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Article

Canadian Health Measures Survey: Clinic operations and logistics

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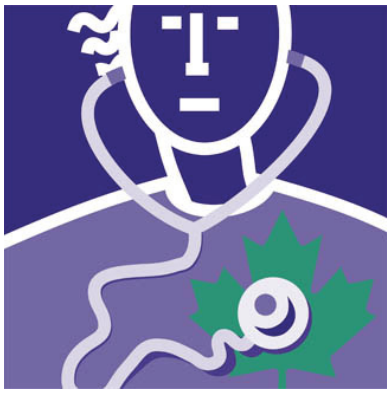

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Canadian Health Measures Survey: Clinic operations and logistics

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Abstract

Objectives

The Canadian Health Measures Survey (CHMS) is conducted in two parts: a household interview and a visit to a mobile clinic. At 15 sites across Canada, the CHMS uses two trailers to collect physical measures on a sample of about 5,000 Canadians. The trailers contain clinic rooms outfitted with physical measures testing equipment; an administration area; and a fully functioning laboratory. The field team consists of 11 household interviewers and 20 clinic staff. At each site, about 350 respondents visit the clinic over a five- to six-week period. At the clinic, respondents participate in all tests for which they are eligible, including blood pressure, anthropometry, spirometry, a blood draw, a urine sample, tests of physical fitness, and an oral health examination. Respondents who are unable to visit the clinic may perform some of the tests in their home.

Keywords

anthropometry, blood and urine specimen collection, mobile clinic, oral examination, physical measures, quality control, spirometry, surveys

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The Canadian Health Measures Survey (CHMS) is being conducted by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada. The CHMS consists of a household interview and a visit to a mobile clinic.[1] The survey will be conducted over two years and will involve a sample of approximately 5,000 Canadians.[2]

This paper describes some of the logistical and operational requirements and procedures employed to perform the clinic component of the survey. The logistical issues include those related to the physical infrastructure (size and layout of the mobile clinics); selection, set-up and maintenance of a clinic site; the informatics environment required to support data collection; set-up of a mobile laboratory; staffing and training of the field team; and the logistics of having staff live on the road during data collection. Operational aspects include an overview of clinic appointments; quality assurance and quality control; processing, analyzing, storing and shipping blood and urine samples in the mobile clinic laboratory; and the role of the CHMS reference laboratories.

The mobile clinic

Based on experiences from the CHMS pre-test,[3] it was decided that physical measures and biological specimen collection be performed in mobile clinics. Each clinic is comprised of two 53-foot long trailers (16 meters)—the administration trailer and the clinic trailer (Figure 1)—which are connected by an enclosed pedestrian walkway.

During each six- to seven-week collection period, tests are conducted at only one clinic site where the entire collection team is working. Meanwhile, the second clinic is being set up at the next site. When collection is completed at one site, the staff travel to the next one.

Mobile clinic layout

Because each trailer has only about 376 square feet (35 square meters) of useable space, considerable time was dedicated to the planning and design of that space. The physical measures that would be conducted in each room were determined based on the type/size of testing equipment, the floor space needed (for example, the anthropometry room has an in-floor scale), the type and size of furniture required (for example, a dental chair and autoclave in the oral health room), and the type of door to be installed (accordion or swing). Whenever possible, the clinic rooms were designed to accommodate multiple measures to allow for flexibility in the flow of respondents (Table 1). For emergency purposes, all testing rooms have a telephone; an automated defibrillator, a first aid kit and a fire extinguisher are available in the reception area or hallways. A utility trailer, which is used as a staff area and as added storage, is parked next to the clinic.

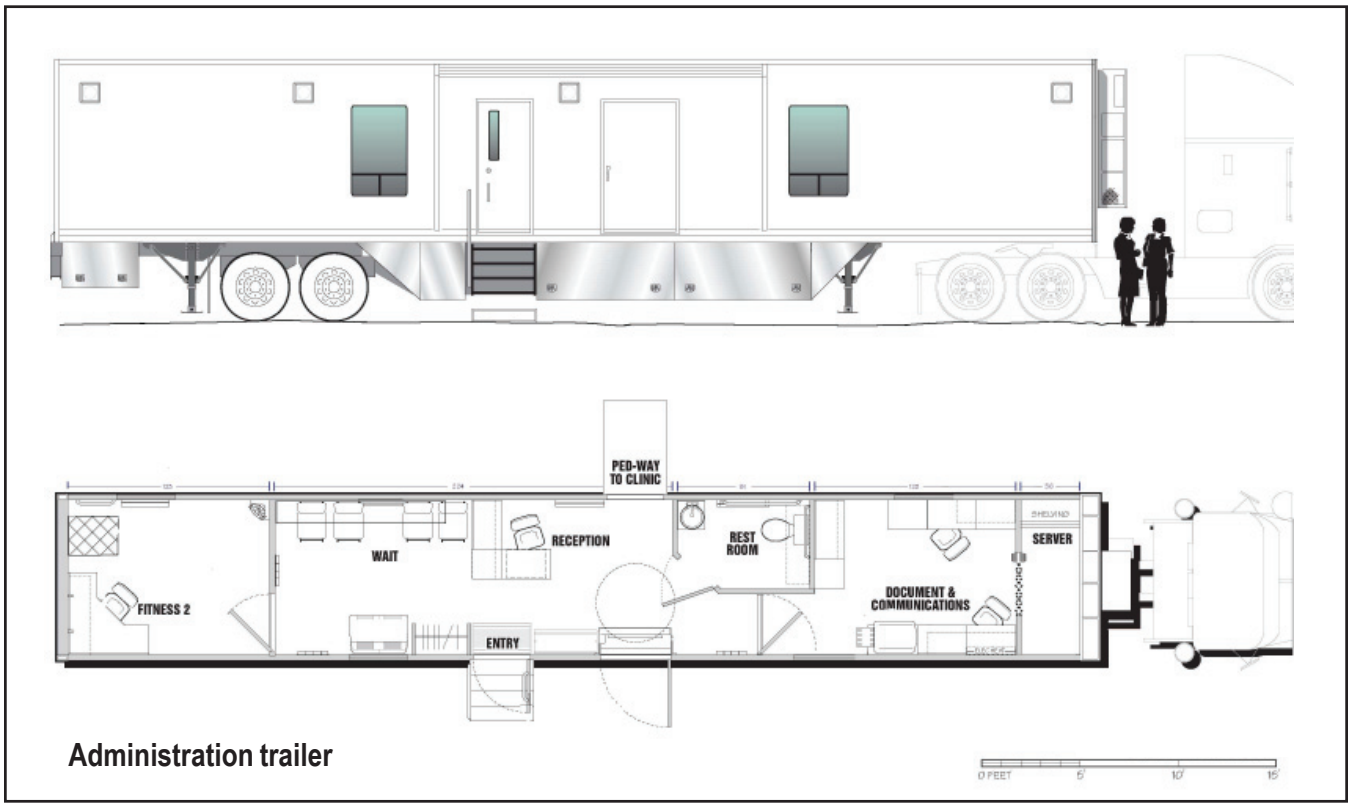
Table 1
Function of rooms in mobile clinic, Canadian Health Measures Survey

Room(s)	Function(s)
Reception	Respondent sign in and verification Consent component Exit component Respondent waiting area
Restrooms	Urine collection component Respondent change room
Administrative office	Booking desk Site manager's office General administrative procedures
Fitness testing rooms	Modified Canadian Aerobic Fitness test (mCAFT) Sit and reach Partial curl-ups Grip strength Spirometry Blood pressure (as needed)
Screening	Screening questionnaire Blood pressure Spirometry
Oral health	Oral health component
Anthropometry	Height (standing and sitting) Weight Skinfolds Waist and hip circumferences Activity monitor
Phlebotomy	Blood collection component
Laboratory	Laboratory component Bio-specimen storage Shipping bio-specimens Complete blood count analysis

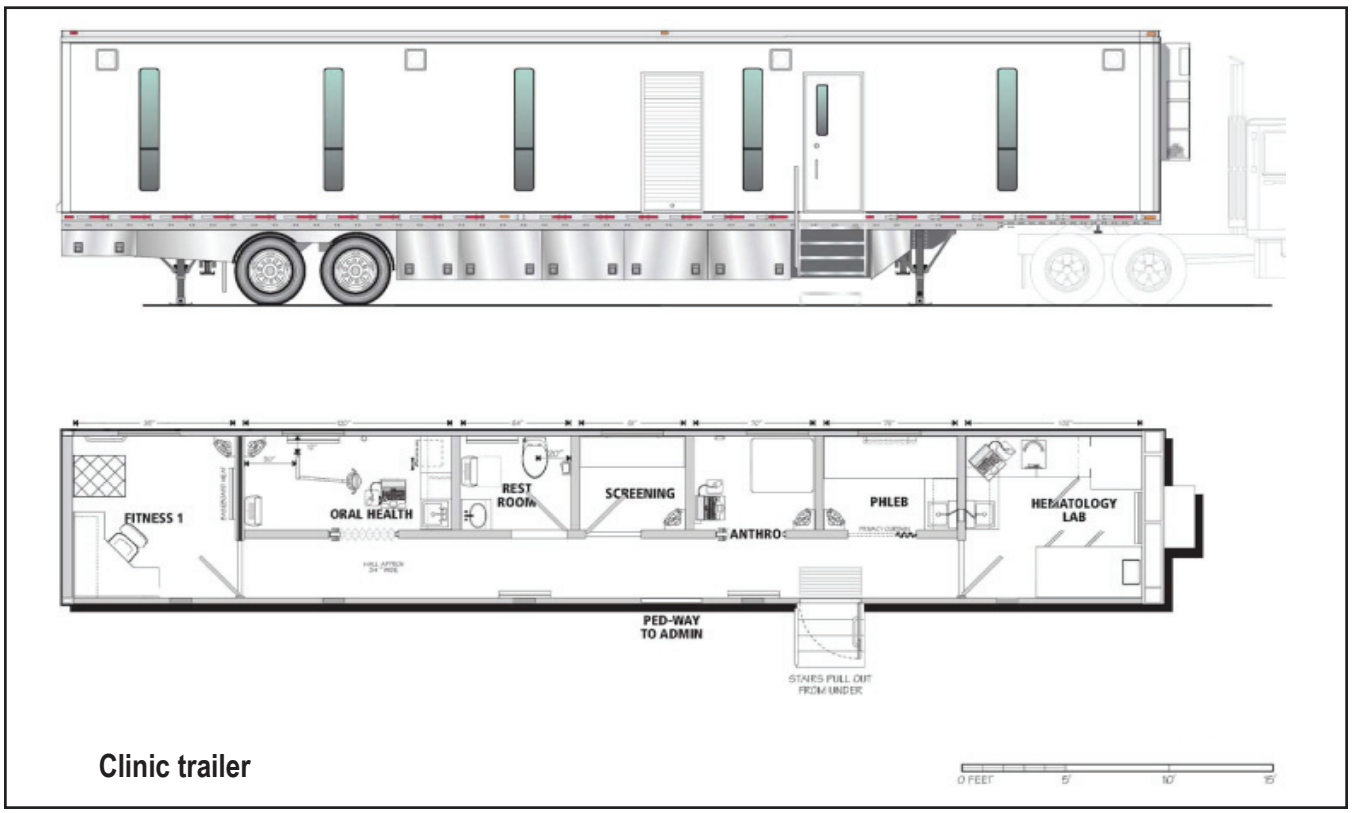
Emergency plans

To ensure a safe working and clinical environment and the security and safety of survey data and physical property, a disruption/disaster response plan was prepared for the CHMS. The plan identifies ways to safeguard the well-being of respondents and staff, limit down time, identify the mission-critical elements of the survey, and conduct a hazard identification and risk assessment. The plan also provides up-to-date contact information for all survey personnel and contingency plans in the event of an emergency affecting normal survey collection. All staff members are trained on the emergency and evacuation procedures for the mobile clinic, the use and location of emergency equipment, and safety procedures to prevent contact with potential hazards such as biological specimen and mercury spills. Mock drills are held periodically to simulate a medical emergency, major disaster, biohazard incident, fire or electrical shutdown.

Figure 1
Canadian Health Measures Survey mobile trailers



Administration trailer



Clinic trailer

Selecting, setting-up and maintaining a clinic site

The CHMS will collect data at 15 sites across the country.[2] Preparations for each new site begin about six months before the mobile clinic is scheduled to arrive. Before visiting a site, the advance arrangements team researches potential locations. They also consider dates of federal, provincial and/or civic holidays and special events or festivals scheduled for the area that might affect operations.

Based on this preliminary information, the advance arrangements team visits potential locations and ranks them according to selection criteria (Appendix A). Contact is made with the owner of the location considered most appropriate (and an alternate location) to explain the project and negotiate location use. Once a location has been secured, at least four to six months before it will be used, arrangements are made for utilities, services, permits, staff accommodations and car rentals.

The trailers at each site are set up so that the pedestrian walkway between them is safe and functional. Utilities (water, sewage, hydro, internet, telephone) are connected, and additional services (garbage removal bins, waste water pumping, courier service, biohazard waste pick up) are arranged with local contractors. The equipment is unpacked, set up, cleaned and calibrated.

Before operations begin at a new site, all clinic systems are tested during a "dry-run day." This involves six to eight volunteers undergoing some of the tests while staff test the equipment, participate in training exercises, and perform quality control procedures.

Maintenance of the mobile clinic is ongoing. The wheelchair lift, on-board generators, heating/cooling systems and plumbing system are tested and serviced regularly. The exterior of the trailers must be clean and free of rust, and the grounds, tidy and free of snow, ice and other potential hazards. Clinic staff clean the interior of the mobile clinic each day. Upon completion of collection at each site, the grounds are returned to their original condition.

Informatics environment

The CHMS uses computer-assisted data capture applications written in Blaise (Statistics Netherlands, Voorburg, The Netherlands) for both the household and clinic components of the survey. As is the case for all other Statistics Canada health surveys, the computer-assisted personal interview (CAPI) environment is used for the household interview.

For computerized data capture in the clinic, a unique data capture architecture was developed to allow multiple users in different rooms to access a single respondent's case file. This required a fully customized data capture application that uses components of the computer-assisted telephone interview (CATI) environment. To reduce data entry errors, increase efficiency of data collection and reduce the need for double entry and data entry verification, the clinic data capture system was developed to accept direct input from other electronic testing equipment. This included communication (one- and two-way) between Blaise software and the measurement devices (for instance, automated blood pressure measurement device).

The mobile clinic has its own CATI server. The data capture computers do not store respondent data, but instead, write all data directly to this server. All informatics equipment has several levels of data encryption and access control. Each day, the CATI server transmits the encrypted data and picks up cases via a dedicated out-going phone line to Statistics Canada headquarters through the existing infrastructure for field data transmission. The data are encrypted during transmissions between the mobile clinic and headquarters.

Back-up systems and contingencies prevent down time and loss of data. The server is on back-up power, and the clinic has secondary machines, such as another server, laptops, hard drives and label printers. Data are backed-up after each clinic session. All informatics and medical equipment have surge protectors, and most informatics equipment can run on battery power or via uninterrupted power supplies.

Setting up a mobile laboratory

Developing the laboratory component of the CHMS involved preparing procedures for the collection, processing, analysis, storage and shipping of blood and urine specimens and setting up a mobile laboratory. To set up the laboratory, it was necessary to consider issues including work flow patterns; specimen collection, storage and shipping procedures; pre-analytical and analytical procedures; staffing, space and equipment needs; and cost.

Laboratory equipment needs were influenced by size (due to space constraints), accuracy and precision, reliability (frequency of breakdown, repair and maintenance), infrastructure needs (use of water, energy consumption, waste disposal), ease of operation and maintenance, training courses included, availability and timeliness of service throughout the country, laboratory biosafety guidelines, test throughput, cost, and comparability with other international surveys.

Detailed equipment specifications were prepared, and equipment was purchased according to Federal Government purchasing guidelines. Specifications for equipment placement were prepared to assist in the design and construction of the laboratory space.

The CHMS laboratory is about 68 square feet (6 square meters) and is outfitted with three 48-cm deep workbenches. It contains a biological safety cabinet to protect staff from inhaling aerosols, and a centrifuge to separate serum and plasma. The complete blood count analysis is performed onsite with a cell counter, since this is a time-sensitive test. An alarm-monitored refrigerator and two -20^{0}C freezers are used to temporarily store the biospecimens until shipping and the calibrators and controls for the cell counter. The laboratory also contains miscellaneous specimen preparation and shipping equipment, and safety/personal protective equipment. During transport of the trailers between sites, temperature and altitude changes must be monitored, as they may affect the calibration of the cell counter.

Laboratory standard operating procedures (SOP) were developed for pre-analytical functions (for example, mixing, aliquoting), testing protocols (for example, complete blood count), non-testing procedures (for example, specimen storage and shipping), quality control procedures and equipment use, calibration, and maintenance. A laboratory safety program was documented. Laboratory personnel were trained according to the SOPs and attended manufacturer training sessions and transportation of dangerous goods training.

The CHMS team

The CHMS field team is comprised of 31 employees: the interviewers who conduct the household component of the survey and the clinic staff who perform the physical measures testing. The 10 household interviewers contact selected households, conduct the household interview, explain the clinic portion of the survey to respondents, and assist in securing their participation, including non-response follow-up. They are supervised by an interviewer manager who plans assignments, conducts data quality assurance for the household component, oversees non-response follow-up, and monitors the household collection rates.

The clinic team consists of health professionals responsible for various components of the physical measures testing. The team is headed by the site manager who oversees the day-to-day operation of the clinic and ensures a seamless operation between the interview and clinic teams. Two senior health measures specialists and four health measures specialists administer most physical measures tests (for example, blood pressure, anthropometry, fitness testing, spirometry) and the screening component. They also assist the site manager with monitoring quality control of the physical measures and providing technical support related to the physical measures testing equipment. Four laboratory technologists/phlebotomists collect specimens (blood and urine), perform the complete blood count analysis, and process the biological samples for storage and shipment to the reference laboratories. A licensed dentist conducts the oral health component, and a dental recorder is responsible for data capture. The clinic

coordinators provide administrative services to the team and to survey respondents including administration of the consent component and booking clinic appointments. A site logistics officer supports the field team by resolving issues related to infrastructure, informatics and inventory, and oversees maintenance of the trailers and collection site.

Prior to collection, the field staff underwent considerable training, most of which was designed to meet the requirements of each position. Training covered standardization of survey procedures, quality control, calibration and maintenance of equipment, health and occupational safety (both respondent and staff), and emergency procedures. Emphasis was placed on techniques for obtaining respondents' cooperation while respecting their privacy and the confidentiality of their data. Formal classroom training, along with mandatory reading of procedures and training manuals, familiarized staff with the survey background, administrative procedures, and general survey methodology.

Hands-on practice with instructors was the core of the position-specific training. Experts in various fields related to the physical measures (for example, blood pressure) conducted seminars and participated in the hands-on training and in a dress rehearsal that was designed to give staff an opportunity to practice the household interview and clinic components.

Initial training lasted from 4 weeks for the interviewers to 8 weeks for the clinic staff, and up to 12 weeks for the site and interviewer managers. In addition to ongoing training, an annual all-staff retraining session is held to reinforce concepts and ensure data quality.

A team at Statistics Canada's headquarters in Ottawa provides logistical, operational, administrative, advisory, communications and technical support to the field staff. The headquarters team monitors response rates, data quality, and through periodic site visits, staff performance. They assess the reference laboratories through a variety of quality control and quality assurance procedures. Headquarters staff also provide human resources support (for instance, hiring and training new staff), process the clinic and laboratory data, prepare and mail reports of laboratory test results to respondents, follow up with respondents about abnormal or sensitive results, and provide general information about the survey to respondents and the media.

Living on the road

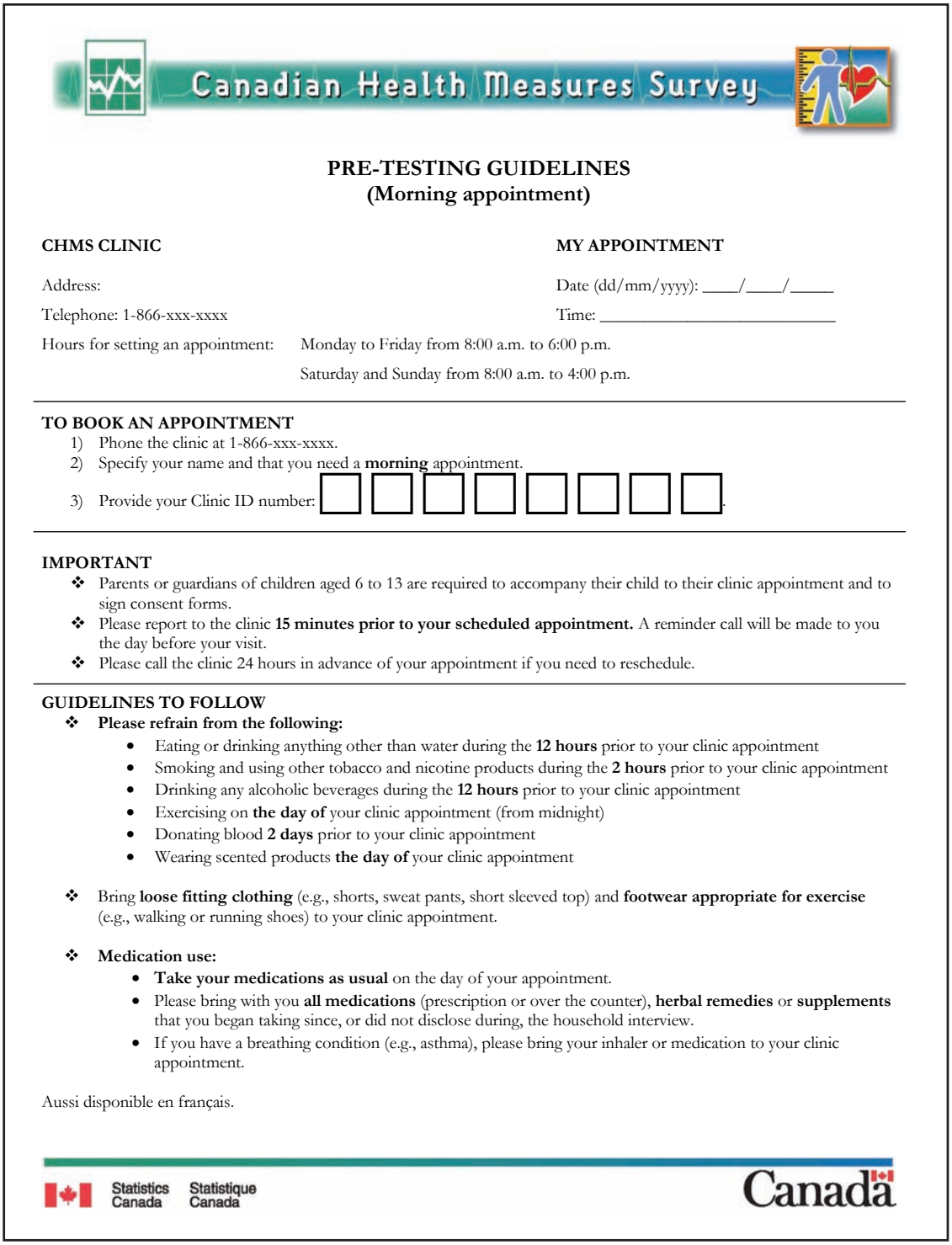
Over two years, the CHMS field team will collect data in 15 different sites across Canada. This means "living out of a suitcase." Staff stay in apartment-style accommodations, equipped with a kitchenette, laundry and exercise facilities, and located close to amenities such as shopping and restaurants. When the team arrives at a new site, they receive an orientation package to familiarize them with the area.

Booking a clinic appointment

For a complete survey response, CHMS respondents must complete the household interview and participate in the clinic portion. During the household interview, respondents are told if they have been selected for a morning appointment, which requires a 12-hour fast, or an afternoon appointment, which requires a 2-hour fast. Respondents are urged to attend the type of appointment to which they have been allocated, although exceptions are made to ensure that everyone who wants to participate is accommodated.

At the end of the home interview, respondents receive a respondent information kit (RIK) that includes a copy of the clinic pre-testing guidelines (Figure 2), information about the clinic tests, and an information and consent booklet. The interviewer describes the contents of the kit, in particular the consent process, and draws their attention to the pre-testing guidelines. These guidelines are intended to standardize the way in which respondents are prepared for the clinic and to minimize the effect of confounding factors (for example, smoking) on data quality. The interviewer encourages respondents to book a clinic appointment and offers to assist them in doing so.

Figure 2
Clinic pre-testing guidelines (12-hour fasting appointment)



Canadian Health Measures Survey

PRE-TESTING GUIDELINES
(Morning appointment)

CHMS CLINIC

Address:

Telephone: 1-866-xxx-xxxx

Hours for setting an appointment: Monday to Friday from 8:00 a.m. to 6:00 p.m.
Saturday and Sunday from 8:00 a.m. to 4:00 p.m.

MY APPOINTMENT

Date (dd/mm/yyyy): ____/____/_____

Time: _____

TO BOOK AN APPOINTMENT

1) Phone the clinic at 1-866-xxx-xxxx.
2) Specify your name and that you need a **morning** appointment.
3) Provide your Clinic ID number: ☐☐☐☐☐☐☐☐.

IMPORTANT

- Parents or guardians of children aged 6 to 13 are required to accompany their child to their clinic appointment and to sign consent forms.
- Please report to the clinic **15 minutes prior to your scheduled appointment.** A reminder call will be made to you the day before your visit.
- Please call the clinic 24 hours in advance of your appointment if you need to reschedule.

GUIDELINES TO FOLLOW

- **Please refrain from the following:**
  - Eating or drinking anything other than water during the **12 hours** prior to your clinic appointment
  - Smoking and using other tobacco and nicotine products during the **2 hours** prior to your clinic appointment
  - Drinking any alcoholic beverages during the **12 hours** prior to your clinic appointment
  - Exercising on **the day of** your clinic appointment (from midnight)
  - Donating blood **2 days** prior to your clinic appointment
  - Wearing scented products **the day of** your clinic appointment

- Bring **loose fitting clothing** (e.g., shorts, sweat pants, short sleeved top) and **footwear appropriate for exercise** (e.g., walking or running shoes) to your clinic appointment.

- **Medication use:**
  - **Take your medications as usual** on the day of your appointment.
  - Please bring with you **all medications** (prescription or over the counter), **herbal remedies** or **supplements** that you began taking since, or did not disclose during, the household interview.
  - If you have a breathing condition (e.g., asthma), please bring your inhaler or medication to your clinic appointment.

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In order to complete approximately 350 clinic visits at each site over six weeks, and to accommodate respondents' schedules, the clinic operates seven days a week. Appointments can be made for the morning, afternoon or evening. Appointments average about 2.5 hours, but the length varies depending on the tests for which each respondent is eligible.

Appointments are made by calling the clinic booking desk using the CHMS toll-free number. Respondents who have completed a home interview but have not contacted the clinic are telephoned to set up an appointment. Under certain circumstances, respondents who are unwilling to visit the clinic, but who wish to be tested, are offered the option of having a subset of the tests performed in their home.

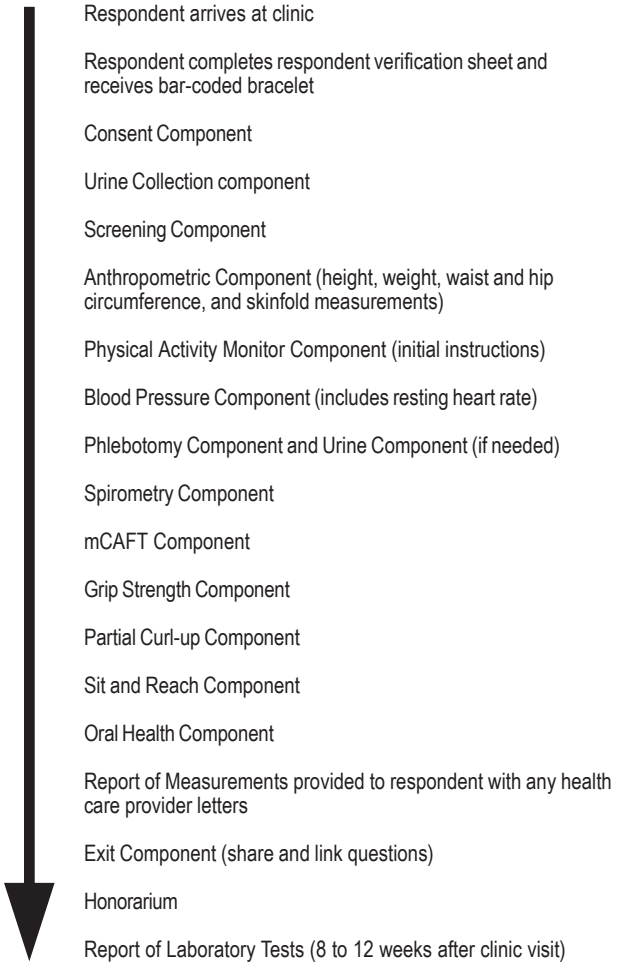
Respondents who have booked an appointment are called 24 hours in advance to remind them of the time and to review the pre-testing guidelines. All missed appointments are followed up on the same day, and rescheduling is attempted.

Overview of a clinic visit

When respondents arrive at the clinic, they are greeted by the clinic coordinator who verifies their identity (Figure 3) and gives them a bar-coded bracelet that contains their random 8-digit Clinic ID. Before testing starts, respondents sign a consent/assent form.[4] They then change into clothing suitable for exercise (if required) and provide a urine sample (Table 2).

A health measures specialist then administers a series of screening questions to determine the respondents' eligibility for the various tests, based on pre-set exclusion criteria (Table 3). In some cases, the screening criteria are "hard-coded" into the Blaise data capture system; once entered, respondents are automatically screened out of the test(s), and no changes to the exclusion can be made. In other cases, the health measures specialist determines if a condition warrants exclusion from (a) test(s) and records the information. The reason for allowing staff to determine some exclusions is to ensure maximum inclusiveness, although they will always err on the side of caution.

Figure 3
Clinic flow



The first screening questions determine whether respondents have followed the pre-testing guidelines, and as a result, whether they should be excluded from any tests. The second set of questions concerns physical and health status, such as pregnancy, breathing conditions, acute conditions (cold, flu, injury, etc.), haemophilia and chemotherapy. Next, the health measures specialist confirms the medications (prescription and over-the-counter), health products and herbal remedies that respondents reported during their home interview, and records any changes. Respondents then fill out, sign and date the Physical Activity Readiness Questionnaire (PAR-Q).[5] At the end of screening, the health measures specialist records any other "health-related" reasons why respondents

Table 2
Urine collection, aliquoting, storage and shipping procedures (in priority test order), Canadian Health Measures Survey

Measure	Age (years)	Eligible sample size	Reference laboratory	Aliquot volume†	Storage/ Shipping	Reported to respondent
Microalbumin	6 to 79	5,000	HC	2.0 mL	Freezer/Dry ice	Yes
Creatinine	6 to 79	5,000	HC	2.0 mL	Freezer/Dry ice	Yes
Cotinine	6 to 79	5,000	INSPQ	5.0 mL	Freezer/Dry ice	No
Phthalates	6 to 49	3,000	INSPQ	10.0 mL	Freezer/Ice pack	No
Metal Panel antimony, arsenic, cadmium, copper, manganese, inorganic mercury, molybdenum, nickel, lead, selenium, uranium, vanadium, zinc	6 to 79	5000	INSPQ	5.0 mL	Freezer/Dry Ice	No
Inorganic mercury	6 to 79	5,000	INSPQ	5.0 mL	Freezer/Dry ice	No
Bisphenol A	6 to 79	2,400	INSPQ	20.0 mL	Freezer/Ice pack	No
Iodine	6 to 79	5,000	HC	4.0 mL	Freezer/Ice pack	No
Organophosphate pesticides	6 to 79	2,400	INSPQ	20.0 mL	Freezer/Ice pack	No
Pyrethoid pesticides	6 to 79	2,400	INSPQ	20.0 mL	Freezer/Ice pack	No
Phenoxy herbicide	6 to 79	2,400	INSPQ	20.0 mL	Freezer/Ice pack	No
Stored urine 1	6 to 79	5,000	NML	5.0 mL	Freezer/Dry ice	...
Stored urine 2	6 to 79	5,000	NML	5.0 mL	Freezer/Dry ice	...

HC = Health Canada; INSPQ = l'Institut national de santé publique du Québec; NML = National Microbiology Laboratory
† aliquot volume = total sample volume sent to reference laboratory
... not available
Note: Urine samples are collected in a 120 mL urine specimen container.

should not participate in one or more of the physical tests. Except for the PAR-Q, respondents (or parents/guardians of respondents aged 6 to 13) reply orally to all screening questions.

After screening, the health measures specialist conducts the anthropometry component of the CHMS. This includes standing and sitting height, weight, waist and hip circumferences, and skinfold measurements at five sites (triceps, biceps, subscapular, iliac crest and calf). Except for hip circumference, all measures are taken according to the procedures outlined in The Canadian Physical Activity, Fitness and Lifestyle Approach (CPAFLA) manual.[6] Hip circumference is measured according to the Canadian Standardized Test of Fitness.[7]

At the end of the anthropometry component, respondents are given an activity monitor (accelerometer) to wear for the next seven days. The health measures specialist explains the correct placement of the monitor (over right hip), when to wear it (remove only at bedtime), and mailing procedures for returning it to Statistics Canada's head office for processing (respondents are given a postage-paid, self-addressed envelope). Respondents receive a reminder in the mail around the day that they are to return the activity monitor. If a monitor is not returned, a second reminder is mailed about a week later. If the monitor is still not returned, headquarters staff phone the respondent.

Respondents then go to a quiet room. After 5 minutes of rest, six blood pressure and heart rate readings are taken using an automated blood pressure cuff. If respondents are aged 6 to 13 years, the health measures specialist stays in the room during the blood pressure measurement; for older respondents, the health measures specialist leaves the room after observing the first measurement. Average blood pressure and heart rate are calculated based on the last five readings, with a

Table 3
Test exclusion criteria, Canadian Health Measures Survey

Measure	Exclusion criteria	
	Hard-coded	Staff decision
Blood pressure	None	**Test exclusion** Blood pressure cuff too small or too large to fit arm Rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms, a-v shunts on both arms **Right arm exclusion** Blood drawn from right arm in last week Right mastectomy Cast on right arm Right arm amputation
Standing height	None	Inability to stand unassisted Acute condition (for example, cast on leg prevents standing upright unassisted)
Sitting height	None	Inability to sit unassisted Acute condition (for example, full leg cast)
Weight	None	Acute condition (for example, plaster cast)
Waist circumference	Pregnancy (more than 12 weeks)	None
Hip circumference	Pregnancy (more than 12 weeks)	None
Skinfolds	BMI greater than or equal to 30 kg/m^2 Pregnancy (more than 12 weeks)	Acute condition (for example, varicose veins, skin condition)
Phlebotomy	Chemotherapy within past 4 weeks Haemophilia	Rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms or limbs missing, damaged, sclerosed or occluded veins, allergies to cleansing reagents, burned or scarred tissue, shunt or IV on both arms
Spirometry	Acute respiratory condition (for example, cold, bronchitis, flu) Pregnancy (more than 27 weeks) Heart attack within last 3 months Major surgery on chest or abdomen within last 3 months	Respondent with a stoma Important language barrier Respondent taking medication for tuberculosis Difficulty breathing at rest Persistent cough Eye surgery within past 6 weeks
Activity monitor	None	In wheelchair
Grip strength	None	Positive response(s) to PAR-Q questions 5, 6, 7 (depending on probing)
Modified Canadian Aerobic Fitness Test	Positive response(s) to PAR-Q questions 1, 2, 3, 6 Resting blood pressure more than 144/94 mmHg Resting heart rate more than 100 bpm Pregnancy (more than 12 weeks) Blood donation in past 24 hours Taking medication for breathing condition such as asthma and did not bring medication Older than 69 Home visit	Positive response(s) to PAR-Q questions 4, 5, 7 (depending on probing) Heart rate- or blood pressure-altering medications Difficulty breathing at rest Appears ill or complains of fever Persistent cough Lower extremity swelling Mentally/Physically impaired Insulin pump Supplemental oxygen
Sit and reach	Pregnancy (more than 12 weeks) Older than 69 Home visit	Positive response(s) to PAR-Q questions 5 and 7 (depending on probing) Colostomy bag
Partial curl-ups	Positive response(s) to PAR-Q questions 1, 2, 3 (automatic) Pregnancy (more than 12 weeks) Resting blood pressure more than 144/94 mmHg Resting heart rate more than 100 bpm Older than 69 Home visit	Positive response(s) to PAR-Q questions 5, 6 and 7 (depending on probing) Difficulty breathing at rest Persistent cough Lower extremity swelling Appears ill or complains of fever Colostomy bag
Oral health (exclusion from probing component only)	Haemophilia Chemotherapy in past 4 weeks Any "yes" answer to one or more questions in oral health restrictions block Younger than 15	None

minimum of three valid readings required to determine an average. If the average blood pressure is more than 144/94 mmHg or the average heart rate is greater than or equal to 100 bpm, a second series of measurements is taken after another 5 minutes of rest.

Following the blood pressure component, respondents go to the phlebotomy room where a certified phlebotomist draws blood. Before doing so, the phlebotomist asks respondents if they have had a transfusion or have donated blood within the last two months, to provide context for the analysis of the blood samples. The phlebotomist draws the amount of blood needed to perform all tests (including storage samples) (Table 4). The amount of blood drawn depends on the respondent's age:

- 6 to 11 years, ~ 28mL (2.0 tablespoons)
- 12 to 13 years, ~ 38mL (2.5 tablespoons)
- 14 to 19 years, ~ 45mL (3.0 tablespoons)
- 20 to 79 years, ~ 75mL (5.0 tablespoons)

Next, the health measures specialist administers the spirometry test. At least three valid attempts and two reproducible forced expiratory manoeuvres are necessary, which are assessed according to the American Thoracic Society criteria.[8] Spirometry results are adjusted for race, based on self-ascribed ethnicity (reported during the home interview), and are compared to predicted values.

After the spirometry test, respondents are taken to the fitness room for the modified Canadian Aerobic Fitness Test (mCAFT), the grip strength test, partial curl-up test, and sit-and-reach test. For eligible respondents aged 15 to 69 years, the procedures follow those outlined in the CPAFLA manual[6] ; however, post-mCAFT blood pressure and heart rate are taken with the automated blood pressure cuff. For respondents aged 6 to 14 years, the mCAFT is performed according to the procedures of the Canada Fitness Survey[9] (again using the automated blood pressure cuff for post-exercise blood pressure and heart rate measurement), and the grip strength, partial curl-up and sit-and-reach tests are performed according to CPAFLA.[6]

Oral health is the final testing component. A dentist asks respondents a series of questions about their oral health and screening questions to determine if they have conditions (for example, congenital heart disease) that might increase their susceptibility to certain infections as a result of the probing. Respondents who answer "yes" to any of the screening questions are excluded from the probing portion of the oral health exam.

The dentist then examines respondents' teeth and gums, assessing the status of each tooth including fluorosis, severity and prevalence of gingivitis, calculus, oral debris, and caries. The dentist records the number of missing teeth, the number of amalgam fillings and whether any of the four permanent upper and four permanent lower incisor teeth have suffered traumatic injury. The dentist also determines if respondents have dental treatment needs.

At the end of the clinic appointment, respondents receive a report of the results of each physical measure and a basic interpretation of findings if reference ranges are available. These interpretations provide details about their specific results and may advise them to take some action. Respondents with out-of-range results for blood pressure or who require oral health follow-up also receive a letter to take to their regulated health professional. Before they leave, respondents have an opportunity to briefly discuss their results with the health measures specialist who administered most of their tests.

If respondents wish to receive a final report package, their mailing address and telephone number are confirmed at this time. The report package provides results of all laboratory tests for which clear clinical guidelines for interpretation exist (Tables 2 and 4) and the spirometry results. The report emphasizes that the results are not to be used for diagnostic purposes and that interpretation should be made by a doctor or regulated health professional. Details on informing respondents about urgent or sensitive results such as hepatitis B and C are provided elsewhere in this publication.[4]

Table 4
Blood collection, aliquoting, storage and shipping procedures, Canadian Health Measures Survey

Measure	Ages (years)	Eligible sample size	Reference laboratory	Collection tube type† and size	Aliquot volume‡	Storage/ Shipping	Reported to respondent (Yes/No)
Lipid profile (fasted) Total cholesterol, HDL, LDL, Triglycerides, total/HDL ratio, Apo B, Apo A1	6 to 79	2,500	HC	Fasting: 8.5 mL Red/Grey SST Non-fasting: 8.5 mL Red/Grey SST	1.0 mL	Freezer/Dry ice	Yes (all but Apo A1 and Apo B)
Insulin (fasted)	6 to 79	2,500	HC		0.5 mL	Freezer/Dry ice	No
Chemistry panel Urea, creatinine, ALT, AST, GGT, LDH, phosphate, chloride, potassium, sodium, CO_2 content, alkaline phosphatase, albumin, calcium, total protein, uric acid, bilirubin	6 to 79	5,000	HC		1.0 mL	Fridge/Ice pack	Yes
C-reactive protein (high sensitivity)	6 to 79	5,000	HC		0.5 mL	Freezer/Ice pack	No
Vitamin B_{12}	6 to 79	5,000	HC		0.7 mL	Freezer/Dry ice	Yes
Glucose (fasted or random)§	6 to 79	5,000	HC	2.0 mL Light grey	1.0 mL	Freezer/Ice pack	Yes
Complete blood count	6 to 79	5,000	MEC	6.0 mL Lavender EDTA	N/A	N/A	Yes
Glycosylated haemoglobin	6 to 79	5,000	HC		1.0 mL	Fridge/Ice pack	Yes
Red blood cell folate	6 to 79	5,000	HC		0.2 mL	Freezer/Dry ice	Yes
Metal screen 1 arsenic, nickel, selenium, uranium, copper, total mercury, lead, cadmium, manganese, zinc, molybdenum **or** Metal screen 2 Metal screen 1 + inorganic mercury	6 to 79	5,000	INSPQ		2.0 mL	Freezer/Ice pack	Yes (only total mercury, cadmium and lead)
Homocysteine	6 to 79	5,000	HC	6.0 mL Lavender EDTA	1.0 mL	Freezer/Dry ice	No
Vitamin D	6 to 79	5,000	HC		1.0 mL	Freezer/Dry ice	Yes
Stored plasma 1	6 to 79	5,000	NML		0.5 mL	Freezer/Dry ice	…
Hepatitis panel 1 Hepatitis A **or**	14 to 79		NML	8.5 mL Grey/Red SST	1.0 mL	Freezer/Dry ice	Yes (only if positive)
Hepatitis panel 2 Hepatitis A, B and C					2.0 mL		
PBDE + organochlorine pesticides + non-coplanar PCB (fasted)	20 to 79	1,500	INSPQ	10.0 mL Lavender EDTA	2.7 mL	Freezer/Ice pack	No
Perfluorinated compounds	20 to 79	1,500			1.8 mL	Freezer/Ice pack	No
Fibrinogen	12 to 79		HC	1.8 mL Light blue	0.5 mL	Freezer/Dry ice	No
Stored serum 1	6 to 79	5,000	NML	5.0 mL Gold SST	0.5 mL	Freezer/Dry ice	…
Stored serum 2	6 to 79	5,000	NML		0.5 mL	Freezer/Dry ice	…
Stored serum 3	6 to 79	5,000	NML		0.5 mL	Freezer/Dry ice	…
Stored serum 4	6 to 79	5,000	NML		0.5 mL	Freezer/Dry ice	…
Whole blood storage DNA	20 or older	3,000 3,000	NML	10 mL Lavender EDTA	10 mL (leave in vacutainer)	Fridge/Ice pack	… No
Whole blood storage DNA	20 or older	3,000 3,000	NML	10 mL Lavender EDTA	10 mL (leave in vacutainer)	Fridge/Ice pack	… No
Stored serum 5	12 to 79	4,000	NML	8.5 mL Red/Grey SST	0.5 mL	Freezer/Dry ice	…
Stored serum 6	12 to 79	4,000	NML		0.5 mL	Freezer/Dry ice	…
Stored serum 7	12 to 79	4,000	NML		1.0 mL	Freezer/Dry ice	…
Stored serum 8	12 to 79	4,000	NML		1.0 mL	Freezer/Dry ice	…
Stored serum 9	12 to 79	4,000	NML		1.0 mL	Freezer/Dry ice	…

† vacutainers from Becton Dickinson
‡ aliquot volume = total sample volume sent to the reference laboratory
§ glucose is drawn as tube number 2 for fasted respondents and as tube number 5 for non-fasted respondents
… not applicable
HC = Health Canada; INSPQ = l'Institut national de santé publique du Québec; NML = National Microbiology Laboratory
HDL = high density lipoprotein; LDL = low density lipoprotein; Apo B = apolipoprotein B; Apo A1 = apolipoprotein A1; ALT = alanaime aminotransferase; AST = aspartate aminotransferase; GGT = gamma glutamyltransferase; LDH = lactate dehydrogenase; CO_2 = carbon dioxide; PBDE = polybrominated diphenyl ether; PCB = polychlorinated biphenyl; DNA = deoxyribonucleic acid
Note: The order in which tests are listed denotes the order of blood draw for fasting appointments.

Before leaving the clinic, each respondent, regardless of age, receives $100 (or $75 if two people from the same household attended the clinic together[2]) to cover visit-related expenses, such as fuel, taxi fare, parking, meal, etc.

Home visit

To maximize response rates, respondents who are unwilling or unable to go to the clinic, but who wish to participate, are offered the option of a home visit. This visit is conducted by a minimum of two CHMS staff members (most often, a health measures specialist and a laboratory technologist) using paper questionnaires to record results. There are no differences in the protocols used to conduct the measurements in the home, but there are minor differences in the equipment (for instance, scale, stadiometer), which must be portable. Because the mCAFT, sit-and-reach and partial curl-up components are not performed in the home, the home visit is shorter than the clinic appointment, averaging about 1.5 hours. As well, the oral health component takes place only if a dentist is available. A report of the physical measures is mailed to respondents within a few days of the home visit, and all respondents are eligible to receive a report of their laboratory test results 8 to 12 weeks later. Respondents opting for a home visit do not receive a reimbursement of expenses.

Quality assurance and quality control

To maximize the reliability and validity of the data and to reduce systematic bias, the CHMS developed quality assurance (in anticipation of problems) and quality control (in response to problems) protocols in accordance with the Statistics Canada Quality Assurance Framework.[10]

Quality assurance (QA) for the clinic covers staff selection and training, instructions to respondents (pre-testing guidelines), and issues related to data collection. All staff have appropriate education and training for their respective positions. For example, the health measures specialists have a degree in kinesiology (or the equivalent) and certification through the Canadian Society for Exercise Physiology as Professional Fitness and Lifestyle Consultants or Certified Exercise Physiologists.[11] To ensure consistency between measurement techniques, procedures manuals and training guides were developed (Table 5) in consultation with, and reviewed by, experts in each field.

A selection and evaluation process of laboratory analytical methods was established in order to reduce errors and increase standardization among laboratory technologists. SOPs were written for the complete blood count analyses performed in the mobile laboratory. The collection order, as well as the blood processing and aliquoting procedures, are programmed in the data capture application. SOPs for shipping biospecimens were developed in accordance with the International Air Transport Associations (IATA) regulations for shipping infectious substances.[12]

QA factors related to data collection include site scheduling; equipment selection, calibration and maintenance; and detailed protocols and procedures for each clinic component. Scheduling of the 15 sites over the two-year collection period took into account temporal effect and seasonality. The selection of equipment was based on a combination of consultations, research, testing and evaluations. An Equipment Calibration and Maintenance Manual (Table 5) was developed to ensure that the calibration and maintenance of equipment meet or exceed the standards established by the manufacturers. All staff are trained in the use, calibration and maintenance of the equipment, and calibration logs are maintained for each piece of equipment.

Quality control (QC) measures in the clinic are designed to standardize data collection and data entry. A professional and relaxed environment is created to ensure that respondents are at ease and comfortable during their clinic visit. Because changes in temperature may affect measures such as spirometry and blood pressure, every effort is made to keep the clinic at a comfortable and constant temperature of 21°C (± 2° C). The order in which tests are performed is such that the residual effects of some (for example, increased blood

Table 5
Protocol manuals and training guides prepared for field collection staff, Canadian Health Measures Survey

Manual	Purpose
Clinic Test Procedures Manuals: Physical Measures (anthropometry, blood pressure, fitness, etc) Oral Health Exam Urine collection Phlebotomy Activity Monitor Initialization and Downloading	Detailed procedures are required on how to perform each test and how to capture the data
Blood/Urine Processing Procedures	Detailed procedures for preparing blood for analysis at reference laboratories, including instructions for centrifuging, aliquoting, storing within the mobile clinic and shipping to reference labs
Home Visit Manual	Home visit protocols, equipment requirements and highlights any changes between clinic collection and home visit collection
Clinic Coordinator's Manual	Information on booking clinic appointments, follow-up on non-response, signing respondents into clinic visit, signing consent forms, disbursing reimbursement, recording data during oral health exam
Site Logistics Manual	Day-to-day procedures/tasks for site logistics officer (for example, equipment maintenance, safety checks, cleaning, inventory control, etc.)
Field Staff Administration Manual	General procedures and information including: filling out travel expense claims, roles and responsibilities of staff, reporting time, frequently asked questions about survey, Statistics Act , confidentiality
Equipment Calibration and Maintenance	Detailed procedures for calibrating, cleaning and maintaining collection equipment
Safety Manual	Information about safety for respondents, staff and visitors to mobile clinic
Site Manager and Senior HMS manuals	Administrative information about human resources, travel policies, leave requests, staff scheduling, etc. and detailed procedures for monitoring survey collection goals and overseeing quality assurance/quality control procedures in clinic
Advanced Arrangements Procedures Manual	Procedures for setting up trailers, preparing site, making accommodation and car arrangements, trailer maintenance, shipping and receiving supplies, arranging contractors, etc.
Business Continuity Plan	Umbrella document that encompasses all aspects of maintaining continuity of field collection during unforeseen circumstances
Mobile Clinic Maintenance Manual	Outlines general maintenance plan for mobile clinic, including infrastructure and computers
Shipping Procedures Manual	Detailed procedures for shipping specimens, confidential material and activity monitors, including use of the CHMS tracking system
IT Support Procedures	Steps to follow regarding IT support, maintenance, upgrades to systems, trouble-shooting, etc.
Inventory User Guide	Outlines process for recording and tracking levels of supplies and equipment, and ordering
Tracking System User Guide	Outlines process for recording and tracking biological specimens, activity monitors and respondent information

pressure from mCAFT) will not affect the results of others (for example, resting blood pressure).

The consistency of results is evaluated through the random collection of replicate measurements at the end of a clinic visit. Data from the replicate measurements are analysed at head office. Some replicate measurements are done during the dry-runs (oral health and laboratory); others during the actual collection period (anthropometry, grip strength and sit and reach). The performance of clinic staff on all components is observed at regular intervals to evaluate protocol adherence, interaction with respondents, and overall data collection quality and functioning of the clinic.

Because of the complexity and subjectivity of the screening and spirometry components, headquarters staff and experts review the data regularly to ensure that proper decisions are being made and that there is consistency in delivery between staff members. Spirometry trials from each health measures specialist are sent to external experts for data quality assessment and interpretation.

A QA/QC advisory committee comprised of experts on each physical measure provides advice and guidance about data quality, reviews procedures, provides training, and periodically visits the mobile clinic to observe staff.

Preparing, shipping and tracking biological specimens

Except for the DNA samples, which are sent to the reference laboratory twice a week for processing and extraction, all biological samples collected in the clinic are processed (for example, centrifuged, aliquoted) before they are shipped to the reference laboratories. Sample trays are shipped once a week to each reference laboratory on pre-assigned shipping days. Shipments are packaged according to IATA regulations for infectious substances. All shipments are sent by overnight delivery using a courier company certified to handle dangerous goods and are scheduled to arrive at the reference laboratories only on weekdays (shipping occurs Monday through Thursday).[12] In coordination with each shipment, the electronic packing slip that contains the tube identifiers, the shipping container bar-code and the courier waybill number are encrypted and sent electronically to the reference laboratory.

A specimen tracking system was developed by Statistics Canada so that staff can determine the status of every tube shipped to the reference laboratories.

Analysis of blood and urine: At the mobile clinic

The only biospecimen test conducted in the mobile clinic is the complete blood count, since accurate results require that this test be done as soon as possible after the blood draw. Internal and external QC, as well as monitoring, allow quick detection of errors related to the complete blood count analysis, so that remedial action can be taken.

The mobile laboratory also participates in the Beckman Interlaboratory Quality Assurance Program (IQAP) and the College of American Pathologists (CAP) proficiency testing (PT) program for each analyte determined by the cell counter.[13,14] The summary report from CAP and remedial action for unsatisfactory performance are documented in the QC logbook, and are available for review.

All changes and problems that occur in the laboratory testing are recorded: date and time, technologist, changes of reagent and standard, and the instrument service record. Based on periodic review of these records, preventive measures can be taken.

The temperature of the refrigerator and freezers used for storage of biospecimens in the clinic are monitored and recorded daily. QC and reagent logs are kept to ensure the reagents and materials are not outdated, and an inventory system is used to track expiry dates. The hematology counter is calibrated daily by running quality control samples, and reproducibility checks and machine maintenance are performed as needed.

Analysis of blood and urine: At the reference laboratories

To detect chronic disease, infectious disease and environmental toxin exposure, the blood and urine

samples are sent to three designated reference laboratories for analysis:

- Health Canada Laboratory, Bureau of Nutritional Sciences, Nutrition Research Division
- The National Microbiology Laboratory
- L'Institut National de Santé Publique du Québec

The Health Canada Laboratory is a federal government laboratory that specializes in the analysis of nutrition and chronic disease markers. The National Microbiology Laboratory, operating under the leadership of the Public Health Agency of Canada, is the reference infectious disease laboratory in Canada and acts as the CHMS biorepository and DNA preparation center. L'Institut National de Santé Publique du Québec, a provincial laboratory, is a world leader in the analysis of environmental biomarkers. Each CHMS reference laboratory is responsible for hiring and training staff, obtaining International Standards Organization certification, and their own internal and external QA/QC programs.[15] The reference laboratories follow SOPs that have been developed for every assay and technique performed in their laboratory.

The reference laboratories compile and transmit test results to Statistics Canada Head Office each week using the Data Return Facility (DRF). The DRF is a software program installed on the data transmission computer at each reference laboratory that encrypts and transmits data in a secure fashion to Statistics Canada.

In addition to sending blind replicates to the reference laboratories to monitor the precision of the assay, the CHMS monitors the accuracy of the analytical testing by using reference QC material with known analyte concentration and field blanks. Periodically throughout collection at each of the 15 CHMS sites, these reference QC samples are sent to each reference laboratory with a regular specimen shipment. Results are sent to Statistics Canada headquarters, along with all other respondent results, where they are assessed to determine the accuracy of the methodology based on the defined analyte concentration. If required, feedback is provided quickly to the reference laboratories for review and remedial action.

The CHMS laboratory staff regularly visit each reference laboratory to ensure that protocols are followed and to address concerns or problems. Weekly reviews of laboratory data to identify inconsistencies in results such as assay drifting are also performed.

Conclusion

A wide range of logistical and operational issues must be considered in the implementation of any physical measures survey. Several years of planning and development went into the Canadian Health Measures Survey. The aim has been to ensure a safe collection environment for staff and respondents, to ensure that appropriate procedures and training materials are in place to yield quality data, and to promote smooth field operations. More information about the field procedures can be found on the CHMS website at www.statcan.ca/CHMS. ●

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Appendix A

CHMS mobile clinic location selection check list

Collection site: _____ Site number: _____

Name of location: _____

Date of visit: _____ Visited by: _____

Criteria	Yes/No	Comments
Characteristics of location		
Is the location flat?		Slope from front to rear must be less than 24"
Is the location paved? (no new gravel or grass)		No gravel or grass
Is the location large enough to accommodate the trailers?		A minimum of 18.3m x 15.25m. Record size of location.
Does the location have a street address?		Record address of location
Is the location considered “neutral”?		Neutral means not privately owned or religious
Is location easy to find on city map?		
Is location wheelchair-accessible?		If not, record what is required to make it accessible
Is location central within collection site?		
Is surrounding neighbourhood safe?		Observe socioeconomic milieu, streetlights, etc. Check crime report
Does location have obstructions that could cause damage or injury?		Large trees, other potential falling objects
Is location sheltered?		From wind, rain, hot sun
Is there parking on site?		Record number of spots
Is location relatively quiet		Noise from train tracks, construction sites, transit systems, airports
Accessibility of location		
Is there close access to public transportation?		Record distance to nearest public transit stop
Is location easily accessible by car?		Close proximity to major thoroughfares
Is location within close proximity to staff accommodations?		Record distance to accommodations
Availability of services		
Does location have security services?		Record type of service (for example, drive by)
Are emergency services near by?		
What is distance to nearest hospital or medical/laboratory facility?		
Is hydro accessible?		Record provider
Is sewer accessible?		Record provider
Are telephone lines accessible?		Record provider
Is DSL (high speed internet) accessible?		Record provider
Is a courier service available?		
Is biohazard waste pick-up available?		Record provider
Is dry ice service available?		Record provider