mL/min/1.73m^2		> =60
Potassium	4.7	mmol/L		3.5-5.3
Total Protein	6.2	g/dL		6.1-8.1
Sodium	140	mmol/L		135-146
Total Cholesterol	133	mg/dL		<200
Total Cholesterol/HDL Ratio	2.6	mg/dL		<5.0
HDL Cholesterol	52	mg/dL		> = 40
LDL Cholesterol	64	mg/dL		<100
Non-HDL Cholesterol	81	mg/dL		<130
Triglycerides	88	mg/dL		<150
Hemoglobin	13.1	g/dL	L	13.2-15.5

**HEMOGLOBIN A1c: For the purpose of screening for the presence of diabetes: <5.7% Consistent with the absence of diabetes 5.7-6.4% Consistent with increased risk for diabetes (prediabetes) > or =6.5% Consistent with diabetes This assay result is consistent with a decreased risk of diabetes. Currently, no consensus exists regarding use of hemoglobin A1c for diagnosis of diabetes in children. According to American Diabetes Association (ADA) guidelines, hemoglobin A1c <7.0% represents optimal control in non-pregnant diabetic patients. Different metrics may apply to specific patient populations. Standards of Medical Care in Diabetes(ADA).*
**LDL-CHOLESTEROL: Reference range: <100 Desirable range <100 mg/dL for primary prevention; <70 mg/dL for patients with CHD or diabetic patients with > or = 2 CHD risk factors. LDL-C is now calculated using the Martin-Hopkins calculation, which is a validated novel method providing better accuracy than the Friedewald equation in the estimation of LDL-C. Martin SS et al. JAMA. 2013;310(19): 2061-2068 (http://education.QuestDiagnostics.com/faq/FAQ164)*

**NON HDL CHOLESTEROL: For patients with diabetes plus 1 major ASCVD risk factor, treating to a non-HDL-C goal of <100 mg/dL (LDL-C of <70 mg/dL) is considered a therapeutic option.*

Laboratory Tests - Urine

	Result	Units	Flag	Reference Range
Creatinine	170	mg/dL		20-320
Glucose	NEGATIVE			
Hemoglobin	<0.4	mg/dL		<1.1
Microalbumin	1.4	mg/g creat		Not Established
Protein	18	mg/dL		5-25
Protein/Creatinine Ratio	0.106	mg/mg creat		0.022-0.128

**HEMOGLOBIN, FREE, URINE: THIS RESULT HAS BEEN VERIFIED BY REPEAT ANALYSIS.*
**ALBUMIN, URINE: Reference Range Not established*

*** Not available due to lab error

Laboratory Information

The following CLIA-certified laboratory performed the named tests on biologic specimens

Quest Diagnostics 10101 Renner Blvd Lenexa, KS 66219 CLIA #: 17D0648226
Quest Diagnostics Nichols Chantilly 14225 Newbrook Drive Chantilly, VA 20151 CLIA #: 49D0221801 *Urine Free Hemoglobin Only*

Appendix XVII. Technical Notes

The measures presented in this report are described below, organized by research question.

Research Question 1: Participation, Component Completion, Biological Measure Analysis, and Reason for Nonparticipation

Participation and Component Completion Measures

Agreed—The Sample Adult (Sample Adult) gave permission for their name, phone number, and other contact information to be passed to the contractor.

Spoke with study staff—Sample Adult spoke with study staff on the phone.

Scheduled appointment—Sample Adult scheduled an appointment for a home visit.

Completed examination—Sample Adult scheduled an appointment and then provided consent when the health representative visited their home at the scheduled time. All Sample Adults who provided consent then completed at least one component of the protocol, and most completed all. All the Sample Adults who provided consent when the health representative visited their home were considered to have completed the examination, no matter how many components they completed.

Completed height, weight, and waist circumference—The health representative successfully measured the Sample Adult's height, weight, and waist circumference.

Completed blood pressure—The health representative successfully measured the Sample Adult's blood pressure and pulse.

Provided a urine sample—Sample Adult provided a urine sample of adequate volume to send to the laboratory for processing.

Provided a blood sample—The health representative was able to collect a blood sample of adequate volume to send to the laboratory for processing.

Completed checkout—Sample Adult received both the initial report of findings and the prepaid gift card, whether or not the participant completed the post-examination survey.

Completed all parts of the examination—Sample Adult completed the height, weight, waist circumference, blood pressure, and checkout components and also provided a blood and urine sample.

Fasted before the examination—Sample Adult fasted for at least 8 hours before the examination.

Biospecimen Processing Measures

Received complete, partial, or no blood test results—Sample Adult provided a blood sample of adequate volume to send to the laboratory for processing and received complete, partial, or no blood test results.

Receive complete, partial, or no urine test results—Sample Adult provided a urine sample of adequate volume to send to the laboratory for processing and received complete, partial, or no urine test results.

Nonparticipation Measures

Sample Adults whose contact information was passed to the contractor but who never completed an examination were categorized by the type of interaction they had with the study staff.

Never spoke to study staff—Sample Adult spoke with neither schedulers nor recruitment specialists.

Maximum contacts—Includes Sample Adults who spoke with a scheduler but never scheduled an appointment before the maximum number of contacts was reached, could not be reached after a scheduled appointment did not occur so the appointment was not rescheduled, or called and left a message or sent an e-mail but never spoke to a scheduler or recruitment specialist.

Refusal—Sample Adult refused the study after speaking with a scheduler or after scheduling an appointment. Note that while the scheduling and refusal conversion protocol took different paths depending on whether the scheduler or refusal converter determined a Sample Adult's behavior to be a hard or soft refusal, there is only one outcome code that refers to verbally refusing to participate.

No show—Sample Adult scheduled one or more appointments but did not keep an initial or rescheduled appointment and did not reschedule (again).

Other—All other Sample Adults whose contact information was passed to the contractor but did not start an examination.

Research Question 2: Reason for Refusal, Motivation for Participation, and Respondent Concern Measures

Reasons for Refusal at Interview

If the Sample Adult refused to be contacted for the National Health Interview Survey Follow-up Health Study (NHIS FHS) when asked by the field representative (FR), the FR asked, "There are several reasons why someone may not want to take part in a study. Please tell me the main reason why you don't want to take part in this study?" The Sample Adult's verbatim responses to this question were coded into categories as described in "Invitation to Study and Collection of Permission to Be Contacted."

Motivation for Participation at NHIS Interview

If the Sample Adult agreed to be contacted for NHIS FHS and gave a valid phone number when asked by the FR, then the paradata section at the end of the NHIS instrument asked the FR "What reasons, if any, did the Sample Adult give for agreeing to be contacted to schedule a home health visit?" The FR's verbatim responses to this question were coded into categories.

Reasons for Refusal at Scheduling

If the Sample Adult refused, the scheduler recorded the reason for refusal, if the Sample Adult gave one.

Participant Concerns Assessed in Post-examination Survey

During the post-examination survey, participants were asked if they had any concerns about participating in the study and to describe their concerns. Westat staff coded the verbatim answers provided into nine categories.

Participant Motivation Assessed in Post-examination Survey

To assess factors that motivated participants to complete the home examination, they were asked after the examination whether any of four reasons contributed to their decision to participate. They were also allowed to provide a reason other than the precoded reasons. After reporting all reasons that impacted their decision, participants were asked to identify the main reason. The answer options provided were the following:

- Free test results
- $75 prepaid gift card
- Help with health efforts in the United States
- Improve information used by policymakers
- Some other reason

Research Question 3: Operational Challenges of Gaining Sample Adult Initial Agreement to Participate

Mean Time FRs Spent Reading Text Describing NHIS FHS to Sample Adult

The text describing NHIS FHS is shown under the headings BIOINT1_A, BIOINT2_A, and BIONAME_A in Appendix I. The amount of time each FR spent reading this text to each Sample Adult was calculated by subtracting the time stamp recorded by the NHIS instrument when the FR entered the BIOINT1_A screen and the time stamp recorded by the NHIS instrument when the FR exited the BIONAME_A screen.

Expected Time FRs Spent Reading Text Describing NHIS FHS to Sample Adult

Six National Center for Health Statistics members of the NHIS FHS planning team timed themselves reading the text, as described in the previous measure, at a leisurely pace, three times. The mean of those 18 times was the expected duration.

FR Survey Measures

The results from the web survey administered to the NHIS FRs who had completed at least one NHIS FHS interview were calculated by the Center for Behavioral Science Methods, the same organization at the U.S. Census Bureau that collected the data and conducted the post-FHS FR focus groups. The measures from that analysis included in this report are listed.

Feeling of preparation to ask Sample Adults about NHIS FHS—FRs were asked, "After you received your Commerce Learning Center training, how prepared were you to ask Sample Adults about the NHIS Biomeasure Follow-up Health Study?" FRs could answer "very prepared," "somewhat prepared," "neither prepared nor unprepared," "somewhat unprepared," or "very unprepared."

Need to rephrase the questions about being contacted for the study—FRs were asked, "In general, how often did you need to rephrase questions in the BIO section in your own words to make this section easier to administer?" FRs could answer "always," "most of the time," "sometimes," or "never."

Could read the introduction screens without being interrupted by Sample Adult—FRs were asked, "How often

were you able to get through the introduction screens in the BIO sections without being interrupted by the Sample Adult?" FRs could answer "always," "most of the time," "sometimes," or "never."

Use of study tools in convincing reluctant Sample Adults to participate—FRs were asked, "How helpful were the following tools for convincing reluctant Sample Adults to participate in the NHIS Biomeasure Follow-up Health Study, CLC BIO section training, FAQs in the instrument, $75 incentive, memo with suggested language." FRs could answer "very helpful," "somewhat helpful," "neither helpful nor unhelpful," "somewhat unhelpful," "very unhelpful," "I don't remember using this tool," or "I didn't use this tool."

Whether it would be easier to convince Sample Adults to provide their contact information for FHS if they could have told them in advance about the study—FRs were asked, "Would it be easier for you to convince Sample Adults to provide their contact information for the NHIS Biomeasure Follow-up Health Study if you could tell them in advance about the study?" FRs could answer "yes," "no," or "I'm not sure."

Whether it would be easier to convince Sample Adults to provide their contact information for FHS if the materials provided more detail on how the data would be used or how participation would benefit the Sample Adult—FRs were asked, "Please select what changes to the materials you think would be helpful for convincing reluctant Sample Adults to participate in the NHIS Biomeasure Follow-up Health Study." FRs could select answer options including providing more detailed information about how the data will be used, and providing more information about how participation will benefit the Sample Adult.

Helpfulness of incentive for convincing reluctant Sample Adults to participate—FRs were asked, "Sample Adults are now offered a $75 incentive for participating in the NHIS Biomeasures Follow-up Health Study. How can this incentive be improved for the future?" FRs could type a verbatim response. These responses were coded by Center for Behavioral Science Methods staff into the following categories:

- Increase incentive or add more benefits
- Talk about incentive before invitation
- Fine as is
- Incentive did not impact decision to participate

Ease or difficulty of convincing Sample Adults to participate—FRs were asked, "How easy or difficult was it to convince Sample Adults to participate in the Biomeasure Follow-up Health Study?" FRs could answer "very easy," "somewhat easy," "neither easy nor difficult," "somewhat difficult," or "very difficult."

Concern that administering NHIS FHS would discourage Sample Adult from completing Sample Child interview—FRs were asked, "How concerned were you that administering the BIO section would affect the Sample Adult's willingness to complete the Sample Child interview?" FRs could answer "very concerned," "somewhat concerned," "neither concerned nor unconcerned," "unconcerned," or "very unconcerned."

NHIS Interview Mode

At the end of the NHIS interview, the FR enters whether the Sample Adult interview was conducted in person, by phone, or partially in person and partially by phone. Interview mode was coded as in person if the first option was selected, and by phone if either of the second two options was selected.

Research Question 4: Operational Challenges of Scheduling Home Health Visit Appointment

Reasons Appointment Was Eligible for Reschedule

Appointments eligible for reschedule were categorized into three groups—eligible for a reschedule due to a participant reason, eligible for reschedule due to a health representative reason, and eligible for a reschedule due to both a participant and a health representative reason.

Post-examination Survey Measures: Ease of Appointment Scheduling

Participants were asked, "How easy or difficult was scheduling your appointment?" They could respond "very easy," "easy," "difficult," or "very difficult." Respondents who answered that scheduling the appointment was anything other than very easy were then asked, "In what ways could the appointment scheduling be improved?"

Research Question 5: Operational Challenges of Conducting In-home Health Visit

Examination Durations

Total examination duration was calculated as the time between completion of the home visit consent process and the completion of the checkout component.

The duration of the examination components was calculated as the time between that component's start and end time stamp. Of the 176 completed cases, 7 cases with durations shorter than 20 minutes and 6 cases with durations longer than 70 minutes were excluded. According to the contractor, very short durations were likely cases in which the health representative completed data entry at the end of the visit.

The very long durations included cases where the laptop was left open after the visit was complete and two cases that spanned two home visits.

Post-examination Survey Measures: Burden of Participation

Participants were asked, "How easy or difficult was it for you to take part in this home visit?" Response options were "very easy," "easy," "difficult," or "very difficult."

Participants were asked, "How easy or difficult was it to get your questions answered?" Response options were "very easy," "easy," "difficult," or "very difficult."

Participants were asked, "How likely or unlikely are you to participate in a study like this in the future?" Response options were "very likely," "likely," "unlikely," or "very unlikely."

Number of Days Between NHIS Interview and Home Visit

Number of days was coded into the following categories: 1–14 days, 15–28 days, 29–49 days, and 50 days or more.

Research Question 6: Operational Challenges of Packaging, Shipping, and Analyzing Biospecimens and Reporting Results of Home Health Examinations

Five reasons were documented for incomplete urine and blood tests:

- Incomplete or inaccurate laboratory requisition forms
- Packaging problems
- Centrifuging problems
- Laboratory error
- Inadequate urine quantity

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