Oregon Health Insurance Experiment: In-Person Data Collection Protocols

October 9, 2012

Overview

This document provides details on the fielding of the in-person data collection component of the Oregon Health Insurance Experiment. Details of the study design and analytical methods are provided elsewhere. The Oregon Health Insurance Experiment in-person data collection was designed and implemented by the Oregon Health Study (OHS) Group. The in-person interviews included an administered survey questionnaire, medication catalog, anthropometric and blood pressure measurement, and dried blood spot collection. The survey instrument and measurement and fielding protocols were modeled on those used in the National Health and Nutrition Examination Survey (NHANES) and were adapted in consultation with the National Center for Health Statistics.

The main in-person data collection effort took place between September 8th, 2009 and September 27th, 2010. The 20745-person sample for the in-person data collection was comprised of a subsample of participants in the Oregon Health Insurance Experiment living in the Portland area. We focused on the Portland area, roughly defined as within 15 miles of one of three Portland-area study clinics, because of the logistical constraints of in-person data collection.

The OHS in-person data collection was fielded out of the Center for Outcomes Research and Education (CORE), a health services research laboratory embedded within Providence Health and Services, Oregon's largest health system. The fielding operated out of three locations in the Portland, OR area—named Eastside, Westside and Southside. Each fielding location featured two elements: a clinic and a fielding office. The clinic resembled a traditional primary care clinic, with a waiting room, a receptionist, and individual rooms in which the questionnaire, physiologic measurements and dried blood spot collection were administered. The fielding office housed the field supervisor's office and spare offices for recruiters to use, and was also the site for team meetings.

Each fielding location was administered by a field supervisor, a clinic coordinator, and two administrative assistants. The study employed 44 interviewers, who were responsible both for recruitment and for conducting in-person interviews, physiologic measurements, and dried blood spot collection. All three fielding locations were supported by, in total, 2 quality assurance specialists, 2 analysts, 4 phone recruiters, and 5 trackers. Additional off-site participant tracking was provided by the University of Washington, Social Development Research Group, Survey Research Division (SRD). SRD provided initial consultation and training of the OHS tracking staff.

Recruitment Protocols

Standard recruitment protocol

A multi-wave, multi-method recruitment strategy was used that included mail, phone, text, email and in-person contacts as well as third-party and social networking contacts. Recruitment was tailored to each individual participant, so recruitment methods did vary; however, recruitment followed this general workflow outlined below.

1. POSTCARD. Once a segment of the sample was released to the fielding team (called a *release)*, a postcard was sent to all study participants (SPs) in that release. This postcard served two purposes. First, bounced (returned) postcards identified bad addresses; participants whose postcards were returned were assigned to the tracking team. Second, the postcard advertised a free health screening and indicated that participants would be compensated for their time. Participants who called the toll-free number that was listed on the postcard spoke to a phone recruiter or an administrative assistant who could answer questions or schedule a person immediately.

2. PHONE RECRUITMENT. In the same week that the postcards were sent to a release, the release was divided among 4 phone recruiters for recruitment. Phone recruiters would call each of the numbers associated with a participant until they found a good number. If phone recruiters were able to speak to a participant, they attempted to schedule an interview. The result of each call would be recorded in the participants' individual contact log, and phone recruiters would mark old, disconnected or wrong numbers. If we had no good phone numbers for a participant or if phone recruiters were unable to recruit after three phone attempts, the case would be assigned to an interviewer for in-person recruitment.

3. ASSIGNMENT TO INTERVIEWERS. Field supervisors assigned cases to interviewers based on a variety of factors such as zip code, the interviewer's strengths and weaknesses, and interviewer caseload. We found that the characteristics of the interviewer were important for successful recruiting. Sometimes cases were matched with interviewers with similar demographics, such as an older interviewer might be assigned to recruit an older study participant. Other times, a field supervisor would note that an interviewer was not particularly successful with a certain demographic, such as one young male interviewer who found it difficult to recruit young female study participants. The field supervisor's role was to work closely with the interviewers to understand their strengths and to assign cases accordingly. The typical interviewer caseload was approximately 30 cases at a time.

4. TAILORED RECRUITMENT. Interviewers used a variety of techniques to recruit participants; their strategies were based on the information in the participant's contact log that might indicate what strategies would be successful. Tailored recruitment required sensitivity and tact to successfully recruit participants. Common recruitment techniques included: Phone call, text message, email contact, in-person doorstep visit, handwritten letters or messages, contact via Facebook or Myspace, calls to third parties (from information participants provided on our mail survey).

   A detailed record of all contacts was kept in the participant's individual contact log, so that a recruiter could examine the results of all previous contacts and plan next steps. For example, if the last doorstep visit had been between 9 and 5 and no one had been home, the recruiter might try a visit in the evening or on the weekend. If, during the last phone call, the participant had been too busy to talk, the recruiter might try an email contact.

   When an interviewer struggled to recruit a particular participant, that interviewer could seek assistance from another recruiter or at a team meeting. The interviewer could also request reassignment of the participant to another recruiter. Weekly meetings with the field supervisor offered an opportunity to discuss recruitment strategies. The field supervisor would review the case history documentation using the contact log and would probe the interviewer for details related to current case status. If the supervisor determined that the case warranted a different approach, he or she would either suggest alternate contact or conversion strategies for the interviewer, or the supervisor would reassign the case to a new interviewer who could offer a fresh recruitment style.

5. TRACKING. The participant sample, which included a high percentage of low-income adults as well as homeless and highly mobile individuals, was a population that presented challenges for survey research. This group moves often and changes phone numbers often, making it difficult to reach many participants for follow-up study. The tracking operation enabled a boost in response rates through an intensive effort to find participants who may have been lost because they had moved or fallen off the grid. Data trackers used consumer bureau filings, court records, online resources and outreach to friends and family to update contact information for hard-to-find participants. Tracking took four forms: informal tracking, advanced tracking, field tracking, and verification.

   Informal Tracking. When an interviewer could not be confident of the validity of the contact information on file for a participant—when, for instance, the interviewer had left three messages but couldn't be certain whether the voicemail belonged to the participant—the interviewer could request informal tracking. A tracker and interviewer would sit together for a half-hour; the tracker would review the contact log, make a strategic selection of a database or two to search, and attempt to give an interviewer a lead within a very short time frame.

*Advanced Tracking***.** When an interviewer had exhausted all leads—all addresses and all phone numbers had proven to be invalid and all third party locators had been attempted—the case would move from the interviewer's caseload to a tracker's caseload for advanced tracking. There was no time limit set on advanced tracking efforts; trackers maintained a caseload of participants who had not been found and they spread their location efforts across their caseload. When a tracker received confirmation of a new phone or address, the tracker transferred the case to a field supervisor, who assigned the case to an interviewer for standard recruitment.

Field Tracking. Although most tracking was done using online resources or outreach via mail and telephone, at times it was necessary to visit an address in person in order to gain confirmation of updated contact information. In these cases, trackers would request that a specially trained interviewer visit an address or location to see if a participant could be found.

Verification. Sometimes an interviewer or tracker received information that led them to believe that a participant was ineligible for the study. Most commonly, this happened when a friend or family member told the recruiter that the participant had moved out of the area, was incarcerated, was medically unfit, or was deceased. Trackers verified whether or not this information was accurate by searching for corroborating evidence. If that evidence was found, the case was exited; but if no evidence was found, the case would be sent back to an interviewer or tracker and remained in the potential recruitment pool.

Tracking Tools. Some of the tools used by trackers to locate participants included: Consolidated Lead Evaluation and Reporting (CLEAR), Oregon Judicial Information Network (OJIN), JIS-Link (Washington State's Judicial Information System), Facebook, Myspace, White Pages, Peoplefinders, Vinelink, Inmate Locator, Zillow, Google, Google Maps, Portland Maps, Oregon Licensing Department, Multnomah County Vital Records.

We excluded sources that could inadvertently differentially advantage finding individuals from the treatment sample over the control sample. For example, we did not use data from the Medicaid enrollment files that likely contained the most up-to-date addresses for our treatment group because the same information would not exist for those who were not selected in the lottery to apply for coverage.

6. SCHEDULING AN INTERVIEW. Participants could choose to schedule an interview at home or in a clinic. Home interviews would be scheduled and conducted by the recruiting interviewer at a time convenient for the participant. If participants preferred a clinic interview, they could call any clinic or the study's toll-free number to schedule an interview. An interviewer recruiting a participant in the field could make a call to the clinic to schedule the interview on the participant's behalf. Appointments were offered 7

days a week between 8:00 a.m. and 8:00 p.m. Participants were asked to bring all prescription and over-the-counter medications in their bottles and to wear loose clothing, such as sweatpants and a t-shirt.

7. PROMOTING ATTENDANCE. Participants were not always able to make the interviews that they had scheduled. The OHS recruitment protocol included efforts to ensure that participants were not lost because they missed a scheduled appointment. A reminder letter was sent to the participant's mailing address about a week before the appointment and included driving directions to the clinic. A reminder phone call was made the day before the appointment to make sure that the participant had all the information he or she needed to attend, and to give the opportunity to reschedule if the time was no longer convenient. In addition, when participants failed to attend a scheduled interview, a follow-up call was made fifteen minutes after the scheduled interview in order to give the participant the opportunity to reschedule. If the participant was not immediately rescheduled, the case returned to the interviewer's caseload for further recruitment.

8. ENDING PROTOCOL. Recruitment halted under the following circumstances:
    - The participant completed an interview
    - The participant requested not to be contacted further
    - The participant explicitly stated that he or she did not want to or could not participate in an interview
    - The participant was found to be out of state, incarcerated, deceased, too ill to complete an interview, or mentally incapacitated
    - Three phone calls and three in-person visits had been made to valid phone numbers and valid addresses with no response
    - The participant failed to attend a scheduled interview on three separate occasions

Intensive follow-up

Over the course of the fielding, participants were routinely dropped from our active recruitment sample. To promote a high response rate, recruitment was regularly limited to a random subsample of the participants who had been released but had not yet responded and the fielding staff continued active recruitment only on the selected group. This allowed the fielding staff to devote additional time and effort ("continuous intensive follow-up") to potential participants who were difficult to locate or recruit, without diverting too many resources away from the rest of the potential participants. Those remaining in the recruitment sample were up-weighted to represent those dropped from the active sample.

In addition to the continuous intensive follow-up described, starting on September 28th, 2010, the fielding moved from the standard recruiting protocols to a set of intensive follow-up

protocols. The standard protocol excluded certain participants from recruitment because such recruitment was deemed too labor-intensive. The intensive follow-up protocols included more resources targeted at fewer participants, and was aimed at the recruitment of the following groups:

- Participants in Oregon or Washington who were less than a 5-hr drive from Portland
- Participants who had not been "found" according to standard OHS protocol, but for whom the tracking team had leads
- Participants who had been coded Out of State but who may have moved back to the area
- Participants who had been coded Incarcerated but who may have been released
- Challenging cases, i.e. participants who had never been directly contacted after multiple attempts, participants who had no-showed multiple times, or participants who had been disinclined to complete an interview
- Participants who were likely homeless, in transition, or living temporarily with friends or family.

Case Review. The first step in the intensive follow-up was to review all cases for which the standard protocol had ended or who had been coded as ineligible and to determine whether participants fell into the above 6 groups. Cases for which the standard protocol had ended in the field were reviewed by a field supervisor, who judged whether further recruitment was appropriate. Cases for which the standard protocol had ended because trackers were unable to find the participant were reviewed by trackers to determine whether it was likely that the participant could be found with additional time and attention. Cases in which the participant had been coded as ineligible were reviewed by trackers to determine whether the participant's eligibility status had changed under the expanded eligibility criteria.

New Recruitment Protocols. For the intensive follow-up, study personnel were trained in recruitment tailored for hard-to-reach participants. In addition to these new approaches, incentives and logistics changed slightly in order to attract participants who had not been successfully recruited in the past, including:

- Expanded incentives: Intensive follow-up participants were offered $100 for a clinic interview and $75 for a home interview. When an interviewer scheduled an appointment face to face, the participant was given $25 in cash at the time of scheduling.
- Taxi rides were offered to participants who appeared to be at risk of failing to show up for the appointment
- In some cases, we were certain that we had the right address for a participant but were unable to confirm because the participant never answered the door or answered any mail. FedEx packages containing gift cards were sent to the addresses in the hopes that a signature for a package could confirm residency.

*Increased Communication between Trackers and Recruiters***.** The standard protocol had largely separated tracking and recruiting. Recruiters followed all contact leads until each was determined to be invalid; the case was then sent to tracking except for limited informal tracking hours when interviewers could meet briefly with trackers. Trackers collected various contact leads but would not pass a case back to a recruiter until contact information was verified.

Intensive follow-up protocol collapsed tracking and recruiting, pairing recruiters with trackers for increased communication. Recruiters could call a tracker from the field to get more information, such as who might be the owner of a house or what family member might be home. Trackers could send recruiters to addresses to see if the address was valid, instead of using mail or telephone contacts.

Mobile Unit. Each interviewer had a car and a suitcase to make recruitment efficient and to make home interviews easy. Home interviewers represented 27% percent of the interviews in the intensive follow-up period compared to 8% percent in the main fielding period.

Teamed pairs of recruiters were assigned territories that extended beyond the original study boundaries, allowing interviews with participants within a 5 hours' drive of Portland. Recruiting pairs used telephone and mail recruitment to schedule interviews ahead of a trip in order to maximize efficiency. Most interviews were scheduled before the recruiters arrived in the area; however, some time was reserved for in-person recruitment. A total of 154 interviews were completed by these teamed pairs of recruiters.

Homeless outreach. Trackers identified a group of potential participants who might be targeted by outreach to service providers for the homeless. This list included participants who:

- Had recently listed service provider—such as shelter—addresses
- Were reported to couch surf or move around a lot
- Appeared or were reported to be in and out of treatment or jail
- Had been reported as homeless by locators or family members

Relationships were cultivated with shelters and service providers. Study representatives explained the nature of the research and the likelihood that results would serve the same population targeted by the service provider. Many service providers maintain strict confidentiality policies, and efforts were made to ensure that confidentiality was not breached during recruitment efforts. Study representatives gave service providers a list of participants identified as candidates for street outreach. In some cases, providers identified names of participants who had or who currently received services at that location, and study packets were given to the providers to pass on. In other cases, the packets were given to providers to give to participants without the providers having to disclose whether or not they recognized the names on the list. Service providers could choose how to pass on study materials, but the most common strategy was to place the study materials in mailboxes used by participants.

Interviewer incentive pay

OHS had a layered incentive structure for rewarding the performance of individual interviewers and teams of interviewers.

- Monthly cash awards ($250) were given to the top three interviewers as determined by recruitment success or improvement.
- Monthly cash awards, clinic-based, were given to each interviewer in the clinic if the team reached a goal response rate for a sample in a defined period ($160 per interviewer and $25 for every 1% over 55%. If the response rate from a previous month was increased by 5%, interviewers received an extra $50).
- Interviewers had regular performance reviews that could result in increased wages for high performers.
- Smaller tokens of appreciation were distributed at the discretion of the leadership team and included small gift certificates (under $25), team parties, and other nominal prizes.
- Interviewers were paid an end-of-study bonus if they maintained employment with the study through the end of the in-person fielding period ($2,000).
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Interview protocols

Arriving at the clinic

Participants arriving at a clinic would be greeted by an administrative assistant in the waiting room. The administrative assistant would prepare a folder for the interviewer that was labeled with the participant's name and included consent forms, study packet, DBS collection card, and cash incentive. The forms and DBS collection card were labeled with the participant's study ID. The folder would be brought to the clinic room and left with the interviewer, who would then pull up the participant's record using a tablet computer.

Once the interviewer was prepared, he or she would bring the participant into the clinic room and close the door for privacy. The interviewer would introduce herself/himself and give a brief, general summary of the study. The interviewer would assure the participant that participation was voluntary (though important) and would guarantee that all answers would be kept confidential.

Before obtaining consent, the interviewer would verify participant identity by asking name and date of birth.

Obtaining consent

The interviewer presented the participant with the Consent Form for Interview and Physical Measurements brochure at the start of the interview. The consent brochure explained the following:

- The study purpose and procedures including length of time for participation
- Risks and benefits

- Participant rights
- Participant remuneration and results
- Confidentiality assurances
- Whom to contact with questions

Before proceeding with the dried blood spots component of the interview, the interviewer would provide the participant with the Consent Form for Blood Spot Collection and Testing section of the consent brochure. This brochure highlighted the following: general procedure of the blood draw, goals of the study, participant benefits and rights, data use, and confidentiality. The consent for blood spot collection also allowed the participant to specify whether he or she consented to have his or her specimen stored for future research. Participants had three choices: 1) Yes, can perform future studies; do not contact me; 2) Yes, can perform future studies; please contact me; and 3) No future studies. Depending on the participant answers, each blood spot sample card was given a green (future studies, no contact), yellow (future studies, contact), or red (no future studies) round sticker. The stickers met the specifications for long-term cryogenic storage.

Conducting the interview

Interviews were conducted in a private exam room with the study participant and the interviewer (occasionally with an observer, as described below). The survey questionnaire was computer assisted and administered by the interviewer. The survey was designed and implemented using DatStat Illume software. The interviewer viewed the questions and any relevant instructions through a web browser on a tablet computer. The questions were presented with answers for the interviewer to select or space for the interview to enter the answer. The data for each participant was saved to the secure DatStat servers as the interview progressed.

Interviewers were trained to preserve a neutral demeanor. They were required to read the questionnaire word for word, with no interpretation. They were also trained to probe for answers in cases where the participant's response did not neatly conform to the questionnaire's instructions. Answers to open-ended questions were recorded verbatim. Some questions required the interviewer to read from a list of acceptable responses. In these cases, a response card was provided for the participant that allowed them to view all acceptable responses before choosing one.

Because OHS included interviews with many people who had had little or no insurance coverage, an interview sometimes uncovered difficulties that participants were having in meeting health or other needs. In these cases, interviewers would assist participants after the interview was completed by linking them to resources—such as community clinics or food banks—that might meet their needs.

Anthropometry measures

The complete set of anthropometry measures included weight, height, mid-arm circumference, and waist circumference. Participants were asked to wear lightweight, loosely fitted clothing to facilitate measurement.

Weight. Weight was measured in pounds using a Seca 876 portable digital weight scale. Participants were asked to remove their shoes and empty their pockets, and then step on the scale facing away from the scale display. Results were recorded in the tablet computer to one decimal place.

Height. Height was measured in centimeters using a Seca 214 portable stadiometer. Participants were asked to remove hair ornaments or braids from the top of their heads. The interviewer asked the participant to stand on the floor-piece with his or her back aligned with the stadiometer but not pressing against it. The interviewer also asked that the participant stand with both heels together, toes pointed outward at a 60 degree angle, both arms hanging freely by his or her sides, and with weight distributed evenly on both feet. The headpiece of the stadiometer was then positioned firmly on top of the participant's head, and the participant was asked to step away from the stadiometer. The results were then recorded into a tablet computer.

Upper Arm Length. Upper arm length was measured in order to obtain a reliable arm circumference and for positioning of the blood pressure cuff. The participant was asked to stand upright with weight evenly distributed, facing away from the interviewer. The interviewer then asked the participant to bend his or her right arm at a 90 degree angle at the elbow, with the palm facing up. The interviewer located the uppermost edge of the posterior border of the spine extending from the acromion process, and drew a horizontal line along this edge with a cosmetic pencil. The interviewer held the zero end of the measuring tape directly over this mark and extended the tape down the posterior surface of the arm to the tip of the olecranon process. The measurement was taken to the nearest 0.1 cm.

Arm length was always measured using the right arm, unless the participant had a cast, prosthesis or amputation on the right limb. Results were double-checked and then recorded in the tablet computer. The software application calculated the midpoint of the measured length, which the interviewer measured and marked on the arm with a cross point.

Upper Arm Circumference. Upper arm circumference was measured at the midpoint of the arm in centimeters. The participant was asked to stand upright with his or her shoulders relaxed and the right arm hanging loosely. The interviewer placed the measuring tape around the midpoint of the arm (marked with a cross point) and recorded the arm circumference to the nearest 0.1 cm.

Waist Circumference. For measurement of waist circumference, participants were asked to gather their shirts above their waists, cross their arms, and place their hands on opposite shoulders. The interviewer marked the uppermost lateral border of the right ilium and crossed this mark at the midaxillary line. The interviewer extended the tape measure around the waist, positioning the zero end of the tape below the section containing the measurement value. A mirror was used to ensure horizontal alignment, and the measurement was taken to the nearest

0.1 cm at the end of the participant's normal expiration. The results were then entered in the tablet computer.

Medication look-up

The medication look-up took place during the 5-minute waiting period before blood-pressure measurement. Participants were asked to bring all current medications in their containers with them to the interview. Interviewers first looked over the prescription information to make sure that they understood the recommended dosage. Then, while the participant rested, the interviewer recorded the name of the medication, dosage, and frequency directly from the containers supplied by the participant. Medication information was entered with the assistance of a commercially available prescription drug database (First DataBank), which populated medication names and possible doses as the interviewer typed. Interviewers also asked if the participant took the medication as directed and, if not, how they actually took the medication.

If the participant did not have medication containers available, the information was recorded from the participant's memory or sometimes a computer-generated list of medications the participant had from their prescribing provider. If the participant could not remember medication information, the interviewer asked permission to call the participant later so that the participant could give that information while at home looking at the bottle. Interviewers then scheduled a time for the phone call; if the participant did not answer, the interviewer would make at least two more attempts to contact the participant by phone.

Blood pressure measurement

Blood pressure was measured using the OMRON IntelliSense unit, model HEM-907XL, which automatically inflates the cuff to the desired level and does not require adjustment by the interviewer. Blood pressure was taken on the right arm unless the arm was injured or showed signs of illness.

Interviewers asked participants to sit back in a chair with spine straight, arms and back supported, and legs uncrossed with both feet flat on the floor. The participant's right arm was bare with the palm of the hand turned upward and the elbow slightly flexed. The right arm was positioned so that the midpoint of the upper arm was at the level of the heart. For short or tall participants, footstools or cushions were used in order to ensure that the participant's body was in the correct position before blood pressure was taken.

Blood pressure cuff size was determined using the arm circumference measurement. The interviewer used palpitation to locate the brachial artery and marked the skin with a small dot; the rubber bladder of the cuff was then placed over the brachial artery at least 1 inch from the crease of the elbow. The participant's elbow was then placed on the table with the hand turned upward.

Participants were asked to sit quietly for five minutes prior to blood pressure measurement; during this time, the interviewer completed the medication look-up. At the end of

4 minutes, the interviewer took arterial pulse by finding the radial pulse at the wrist and counting pulse beats for a 30 second period using a stopwatch and recorded the pulse on the tablet computer.

After taking the pulse, the interviewer took blood pressure measurements using the OMRON unit. Three measurements are automatically taken 30 seconds apart; the interviewer recorded all three and the average of the three (computed by the OMRON unit). The interviewers were required to enter the measurements twice; if there was discrepancy between the two entries, they were asked to enter the measurements again.

Dried blood spot collection

After obtaining consent, interviewers confirmed that the participant did not have hemophilia before continuing with dried blood spot collection. The interviewer scanned five labels, sharing a unique identifier that was unrelated to any identifier associated with the participant, into Illume to associate that identifier with the participant. One label was applied to the Whatman 903 protein saver card, the filter paper that absorbs the whole blood. The second and third labels were applied to the study and participant copies of the dried blood spot consent form. A fourth label was applied to the log-book in the drying room, after the interview was completed and the card was placed in a holding rack to dry. The fifth label was an extra, in case a second Whatman 903 card was needed. Interviewers at this time also applied the green, yellow, or red stickers associated with the consent for future testing to the Whatman 903 card.

Study participants were asked to warm their hands by rubbing them together or placing them in warm running water in the sink and to increase blood flow to the hands by pumping their fists, keeping the hands below the heart, or by using a squeeze ball. While the study participant was preparing, the interviewer would lay out the supplies on a sterile Chux pad. The supplies included: two Whatman 903 protein saver cards, two BD Micro-fine Genie lancets (blue, blade dimension 2.0L by 1.5mmW), alcohol wipes, gauze, band-aids, two non-latex gloves, and a sharps container. The interviewer used hand sanitizer and then put on the gloves. The participant's fingers on the non-dominant hand were examined for the best place to take the sample. Interviewers were instructed to avoid fingers that had open sores or wounds, were on a hand with casts, bandages, or splints, were swollen or appeared injured in some way, or were on the side of the body where a mastectomy had been performed (for women). The finger was cleaned with the alcohol pad and the interviewer waited until the alcohol dried before releasing the lancet on the inside tip of the chosen finger. The first drop of blood was wiped off and successive drops were collected onto the filter paper. Each Whatman 903 card featured five ½ inch circles of filter paper which could hold 75 to 80 µl of sample. The interviewers were instructed not to let the finger touch the filter paper, nor to overlap spots. The fingers were massaged gently to obtain the blood but interviewers were discouraged from "milking" the finger, which could dilute the sample. If inadequate sample was obtained, the participants were asked if they would consent to another finger-stick. After the sample was collected, the interviewer would clean the participant's finger and apply a band-aid. The number of finger

sticks and number of blood spots obtained were recorded in Illume, along with any difficulties encountered during the procedure (participant feeling light-headed or nauseated, not enough blood, fainting, problem with equipment or supplies, etc.)

After the interview was over, the interviewer placed the card on a drying rack and entered the participant's label and consent in the dried-blood-spot log book. Cards were left in a drying rack at room temperature for a minimum of four hours, but usually overnight. In the morning, administrative staff collected the samples from the drying rack and confirmed that participant names were linked to the appropriate study ID; that the sticker on the card matched the consent given by the participant; and that all cards were accounted for in the log. The cards were then sealed in a zip locked bag with two or three WWR Humidity Sponge desiccant packs and placed in the designated DBS refrigerator for storage at 4 degrees Celsius. On Mondays and Thursdays, the Administrative Assistant would pull the cards from the refrigerator, pack them in a water-tight insulated cooler with frozen reusable cold gel ice packs, place the insulated cooler within another insulated cooler, and both of these within a third corrugated box. The boxes were labeled "Exempt Human Specimen" and shipped priority overnight by FedEx to the University of Washington, Department of Laboratory Medicine in Seattle, WA. Fed Ex confirmed delivery electronically by 10 am the next day. After shipping, the Administrative Assistant recorded the shipment in RMS using the DBS log.

On receiving the shipment, The University of Washington, Department of Laboratory Medicine placed the samples in short-term freezer storage at -70 degrees Celsius, both prior to and following the processing of the four assays. At the end of the study, the samples were shipped back to Providence for long-term storage in a freezer monitored at -70 degrees Celsius, as is the industry standard.

Compensation

Participants were offered cash compensation: $30 for an in-person interview, $20 for dried blood spots, and $25 for travel (if the interview took place in a clinic rather than the participant's home). Participants were therefore offered $75 for a typical in-clinic interview with dried blood spot collection and $50 for a home interview.

Report of findings

At the end of the interview, the interviewer gave the participant a preliminary report of findings that listed the participant's name, age, gender, date of exam, height, weight, BMI, blood pressure, and heart rate. The report informed participants if they were overweight or underweight; it also informed them whether their blood pressure was higher than normal. If their blood pressure was high, the report advised them to see their doctor and gave a suggested time frame for that visit. Study participants who indicated need were also provided a local resource book of low-cost health or behavioral health clinics and other resources for low-income individuals, such as food banks.

After the in-person interview was completed, administrative assistants sent thank-you letters to participants. Within six weeks, once any necessary medication follow-up was complete and DBS results were available, the study participant was mailed a Final Report of Findings. This document repeated the information provided during the interview and detailed above, but contained the results of the DBS analysis and the depression screening. Study participants were provided contextual information about their results, including when to consult a physician for further testing or evaluation. The Final Report of Findings included contact information for inquiries related to their results. OHS leadership would respond to the calls and put the study participants in touch with a contracted physician to answer questions as appropriate.

Home interviews

Home interviews presented a set of challenges with respect to data collection and data quality. It was important that interview conditions allowed the participant to give true and forthright answers; it was also important that physical measurements and blood spots were collected with the same standards used in the clinics. Interviewers worked carefully to obtain privacy for the interview, to minimize noise and distractions, and to arrange suitable seating that did not allow the participant to view the tablet computer as the questionnaire was being filled in.

Interviewers were provided with suitcases complete with all necessary equipment for conducting a home interview—including blood pressure machine, stadiometer, scale, lancet, gloves, wipes, and measuring tape. A level, hard floor surface was sought for anthropometry measurements. A chair next to a surface upon which the participant could rest his or her arm was necessary for blood pressure measurement. Additional protocols and supplies were needed for transporting the dried blood spots to the clinic. The suitcases included a small plastic box with air holes the interviewers used to temporarily store DBS cards in, allowing them to dry until they could be transported back to the clinic and placed in the drying rack.

Quality assurance and quality control

General procedures

*Initial Training and OHS Certification***.** An intensive three-week training program was instituted for all staff immediately upon hiring. Our national consultants were on-site to help provide assistance during the training process. We recruited Providence employees who were not affiliated with the study to allow our interviewers to practice collecting dried blood spots. Several hundred Providence employees participated in the training this way and were compensated with a $25 gift card to Providence food services. Interviewers were required to pass a certification test on all biomarker protocols in order to move beyond the training phase, and to later pass re-certification (approximately five months after initial training).

*Dress Rehearsal***.** Once the staff had been recruited and trained, a dress rehearsal was organized to test study workflow, systems, technology, and logistics. Oregon Health Study leadership team members recruited 200 real study participants and scheduled interviews for both the clinic and home. Throughout the course of a week, interviewers conducted each interviews while under observation by a consultant from National Center for Health Statistics. Each clinic's team debriefed daily to discuss what systems were succeeding and where improvements were needed, and a final debrief session occurred at the end of the week with all clinics together. The dress rehearsal enabled the study team to make protocol corrections that smoothed the study workflow and enabled greater consistency throughout the in-person data collection effort. The dress rehearsal, for instance, helped to troubleshoot connectivity problems, identified inconsistencies between the cards used as visual aids during the interview and the survey questions, and enabled clarification of blood pressure measurement protocols.

Calibration. All biomedical equipment was subject to stringent calibration. Interviewers cleaned and checked equipment before and after each interview. Administrative assistants calibrated equipment monthly, and results were recorded into an equipment management system. Additionally, equipment from clinic rooms was rotated with equipment in the suitcases used for home visits, because they received varying levels of use.

*Data Systems Monitoring for Outliers***.** All interview data was collected and managed in a web-based software program, which allowed quality assurance managers to review data immediately for accuracy and quality. Analysts provided weekly data reports to the QA team, who monitored completion rates as well as outliers for anthropometry, blood pressure, and other component variables.

Questionnaire completion times were used to assess interviewer performance. Questionnaire times shorter than 15 minutes triggered review to ensure that interviewers were not skipping sections or rushing the participant. Short anthropometry or DBS times also triggered review to ensure that protocols were being followed. After a QA manager engaged in retraining, most interviewers were able to correct timing problems.

Interview Observations. Interview observations played a vital role in quality assurance, since procedures such as placement of measuring tape, body marking, or cuff positioning could

only be assessed by watching in person. If an interviewer emerged as an outlier in data reports, the reason could usually be discovered quickly with one or two observations. In addition, QA managers observed all interviewers once every eight weeks and gave direct feedback and retraining in order to quickly address inconsistencies.

A checklist was used for interview observations to ensure that all protocol components were reviewed for accuracy. Interviewers were evaluated based on:

- the ability to establish and maintain rapport
- proper probing techniques
- general interviewing skills
- accuracy of body positioning, marking and measuring for anthropometry
- use of equipment
- following standard precautions when collecting DBS
- blood spot quality and quantity

Validations. To check interviewers' work, the study team validated 10% of all completed interviews. Participants were contacted by phone and occasionally in person; they were asked to confirm their name, date of birth, participation in the study, remuneration, and whether certain protocols were administered during the interview such as arm, waist, height, weight, and blood pressure measurements. If anything unusual came up in a phone validation, QA managers investigated the issue and provided feedback to the interviewer to help improve his or her performance.

Troubleshooting. When data monitoring suggested that an interviewer was consistently deviating from study protocol, a formal investigative inquiry began immediately, during which QA managers would:

- observe one or two interviews as soon as possible
- meet with an interviewer to provide immediate retraining
- review all data collected by the interviewer to check for unusual outliers or other deviations
- implement a series of validation calls to participants who had been interviewed by the interviewer to hear from the participant how the interviewer had performed
- perform in-person validations of anthropometry measurements when necessary
- work with field supervisors to implement corrective measures

Comments. Each section of the interview software featured a comments field for interviewers to post deviations from protocol, comments, problems, or questions. The QA team regularly reviewed these comments and was often able to address interviewers' issues or implementation difficulties.

Dried blood spot procedures

DBS protocols were monitored for fidelity during the routine QC in-person observations by our QA/QC team. Interviewers who were demonstrating protocol drift would be asked to re-

train and re-pass the DBS certification. Regular monitoring was also used to assess if individual interviewers were experiencing unusual difficulty in obtaining consent, the number of finger sticks required to obtain adequate sample, or the adequate blood spots. Interviewers who were flagged as outliers were re-trained and observed for protocol fidelity. Finally, each week, the QA/QC team would select a DBS shipment (each shipment contained an average of 50 DBS cards) to evaluate each card for the quality of spots obtained. They would document the name of the interviewer and assign a numeric value to each card representing the quality of the DBS card, including number and quality of spots, assessed by turning the card over and measuring the diameter (1/2 inch diameter is a full spot) of red blood that fully saturated the card. The lowest numeric value was 0, indicating no high-quality spots, and the highest was 5, indicating five high-quality spots.

To further assure quality of the laboratory assays, UW Department of Laboratory Medicine prospectively re-assayed 2% of a random selection of cards with red stickers (indicating the study participant had not consented for future assays and that the remaining stored blood was only appropriate for quality assurance purposes). The laboratory considered these as QA samples and monitored variance from the first assays to the repeated assays. The laboratory also assayed 51 samples, labeled and handled identically to OHS samples, but not associated with any study participants. These samples had blood with known clinical values provided by Thomas McDade PhD, at Northwestern University. The results of these assays were then compared to the known clinical measures for those samples.