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..	not available for specific reference period
...	not applicable
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r	revised
x	suppressed to meet the confidentiality requirements of the *Statistics Act*
E	use with caution
F	too unreliable to be published

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Canadian Health Measures Survey

In March 2007, Statistics Canada launched the Canadian Health Measures Survey (CHMS), the most comprehensive, national direct health measures survey ever conducted in Canada. The survey will provide population-representative data on important public health indicators including obesity, nutrition, physical activity, physical fitness, cardiovascular disease, and environmental exposures.

There is good evidence of the need for directly measured health data as an integral part of a national health surveillance system. While Statistics Canada has been collecting health status and related data for many years, these data are limited in two important ways. First, a considerable amount of essential information, for instance, blood pressure and physical fitness, cannot be ascertained through an interview; direct physical measurement is required. Second, health data from self-report surveys or administrative records may be seriously biased for some variables. For example, even simple measures like height and weight are subject to reporting bias.

The CHMS was developed to address important data gaps and limitations in current health information by collecting directly measured indicators of health and wellness on a representative sample of approximately 5,000 Canadians aged 6 to 79 years. The survey entails an in-home general health interview and a subsequent visit to a mobile clinic where direct physical measures are taken (anthropometry, spirometry, blood

pressure, fitness, physical activity, oral health examination, blood and urine specimens). These data are analyzed for indicators of general health, chronic disease, infectious disease and environmental biomarkers, and biospecimens are stored for future research.

The CHMS was developed in partnership with Health Canada and the Public Health Agency of Canada, and with the assistance of several advisory committees, stakeholders, experts, reviewers and supporters. The CHMS has received approval from the Health Canada Research Ethics Board.

The five articles in this supplement to *Health Reports* provide detailed information on:

- the rationale and background of the CHMS;
- the pre-test that took place in the fall of 2004;
- the sampling strategy;
- the ethical, legal and social issues involved in a direct measures survey; and
- the operations and logistics of the mobile clinics.

The first article, "Rationale, background and overview," outlines the need for direct measures surveys, describes Canada's experience with such surveys and the experience in other countries, and provides an overview of all aspects of the CHMS.

The second article, "Pre-test: Design, methods, results," is a detailed description of the pre-test conducted in Calgary, Alberta from October through December, 2004. The objectives of the pre-test, which replicated the planned design for the full CHMS as closely as possible, were to: determine Canadians' willingness to participate in a direct health measures survey; assess the human resource and financial costs; examine response rates, processes and materials; and test planning assumptions.

The third article, "Sampling strategy overview," deals with survey design; sample size; creation, selection and allocation of sites; and dwelling and respondent sampling. A balance between logistical and cost considerations and national coverage resulted in 15 collection sites being selected that covered 96.3% of the Canadian population.

The fourth article, "Ethical, legal and social issues," outlines the unique challenges surrounding consent and privacy that are involved in a direct measures survey and how the CHMS went about addressing them. The CHMS is the first survey for which Statistics Canada sought the expertise of a Research Ethics Board, with informed consent being its key focus.

Finally, "Clinic operations and logistics," describes the practical aspects of equipping, staffing, setting up and closing down mobile clinics; the details of a clinic visit; and the complex logistics involved in gathering and transmitting the data collected at the clinics.

Data from the CHMS should be available in early 2010 and will be integral for informing future public health policy in Canada. The CHMS has a detailed analytical plan that was developed to ensure that priority health information needs that led to the funding of the survey are met and that CHMS data will be used extensively for scientific publications, research training, policy development, and knowledge creation in a timely fashion.

The information collected in the CHMS will be used to establish national baseline data for a variety of important health indicators of obesity, hypertension, cardiovascular disease, nutrition, exposure to infectious diseases, and exposure to environmental contaminants. In addition, the survey will provide insight into the fitness of the nation and the extent of undiagnosed disease among Canadians.

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Canadian Health Measures Survey: Rationale, background and overview

Mark Tremblay, Michael Wolfson and Sarah Connor Gorber

Abstract

The Canadian Health Measures Survey (CHMS) was developed to address important data gaps and limitations in existing health information by collecting directly measured indicators of health and wellness on a representative sample of approximately 5,000 Canadians aged 6 to 79 years. The survey entails an in-home general health interview followed by a visit to a mobile clinic, where direct physical measures of health are taken (anthropometry, spirometry, blood pressure, fitness, physical activity, oral health examination, blood and urine specimens). Reference laboratories analyze biological specimens for indicators of general health, chronic disease, infectious disease and environmental biomarkers. This important and ambitious survey provides comprehensive and robust health information to advance health surveillance and research in Canada, while providing training opportunities to enhance research capacity.

Keywords

health surveys, data collection, direct measures, health measurement, national survey

Authors

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The Canadian Health Measures Survey (CHMS) is a new, comprehensive, direct health measures survey that is being conducted by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada. This paper summarizes the background, history and rationale for the survey, and provides an overview of the objectives, methods and analysis plans.

Rationale and background

The principal objective of the CHMS is to collect new and important data on Canadians' health status. While Statistics Canada has been collecting health status and related data for many years, these data are generally limited in two important ways. First, many kinds of data, such as blood pressure and physical fitness, simply cannot be ascertained in an interview; they require direct physical measurement. Second, health information derived from self-report surveys or administrative records may be seriously biased for some variables.[1] For example, a recent review shows a consistent reporting bias of even simple measures like height and

weight, which has the potential to misinform data users.[2] Moreover, efforts to correct for self-reporting bias are complicated by the probability that bias for some measures may be unstable over time and susceptible to media attention and social marketing campaigns, among other influences.

Direct health measurements can be reported on continuous scales; provide more robust, objective measures; and allow for the assessment of variables that simply cannot be determined accurately through self-reports (for example, metabolic syndrome, environmental toxin exposure, lung function). Such data are needed for public health education, health promotion programs, health care planning, health surveillance and research.

Accordingly, several countries have a history of conducting surveys that include direct physical measures and that have yielded important findings. For example, the U.S. National Health and Nutrition Examination Survey (NHANES)[3] has provided data to construct standard growth charts for children, thereby allowing doctors and parents to better understand developmental health trajectories.[4] In the 1960s, the NHANES confirmed findings linking high cholesterol and heart disease. It also provided the first evidence that Americans had high blood lead levels, which motivated governments to phase out the use of lead as an additive in gasoline and paint.[5] In Australia, a health measures survey conducted from 1999 to 2001 found that for every known case of diabetes, there was one undiagnosed case, and that nearly 1 million Australians over age 25 have diabetes.[6] Finland, too, has a legacy of important public health and scientific findings from national direct health measures surveys.[7,8]

Table 1
Summary of Canadian direct health measures surveys, 1970 to 1972 to 2004

Survey	Year(s)	Direct measure sample	Age range (years)	Response rate to direct measures and biospecimen collection (if applicable) of eligible respondents	Direct health measures
Nutrition Canada Survey[9]	1970 to 1972	12,795	0+	46%	Biochemical blood tests: protein, albumin, calcium, phosphorous, bilibrubin, alkaline phosphate, iron, transferrin saturation, vitamins (A, C, E), cholesterol, folic acid, triglycerides. Biochemical urine tests: glucose, iodine, creatinine, urea nitrogen, riboflavin, thiamine, pyridoxine, hct, Hb; Physical measures: dental exam, standing and sitting height, height of anterior superior iliac spine, biacromial diameter, bi-ilio-cristal diameter, antero-posterior and transverse chest diameters, wrist breadth, bicondylar femur breadth, calf and upper arm circumferences, head circumference, upper arm and subscapular skinfolds, weight.
Canada Health Survey[10]	1978 to 1979	8,751	2+ Physical measures 3+ blood	28%	Biochemical tests: immune status (polio, measles, mumps, rubella, diphtheria, tetanus), zinc, copper, lead, cholesterol, uric acid, creatinine, transaminase, glucose, Hb. Physical measures: height, weight, upper arm length, arm midpoint, arm girth, upper arm skinfold, blood pressure, cardiorespiratory fitness.
Canada Fitness Survey[11]	1981	16,000	7 to 69	59%	Physical measures: height, weight, skinfolds, chest, waist, hip, thigh, calf and upper arm circumference, knee and elbow diameter, somatotype, blood pressure, resting heart rate, cardiorespiratory fitness, flexibility, push-ups, sit-ups, grip strength.
Campbell's Survey on Well- being[12,13]	1988	4,000	10 to 69	80%	Physical measures: height, weight, skinfolds, chest, waist, hip, thigh circumference, blood pressure, resting heart rate, cardiorespiratory fitness, flexibility, push-ups, curl- ups, grip strength.
Canadian Heart Health Surveys[14]	1988 to 1992	20,095	18 to 74	67%	Biochemical blood tests: cholesterol, triglycerides. Physical measures: height, weight, waist and hip circumference, blood pressure.
Canadian Study of Health and Aging[15]	1991 1996 2001	2,914 2,305 1,322	65+	82%, 90%, 91% institutionalized sample 74%, 85%, 89% community sample	Biochemical blood tests: complete blood count, glucose, folate, vitamin B12, genetic screen. Physical measures: height, weight, blood pressure, hearing, vision, vital signs, neurological and neuro-psychological exams, mobility, balance, CT scan.
Canadian Community Health Survey[16]	2004	31,925	2+	57.5%	Physical measures: height, weight.

Notes: Some participants were screened out of participation - proportion unknown. Hb = haemoglobin; hct = haematocrit; RBC = red blood cell.

Despite the advantages for surveillance and research, population-representative direct health measures surveys have been rare in Canada. As the summary in Table 1 indicates, no comprehensive, national health measures survey has been conducted in Canada since the 1978/1979 Canada Health Survey.

Since then, however, the need for such a survey has been discussed, with varying degrees of intensity, although the cost proved to be a difficult barrier. Early preparations for the 1994/1995 National Population Health Survey, for instance, included direct physical measures that were eventually dropped. Between 1998 and 2001, an Expert Working Group for the Cardiovascular Disease Surveillance System of Health Canada met periodically to discuss the content of a potential survey that would collect direct measures. Support, endorsement and encouragement for such a survey came from several government departments and scientific groups. Technical improvements and decreased costs for biospecimen analyses gave the project added momentum. A number of program and policy initiatives that occurred from 2001 to 2006 (Table 2) further demonstrated the need for surveillance of public health indicators and provided direct or indirect impetus for the creation and ongoing support of a direct health measures survey.

In response to growing demands for the surveillance of public health indicators and to address long-standing limitations in Canada's health information system, Health Canada and the Public Health Agency of Canada supported Statistics Canada in obtaining funding for a direct measures health survey. This support was announced in the 2003 federal budget as part of an extension of the Health Information Roadmap Initiative.[17,18]

The Canadian Health Measures Survey (CHMS) aims to advance the Health Information Roadmap Initiative[17,18] by addressing important data gaps and

Table 2
Program and policy initiatives instrumental in development of Canadian Health Measures Survey

Program or policy initiative	Role / Mandate	Year
Physical Measures Survey Proposal Working Document prepared by Health Statistics Division at Statistics Canada[19]	Initial guiding document for the conceptualization and development of the Canadian Health Measures Survey.	2001
Creation of the Chronic Disease Prevention Alliance of Canada (www.cdpac.ca)	Advocacy for integrated research, surveillance, policies and programs, and the resources needed to positively influence the determinants of health and reduce incidence of the chronic diseases that account for the largest burden of morbidity, mortality and cost in Canada, namely, cardiovascular disease, diabetes and cancer.	2001
The Canadian Sport Policy (www.canadianheritage.gc.ca/progs/sc/pol/^pcs-csp/Index_e.cfm)	Vision of enhanced participation with a significantly higher proportion of Canadians from all segments of society involved in quality sport activities at all levels and in all forms of participation. Monitoring required.	2002
Building on Values: The Future of Health Care in Canada (Romanow Report) (www.hc-sc.gc.ca/english/care/romanow/hcc0086.html)	Report of the Commission on the Future of Health Care in Canada, which reported on consultations with Canadians on the future of Canada's public health care system and recommended policies and measures that offer quality services to Canadians and strike an appropriate balance between investments in prevention and health maintenance and those directed to care and treatment.	2002
Federal Budget (www.fin.gc.ca/budget03/pdf/bp2003e.pdf)	Included the initial $20 million funding for the CHMS.	2003
Creation of Health Council of Canada (www.healthcouncilcanada.ca)	Mandated to monitor and report on the progress of health care renewal in Canada.	2004
Creation of the Public Health Agency of Canada (www.phac-aspc.ca)	Mission to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health. Monitoring required.	2005
Development of Public Health Goals for Canada (www.phac-aspc.gc.ca/hgc-osc/pdf/goals-e.pdf)	Overarching goal is that, as a nation, we aspire to a Canada in which every person is as healthy as they can be—physically, mentally, emotionally, and spiritually. Monitoring required.	2005
Integrated Pan-Canadian Healthy Living Strategy (www.phac-aspc.gc.ca/hl-vs-strat/pdf/hls_e.pdf)	A conceptual framework for sustained action based on a population health approach. Its vision is a healthy nation in which all Canadians experience the conditions that support the attainment of good health. Monitoring required.	2005
Conference of F/P/T Deputy Ministers of Health[20]	Report identified that surveillance is an essential tool for planning and evaluating policies and programs to address chronic disease risk factors and determinants.	2006
Review of Human Biomonitoring Studies of Environmental Contaminants in Canada 1990-2005 Final Report released[21]	Provided strong evidence of a need for more comprehensive and intensive biomonitoring of environmental contaminants in Canada.	2006

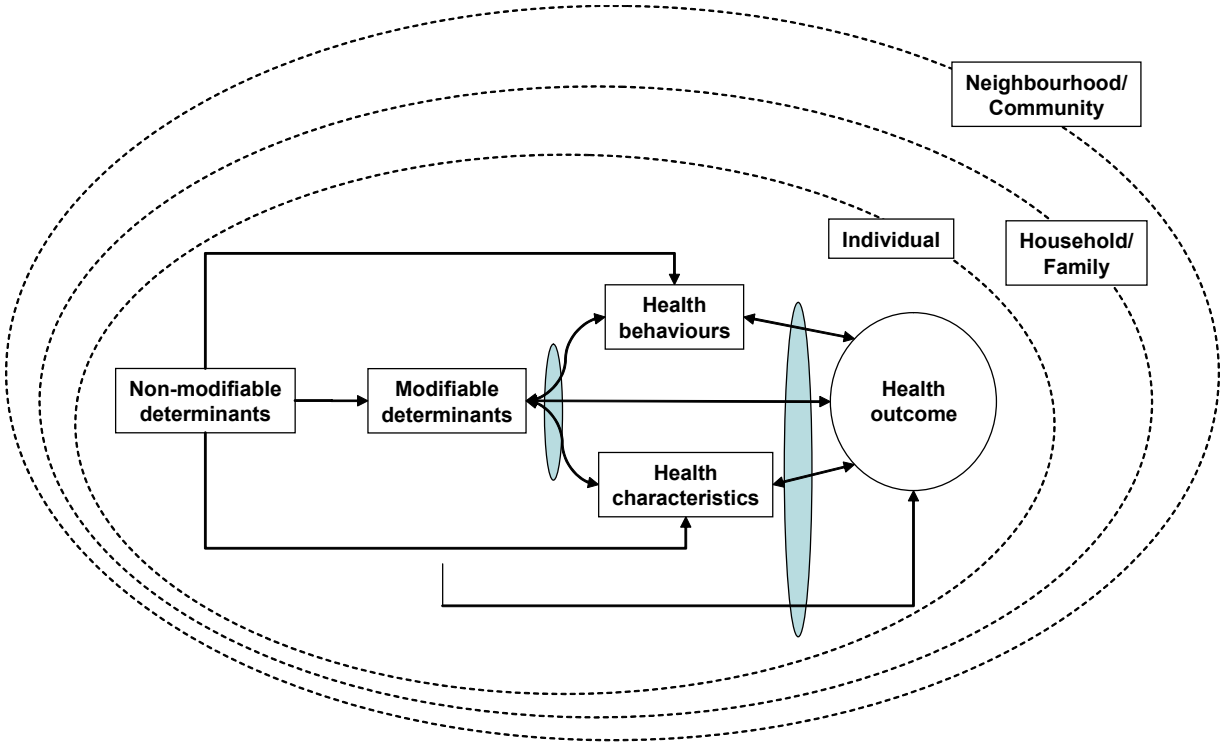
limitations in existing health information through direct physical measures of Canadians' health. The information will be used to establish national baseline data for a range of important health indicators such as obesity, hypertension, cardiovascular disease, exposure to infectious diseases, and exposure to environmental contaminants. In addition, the survey will provide insight into the fitness of the nation and the extent of undiagnosed disease.

The CHMS design has been informed by a conceptual framework that recognizes the importance of both individual- and non-individual-level measures of health. The concentric circles in Figure 1 illustrate the importance of measuring variables at other levels that may be mediators or moderators of individual health. Such variables could include reported or direct measures of geography, culture, climate, social inequality, workplace or school health policies, air quality, water quality, food access, local land use, green space availability, public safety (crime), traffic patterns, health care availability, and population density. Although most of these variables are not being collected in the CHMS at this time, it should be possible in some cases to collect these data and add them in the future.

Additionally, the CHMS anticipates the linkage of interview and clinic data, given respondents' consent, to their provincial health care records. This kind of linkage will provide unprecedented new information enabling, for example, the relationships between obesity and physical fitness to health care costs to be directly assessed.

The development and design of the CHMS entailed a comprehensive consultation process involving Health Canada, the Public Health Agency of Canada, expert advisory committees, professional

Figure 1
Conceptual framework for Canadian Health Measures Survey



Notes: Shaded circles indicate interactions among the arrows. Examples of non-modifiable population health determinants include: age, sex, ethnicity, genotype; examples of modifiable population health determinants include: income, education, social environment, physical environment, health care system; examples of health behaviours include: physical activity, nutrition, alcohol and substance abuse, smoking status, medication use, sex behaviours, stress exposures; examples of health characteristics include functional status, immunization status, stress reactivity, body weight, cardiovascular fitness, musculoskeletal fitness, metabolic fitness; examples of health outcomes include detectable disease, health care system contact, disability.

and scientific stakeholder groups, the National Centre for Health Statistics in the U.S., federal and provincial privacy commissioners, the Health Canada Research Ethics Board, and several Statistics Canada committees. Because of the invasiveness of some of the measures, many complicated and delicate ethical, legal and social issues required investigation, discussion, consultation and compromise; details of these issues are provided in Day et al.[22]

The early development of the CHMS coincided with substantial interest and activity around the creation of large representative cohort studies designed to include comprehensive direct measures of health (for example, Canadian Longitudinal Survey on Aging, CARTaGENE, Multi-generational Cohort Study, Canadian National Children's Study, Ontario Cohort Consortium). The opportunity for the CHMS to contribute to and learn from the discussions surrounding these studies not only assisted the development of the CHMS, but also expanded the base of support for the survey.

In the fall of 2004, a pre-test was conducted to assess costs and response rates, examine processes and procedures, and evaluate operations and planning assumptions.[23] The pre-test findings provided important direction for the ultimate design of the CHMS.[23]

Two months before data collection began, a dress rehearsal was held. Approximately 120 volunteers from selected age groups underwent the full survey collection procedures and laboratory testing. This dress rehearsal was an opportunity to simulate both normal and emergency situations and interruption procedures. Several minor modifications to procedures, processes and applications were made based on the dress rehearsal.

To prepare the CHMS, new computer applications, processes and procedures needed to be developed; measurement spaces and infrastructures built; data security features tested and confirmed; sampling strategies created; communications strategies developed and implemented; logistical and operational procedures tested; staff hired and trained; biospecimen and statistical analysis planning completed; biorepository established; data processing procedures instituted; ethical, legal, privacy and social issues resolved; and financial planning completed.[22-25] Approximately 3.5 years of development were needed before data collection started, with a staff that began as one, growing to nearly 70 when the survey went into the field in March, 2007.

Survey overview

Objectives

The objectives of the CHMS are to:

- estimate the numbers of people with selected health conditions, characteristics and exposures;
- estimate the distribution of selected diseases, risk factors and protective characteristics;
- assess the validity of prevalence estimates based on self- and proxy-reported information;
- monitor temporal trends of directly measured variables to the extent possible with available survey data;
- ascertain relationships among risk factors, health promotion and protection behaviours, and health status;
- explore emerging public health issues and new measurement technologies;
- establish a biorepository of biospecimens (urine, plasma, serum, isolated genomic DNA) from a representative sample of Canadians to be used for future research and surveillance;
- provide a data collection platform and infrastructure for ongoing physical measures surveys and add-on studies;
- provide training opportunities for staff, students and researchers interested in direct health measures data collection operations and data analysis;
- share experiences and expertise with others domestically and internationally.

Survey sampling

The CHMS was designed to provide nationally representative estimates (for conditions that have a prevalence of 10% or more, with a coefficient of variation of 16.5%) from a sample of approximately 5,000 Canadians aged 6 to 79 years, with roughly

500 females and 500 males in each of the following age groups: 6 to 11, 12 to19, 20 to 39, 40 to 59, and 60 to 79 years. The Labour Force Survey area frame, supplemented by the 2006 Census, was used as the sampling frame. The use of mobile clinics required a clustered sample design. Logistical and financial considerations limited the number of sites to 15. Collection sites were selected so as to contain a population of at least 10,000 respondents, with a maximum travel distance of 100 km to a site without crossing census metropolitan area boundaries. This sampling protocol covers approximately 96% of the Canadian population and resulted in data collection sites in five provinces. Further details of the sampling strategy are provided elsewhere in this publication.[25]

Within each site, dwellings were stratified and randomly selected using the sampling frame. Initial contact with selected dwellings is made through a mail-out containing information about the CHMS. Subsequently, a roster of all residents from each participating dwelling is obtained, and one or two eligible respondents are selected per dwelling. The probability of a respondent being chosen varies by stratum, depending on the age group being targeted, and is designed to achieve the desired age and sex stratification. The CHMS is voluntary and includes only respondents who agree to participate.

Field operations staff

The field interviewer staff consists of 10 or 11 Statistics Canada interviewers and an interviewer manager. The clinic staff consists of a manager, two senior health measures specialists, four health measures specialists, four laboratory technicians or technologists, four clinic coordinators, two licensed dentists, two dental recorders, and a site logistics officer. All health measurement specialists are Certified Exercise Physiologists.[26] As part of contingency planning, trained replacement staff are available.

The staff travel from site to site and live at each location for 6 to 7 weeks. The advance arrangements staff orchestrate living arrangements at each site.[24] The clinic staff work as two teams (morning shift and afternoon shift). The survey shuts down for holidays.[24]

Statistics Canada staff at head office in Ottawa provide central support for advance arrangements; public relations and communications; technical support; training and retraining; data capture and processing; quality assurance and quality control; survey management and administration; and data analysis.

Survey methods

Data collection is performed in two stages: a health questionnaire administered in the respondents' home by a Statistics Canada interviewer (computer-assisted personal interview—CAPI), and, one day to six weeks later, direct physical measurements and biospecimen collection in a mobile clinic.

Consent for participation in the health interview is implied when respondents answer questions. However, a comprehensive consent process is employed for the physical measures at the clinic. Specific written consent is obtained for participation in the physical measures (including biospecimen collection); receipt of lab results; measurement and reporting of reportable diseases; storage of biospecimens (except DNA); and separately for DNA storage. In addition to consent from their parent or guardian, assent is obtained from children.

Table 3
Summary of household questionnaire content, Canadian Health Measures Survey

Theme areas	Modules
Health status	general health; sleep; height and weight; weight change; Health Utility Index; chronic conditions; hepatitis; family medical history; oral health; phlegm; pregnancy; birth information; breast-feeding information
Nutrition and food	grains consumption; fruit and vegetable consumption; meat and fish consumption; dietary fat; salt; water and soft drink consumption; milk and diary product consumption
Medication use	medications; other health products and herbal remedies
Health behaviours	physical activities; sedentary activities; smoking; alcohol use; illicit drug use; sexual behaviour; maternal breast-feeding; strengths and difficulties
Environmental factors	exposure to second-hand smoke; sun exposure; housing characteristics; grooming product use
Socio-economic information	socio-demographic characteristics; education; labour force activity; income

Details of the consent process are provided by Day et al.[22]

The household questionnaire has 46 modules containing 722 questions (Table 3). The questionnaire was designed to provide background and contextual information for the direct measurements. For most respondents, the household interview takes 60 to 90 minutes, including an introduction to the clinic visit (flash video) and the consent process. Immediately after the household interview, respondents are encouraged to call to make an appointment for the physical measurements.

Each of the two mobile clinics used for performing the physical measures is comprised of two 53-foot trailers joined by a pedway.[24] Advance arrangements staff ensure that the clinics are set up in safe locations at each site and that all services are connected (for example, power, water, sewer, telephone, internet, waste disposal, parking, wheelchair access, etc.).[24] Each site operates for approximately 6 weeks, 7 days a week, with morning, afternoon and evening appointments. Measurements of 18 respondents can be completed each day. At each site, 330 to 350 respondents are measured. Data collection is being performed over a two-year period (March 2007 to March 2009).

Clinic operations

A detailed description of the mobile clinic logistics and procedures is provided in the accompanying paper by Bryan et al.[24] Briefly, respondents arrive at the mobile clinic for their scheduled appointment; their identity is verified; consent is obtained; screening procedures are employed; physical measures are taken; and biospecimens collected. (The list of physical measures obtained is provided in Table 4; the list of analytes assessed in blood and urine is provided in Table 5; and the specific measurement equipment used is summarized in Table 6). Respondents selected for morning appointments arrive at the mobile clinic after a 12-hour fast; those with afternoon or evening appointments require only a 2-hour fast. All respondents follow specific pre-testing guidelines.[24]

Table 4
Physical measures included in Canadian Health Measures Survey

Measure	Age group	Sample size
Anthropometry	All ages	5,000
Standing height		
Sitting height		
Weight		
Waist circumference		
Hip circumference		
Skinfolds		
Blood pressure	All ages	5,000
Resting heart rate	All ages	5,000
Accelerometry (physical activity monitoring)	All ages	5,000
Spirometry (lung functioning)	All ages	5,000
Cardiovascular fitness (mCAFT step test)	6 to 69 years	4,525
Muscular strength, endurance and flexibility		
Hand grip strength	All ages	5,000
Partial curl-ups	6 to 69 years	4,525
Sit and reach	6 to 69 years	4,525
Oral health exam	All ages	5,000
Blood sample	All ages	5,000
Urine sample	All ages	5,000
Storage of blood and urine	All ages	5,000
Storage of DNA	20 years or older	3,000

Note: Answers to the screening/consent questions, as well as respondents' withdrawal of consent for some or all parts of the survey, affect which physical measures are taken and captured (that is, for each measure, the number of test results could be less than the targeted sample size).

Home visit

Surveys in Finland demonstrated that giving individuals who are unable (for a variety of reasons) to attend the mobile clinic an opportunity to have the physical measures performed in their home reduces bias, especially among the elderly. The CHMS, therefore, offers a home visit option, as described in detail by Bryan et al.[24]

Reporting results

A major motivation for individuals to participate in the CHMS is the opportunity to receive the results of a variety of measurements of health and wellness. At the mobile clinic, respondents can have immediate results of the physical measurements that can be interpreted quickly (for example, blood pressure, oral health, and physical fitness).

Table 5
Laboratory tests on blood and urine, Canadian Health Measures Survey

Blood	Age group	Sample size
General		
Complete blood count (CBC) (White blood count, lymphocytes, monocytes, neutrophils, eosinophils, basophils, red blood count, haemoglobin, haematocrit, mean corpuscular volume (MCV), mean corpuscular haemoglobin concentration (MCHC), mean corpuscular haemoglobin (MCH), red cell distribution width, (RDW), platelets)	All ages	5,000
Blood chemistry panel (Alanine aminotransferase (ALT), albumin, alkaline phosphatase, aspartate aminotransferase (AST), bicarbonate, calcium, chloride, creatinine, gamma- glutamyltransferase (GGT), lactate dehydrogenase (LDH), phosphate, potassium, sodium, total bilirubin, total protein, urea, uric acid)		
Heart health		
Homocysteine, high sensitivity C-reactive protein	All ages	5,000
Total cholesterol, total cholesterol/HDL ratio, high and low density lipoproteins (HDL and LDL cholesterol), triglycerides, apolipoproteins A1and B	All ages	2,500
Fibrinogen	12 years or older	4,000
Diabetes		
Glycohaemoglobin (HbA1c)	All ages	5,000
Glucose (fasting or random), fasting insulin	All ages	2,500
Nutritional status		
Red blood cell folate, vitamin B12, vitamin D	All ages	5,000
Infectious disease measures		
Hepatitis A (anti-HAV) Hepatitis B (anti-HBs and anti-HBc) Hepatitis C (anti-HCV)	14 years or older	3,750
Hepatitis B (HBsAg for subsample that tests positive for anti-HBc; polymerase chain reaction used to verify positives)	14 years or older	200 (estimate)
Environmental exposure		
Metals: arsenic, copper, molybdenum, nickel, selenium, uranium, zinc, lead, cadmium, mercury (total), manganese	All ages	5,000
Inorganic mercury	All ages	1,000
Non-coplanar PCBs/organochlorine pesticides/ Polybrominated diphenyl ethers, Perfluorinated compounds	20 years or older	1,500
Urine		
Kidney health		
Creatinine, microalbumin, microalbumin/creatinine ratio	All ages	5,000
Nutritional status		
Iodine	All ages	5,000
Environmental exposure		
Metals: antimony, arsenic, cadmium, copper, inorganic mercury, manganese, molybdenum, nickel, lead, selenium, uranium, vanadium, zinc	All ages	5,000
Cotinine	All ages	5,000
Organophosphate pesticides, Dialkyl phosphate metabolite diethylphosphate pesticides and metabolites, phenoxy herbicide (2,4-Dichlorophenoxyacetic acid and the metabolite 2,4 dichlorophenol), pyrethroid pesticide metabolites, bisphenol A	All ages	2,400
Phthalate metabolites	6 to 49 years	3,000

Laboratory results and results from measurements that require further assessment are provided in a final report sent to respondents 8 to 12 weeks after their clinic visit. Urgent (potentially dangerous) laboratory findings and positive results from hepatitis B and C analyses are reported more rapidly. The process of reporting to respondents, including early reporting and the reporting of infectious disease, is detailed by Day et al.[22]

Quality assurance and quality control

Because the CHMS aims to provide the highest quality data possible, quality assurance and quality control procedures are comprehensive. These procedures are outlined elsewhere.[24] Detailed manuals describe quality assurance and quality control procedures for each measure. A quality assurance/quality control advisory committee, composed of experts from each area of measurement included in the CHMS, has been established. Regular observations are made of the measurement staff, and feedback is provided. Repeat measures are performed on a subset of respondents to test both intra-tester and inter-tester reliability. Standard quality control procedures for laboratory measures are used (controls, external quality control programs, blanks, blind samples, regular equipment calibration) and monitored regularly.

Biorepository

The biological specimen flow, which has been described in detail by Bryan et al.,[24] is summarized in Figure 2. Biospecimens (whole blood, plasma, serum, urine) are sent regularly (once or more per week) from the mobile clinic to each of the testing laboratories. Surplus samples from the testing laboratories are sent to the National Microbiology Laboratory (NML) in Winnipeg, which is the biorepository for the CHMS. Deliberate over-sampling is carried out in order to obtain pristine samples for storage in the biorepository. Biospecimens are stored (with consent) for all ages, but isolated genomic DNA is stored only for consenting respondents aged 20 to 79 years. The

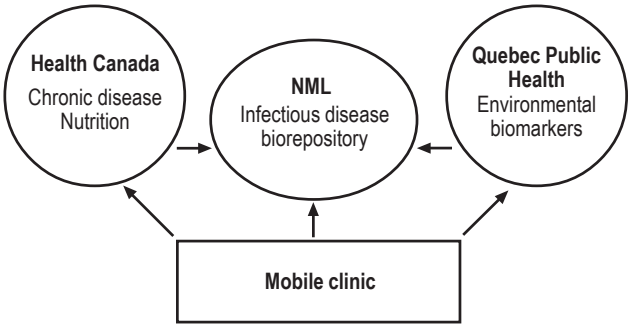
Table 6
Measurement equipment used for Canadian Health Measures Survey

Measure	Principal equipment used (manufacturer)
Anthropometry	
Standing height	Proscale 200 stadiometer (Accurate Technology Inc., Fletcher, NC)
Sitting height	Custom-built sitting height block with stadiometer
Weight	Mettler Toledo scale with Panther Plus digit readout (Mettler Toledo Canada, Mississauga, ON)
Waist and hip circumference	Gulick tape measure
Skinfolds	Harpenden skinfold caliper (Baty International, West Sussex, UK)
Blood pressure	VSM MedTech BpTRU BPM-300 (Health Check Systems, Inc., Brooklyn, NY)
Resting heart rate	Polar FS1 heart rate monitor and straps (Polar Electro Canada Inc., Lachine, QC)
Accelerometry (physical activity monitoring)	Actical Activity Monitor with Step Count (Mini Mitter, a Respironics, Inc. Company, Bend, Oregon)
Spirometry (lung functioning)	Respironics KoKo spirometers (PDS Instrumentation, Louisville, CO)
Cardiovascular fitness (mCAFT step test)	Custom-built steps, CD Player
Muscular strength, endurance and flexibility	
Hand grip strength	T-18 Smedley III hand dynamometer (Takei Instruments Ltd., Tokyo, Japan)
Partial curl-ups	Generic floor mats; metal distance indicator; goniometer; metronome
Sit and reach	Flexometer (Fitsystems Inc., Calgary, AB)
Oral health exam	Patient chair and oral health exam equipment and probes
Lab	
Complete blood count	Beckman Coulter HMX analyzer (Beckman Coulter, Mississauga, ON)
Centrifuge	Brinkman Eppendorf 5702R centrifuge (Eppendorf Canada, Ltd., Mississauga, ON)
Biosafety cabinet	NuAire 425-200 biosafety cabinet (NuAire Inc., Plymouth, MN)

biorepository is an important feature of the CHMS because:

- It provides future research and surveillance opportunities on a nationally representative sample of Canadians.

Figure 2
CHMS biospecimen (whole blood, plasma, serum, urine) flow from mobile clinic to reference laboratories and biorepository, Canadian Health Measures Survey



NML – National Microbiology Laboratory; Québec Public Health - L'Institut National de Sante Publique du Quebec (INSPQ)

- It enables current surveillance priorities, for which resources for analysis are not immediately available, to be conducted as soon as resources can be made available.
- The frontier of large-scale genetic and genomic research has arrived, offering enormous possibilities for future health benefits from such research.
- Having stored samples available to researchers reduces the burden on Canadians, since it will not be necessary to repeat a national survey, taking samples from another group of Canadians.
- Stored samples could provide important baseline information for the future by providing an indication of what existed when the CHMS was conducted.
- New technology and testing techniques (often more sensitive and less expensive) are advancing at a rapid pace, particularly in genetic and genomic research. Storing samples gives

the CHMS the opportunity to wait for new analytical procedures to be developed and for costs to decrease.

- It allows for exploration of explanatory factors in the future once the health outcomes of CHMS participants are known, through possible linkages with hospital data, cancer registries, mortality databases, etc.

An overview of the process to utilize the de-identified samples stored in the biorepository is provided by Day et al.[22]

Communications

To ensure respondents are informed and to maximize response rates, a comprehensive array of communications materials was prepared (Table 7). All materials are available in French and English; some core materials were translated into languages common at some sites (for example, Mandarin and Punjabi).

A proactive communication strategy is important to the success of the survey. Immediately before operations begin at each site, a media launch is held to allow local media to see the mobile clinic, obtain pictures of staff performing tests, and publicize the survey. The media launch is coordinated with the Medical Officer of Health in each region to ensure that local public health officials are aware and involved. Local dignitaries and celebrities (mayor, councillors, athletes, medical officials, etc.) are invited to tour the trailers and be tested. This coverage lends credibility to the survey and encourages participation

Table 7
Respondent relations support materials, Canadian Health Measures Survey

Timing of distribution	Material	Purpose
Submitted before collection	Introductory letter	Prepare respondent for visit from interviewer
	Introductory brochure	Explain purpose of survey; encourage participation
Provided at time of interview	Information and consent booklet	Introduce survey to respondent; outline survey goals; inform respondent about scope of tests; explain consent procedures
	Information for 6- to 13- year-olds (assent folder)	Explain purpose of survey and prepare child for collection process
	Measure sheets and activity monitor sheet	Prepare respondent for collection process and explain tests and measures
	Note to parents and guardians (ages 6 to 11, 12 to 17)	Give more information to respondent's parents/guardians
	Pre-testing guidelines	Instruct respondent re: diet, exercise, and other preparations for test day
	Map to site	Show directions to site
	Flash video presented via interviewer's laptop	Inform respondent using visual images
	Survey endorsement letters	Demonstrate validity and benefits of survey
	Press clippings of news articles about survey	Inform respondent and establish validity of survey
	Absence from work/school letter	Official record of survey participation
Provided after clinic visit	Preliminary report	Provide test results of physical measures to respondent
	Activity monitor letters	Remind respondent to return activity monitor
	Early reports or test results and letters to physicians	Inform respondent of test results outside normal range that should be brought to a physician's attention
	Final reports of test results	Provide all test results to respondent

Analysis planning

The expertise and logistical constraints required to manage, collect, analyse and interpret information from health measures surveys make them resource-intensive. Relying on traditional analytical capacity and funding mechanisms may limit the use of such data by focusing on classic, risk factor and outcome relationships, rather than on more complex interactions. To minimize these limitations and exploit the full potential of the CHMS, an analytical plan was developed.

The plan is a strategic document describing the multidisciplinary analytical strategy until 2010. It is intended to be a living document that defines the broad analysis objectives, as well as the specific analytical activities related to the survey, including those that support analytical activities.

The strategic analytical goals are to:

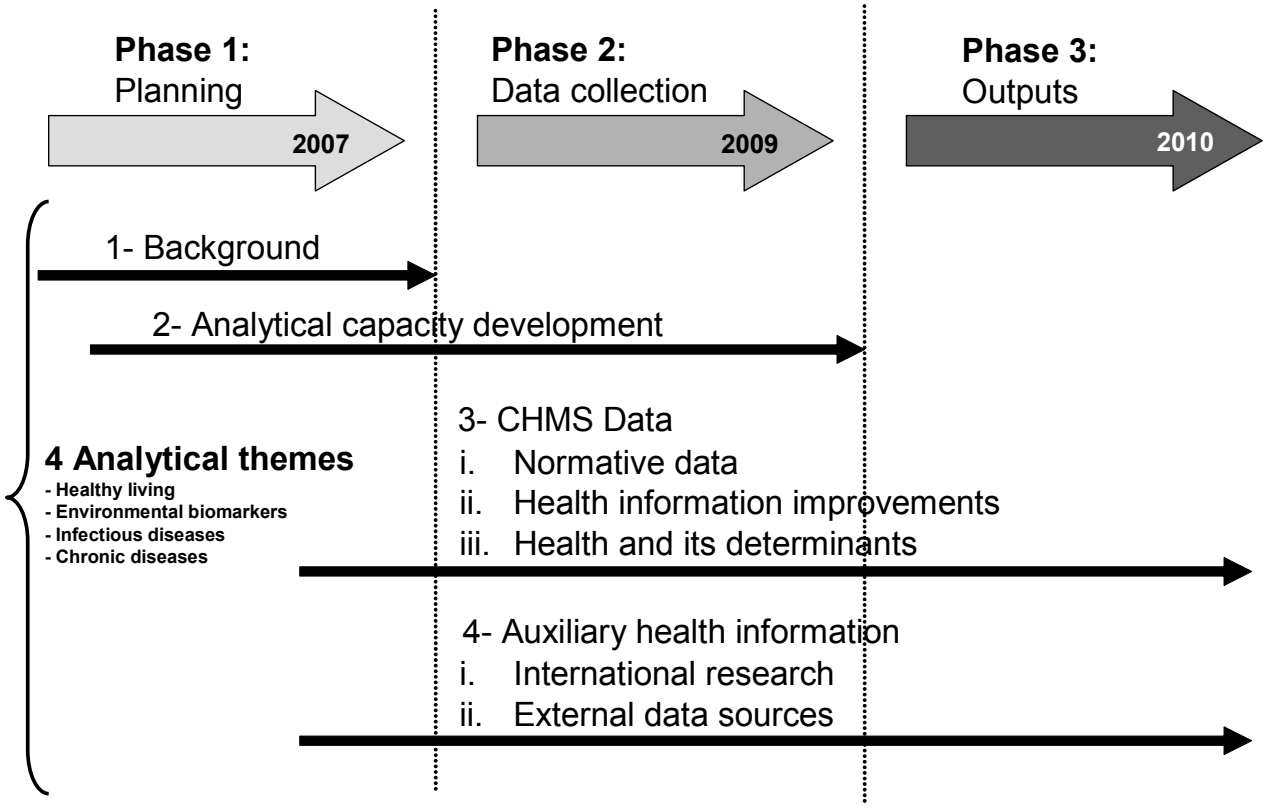
- Ensure that the priority health information needs that led to the funding of the CHMS are met.
- Conduct sufficient advance planning to ensure extensive use of the data for scientific publications, research training, policy development, and knowledge creation.
- Enhance the research process by promoting good practices, collaborative multidisciplinary partnerships, knowledge translation, and innovative funding mechanisms.
- Build capacity in Canada related to the appropriate analysis of results of direct physical measures surveys.
- Develop a specific, comprehensive and timely dissemination strategy directed to all partners.
- Monitor the progress and the quality of all analytical activities involving CHMS data.

The CHMS analysis structure is divided into three classification systems that have been further subdivided into analytical activities (Figure 3).

1. *A chronological system: Three phases*

   The analysis activities are divided into three

Figure 3
Data analysis strategy, Canadian Health Measures Survey



phases between 2005 and 2010. The first phase, "Planning," lasted until the Spring of 2007 when data collection began. "Data collection," the second phase, will take two years. The third phase, "Outputs," will begin during data collection and will include the official CHMS data release; it will end in 2010.

2. *A subject-matter system: Four themes*
   Analytical outputs can be classified into one of four themes: Healthy Living, Environmental Bio-markers, Infectious Diseases, and Chronic Diseases. This classification system was employed to ensure that analytical outputs capture the comprehensive array of variables in the CHMS.
3. *A priority-based system: Four categories*
   To ensure that the analytical objectives are met and to facilitate analysis management, the analytical activities are divided into four categories: Background, Analytical Capacity Development, CHMS Data, and Auxiliary Health Information, with time-sequenced priority in this order.

   Background research refers to reference documents such as this series of papers, which can be used by research, policy and professional communities across the country. We hope that the availability of these documents will reduce the burden for authors of subsequent papers that use CHMS data.

   Building capacity and expertise for CHMS staff and partners in physical measures is the focus of analytical capacity development. Analytical work in this component will not use CHMS data, but will support analyses when CHMS data are available. Examples include a series of systematic reviews comparing the discrepancy between self-reported and measured values of health indicators,[2] and validity testing of the Actical accelerometer/pedometer.[27]

   Analytical efforts using partial datasets will intensify as collection nears completion in 2009. The focus then will be on normative data analysis to establish representative national distributions of the measures in the survey. Normative data will, in most cases, be stratified by age and sex, and where applicable, by other health determinants.

   Analyses falling under the themes of "health information improvements" and "health and its determinants" will examine associations between various determinants and health, and compare the validity and reliability of self-reporting to direct measures in order to inform public health programs and policies.

   Information collected as part of the auxiliary health information theme will increase analytical potential by building partnerships with international researchers to share data and examine the comparability of international data. The most important external data source will be health care encounter data from provincial administrative data sources, such as hospital and doctor visits. The linkage of these data at the individual level (subject to respondents' consent) will open major new areas of analysis, in particular, direct associations between risk factors and health care utilization. Additionally, the feasibility of appending other external sources of data to the CHMS database is being explored so that the influence of variables such as temperature and air and water quality can be investigated.

Unique challenges

The CHMS faces challenges rarely experienced by Statistics Canada surveys. These include: a much higher respondent burden (travel, time, expense, physical exertion, discomfort); data transfer complexity (interviewer→clinic→lab→Statistics Canada→respondent report); privacy and ethical considerations (age range for testing, consent, data flow security, storing biospecimens for future analysis, collecting DNA samples); communications (reporting to respondents, reportable diseases, media, public); and the potential for adverse events (phlebitis, cardiac event during fitness testing) or

adverse findings (previously undiagnosed infectious disease). Details about these unique challenges are provided elsewhere.[28]

Conclusion

The CHMS aims to overcome important data gaps in Canada's health information system through the collection of direct measures of health and wellness. The survey will create a unique and nationally representative dataset, including stored samples of serum, plasma, isolated genomic DNA and urine, for future research. The complex and intricate data collection platform and infrastructure provide opportunities for ongoing, direct physical measures surveys. The CHMS has the endorsement of the Canadian Medical Association, Canadian Dental Association, Canadian Hypertension Society, Canadian Lung Association, Canadian Red Cross, Dieticians of Canada, Heart and Stroke Foundation of Canada and the support of the Canadian Public Health Association, and the College of Family Physicians of Canada.

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Additional information on the CHMS is available at www.statcan.ca/chms.

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Canadian Health Measures Survey Pre-test: Design, methods, results

Mark Tremblay, Renée Langlois, Shirley Bryan, Dale Esliger and Julienne Patterson

Abstract

The Canadian Health Measures Survey (CHMS) pre-test was conducted to provide information about the challenges and costs associated with administering a physical health measures survey in Canada. To achieve the specific objectives of the pre-test, protocols were developed and tested, and methods for household interviewing and clinic testing were designed and revised. The cost, logistics and suitability of using fixed sites for the CHMS were assessed. Although data collection, transfer and storage procedures are complex, the pre-test experience confirmed Statistics Canada's ability to conduct a direct health measures survey and the willingness of Canadians to participate in such a health survey. Many operational and logistical procedures worked well and, with minor modifications, are being employed in the main survey. Fixed sites were problematic, and survey costs were higher than expected.

Keywords

health surveys, data collection, direct measures, health measurement, physical fitness, biological specimens, national survey

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The Canadian Health Measures Survey (CHMS) is a new comprehensive direct health measures survey that will be conducted from 2007 to 2009 by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada. The CHMS is voluntary and will collect data from a nationally representative sample of Canadians aged 6 to 79. Further details on the background and rationale for the CHMS are presented elsewhere in this supplement.[1]

The collection of direct health measures from a nationally representative sample[2] has rarely been done in Canada. Details of the socio-ethical and legal issues and the logistical challenges are described in detail elsewhere in this supplement.[3,4] Given the complexity and the novelty of such a survey, Statistics Canada adopted a cautious and systematic approach. Based on an examination of similar surveys previously carried out in Canada and elsewhere (for example, National Health and Nutrition Examination

Survey;[5] Finrisk Surveys[6]) and extensive consultations with partners, stakeholders and experts,[3] it was decided that a pre-test should be conducted. This article summarizes the design, methods and results emerging from the pre-test, in the hope that this experience may assist other researchers planning similar surveys. More complete details are available in the *CHMS Fall 2004 Pre-Test Final Evaluation Report*.[7]

The objectives of the pre-test were to:

1. Determine Canadians' willingness to participate in a direct health measures survey.
2. Assess the costs from both the human resources and financial perspectives.
3. Calculate response rates by age group and non-response bias to both components (household questionnaire and physical health assessment).
4. Examine processes and materials.
5. Evaluate the planning assumptions associated with using fixed sites for the physical measures, including logistics and costs of setting up clinical sites, conducting physical measures, and performing laboratory analyses of samples.

Pre-test design

As closely as possible, the pre-test replicated the design proposed for the full CHMS.[1] The pre-test took place from October through December 2004 in the Calgary Health Region, Calgary, Alberta. The Calgary Health Region was selected because sufficient sample remained from a recent Labour Force Survey to allow the CHMS to simulate a "stand" (survey collection site).[2] A raw sample of 875 households was used for the pre-test. Although this sample was not statistically representative, it did allow for age group stratification (6 to 11, 12 to 19, 20 to 39, 40 to 59, and 60 to 79 years). Approval to conduct the pre-test was received from the Health Canada Research Ethics Board (REB) and the Calgary Health Region REB. All structures and processes used in the pre-test met Statistics Canada's requirements for data security, confidentiality and privacy.[3]

The pre-test consisted of a detailed in-home computer-assisted interview (CAPI) about the respondent's health. This was followed, one day to five weeks later, by a series of direct physical and laboratory measures conducted in a clinic in the South Calgary Health Centre. The physical assessment included anthropometry, spirometry, blood pressure, fitness and physical activity. Blood and urine samples were also collected at the clinic and analyzed for chronic disease, infectious disease, and nutritional and environmental biomarkers.[1]

Because the health centre was new, it was possible to construct and retrofit the offices to meet Statistics Canada's security requirements. The space allocated to the CHMS consisted of a reception office, three examination rooms for physical measures, one phlebotomy room for obtaining and processing biological specimens, and an office for clinic staff and interviewers. A cost-recovery memorandum of understanding with the Calgary Health Region secured the clinic space, office furniture, phlebotomy and laboratory services, and standard office support systems such as shipping/receiving, IT support, and parking. To simulate the logistics of the full survey, CHMS staff from across Canada lived in temporary housing for the duration of the pre-test.

Counselling services for respondents found to have sexually transmittable infections were provided on a cost-recovery basis by the Calgary Health Region Sexually Transmitted Diseases Clinic. Rapid follow-up services for urgent laboratory findings which required immediate attention were arranged in collaboration with the Calgary Health Region Medical Officers of Health. No urgent findings were observed, so ultimately, these services were not required. All Calgary Health Region staff involved in these procedures were "deemed" Statistics Canada employees and were governed by the data security and confidentiality provisions of the Statistics Act.

In consultation with the Calgary Health Region staff, a communications plan was designed to introduce the project and encourage participation. Before data collection, all levels of government (municipal, provincial and federal), provincial and regional medical associations, and public health

stakeholder groups were notified of the pre-test. Government support and endorsement were obtained. Strategies were developed for coverage on television and radio and in print. Communications material for respondents was designed, including a respondent information kit that contained details about the survey, the consent process, and how to obtain additional information.

Community relations for the pre-test were extensive. The Calgary Health Region's Medical Officer of Health was involved in the co-ordination of the pre-test communications activities. For the purpose of information dissemination, medical associations in Alberta and Calgary were contacted. Information about the CHMS and/or the pre-test was published in newsletters and/or on the websites of the following organizations:

- Alberta College of Physicians and Surgeons
- Alberta College of Family Physicians
- Alberta Medical Association
- Calgary Regional Medical Staff Association

Other communications avenues included a toll-free number, an e-mail address, and a website. Compared with other Statistics Canada health surveys in the field at the time, the website received substantial traffic during data collection. Endorsements from Alberta organizations were facilitated by the preparation and distribution of survey updates in a quarterly electronic newsletter.

Methods

The household interview

Ten Statistics Canada interviewers from across Canada worked on the household interviews. After survey orientation, training and interview simulations, each interviewer was assigned approximately 85 cases in a particular region of Calgary.

Sampled households were notified by mail in September and given brief background information. In October, interviewers began contacting the households to create a roster of household members, and select a respondent, based on a computerized sampling vector that was designed to provide the desired age distributions.[2] Once a respondent was selected and agreed to participate, an appointment was made for the household interview. If the selected respondent was younger than 14, a parent or guardian was present while he or she answered the questionnaire. The cycle 2.1 Canadian Community Health Survey questionnaire,[8] which contained modules on general health, height and weight, chronic conditions, activity restrictions, health and lifestyle behaviours, nutrition, activity levels and medication use, was modified and used for the household interview. Household interviews averaged about 50 minutes.

Before the interview began, all respondents were shown a video that provided an overview of the CHMS Pre-test. After completing the interview, respondents were told that they would receive an honorarium to cover expenses associated with their clinic visit. They were also given pre-testing guidelines,[4] consent forms and a map with directions to the clinic. At this time, interviewers offered to call the clinic on the respondent's behalf to book an appointment. A respondent information form containing key information (for example, age, sex, address, telephone numbers, physical or mental limitations reported by the respondent or observed by the interviewer) was relayed to the clinic. Each evening, the completed questionnaires were sent via encrypted telephone lines to Statistics Canada's head office in Ottawa.

The clinic visit

Qualified professionals were hired as Statistics Canada employees to staff the clinic. They included a manager, Professional Fitness and Lifestyle Consultants,[9] phlebotomists, and administrative personnel. Technical and communications support was provided from head office in Ottawa. Clinic staff underwent training that involved orientation to the survey, an overview of the household interview, cardio-pulmonary resuscitation (CPR), spirometry, and a course on including people with disabilities in the pre-test. Practical training at the clinic allowed staff to practice the measurement procedures, perform data entry, and refine protocols and clinic flow.

Clinic visits were scheduled over six weeks from October to December 2004, Wednesday through

Sunday. Weekday appointments were set up on a split-shift basis from 7 a.m. to 12 noon and from 4 p.m. to 9 p.m.; weekend appointments, from 7 a.m. to 3 p.m. To facilitate the scheduling of appointments, the booking desk hours were from 6:30 a.m. to 10 p.m. Wednesday through Friday, and from 6:30 a.m. to 6 p.m. Saturday and Sunday.

During the household interview, respondents were randomly assigned as morning (50%) or afternoon/evening (50%) appointments. This designation affected some of the testing protocols, since morning appointments required a 12-hour fast, whereas the afternoon/evening appointments required a 2-hour fast.

If respondents failed to book an appointment, the clinic staff followed up. Reasons for refusals were recorded in the clinic database. The clinic booking staff also made an appointment reminder call 24 hours before all scheduled visits, during which respondents were reminded of the pre-testing guidelines, and directions to the clinic were confirmed. No-shows were contacted to re-schedule the missed appointment.

When respondents arrived at the clinic, their identity was verified, they completed consent forms, and pre-test screening was completed to confirm their suitability for the various tests (Table 1). If, according to screening guidelines, a test was contraindicated,[4] respondents were eliminated from that specific test. To ensure confidentiality, each respondent was assigned a 20-digit identification number, which was used throughout the testing procedures, and for labelling paper documentation and biological specimens. All measures were voluntary; respondents could decline to participate in any test or withdraw at any time.

After the testing, respondents completed an exit questionnaire that asked their opinions about the length of the clinic visit, and agreement (hypothetical) to data-sharing and linkage, biospecimen (serum, urine, DNA) storage, and re-contact. They received an honorarium to cover expenses related to the clinic visit, a small gift of appreciation, and a preliminary report of their test results. In January and February 2005, all respondents received a final report of their laboratory results, including suggestions for medical follow-up if needed.

All data collected during the clinic visit were recorded on paper forms and entered into a single clinic database. Respondent database files were verified against the paper versions before they were transmitted to Statistics Canada's head office. Twice daily, copies of the entire database file were encrypted and sent electronically to Ottawa. Hard-copy respondent files were sent to Ottawa weekly in accordance with Statistics Canada's confidential shipping procedures. Several times each day, blood and urine specimens were shipped to the Diagnostic Services Centre of the Calgary Laboratory Services for analysis and storage. Once a week, specimens were sent to the National Microbiology Laboratory in Winnipeg and l'Institut national de santé publique du Québec in Ste.-Foy for additional analyses.

Table 1
Clinic measures, Canadian Health Measures Survey Pre-test, October to December, 2004

Physical measures
resting blood pressure
resting heart rate
height
sitting height
weight
waist circumference
skinfolds (triceps, biceps, subscapular, iliac crest, medial calf)
spirometry
physical activity monitoring (accelerometry)
fitness testing (modified Canadian Aerobic Fitness Test, grip strength, partial curl-ups, sit-and-reach (flexibility)

Laboratory measures

Blood
blood chemistry panel
complete blood count
total cholesterol (fasted)
HDL cholesterol (fasted)
LDL cholesterol (fasted)
triglycerides (fasted)
apolipoprotein B (fasted)
fasting glucose
random glucose
oral glucose tolerance test (morning only)
red blood cell folate
vitamin B12
lead
varicella antibody
herpes simplex virus-2 antibody
hepatitis A
helicobacter pylori

Urine
microalbumin
creatinine
human papillomavirus

Results

Objective 1: Determine the willingness of Canadians to participate in a health measures survey

Initially, 875 Calgary households were selected for the CHMS Pre-test, 800 of which were eligible for the survey (Table 2). Of the eligible households, 590 (74%) responded, and in 526 (66%) of these households, the selected person completed the household questionnaire. However, just 369 of these individuals went on to complete the clinic component of the pre-test, yielding an overall response rate of 46%.

Table 2
Household, person and clinic visit response rates, Canadian Health Measures Survey Pre-test, October to December, 2004

Response level	Number	Response rates %†
Total households	**875**	...
Eligible households	800	100
Responding households	590	74
Responding person	526	66‡
Respondent went to clinic	369	46§

† percentage of eligible households
‡ 90% of responding households
§ 70% of responding persons
... not applicable

Among the factors that may have affected participation in the clinic portion of the pre-test was the time of day at which appointments were scheduled. Afternoon and evening appointments were better attended than morning appointments (74% versus 66%). Based on post-appointment questionnaire results, 26% of respondents who had an afternoon appointment would not have been able to participate if only morning appointments had been available. The main barrier to attending morning appointments was work responsibilities.

The length of appointments was another deterrent to clinic visits. Because of the types of tests done in the morning, particularly the oral glucose tolerance test (OGTT), these appointments averaged 2 hours and 19 minutes, compared with 1 hour and 23 minutes for those in the afternoon.

When interpreting the clinic response rates, three points should be considered: 1) clinic appointments filled up quickly, that is, too few openings were available; 2) interviewers and clinic staff did not have time to try to convince potential respondents to complete the clinic portion of the survey; 3) if clinic operations could have been extended a few more days, it is anticipated that the final response rate would have been much higher.

Objective 2: Determine the human resources and financial costs

Determining the costs of conducting a physical measures survey was a major impetus for the pre-test. To simulate a CHMS site, 10 interviewers and 11 clinic staff were considered sufficient. Support from Statistics Canada head office employees is not reflected in these numbers, although head office staff worked many overtime hours to ensure that the clinic and operations in Calgary were ready on time, and that the Calgary team had the support they needed. This support carried through to the mail-out of final reports to respondents, which involved reception and collation of the report, confirmation of addresses, secure mail delivery, and follow-up, all of which proved to be more burdensome and time-consuming than anticipated. Preparation of respondent information kits, interviewer manuals, clinic protocol manuals and report forms required extensive effort that is difficult to quantify.

The number of interviewers was appropriate for the number of respondents (about 85 per interviewer). However, the burden on the clinic staff associated with scheduling appointments and accommodating respondents was underestimated. Insufficient appointment times were available, which increased the need for follow-up. The split-shift schedule often meant that staff worked considerable overtime to accommodate respondents who arrived early or late. In general, the number of clinic staff was not sufficient for the hours of operation.

The estimated cost of the pre-test was $1.78 million (Table 3). Most of this amount reflects head office costs of approximately $1.2 million covering the period from May 2004 to early 2005. These costs included:

- negotiation with the Calgary Health Region for space and services;

Table 3
Summary of costs, Canadian Health Measures Survey Pre-test, October to December, 2004

Item description	Cost
	$000
Ottawa operations	
Head office	
Planning and development	650
Sample selection and methods	180
Interview staff material and operations development	123
Data systems and applications development	57
Communications	15
Data capture development	7
Translation	11
Printing	15
Shipping and postage	6
Travel	68
Returning results to respondents	21
Head office costs	1,153
Calgary operations	
Interviewers	
Salaries	77
Living expenses	133
Non-salary expenses	15
Interviewer costs	225
Clinic	
Salaries	147
Living expenses	75
Testing equipment and disposables	36
Office equipment and supplies	42
Respondent expenses	24
Non-salary expenses	6
Site set-up	35
Clinic costs	406
Total costs	**1,784**

- drafting Memoranda of Understanding with the Calgary Heath Region, the National Microbiology Laboratory and l'Institut national de santé publique du Québec;
- developing the survey sampling frame and statistical methodology;
- developing collection methods and materials;
- developing, translating and printing respondent relations material;
- preparing and presenting a submission on the pre-test to the Research Ethics Boards of Health Canada and the Calgary Health Region; and
- communicating and liaising with stakeholder groups, including media.

Borrowing the questionnaire from the Canadian Community Health Survey (cycle 2.1) reduced development time for the household interview. Even so, modifications and the creation of additional materials necessitated changes to CAPI applications and testing to ensure that the questionnaire application was functional.

The data capture and data transfer systems created for the pre-test were rudimentary, with many of the data capture and verification processes conducted by hand. This was adequate for the pre-test, but was prone to error, and the scale of the full CHMS required more advanced systems. Consequently, the costs of an appropriate data transfer system are not reflected here. As well, some other administrative and production costs related to the pre-test activities, including the preparation of this report, are not included.

Objective 3: Evaluate response rates, by age group, and non-response bias to household questionnaire and clinic visit

The likelihood that a respondent who completed the household questionnaire would participate in the clinic component of the CHMS Pre-test varied by age (Table 4). The highest clinic participation rates were among children aged 6 to 11 and seniors aged 60 to 79 years: 77% and 79%, respectively. Among youths aged 12 to 19 years, the rate was 70%, and for people aged 40 to 59 years, 68%. Younger adults aged 20 to 39 years had the lowest rate: 65%. Overall, 30% of respondents who completed the household questionnaire were either unwilling or unable (personal conflicts or barriers; scheduling limitations; logistical issues such as transportation or weather) to visit the clinic.

Because the survey was conducted in two phases (in-home interview and clinic appointment), some

Table 4
Participation in household interview and clinic, by age group, Canadian Health Measures Survey Pre-test, October to December, 2004

Age group (years)	Respondents		Clinic visits as % of household interviews
	Household interviews	Clinic visits	
	number		%
Total	**526**	**369**	**70**
6 to 11	90	69	77
12 to 19	83	58	70
20 to 39	188	122	65
40 to 59	93	63	68
60 to 79	72	57	79

information was collected about respondents who did not visit the clinic. Non-response bias was assessed by comparing the household interview data of those who attended the clinic with those who did not, using the following variables: age, sex, marital status, household size, mother tongue, race, student status, labour force attachment, work schedule, number of weeks worked, income adequacy, time of appointment, self-rated general health, mental health, level of stress, self-reported BMI, and self-reported high blood pressure. For only four of these variables was the difference between clinic participants and non-participants significant. Higher reported stress levels, non-white race, employment, and morning appointments were each associated with a reduced likelihood of participating in the clinic portion of the survey. It was not possible to assess non-response bias for those who did not participate in the household interview.

Objective 4: Evaluate survey processes and materials

To administer the pre-test, CHMS staff developed new methods, procedures and processes, as well as a large amount of new material. This was achieved by drawing on experience within Statistics Canada and from direct health measures surveys previously conducted in Canada and elsewhere. The successes and failures of communication materials and processes, interviewer materials and clinic practices and protocols (see objectives) were all assessed.

Communications – Media coverage and respondent relations

Media coverage of the pre-test was positive, but not extensive. During the planning of the media event to launch the pre-test and open the clinic, several challenges emerged: provincial and municipal elections were called after planning was complete but before the clinic opened; an e-coli outbreak in the Calgary area pulled public health officials and journalists away from the media event; and the Olympic athlete who agreed to undergo the clinic testing for the media had a personal emergency and was unable to attend. Nevertheless, the objectives of informing the community about the survey and maintaining a positive relationship with the media and opinion leaders were achieved. Although it was not directly assessed, it is likely that the media plan had a positive impact on respondent relations, and that this could be accomplished at each CHMS data collection site. In general, media relations should focus on local exposure (for instance, clinic opening attended by local health and political officials) and be sensitive to the culture of the particular community.

Communications activities also included telephone and electronic contact with the public. Evaluation of the dedicated phone line suggested that the nature and number of calls did not justify the expenditure; regular Statistics Canada phone lines would be able to handle CHMS enquiries.

The e-mail account set up for the pre-test proved valuable, not only for answering enquires, but also for disseminating information and seeking endorsements from government and non-government organizations. The e-mail account is currently used to distribute a quarterly electronic newsletter that informs subscribers about the progress of the CHMS.

A webpage was also developed for the pre-test. Although traffic was modest (~700 page views during the pre-test), the webpage is an excellent medium for disseminating information to the public and the media.

A considerable amount of respondent relations material was prepared for the pre-test (Table 5) in order to: 1) ensure that respondents were informed; 2) maximize participation; and 3) minimize misunderstanding and miscommunication.

Table 5
Respondent relations materials, Canadian Health Measures Survey Pre-test, October to December, 2004

Sent in advance of collection	Introductory letter Introductory brochure
Provided at time of interview	Information and consent booklet Sample consent forms Assent booklet for 6- to 13-year-olds Examples of data uses Explanations of laboratory tests on blood and urine Descriptions of each physical measure Pre-testing guidelines Flash video on interviewer's laptop
Provided after clinic visit	Report of physical measures taken at clinic Report of laboratory tests on blood and urine

Interviewers rated the communications material favourably, reporting that reactions to the respondent information kit and the video were "positive" or "very positive." However, the video did not engage children as well as it did adults.

Many respondents commented positively on the quality and professional appearance of the communications material, but some questioned the cost of producing it. Consequently, it was recommended that while some documents must be designed to capture attention, others should be plain and simple.

Respondents appreciated that their expenses for participating in the survey were covered and that the survey included a fitness test. These benefits are strong selling points for participation in the survey and should be emphasized in the respondent relations materials.

To determine the effectiveness of the communications material, focus group meetings were held with a sample of pre-test participants in February 2005. In general, the respondent relations materials seemed to have provided the right amount of information to help respondents understand the survey and were instrumental in convincing them to participate.

Overall, feedback from interviewers, respondents and focus groups identified minor improvements, but generally indicated that the communications material contained appropriate information.

No evidence suggested that the CHMS Pre-test had a negative impact on other Statistics Canada surveys that were in the field at the same time.

More specific details on the evaluations of the pre-test communications and material can be found in the *CHMS Fall 2004 Pre-test Final Evaluation Report*[7] and in the *Pre-test Follow-up Respondent Consultation Report*.[10]

Household interviewers

Material and procedures used for the household interview were evaluated through debriefings with the interviewers. Their recommendations included: better integration of the household interview and clinic components of the CHMS during training, orientation and data collection; better orientation to a new city; and a household questionnaire specifically designed for the CHMS.

The interviewers felt that clinic participation rates could be increased if it was easier to schedule appointments, and that reaching a live voice at the clinic would be preferable to having respondents leave messages when trying to book appointments. Additional booking staff would be required to comply with this recommendation.

Normally, Statistics Canada interviewers work on several surveys at the same time. However, for the pre-test, interviewers worked solely on the CHMS. This was regarded as important for maximizing response rates and facilitating communication with the clinic staff. The interviewers enjoyed working with clinic staff and saw this as a positive team-building element of the survey.

Objective 5: Evaluate planning assumptions associated with using fixed sites for the physical measures, including logistics and costs of setting up clinical sites, conducting physical measures and performing laboratory analyses of samples.

The clinic setting was a new venue for a Statistics Canada survey. The fixed site used for the CHMS Pre-test was a trial of one of two possible clinic formats, the second being a mobile clinic.

Moving into a newly constructed medical building brought a number of advantages: municipal services were already connected; there was ample parking space; some office equipment was present; and clinic examination rooms were available. A good working relationship was established with the South Calgary Heath Centre, and the facility provided, at no extra cost, access to some of their equipment such as the stadiometer and wheelchair scale, and use of laboratory specimen transporting services. The space allocated to the CHMS needed some reconstruction. This was expensive, but sincere efforts were made to accommodate Statistics Canada's needs.

Although the clinic space was pristine and functional, several disadvantages were associated with the fixed site. The Health Centre is in a new industrial development in the southeast corner of Calgary. This location, combined with traffic patterns and construction, caused some

Table 6
Comparison of fixed versus mobile clinics, Canadian Health Measures Survey Pre-test, October to December, 2004

	Advantages	Disadvantages
Fixed clinic	• Existing structure and infrastructure • Low initial capital expense • Less susceptible to damage and vandalism • Support services in place (shipping and receiving, security, laundry, office cleaning services, snow removal) • Parking • Accessible, known location • Opportunity to exploit partnership with regional health authority • On-site staff room	• Repeated research ethics reviews • Unknown costs and infrastructure challenges at each new site • Maintenance, renovations and space controlled by landlord • Substantial and ongoing structural and infrastructural investments are lost • Based on pre-test expenses, total cost expected to be higher • Staff must attend occupational health and safety training at each site • Location options limited to existing structures • Statistics Canada security and access requirements instituted at each site • Possible labour (union) issues • Provincial licensing for health professionals required • Ambient conditions (temperature, humidity) cannot always be controlled and/or harmonized across sites • Need to accept existing work flow at fixed site • Building access problems
Mobile clinic	• Standardized testing environment and conditions • Single research ethics review • Retain assets • One-time staff occupational health and safety training (with periodic updates) • Maintenance, renovations and space controlled internally • Many location options • Statistics Canada security and access requirements built in • Mobile federal property with associated jurisdictional oversight	• Service and utility set-up required at each site • High initial capital expense • Location options require cooperation of property owner • More susceptible to damage and vandalism • Space – small rooms • Equipment must tolerate transport • Storage limitations • Insufficient room for interviewers to work out of clinic • No staff room (additional trailer required) • Cold climate

transportation problems and delays during peak commuting hours. No examination rooms were available on Mondays and Tuesdays, which required the storage and set-up of the testing rooms each week. Some rooms were less than ideal for the needs of the CHMS; for example, the reception area was too small and ill-equipped, causing limitations in some tasks and duplication of others.

Thus, while fixed sites have undeniable advantages, these are outweighed by some serious shortcomings, and fixed sites do not match the flexibility afforded by mobile clinics (Table 6). Indeed, many facility-related experiences that came out of the pre-test support the use of mobile clinics. The survey will be successful only if the response rate is high. This requires a good location and accessibility, which the mobile clinic option is best suited to accommodate. Moreover, other countries (for example, Finland and the United States) have successfully used the mobile clinic model for their physical measures surveys.[5,6,11]

Conclusions

The pre-test provided valuable insight about the challenges and costs involved in implementing the full Canadian Health Measures Survey. The most important findings are that Statistics Canada is able to conduct an extensive, direct measures health survey and that the Canadian public is willing to participate in such a survey. More specifically, the pre-test yielded essential information about staffing and living accommodation needs and the extent of technological and head office support required. The lessons learned from the pre-test were used to refine the design and methods for the full CHMS to: 1) increase response rates; 2) limit non-response bias; 3) optimize survey outcomes while controlling costs; 4) optimize respondent and media communications; 5) optimize interview, clinic, and head-office staffing and training; and 6) redesign the direct health measures collection infrastructure by using mobile clinics rather than fixed sites.

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Canadian Health Measures Survey: Sampling strategy overview

Suzelle Giroux

Abstract

This article presents an overview of the sampling strategy developed for the Canadian Health Measures Survey (CHMS). The CHMS was designed to collect key health information using a computer-assisted personal interview and a physical health examination. It began in March 2007 and will be conducted to 2009. A nationally representative sample of approximately 5,000 respondents aged 6 to 79 will be interviewed at home and asked to visit a mobile clinic where health care professionals measure several aspects of their physical health. The CHMS presents several challenges including: the need to have respondents who live within a reasonable commuting distance of the clinics; the difficulty of reaching the desired sample size for youths; and sub-sampling of measures related to exposure to environmental pollutants. The sampling strategy described in this article will address these challenges.

Keywords

area-frame, collection sites,cross-sectional studies, direct measures, health surveys, multi-stage sample, rejection method, sub-sampling, vector of selection, probabilities

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Through personal interviews and physical health examinations, the Canadian Health Measures Survey (CHMS) will collect information from Canadians about their general health and lifestyle. The results of this voluntary survey will be used to estimate the number of people with selected diseases and risk factors.

The CHMS questionnaire will be used to gather information about medical history, diet, smoking habits, alcohol use, current health status and sexual behaviour, as well as demographic and socioeconomic characteristics. In addition, information will be collected in the form of direct physical measurements such as height and weight, blood pressure, blood and urine samples, and physical fitness testing. The results will create national baseline data on the prevalence of health concerns such as obesity, hypertension, cardiovascular disease and exposure to infectious diseases and environmental contaminants. The CHMS is one of the few Statistics Canada surveys to collect direct measurements.

This overview describes the sampling strategy used to meet the collection and estimation requirements of the CHMS. Other articles in this publication describe the survey's background,[1] the ethical, legal and social issues surrounding the CHMS,[2] the logistical and operational challenges,[3] and the pre-test results.[4]

Survey design

Data collection for the CHMS will take place over two years and is done in two steps. First, an interviewer visits the respondent's home to administer the household questionnaire. Second, respondents are asked to attend an appointment at a nearby CHMS mobile clinic. At the clinic, trained health professionals take some physical health measurements. Respondents are also asked to wear a physical activity monitor (accelerometer) for a week to measure their activity levels.

The CHMS mobile clinic is stationed at each site for six to seven weeks. In determining collection sites, consideration must be given to the location of respondents' dwellings to ensure that selected dwellings are within a reasonable travelling distance from the clinic.[3]

The CHMS targets individuals aged 6 to 79 years who live in private households. People living on Indian reserves or Crown lands, residents of institutions, full-time members of the Canadian Forces and residents of certain remote regions are excluded.

Sample size

To meet the objective of providing national baseline estimates on a variety of health indicators, the CHMS requires 5,000 respondents equally distributed by age group (6 to 11, 12 to 19, 20 to 39, 40 to 59, and 60 to 79 years) and sex, for a total of 10 groups. Before the survey moves into the field, this number is inflated to take out-of-scope dwellings and non-response into account. This sample size should yield national level estimates by sex for each of the 5 age groups for conditions that have a prevalence of 10% or higher, with a coefficient of variation of the estimate of 16.5%.

Sub-samples of the survey's respondents are also required for laboratory analyses of environmental chemicals in the blood or urine.

Area frame—creation, allocation and selection of sites

Because the CHMS requires that respondents report to a clinic, they should be able to travel to that clinic within a reasonable period of time. The Labour Force Survey (LFS) area frame was used to design and control the size of collection sites in order to accommodate these requirements.

Using the LFS frame clusters,[5] a total of 257 collection sites were created.[6] Clusters are small geographic units that contain approximately 200 dwellings. A collection site is a geographic area with a population of at least 10,000 and a maximum respondent travel distance of 100 kilometres (km) (50 km in an urban area and 100 km in rural areas). Areas not meeting these criteria were excluded. The sites cover 96.3 % of the Canadian population.[7]

Although only national estimates were required, the collection sites were stratified in five regions to ensure a representative distribution of the sample across the country. Statistics Canada's standard regional boundaries were used: British Columbia, the Prairies (Alberta, Manitoba and Saskatchewan), Ontario, Quebec, and the Atlantic provinces (Newfoundland and Labrador, Prince Edward Island, Nova Scotia and New Brunswick).

A large number of collection sites with few respondents is recommended because it helps optimize the precision of the estimates.[8] However, the logistical and cost constraints associated with the use of mobile clinics restricted the number of collection sites to 15. Each site will collect data on approximately 350 respondents, on average, for a total of roughly 5,000 respondents. The 15 collection sites were allocated to the regions in proportion to the size of the population (Table 1).

Within each region, the collection sites were sorted according to whether they belonged to a census metropolitan area (CMA), and then by the size of the population before the selection. A CMA is an area consisting of one or more adjacent

Table 1
Selection of Canadian Health Measures Survey collection sites, by region

Region	Estimated target population, aged 6 to 79, 2001 Census	Sites in region	Allocated sites	Sample
		number		
Total	**26,949,315**	**257**	**15**	**4,995**
Atlantic (Newfoundland and Labrador, Prince Edward Island, Nova Scotia, New Brunswick)	2,061,425	36	1	333
Quebec	6,560,375	50	4	1,332
Ontario	10,248,545	61	6	1,998
Prairies (Alberta, Saskatchewan, Manitoba; includes Yellowknife)	4,538,970	77	2	666
British Columbia (includes Whitehorse)	3,540,000	33	2	666

municipalities centered on a large urban area (known as the urban core). The urban core must have a population of at least 100,000 to form a CMA. The sites were then sampled systematically with a probability of selection proportional to the size of their population. This method of selection, combined with the sorting of sites by CMA and non-CMA and by population size, ensured that the selected sites would be distributed among CMA and non-CMA areas and among areas with larger and smaller populations.

While not every province/territory will have a collection site, the CHMS sites were chosen to represent the Canadian population, east to west, with larger and smaller population densities (see *Canadian Health Measures Survey collection sites*).

Dwelling sampling

Several options were examined to determine how best to obtain the required number of respondents by age group. One option proposed using dwellings with known household composition from the 2005 Canadian Community Health Survey (CCHS cycle 3.1) and a fresh sample of dwellings with unknown household composition from the Labour Force Survey frame.[9] Although this approach met the objectives of reaching the target number of respondents by age group, a random rejection method[10] for households was required to avoid interviewing too many people in the age groups that constitute relatively large shares of the population (20 to 59 years) before reaching the target number of respondents for the other age groups.

Another option was using the 2006 Census as a frame. The household composition of dwellings as of May 2006 was available and could be used to develop a design to meet the sample requirements more efficiently in each age group. This option was chosen.

Within each site, dwellings with known household composition at the time of the 2006 Census are stratified by age at the time of the survey. Five age-

Canadian Health Measures Survey collection sites

Atlantic
- Moncton area, New Brunswick

Quebec
- Québec City area
- Montréal area (two sites)
- South of Mauricie area

Ontario
- Oshawa area
- Toronto area (two sites)
- St. Catharine's-Niagara area
- Kitchener-Waterloo area
- Northumberland County area

Prairies
- Edmonton area, Alberta
- Red Deer area, Alberta

British Columbia
- Vancouver area
- Williams Lake and Quesnel area

group strata corresponding to the five CHMS age groups (6 to 11, 12 to 19, 20 to 39, 40 to 59, and 60 to 79 years) were created. Age is determined based on the starting date of data collection at each site.

- Stratum 1: dwellings where at least one 6- to 11-year-old is present, else,
- Stratum 2: dwellings where at least one 12- to 19-year-old is present, else,
- Stratum 3: dwellings where at least one 60- to 79-year-old is present, else,
- Stratum 4: dwellings where at least one 20- to 39-year-old is present, else,
- Stratum 5: dwellings where at least one 40- to 59-year-old is present, else,
- Stratum with dwellings not falling in the above strata, such as vacant dwellings at the time of the Census or dwellings with people outside the CHMS age range based on household composition at the time of Census.

Each stratum has a high probability of having dwellings with respondents in the desired age groups. Within each site, a simple random sample of dwellings is selected in each stratum. The sample is allocated to each stratum so that, combined with the respondent sampling strategy, an equal number of respondents by age group can be obtained. No random rejection of dwellings is expected at the beginning of the survey. Towards the end of the two-year collection, however, the 2006 Census strata may be less efficient in reaching specific age groups, and random rejection of households with predominant age groups in the 20- to 59-year-old population may be necessary.

Each selected dwelling is contacted and asked to provide a list of current household members, and this list is used to select survey participants.

Because CHMS data collection continues until 2009, other sources may be used to supplement the addresses provided at the time of the 2006 Census to compensate for new or missed dwellings and to reduce undercoverage. Possible alternative sources are the Address Register or the Labour Force Survey Frame.[5]

Respondent sampling

Different selection probabilities by age group within each stratum are used to ensure that the sampling targets are attained. The dwellings selected are contacted and asked to provide a list of current household members. One or two people are selected, depending on the household composition. Because children have to be accompanied to the clinic, two people are selected from households with children aged 6 to 11: one child randomly selected among those aged 6 to 11, and a second person aged 12 to 79. If no 6- to 11-year-olds live in the household, only one person is selected among the household members aged 12 to 79 years.

The weight vector for the selection of people aged 12 to 79 years has been designed to avoid large person sampling weights. Since some age groups have a weight that is twice that of the other age groups, it is possible that a selected person would have a very high sampling weight when there are many household members in a dwelling. Hence, when a specified minimum number of people aged 12 to 79 live in a household, the weight for each person is reset to 1. In such cases, each household member has an equal chance of being selected.

A careful balance of the parameters required for each of the measures put in place was obtained through studies and simulations. It is expected that the target number of respondents (n=1,000) by age group will be reached.

Sub-sampling

Sub-samples of the survey's respondents are also selected for laboratory analysis of specific environmental chemicals in their blood or urine.[1,3] The entire sample population is not used because of the high cost of the laboratory tests.

The sub-samples are selected independently; that is, without consideration of who was selected for testing for the other groups of environmental chemicals. This means that a specific respondent can be selected for testing of one, two, or all environmental chemicals.

However, two people in the same household should not be selected for the same environmental chemical. It is believed that environmental chemicals will affect people within the same household in the same way. In order to avoid obtaining more or less the same information, two members of one household should not be selected for the same environmental chemical. Two people might be selected in households where sub-samples are required for both children aged 6 to 11 and other age groups. A collocated sampling method has been used to minimize or prevent this situation by using different selection intervals for 6- to 11-year-olds and the other age groups.

Other considerations

Each sampled dwelling is randomly flagged to indicate whether a respondent should be offered a clinic appointment in the morning or in the afternoon. A morning appointment requires that respondents fast overnight, whereas shorter eating restrictions are imposed on those with afternoon appointments. This random allocation reduces the potential for bias, which could occur if respondents were permitted to choose their appointment times. Pregnant women, people with diabetes and other special cases are not asked to fast, even if they are given a morning appointment.

Dwellings are randomly selected in order to monitor some of the physical measures taken of the respondents at the clinic as part of the quality control and quality assurance monitoring. For these cases, some physical measures are repeated on the same respondent and compared with the original measures taken.

During the two-year data collection period, Statistics Canada will ensure that the required number of respondents in the appropriate age and sex groups is reached. As a result, adjustments to the parameters will be made on the sample file and the number of dwellings as required in order to reach the expected number of respondents and to try to reduce potential non-response bias.

Data collection at the 15 sites will be done sequentially over the two years. The sites have been ordered to take into account seasonality by region and the temporal effect, subject to operational and logistical constraints. The temporal effect means that the number of sites by region is distributed evenly in year one and year two (with the exception of the Atlantic region which has only one site).

Concluding remarks

The sample design of the Canadian Health Measures Survey (CHMS) is unique. For the first time in decades, both household and physical measures data will be collected on a representative sample at the national level. The CHMS builds on the successes of previous health surveys, and will fill data gaps to ensure that emerging needs can be addressed ●

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Canadian Health Measures Survey: Ethical, legal and social issues

Brent Day, Renée Langlois, Mark Tremblay and Bartha-Maria Knoppers

Abstract

This article describes how the Canadian Health Measures Survey (CHMS) of Statistics Canada has addressed the ethical, legal and social issues (ELSI) arising from the survey. The development of appropriate procedures and the rationale behind them are discussed in detail for some specific ELSI. Health Canada's Research Ethics Board, the Office of the Privacy Commissioner of Canada, and the Data Access and Control Services Division at Statistics Canada, provided advice to the CHMS on ELSI. Statistics Canada's legal obligation to protect confidentiality, the oath of office, and security measures at Statistics Canada are explained. Additional information on safeguards specific to the CHMS is presented. The ELSI discussed include communication and consent, privacy and confidentiality, reporting results to survey respondents, inclusiveness, and storage of biospecimens. Common to all ELSI is the need for respondents' awareness and acceptance of their role in the survey process, and the obligation of the CHMS to respect respondents and the data they provide.

Keywords

blood specimen collection, confidentiality, consent forms, disclosure, ethics, ethics committees, health surveys, privacy

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The Canadian Health Measures Survey (CHMS) is the most comprehensive, nationally representative direct health measures survey ever undertaken in Canada. It is a voluntary survey conducted by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada. In 2007-2009, data will be collected from a nationally representative sample of Canadians aged 6 to 79 years.

The CHMS consists of an in-home health interview and a physical health examination at a mobile clinic where measures of anthropometry, spirometry, blood pressure, fitness, physical activity and oral health are taken. Blood (serum and plasma) and urine samples are collected to be analyzed for chronic disease, infectious disease, and nutritional and environmental biomarkers (for a complete list of analytes see Tremblay et al, 2007[1]), and then stored in a secure biorepository for future research. Details on the background and rationale for the survey,[1] sampling strategy,[2] logistical and operational challenges[3] and results of pre-test research[4] are described elsewhere in this supplement.

Table 1
Key consultative partners: Health Canada Research Ethics Board (REB) and Office of the Privacy Commissioner of Canada (OPC)

	Health Canada Research Ethics Board (REB)	Office of the Privacy Commissioner of Canada (OPC)
Who they are	The Health Canada REB has eight members: two ethicists; three researchers (two from Health Canada and one from outside); two community representatives; and one member with legal expertise. Members will participate for three to six years.	The Office of the Privacy Commissioner of Canada (OPC) consists of the Privacy Commissioner of Canada, two Assistant Privacy Commissioners, and their staff. The Privacy Commissioner is an Officer of Parliament who reports directly to the government (House of Commons and Senate). The Office also seeks guidance from an External Advisory Committee made up of approximately 15 members from a variety of backgrounds.[8]
Role	The REB "helps ensure that research meets the highest ethical standards, and that the greatest protection is provided to participants who serve as research subjects."[5] The Health Canada REB reviews research that is carried out by Health Canada, in collaboration with Health Canada, funded by Health Canada through grants to external researchers, or done on Health Canada premises. Because of the close involvement of Health Canada with the CHMS and because Statistics Canada does not have an REB, Health Canada agreed to provide the services of its REB. The Board has reviewed and will continue to review CHMS survey and research documentation and to monitor the treatment of survey participants.	In the context of the CHMS, the OPC is responsible for ensuring that the federal government collects, uses and discloses personal information in a responsible and transparent manner. The OPC also oversees how private sector organizations handle the personal information of Canadians in the course of commercial activities.
Governing policy/legislation	The REB is guided by the ethical principles set out in the standard for research ethics boards in Canada—the Tri-Council Policy Statement (TCPS).[6] The main guiding ethical principles of the TCPS are: Respect for human dignity Respect for free and informed consent Respect for vulnerable persons Respect for privacy and confidentiality Respect for justice and inclusiveness Balancing harms and benefits Minimizing harm Maximizing benefit In addition, the Canadian Institutes of Health Research (CIHR) has developed 10 privacy best practices that are intended to help research ethics boards in the interpretation of the TCPS by offering "additional detail and practicality."[7] These principles are similar to the 10 privacy principles described under the OPC's Governing Policy/Legislation (at the right).	The Canadian federal government, including Statistics Canada, is subject to the Privacy Act, "an Act to extend the present laws of Canada that protect the privacy of individuals and that provide individuals with a right of access to personal information about themselves."[9] The Act allows individuals to complain in writing to the Privacy Commissioner about how their personal information has been used or disclosed other than in accordance with the Act. Federal government and Statistics Canada's privacy impact assessment policies have been developed in keeping with the Code of Fair Information Practices in the Privacy Act and the 10 privacy principles from the Canadian Standards Association.[10] The 10 privacy principles are: Accountability Identifying purposes Consent Limiting collection Limiting use, disclosure and retention Accuracy Safeguards Openness Individual access Challenging compliance
Information submitted	Detailed information about the survey was presented to the REB so that they could evaluate how the CHMS has followed the TCPS ethical principles and the CIHR privacy best practices described above. This information included: • Background and rationale of the survey including information on the consultative process • Informed consent process and forms • Communications materials and strategy • Physical and lab measure tests • Survey procedures (household, clinic and lab; safety; reporting results to respondents) • Household and clinic questionnaires • Infrastructure and security measures • Quality assurance/quality control strategy • Access to data strategy • Analysis and dissemination plans • Proposal for storage of biospecimens	To meet the requirements of federal government/Statistics Canada policies, a Privacy Impact Assessment (PIA) was sent to the OPC, outlining the potential privacy, confidentiality and security risks posed by the survey, and identifying measures that will be put in place to minimize these risks. The PIA includes a specific assessment of the 10 privacy principles for the CHMS, process flows and threat and risk assessments for the household interview, clinic visit, home visit, laboratories and reporting of results to respondents. In addition, a CHMS proposal for the collection, storage and management of bio-specimens, including information on consent and access to data, was provided. The PIA and other documentation was also used to inform provincial privacy commissioners about the survey.
For more information	Further information is available from Health Canada's REB: Research Ethics Board Office of the Chief Scientist Health Canada Holland Cross, Tower B Postal Locator 3104A Ottawa, Ontario, K1A 0K9 Telephone: 613-941-5199 Fax: 613-948-6781 E-mail: reb-cer@hc-sc.gc.ca Online: http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/index_e.html	Further information is available from the OPC: Office of the Privacy Commissioner of Canada 112 Kent Street Place de Ville Tower B, 3rd Floor Ottawa, Ontario, K1A 1H3 Telephone: 613-995-8210 Fax: 613-947-6850 TTY: 613-992-9190 Toll-free: 1-800-282-1376 Online: http://www.privcom.gc.ca

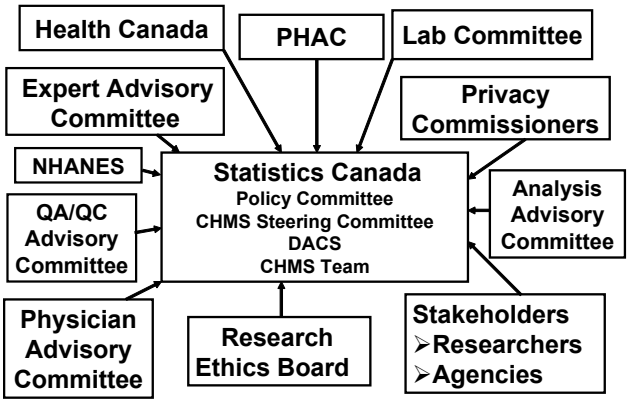
For a variety of reasons—sampling, operational logistics, managing stakeholder expectations, communications, and staffing—the CHMS is complex. However, the ethical, legal and social implications are arguably the most intricate elements of a survey of this nature. Accordingly, considerable time and resources have been dedicated to preparing and implementing protocols and procedures to address ethical, legal and social issues (ELSI). This paper discusses the consultation process and some of these issues: communication/consent, privacy/confidentiality, the return of results, reportable diseases, inclusiveness, and storage of biospecimens.

Consultations

Consulting a wide variety of groups has been instrumental in developing the CHMS. Advice was obtained from several countries with significant experience and distinguished histories in conducting surveys of this nature.[11,12] Notable among them are the National Health and Nutrition Examination Survey (NHANES) in the United States[13] and the Health 2000[14] and Finrisk[15] surveys in Finland. International efforts to address and catalogue ELSI have been widespread.[12, 16-19] The CHMS benefited tremendously from research on, guidance from, and interaction with many of these international studies.

To further assist and advise the CHMS, Statistics Canada established a network of consultation processes and committees (Figure 1). These included expert advisory committees on scientific, medical, laboratory and analytical issues; content and funding partners; other international surveys and experts; stakeholders; privacy commissioners and officials; the Health Canada Research Ethics Board; and focus groups in which Canadian citizens participated. Within Statistics Canada, the CHMS received guidance on ethical, legal and social matters from the Data Access and Control Services Division (the Agency's Access to Information and Privacy Office), departmental legal counsel, a multi-disciplinary Steering Committee, and ultimately, the Policy Committee (committee of the Chief Statistician and Assistant Chief Statisticians).

Figure 1
Canadian Health Measures Survey consultation structure



PHAC – Public Health Agency of Canada
NHANES – National Health and Nutrition Examination Survey
QA/QC - quality assurance/quality control
DACS - Data Access and Control Services Division

Statistics Canada policies and procedures have been developed in accordance with the requirements of the Statistics Act[20] and the Privacy Act.[9] Both Acts have been in the forefront of discussions with Statistics Canada's legal counsel, the various committees, and particularly, in discussions with Health Canada's Research Ethics Board (REB) and the Office of the Privacy Commissioner of Canada (OPC) (Table 1).[5,8-10]

The CHMS is the first survey for which Statistics Canada has sought the expertise of a REB. Physical measures tests and the taking of blood and urine samples demand such review. The possibility of Statistics Canada having its own REB has been explored in the past.[21] In the meantime, plans are in place to create an REB and/or Data/Specimen Access Committee specific to the CHMS, at arms length from Statistics Canada, to provide ongoing oversight for ELSI that arise from the survey.

With regard to a privacy impact assessment (PIA), the CHMS has followed federal government and Statistics Canada policies that require:

- a PIA "for all new and significantly redesigned collections, uses or disclosures of personal information that raise privacy, confidentiality or data security risks";[22]
- the PIA to be sent to the OPC for review;

Table 2
Key Canadian Health Measures Survey committees addressing ELSI

Expert Advisory Committee	Physician Advisory Committee	Laboratory Advisory Committee
Provide advice and guidance about all aspects of survey objectives, development, testing, implementation, analysis and dissemination.	Provide advice on appropriate engagement and communication with physicians and wider medical community.	Provide advice on standard collection, processing, storage and shipping procedures for biospecimens collected.
Share specific expertise on technical, scientific, logistical, ethical, legal and social issues to assist in meeting overall survey objectives.	Provide advice on content, format and process of reporting health measures results to participants.	Provide advice on the content, format and process of reporting biospecimen results to respondents.
Provide information about the survey and serve as a conduit for information exchange, particularly within their geographic and scientific constituency.	Identify potential problems and solutions arising from the CHMS as they may affect medical community.	Identify potential problems and solutions related to the collection and analysis of biological measures.
Advise on important and emerging health issues and technologies that may affect need for data, relevancy of measures or survey content, survey parameters and/or sample design.	Provide general advice on the CHMS, particularly as it relates to interactions with physicians (ensuring appropriate communication occurs between respondents and their physician) and on how the CHMS team can exploit the survey in an educational fashion with the medical community.	Provide advice on the purchase of laboratory equipment, staff qualifications, mobile laboratory set-up and licensing and quality control/assurance procedures.
	Provide communications support and liaise with the Canadian Medical Association and medical community.	Provide support for the development of communications material related to biospecimens.

- CHMS team members to meet regularly with Statistics Canada's PIA Review Committee to discuss the PIA;
- the Chief Statistician to approve the PIA before sending it to the OPC.

A summary of the final version of the PIA is available on Statistics Canada's website.[23]

The importance of the REB and the OPC was highlighted by the Policy Committee's request to receive the approval of the REB and the views of the OPC before a final decision was taken on the storage of blood and urine. The Policy Committee also recommended that the CHMS obtain the views of the privacy commissioners or equivalent in each province where collection takes place (New Brunswick, Québec, Ontario, Alberta and British Columbia).

Among the other groups that have been influential in decision-making about ELSI are the Expert Advisory Committee, the Physician Advisory Committee and the Laboratory Advisory Committee (Table 2).

Informed consent process

A well-reasoned consent strategy enables survey respondents to feel knowledgeable about and comfortable with their participation and helps researchers justify and document their goals. Governing policies for both the REB and OPC incorporate the principle of consent. In fact, obtaining informed consent "has been the focal point of research ethics review."[24] A number of Statistics Canada policies incorporate principles related to consent: the Policy on Informing Survey Respondents,[25] the Policy on Record Linkage,[26] and the legal requirements of section 12 of the Statistics Act.[20]

The CHMS follows the Policy on Informing Survey Respondents by telling respondents, before and at the time of collection, that their participation is voluntary. Information about the voluntary nature of the CHMS is included in all materials presented to or available to potential respondents before they agree to participate. Even after agreeing, they can decline to answer specific questions that they consider sensitive or that make them uncomfortable. They can also withdraw from any part of the survey at any time, including having their biospecimen samples withdrawn.

The Statistics Canada Policy on Record Linkage requires that respondents be notified of record linkage plans at the time of data collection. Section 12 of the Statistics Act[20] sets out the legal requirements Statistics Canada must follow for sharing survey information with federal departments. For the CHMS, data-sharing agreements are in place only with Health Canada and the Public Health Agency of Canada.

The CHMS has produced a large amount of documentation to inform respondents about what their participation entails. Before any personal contact is made, an advance letter and brochure are sent to the household. Both documents state that participation in the survey is voluntary and direct potential respondents to Statistics Canada's toll-free number and website for more information. The question-and-answer section of the website also explains the voluntary nature of the survey.

The voluntary nature of the survey is reiterated in the interviewer introduction, when potential respondents are first contacted to arrange for an interview appointment, and also in the introductory video that is played for each respondent before the household interview begins.

Voluntary participation extends throughout the interview. Standard interviewing procedures advise respondents that they may skip questions they do not feel comfortable answering. For the CHMS household interview, consent is implied when the respondent begins answering questions; no consent forms are used for this part of the survey.

The advance letter, brochure and introductory video provide information not only about the household interview, but also about the clinic visit, which takes place a few days to several weeks after the household interview. As well, during the household interview, respondents receive an *Information and Consent Booklet* that explains the clinic portion of the CHMS. Interviewers draw respondents' attention to information about the consent form that they will be asked to sign in the clinic and provide explanations about the informed consent process. The booklet is left with the respondents to read and consider before their clinic visit.

When a respondent arrives at the clinic, Statistics Canada staff use the clinic questionnaire (computer application) to guide him or her through the consent process, providing ample opportunity to review the consent material and ask questions. The respondent (or the respondent's parent/guardian if he or she is aged 6 to 13 years) is asked to give written consent for participation in various parts of the clinic portion of the CHMS and to sign the form. If requested, a copy of the signed form is given to the respondent.

At the end of the clinic questionnaire, respondents are asked if they agree to data-sharing and data linkage. Their responses are recorded in the clinic application and apply to all data collected as part of the CHMS—household components, clinic test results, activity monitor data, and the results of tests on stored blood and urine samples. The *Information and Consent Booklet* provides additional information about what data-sharing and data linkage entail (Appendix Figure A).

Consent forms

Using consent forms for direct measures surveys and research projects is standard practice.[6,7] These forms serve as legal reassurance and protection for both respondents and researchers, and highlight the importance to both groups of understanding the possible implications and consequences of participation.

"The primacy of consent necessarily carries with it the right of withdrawal."[24] Signing a consent form does not prevent respondents from later declining to participate in some or all parts of a survey or from later withdrawing their data or samples, provided that the data have not been aggregated. This right to withdraw should be made clear on the consent form itself and/or in supplementary material.

Consent forms can range from broad consent to participate in an entire survey to explicit signed written consent for each topic or measure. Nationally representative direct measures surveys in the United States[13] and Finland[14] have asked for relatively broad consent on a form that summarizes the details of participation. The CHMS has taken a more specific approach by separating the survey into several key areas and offering respondents the option of participating or not in each one (Appendix Figure B).

Feedback from focus groups in November 2005 indicated a preference for consent forms that are short and simple, but offer some choice. As a result, CHMS forms have been kept to one page each, and choice has been limited to no more than

five distinct areas (Appendix Figure B). In addition to minimizing response burden, a short form reduces the development and processing costs related to the consent portion of the survey. The trade-off is some loss of detail on the forms. However, the CHMS treats consent as an ongoing process that starts before data collection and continues until after its completion, with communication materials provided to respondents throughout (as previously discussed). The right to withdraw from any part of the survey is presented explicitly on the form. This reminds respondents that if they are not comfortable with an aspect of the survey to which they previously consented, they can refuse to participate in that specific part.

Based on results of the November 2005 focus groups, the consent form for respondents aged 20 to 79 years has separate clauses for the storage of DNA for use in future health studies and for the storage of blood and urine. To maximize consent for the DNA portion, respondents are assured that their DNA samples will be kept confidential and not made available to law enforcement agencies, insurance companies or employers, and will not be used for maternity or paternity verification. The specific components of "participating in the physical measures tests" (for example, strength test, cardiovascular test) are not presented in separate clauses, since they were viewed in a similar way by the focus groups and are expected to be accepted to the same degree by respondents.

Different consent forms are often required for people of different ages in order to allow for the role of parents and guardians in the consent process and to apply various parts of a survey to particular age groups. The CHMS uses four forms: a consent form for respondents aged 20 to 79 years, for respondents aged 14 to 19 years and for parents/guardians of respondents aged 6 to 13 years, and an assent form for respondents aged 6 to 13 years.

The consent form for respondents aged 20 to 79 years is the most complete, since all parts of the CHMS apply to this age group. The consent form for respondents aged 14 to 19 years is virtually identical, except that it does not include the clause asking for consent to store DNA for use in future studies, since DNA is not stored for this age group.

The consent form for parents/guardians of respondents aged 6 to 13 years does not include the DNA clause or the clause on testing respondents' blood for hepatitis B and C viruses. These measures are not performed on respondents in this age group.

On the assent form for 6- to 13-year-olds, the child is asked if he or she wants to participate in the survey as a whole; no choice as to specific areas is offered. The assumption is that children are too young to comprehend the details of the survey and that the parent/guardian will oversee their participation. If the parent/guardian or the child does not give consent, the child does not participate in the survey. When the child reaches 14 years of age, he or she will be recontacted by the CHMS to provide permission for the CHMS to continue to store his or her blood and urine.

Privacy and confidentiality

Respecting the privacy of respondents and maintaining the confidentiality of their information are important ethical, legal and social considerations for surveys such as the CHMS (see *Key concepts*[27]). Statistics Canada has developed a generic privacy impact assessment (PIA)[28] that works well for most of its surveys. Principle 7 of this PIA, which is similar to the "Safeguards" principle in Table 1 (OPC, Governing policy/legislation), outlines many of the precautions Statistics Canada takes to protect the information collected.

Statistics Canada has a legal obligation to safeguard respondents' personal information and

Key concepts

Privacy	The right to be left alone, to be free from interference, surveillance and intrusions.
Confidentiality	Implies a trust relationship between the person providing information and the individual or organization collecting it. This relationship is built on the assurance that the information will not be disclosed without the provider's permission.
Security	The procedures, infrastructure and oversight mechanisms implemented to ensure that each person's privacy and confidentiality are respected.

has made a commitment to keep in trust the information it obtains from the Canadian public. Statistics Canada has a framework of policies, procedures and practices to protect confidential information against loss, theft, unauthorized access, disclosure, copying or use, which includes physical, organizational and technological measures.

The Statistics Act[20] provides the legal basis for maintaining the confidentiality of information that Statistics Canada collects. No unauthorized person may examine any information collected under the Act or disclose or knowingly cause to be disclosed any information collected under the Act in such a manner that it is possible to relate the particulars to an identifiable individual person, business or organization.

Before assuming their duties under the Statistics Act, all Statistics Canada employees take an oath or solemn affirmation that they will conform to the requirements of the Act and will not, without due authority, disclose or make known confidential information. Employees who contravene the confidentiality provisions of the Act are subject to prosecution and are liable on summary conviction to a fine and/or imprisonment. Actions that contravene the security policies of the Government of Canada or Statistics Canada could lead to administrative, disciplinary or statutory penalties when misconduct or negligence is involved. The nature of the penalty depends on the nature of the offence.

Statistics Canada has taken extensive measures to maintain a secure environment and to make the principle of security a priority (see *Security measures at Statistics Canada*).

Privacy safeguards

One of the ways in which the CHMS is an atypical survey for Statistics Canada is that collection and processing sites include not only the respondent's dwelling, but also a mobile clinic, laboratories and a biorepository (storage facility for blood and urine). Although the previously outlined policies and procedures apply to the CHMS, some modifications were needed because of these different sites.

Physical security measures at the clinic include break-proof windows, bolted panels and steel doors, and security alarms and lights. Paper documents such as consent forms are stored in locked cabinets. Computers in the clinic and the clinic laboratory are locked to desks, and the server is in a locked cabinet in a locked room. All computer data are password-protected and encrypted, and data transmissions from the clinic to head office are encrypted or double-encrypted. An overview of the Information Technology infrastructure and data flows for the clinic is presented elsewhere in this supplement.[3]

Only the complete blood count (CBC) is done in the laboratory at the clinic. Other tests on the blood and urine samples are conducted in three other laboratories: the Public Health Agency of Canada's National Microbiology Lab (NML) in Winnipeg, l'Institut national de santé publique du Québec in Ste-Foy, and the Bureau of National Sciences Laboratory in Ottawa. Each laboratory specializes in a different group of tests.

These laboratories meet the physical and data security requirements of Statistics Canada. Blood and urine samples are sent from the clinic to the laboratories in de-identified tubes (identity of respondents cannot be determined by researchers or laboratory staff). Access to the personal information associated with the identification number on the tube is restricted; it is granted on a need-to-know basis to selected Statistics Canada employees only at head office when it is essential to their work. This occurs when, for example, respondents' blood and urine test results are combined with their household and physical measures data or when respondents request that their samples be withdrawn from the survey. The electronic data based on the results of the blood and urine tests, like other data collected by Statistics Canada under the authority of the Statistics Act,[20] are kept confidential and secure, and are transmitted to head office only after encryption.

Some blood and urine samples are stored indefinitely at the NML biorepository, a facility that meets the physical and data security requirements

Security measures at Statistics Canada

The following security measures are in place at Statistics Canada:

- Access to Statistics Canada buildings is controlled by a combination of physical measures and access procedures.
- All visitors are escorted to the work area and escorted back to the building entrance at the end of the visit.
- Employees' and visitors' identification cards must be visible at all times.
- All staff undergo a reliability (security) check.
- Only Statistics Canada employees with a "need to know" have access to sensitive statistical information and then only to the information required to do their job.
- Within Statistics Canada, interdivisional access to sensitive statistical information must be approved by the director of the division holding the information.
- Disposal of sensitive statistical information is carried out under secure conditions according to government-approved procedures.
- Non-computerized confidential data are stored in security-approved containers.
- Statistics Canada's EDP (electronic data processing) Security Policy outlines the safeguards the Agency has put in place to ensure that its information systems are secure, including:
  - Two separate data processing and communications networks are maintained, one of which is a closed internal computer network preventing physical and electronic access from outside Statistics Canada's facilities and to which public access is not permitted.
  - Access to files is protected through access controls, passwords and servers located in access-controlled areas.
  - Communications within the closed internal computer network between Statistics Canada locations are facilitated through the use of secure data transmission lines and services specifically approved for that purpose.
  - Computing devices with external wireless connections may not be connected to any Statistics Canada network.
  - Electronic transmission of sensitive statistical information under specific special circumstances must adhere to approved security procedures.
  - Transmission of microdata files containing sensitive statistical information to Statistics Canada Regional Offices, Research Data Centres or to data-sharing partners must follow approved security procedures. Such information must be encrypted.
  - Sensitive statistical information is not transmitted from Statistics Canada by fax, except under certain specific conditions.
  - Storage of sensitive statistical information on removable storage media must follow approved security procedures. Such information must be encrypted.
  - Sensitive statistical information may not be taken out of Statistics Canada's secure premises.
  - Personal identifiers are removed from statistical master files after they are no longer required for data processing.
  - Breaches of security are formally reported to the Departmental Security Officer and to the Chief, Departmental Security.

Documents on security are available to all employees on Statistics Canada's Internal Communications Network. These documents include the Statistics Act,[20] the Privacy Act,[9] Statistics Canada's "Security Practices Manual," Statistics Canada's "Policy Manual," "An Employees' Guide to Security at Statistics Canada," "Data Security and You" (a summary of the most important security rules at Statistics Canada), a list of departmental contacts for security-related matters, and the "Companion Guide to the Statistics Act."

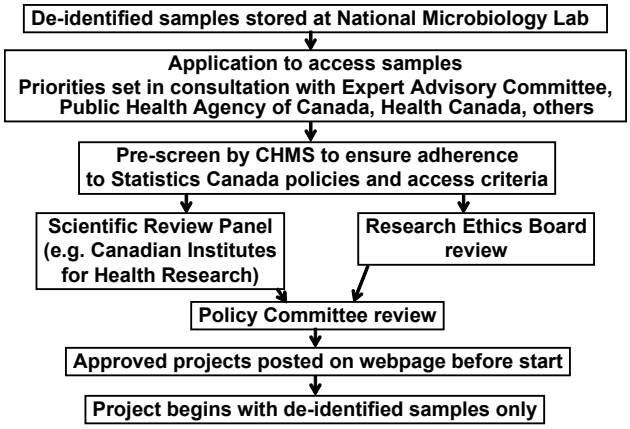
of Statistics Canada. Again, these samples are in de-identified tubes. The process for accessing these blood and urine samples is illustrated in Figure 2.

Reporting results to respondents

The November 2005 focus groups and the CHMS pre-test experience[4] showed that one of the reasons motivating people to participate in the survey is the opportunity to receive the results of their health measures and laboratory tests. To develop a process to inform respondents about their results, the CHMS had to identify, analyze and resolve a number of ELSI.

Typically, respondents to Statistics Canada surveys know the information that they provide about themselves. However, for the CHMS, the data collected from the physical measures and the laboratory tests are often unknown to respondents (for example, blood pressure). Although most people want to receive information about their health, some do not.

Figure 2
Canadian Health Measures Survey biospecimen access and use procedures



De-identified samples - Researchers are not given information about the person who provided the sample; they are given an anonymous number. Only a select few Statistics Canada employees at head office, on a need-to-know basis, have access to the key that makes it possible to combine results from a specific sample with the rest of that respondent's survey data. This key is needed to add new data to each respondent's file. The key is also used to identify samples destined for destruction if a respondent requests that his or her sample be withdrawn.

In accordance with ethical, legal and social principles, any information collected about a person should be provided to that person if requested.[6,7,10] To respect the preferences of respondents, the CHMS consent form (Appendix Figure B) seeks permission to provide them with their results. In addition, respondents are asked, as part of the computer application at the clinic, if they want to receive their clinic and laboratory results via regular mail or via a method such as courier where the delivery can be tracked. More details about the reporting process can be found elsewhere in this supplement.[3]

Parents or guardians of 14- to 17-year-olds are advised that if their adolescent agrees to participate in the survey and to receive his or her results, the results will be sent to the adolescent, not to the parent. This ensures that the privacy of these youths is respected. Results for children aged 6 to 13 years are sent to the child's parent/guardian if the parent/guardian consents to receive these results.

By law, when some infectious diseases are detected, they must be reported to public health officials. The CHMS lab analyses can yield two such reportable results: hepatitis B and hepatitis C. Under provincial public health legislation,[29-33] positive results to the hepatitis B core antigen and to the hepatitis C virus must be reported to provincial health authorities. This requirement creates a potential conflict for Statistics Canada since the CHMS data are collected under the Statistics Act,[20] which guarantees that individual results are confidential and are not shared without the respondent's consent.

Although from a legal point of view it would seem that the Statistics Act would take precedence, Statistics Canada's Policy Committee recognized the importance of contributing to the improvement of public health. The solution for the CHMS is to inform respondents about the requirement to share positive hepatitis B and hepatitis C results with provincial health authorities. If respondents are unwilling to share such results, they do not consent to having the hepatitis tests.

Because of the sensitive nature of such results, a personal contact process was developed to advise respondents who test positive. A CHMS Medical Advisor telephones to inform them and to provide counselling. Respondents are then sent the results and a letter to take to a regulated health care professional for follow-up.

The CHMS devoted considerable effort to the design of the results package that is sent to respondents. The objective is to provide useful information in an intelligible format for both respondents and health care providers.

Expert advice on the design of the results package was obtained from the Health Canada Research Ethics Board (Table 1) and other key CHMS committees (Table 2). Debriefings with participants in the CHMS pre-test that took place in the fall of 2004[4] were held to obtain their feedback on the usefulness of the report. Based on these consultations, the report provides the results of each physical measure taken at the clinic, the results from the laboratory analyses of the blood and urine samples, definitions of the laboratory

tests, and interpretations of the findings where reference ranges have been established. These interpretations are presented in a simple message that gives details about the respondent's specific results and/or advises the respondent to take some action (in most cases, follow-up with a health care professional).

For results that require immediate attention, a process was developed to advise respondents at the clinic. For blood pressure and oral health results that are potentially dangerous, a letter is generated and given to respondents before they leave the clinic, which they can take to a health care professional. This follow-up is required because the CHMS does not provide diagnoses.

Results of the blood and urine tests are normally provided to respondents 8 to 12 weeks after their visit to the clinic. If a laboratory result is not within established reference ranges, respondents receive an early report containing all results that have been analysed up to that point. This early report includes information about the abnormal results and contact information for the CHMS Medical Advisor, who is available to discuss the results, provide more in-depth information and offer counselling. Again, no diagnosis is given—respondents are advised to follow up with a health care professional as soon as possible.

The CHMS intends to conduct an extensive array of analyses of blood and urine samples.[1] Some results will be difficult, if not impossible, to interpret. For instance, this is the first time in Canada that a national population survey has included many of the environmental measures. The results will be used to establish baseline levels and reference ranges, to support population health risk assessments, and to guide potential interventions and control measures. Because baseline data for such measures currently do not exist, it is not possible to tell respondents how they compare to "normal" or "acceptable" levels. The CHMS team sought advice on this issue from its expert committees and the Health Canada REB, and investigated practices used elsewhere.[13] Consequently, respondents are informed about the exploratory nature of some variables and advised that these results are not routinely included in their results report. However, respondents are given a telephone number to call if they wish to obtain this information.

Inclusiveness

One of the guiding principles set out in the standard for research ethics boards in Canada—the Tri-Council Policy Statement (TCPS)[6]—is respect for justice and inclusiveness (Table 1)[6]: While "no segment of the population should be unfairly burdened with the harms of research,"[6] the statement also "imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances to research."[6]

The CHMS includes children, physically or mentally impaired/disabled individuals, and people who have difficulties reading, speaking and understanding English or French. Some consent procedures were modified for these groups, and CHMS staff have some procedural flexibility, as long as respondents' safety and dignity are not compromised. All CHMS physical measures clinic staff participated in a special workshop[34] to help them determine when and how to adapt procedures to accommodate physical and mental impairments.

Children aged 6 to 17 years participate in both the household and clinic portions of the CHMS. For those aged 6 to 11 years, the parent/guardian answers the questions on the child's behalf, with aid from the child as necessary. Statistics Canada experience has shown that for children younger than 12 years, proxy interviews (information provided by a parent/guardian) often yield more accurate data than do interviews with the child alone.

For almost all parts of the CHMS household interview, respondents 12 years of age or older reply on their own behalf. Unless adolescents grant permission, their responses are not made available to anyone else, including parents. Proxy interviews are conducted for respondents 12 years of age or older only if their mental or physical health makes it impossible for them to complete the interview without assistance.

The age at which children are capable of making their own decisions has been debated extensively.[35,36]

Consent for health care is probably the most closely related area of consent for a survey such as the CHMS, since respondents will receive results on which they may base decisions about their health care and health habits. The age of consent in Canada varies by province and by the topic for which consent is sought. In Ontario, the age of consent for health care is based on competency not age,[37] consistent with the mature minor concept.[38] In Quebec, the age of consent is legislated as 14.[30]

For the clinic portion of the CHMS, respondents aged 14 or older provide their own consent. This age was chosen for both the pre-test[4] and the main survey based on consultations with the Expert Advisory Committee, the Physician Advisory Committee, federal and provincial privacy commissioners, and others.

Physically impaired individuals are included in the CHMS, although some may be excluded from specific measures. Protocols are adapted where possible, depending on the type and degree of impairment.

For visually impaired respondents, at the household, interviewers verbally review the *Information and Consent Booklet*, including the consent forms. At the clinic, staff provide large-print consent forms to respondents whose visual impairment is moderate. For those whose visual impairment is more severe, clinic staff read the written consent form out loud and mark off each box as the respondent replies. If a family member or friend accompanies the respondent, they can observe clinic staff as they complete the form.

For hearing impaired respondents, the laptops used for collection at both the household and clinic interviews are turned to face them so that they are fully informed. The interviewers/clinic staff point to the appropriate text. Physical tests are demonstrated. For the household portion of the survey, respondents have the option of replying through a TTY/TDD service (a telecommunications device that enables conversation in written text by printout or electronic screen). The TTY/TDD number is included in the CHMS introductory brochure. The services of a sign language interpreter are made available if requested.

Interviewers and clinic staff use their judgment to determine if mentally impaired individuals aged 14 or older are able to understand the survey and the consent process well enough to give informed consent. If they cannot, their parent/guardian is asked to provide consent on their behalf. Mentally impaired individuals may be excluded from some physical tests if it is determined that they cannot understand the instructions.

All CHMS information is available in English and French. In addition, various documents relating to consent (brochure and consent form) and to the safety of tests are translated into some of the more common non-official languages. When available, interviewers/clinic staff fluent in the non-official language conduct the interviews and administer the tests. If this is not possible, the assistance of a family member fluent in one of the official languages and the non-official language or an outside interpreter may be used.

Storage

The CHMS plans to store biospecimens indefinitely so that researchers can take advantage of new tests and technologies as they emerge. Further information on the rationale of storage can be found in the CHMS background paper.[1]

National and international legislation and guidelines for the storage of blood and urine generally do not specify how long samples should be stored,[6] and the length of storage varies considerably across research projects. At both the household and the clinic, CHMS respondents are told that storage will be indefinite, and the benefits of indefinite storage are explained. Most participants in the November 2005 focus groups did not consider duration of storage to be an issue, nor could they suggest an ideal length of time for storage.

The ELSI related to access to stored samples received considerable attention during development of the CHMS. Once respondents have provided consent to collect their samples, Statistics Canada becomes the custodian of these samples. However,

respondents can request that their samples be withdrawn at any time, no matter how long they have been at the NML biorepository. Although information about specific projects that will use their samples is not known when respondents consent to storage, as soon as a project is approved the information will be posted on Statistics Canada's website.[39] This gives respondents an opportunity to withdraw their samples if they are uncomfortable with a particular study. Individual respondents will not be contacted for studies using stored biospecimens.

Over time, some respondents may lose the capacity to provide informed consent. They may no longer be able to understand details posted on the Statistics Canada website about projects that have received approval, or at least not in the same way that they understood when they originally consented to the use of their samples. Their ability to make an informed decision about whether they want their samples to be used in a particular study or whether they want them withdrawn may be compromised. The longer the period of storage, the more this becomes an issue.

A biorepository oversight committee has been established to address issues such as this and to ensure the confidentiality and privacy of the information obtained from the specimens. This committee provides oversight, advice and direction to Statistics Canada on established protocols for accessing the specimens and conducting research with them, and makes recommendations for changes to the protocols.

To obtain access to the samples and data files, researchers must follow a prescribed process (Figure 2). Those whose proposals are approved must become deemed employees of Statistics Canada, which entails taking an oath to uphold the confidentiality provisions of the Statistics Act.[20,40]

Summary

Development of the Canadian Health Measures Survey has necessitated addressing ELSI related to consent, privacy, confidentiality of data, reporting of results, inclusiveness, and storage of blood and urine samples. A variety of groups and individuals have been instrumental in establishing procedures to deal with these issues. Based on the specialized knowledge gleaned from the many groups consulted, the CHMS has been able to establish transparent protocols appropriate to the survey. Involvement by the Health Canada Research Ethics Board and the Office of the Privacy Commissioner of Canada has been especially useful. Ongoing oversight of not only the issues presented in this paper, but of all ELSI that arise is critical, especially given the indefinite storage aspect of the survey. This oversight will help ensure that the scope and understanding of the original consent provided by respondents, as well as their trust, are respected. ●

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Appendix

Figure A

Linking and sharing your data

Linking

The data we collect from you will contribute to a greater understanding of the general health of Canadians. It is even more valuable, however, to combine this data with provincial sources of health information, to provide as complete a picture of the health status of Canadians as possible. This is known as data or record linkage, and is only done for statistical purposes.

If you don't agree to have your data linked, it will not happen. However, findings from projects based on linkage could be used by governments to monitor, evaluate and change policies related to health care, health promotion and the use of health services. Further information can be found at www.statcan.ca/english/recrdlink.

At the end of your clinic visit, you will be asked whether you consent to the linkage of all your information. This information includes the responses to your household interview, results from your tests done at the clinic, information from your activity monitor, and results from laboratory tests done on your blood and urine samples. If you agree to linkage, we will

- ask you for your health card number to help with the linkage process
- combine the information that we collected during this survey with some of the information that your provincial health department, health registries or other recognized health organizations already have on file about you
- remove your name, address, date of birth and health card number from the linked file as soon as the linkage is complete
- destroy all linkage files after the project for which linkage was done is finished.

The linkage will take place at Statistics Canada and will be done only by Statistics Canada employees; all linked data will remain confidential under the Statistics Act. We will not provide any information about you to your provincial health department or registries-the flow of information is one-way only, to Statistics Canada.

Sharing

You will also be asked whether you consent to share the same data with Health Canada and the Public Health Agency of Canada (PHAC). This is done to reduce the number of times we have to survey Canadians. If you agree to share your data, this will mean that

- We will share your information with Health Canada and PHAC; however, your name, address, date of birth and health card number will be removed from any files before they are sent.
- Your information will not be shared with anyone else without your consent.
- Health Canada and PHAC will only use the information for statistical and research purposes and must keep the information confidential.
- No information from your provincial health department or registries will be shared.

If you don't agree to share your data, it will not be shared. This would be a missed opportunity, however, since researchers and experts at Health Canada and PHAC could help put the information we collect to its full use, potentially improving health policies and, as a result, the health of Canadians.

Figure B

CONFIDENTIAL WHEN COMPLETED

Date (yyyy/mm/dd):	2007/04/02
Identification Number:	10100015
Name:	JOHN DOE
Age at clinic exam:	45
Gender:	Male

I have read and understood the information provided to me in the Information and Consent Booklet for the Canadian Health Measures Survey. By marking the boxes below and signing this form, I am choosing to consent ("Yes") or not consent ("No") to the following:

participating in the physical measure tests, including providing samples of my blood and urine	Yes ☐	No ☐
receiving a copy of my Report of Laboratory Tests	Yes ☐	No ☐
allowing Statistics Canada to test my blood for the hepatitis B and C viruses and to contact me, as well as the appropriate provincial authorities, if the results are positive	Yes ☐	No ☐
storage of my blood and urine for use in future health studies	Yes ☐	No ☐
storage of my DNA for use in future health studies	Yes ☐	No ☐

I have had time to decide on participating in the clinic portion of the survey. I understand that even though I have consented to some or all of the items on this form, I can still withdraw from any part of this survey or subsequent studies at any time.

JOHN DOE

_____ _____
Signature of participant Date

_____
Name of witness (please print)

_____ _____
Signature of witness Date

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Canadian Health Measures Survey: Clinic operations and logistics

Shirley Bryan, Marc St-Denis and Dana Wojtas

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.

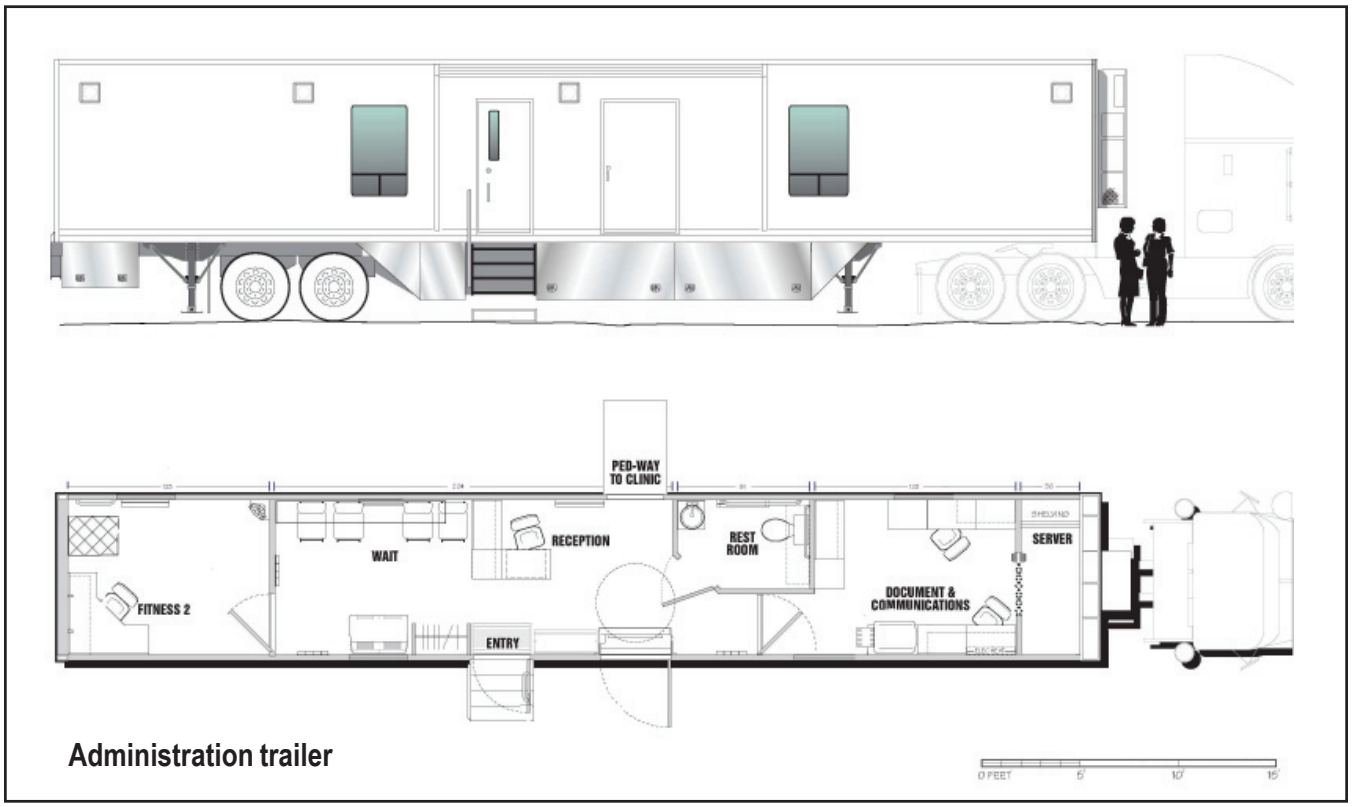
Table 1
Function of rooms in mobile clinic, Canadian Health Measures Survey

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

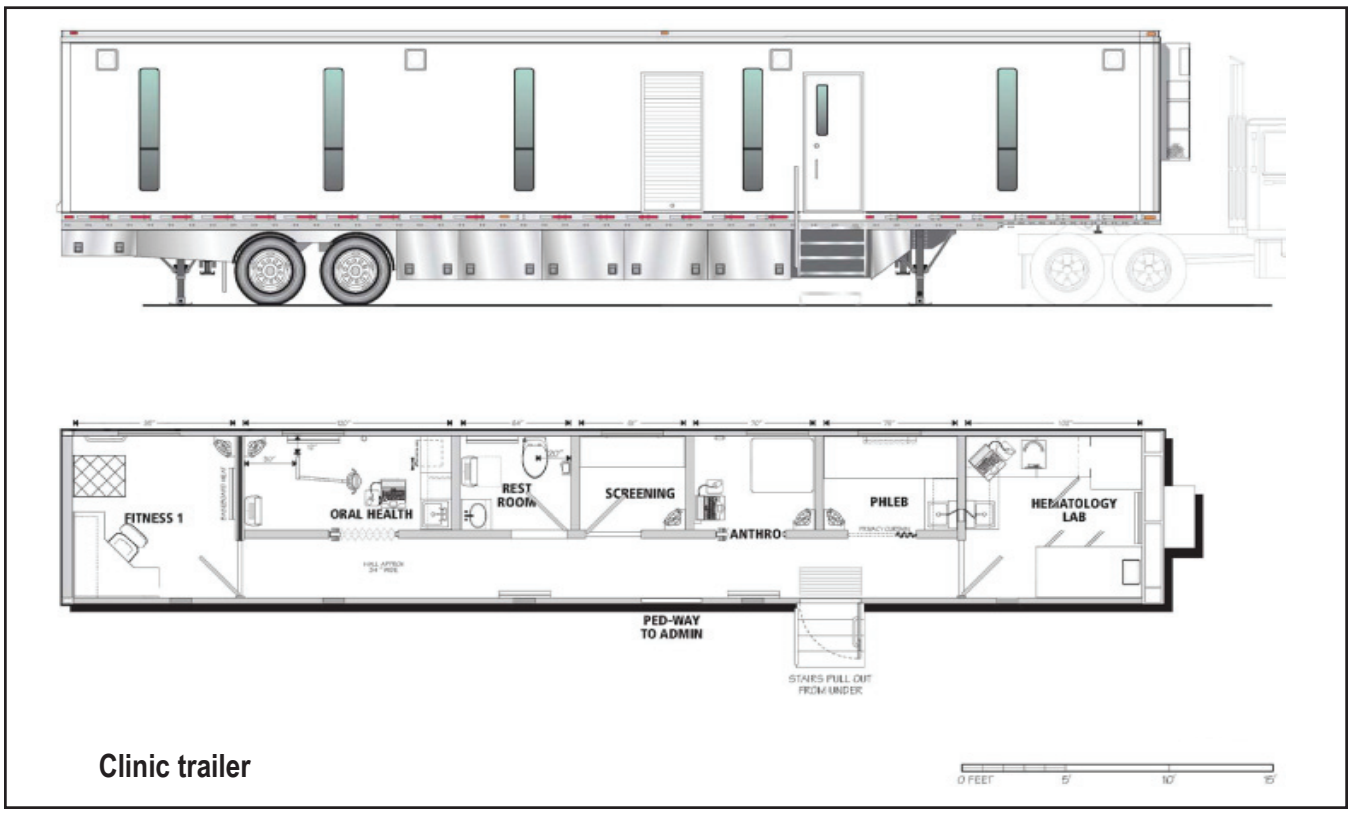
Emergency plans

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

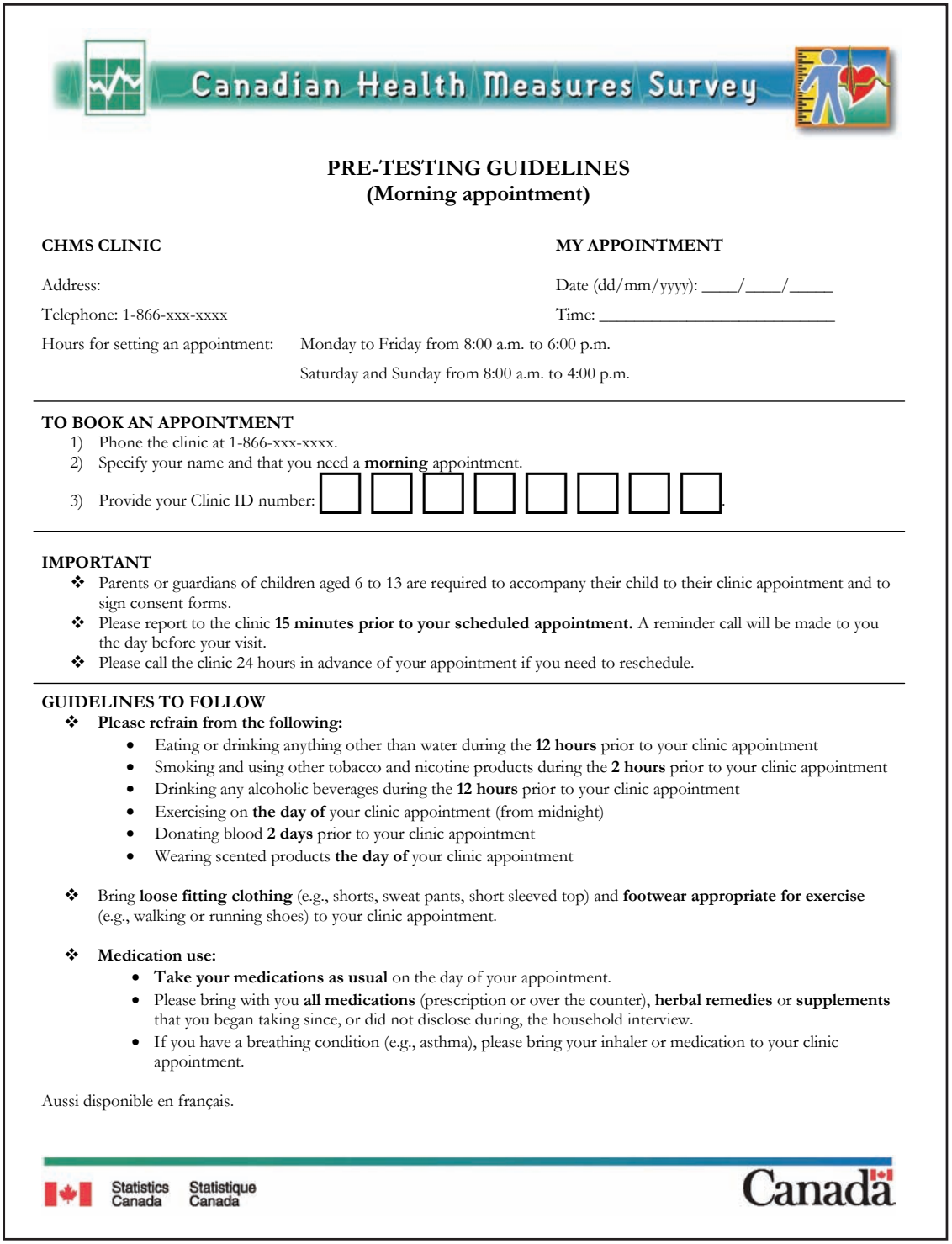
Over two years, the CHMS field team will collect data in 15 different sites across Canada. This means "living out of a suitcase." Staff stay in apartment-style accommodations, equipped with a kitchenette, laundry and exercise facilities, and located close to amenities such as shopping and restaurants. 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.

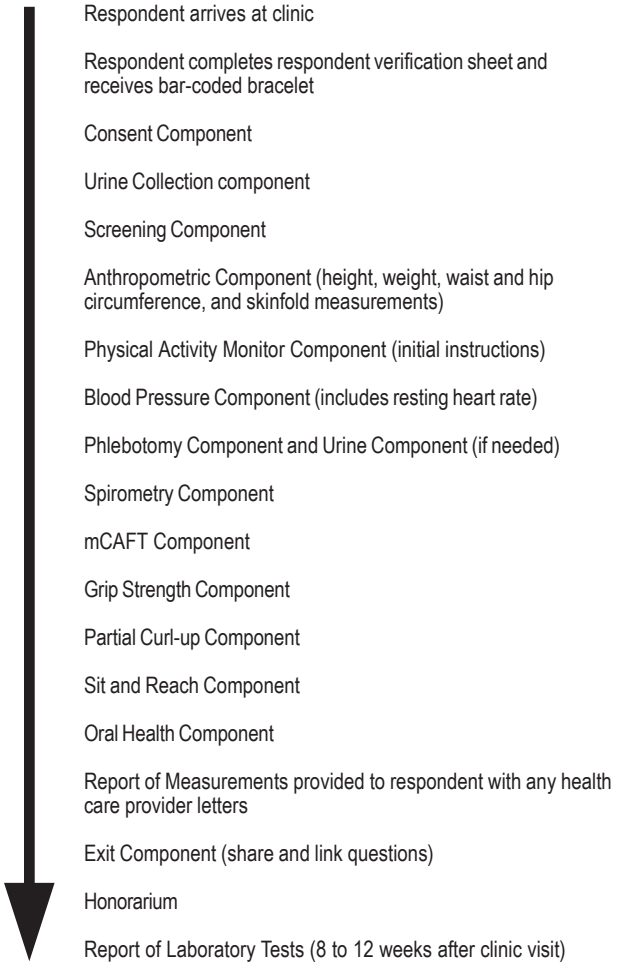
Respondents who have booked an appointment are called 24 hours in advance to remind them of the time and to review the pre-testing guidelines. All missed appointments are followed up on the same day, and rescheduling is attempted.

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