

Division of Health and Nutrition Examination Surveys



**Report for:
NCHS Board of Scientific Counselors
NHANES Review Panel**

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NHANES OVERVIEW

Since 1959 the National Health Examination Surveys (NHES) and the National Health and Nutrition Examination Surveys (NHANES) have collected data which can best or only be obtained by direct physical examination, clinical and laboratory tests, personal interviews, and related measurement procedures. These data, which cannot easily be reported by sample persons themselves or by their health care providers, are used to estimate either the prevalence of disease or disorder or to estimate the normative distribution of the characteristic in the total population.

Three National Health Examination Surveys (NHES I, II, and III) were conducted in the 1960s. A large nutrition component was added to the basic design in 1970 and the name of the survey was changed to the National Health and Nutrition Examination Survey. The first National Health and Nutrition Examination Survey (NHANES I), started in April 1971 and was completed in October 1975; NHANES II began in February 1976 and was completed in February 1980. A special study of Hispanic populations in the United States (HHANES) began in July 1982 and was completed in December 1984. NHANES III began in October 1988 and was completed in October 1994. More recently, NHANES became a continuous survey in which data are aggregated over two year periods. NHANES has now been in operation as a continuous survey since 1999.

There are four public laws which authorize or necessitate the collection of information about the health of the American people. These laws have direct or indirect impact on NCHS and NHANES, guiding the type of data to be collected. These four laws are:

1. Section 306 of the Public Health Service Act (42 U.S.C. 242k) directs the National Center for Health Statistics to collect statistics on subjects such as: the extent and nature of illness and disability of the population; environmental, social and other health hazards; and determinants of health.
2. The National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990) specifies that NHANES be maintained as a component of the comprehensive nutrition monitoring plan with continuous coverage of dietary and nutritional status for the population and high-risk subgroups¹.
3. The Food Quality Protection Act of 1996 (P.L. 104-170) requires the implementation of surveys to collect data on food consumption patterns of infants and children and data on dietary exposure to pesticides among infants and children.
4. Title 21 – Food and Drugs, Chapter 9 of the Federal Food, Drug, and Cosmetic Act (21 USC 393) authorizes the collection of information to support the Food and Drug Administration’s objective to obtain current,

¹ The original law was authorized in 1990 for ten years. The legislation has not yet been re-authorized.

timely, and policy-relevant consumer information to carry out its statutory functions.

NHES and NHANES use(d) complex multi-stage probability samples of the U.S. population to provide representative national data. The HHANES was an exception to this approach in that sampling was only carried out in the five southwestern U.S. states (Texas, New Mexico, Colorado, Arizona, and California), Dade County, FL, and the areas in and around New York City, NY. Successive surveys in the NHES and NHANES programs have targeted different U.S. population subgroups and different health conditions. During the NHES Cycle I, for example, a sample of adults was selected and the focus was primarily on selected chronic diseases. NHES Cycles II and III were directed toward children 6-11 years and youth 12-17 years, respectively; both surveys emphasized growth and development data and sensory defects. The nutrition component of NHANES I was directed at a national probability sample ages 1-74 years, while the detailed health examination component focused on the population 25-74 years of age. NHANES II and the HHANES were directed to the U.S. population aged 6 months to 74 years; the nutrition data were used to monitor changes in nutritional status over time. NHANES III was the first survey to include infants as young as 2 months of age and adults over 74 years; a home examination was designed to assess the health status of persons who were unable or unwilling to come to the mobile examination center. The continuous NHANES includes persons of all ages; oversamples of pregnant women (1999-2006), Mexican Americans, African Americans, youth 12-19 years of age (1999-2006) and persons 60+ years are included. In 2000, NHANES began oversampling the low income population. Beginning in 2007, the sample design was changed to allow for total Hispanic estimates as well. Appendix A describes the individual surveys.

NHANES data collection begins with an interview administered in the household. Upon completion of the household interview, participants are asked to schedule an appointment for a physical examination at the Mobile Examination Center (MEC). Blood and urine specimens are collected in the MEC, and additional interview questionnaires are completed guided by an interviewer, and via self-administered computer-assisted mode. (Additional questionnaires or tests may be completed in the household and via the telephone some time after the exam.)

The NHANES survey teams are comprised of highly trained interviewers and examiners, including physicians, nurses, dentists, dietitians, laboratory technologists, and radiological technicians (all of whom are contract staff.) The examinations are conducted in MECs, each consisting of four tractor-trailer units. The trailers are interconnected and provide a standardized environment for the health examination component of the survey. Standardized equipment is required for all survey components; for example, NHANES uses audiometry hearing chambers which conform to the American Speech Association standards for ambient noise and acoustical measurements. These chambers must be identical in all MECs.

In the past, a survey cycle lasted from three to six years. However, this was predicated on several years of planning, design, development, and pilot testing. After the completion of a cycle, several years were needed to edit and disseminate the data for

analysis. The step-wise approach allowed for careful and well-planned movement between different stages of the project. When the study became continuous in 1999, the program no longer had this luxury and instead needed to simultaneously plan, design, develop, conduct, pilot test, edit, release and analyze data. Data are now aggregated over two year cycles and are released to the public as quickly as possible. Innovations in information technology, regular field visits, intensive quality control, and stakeholder involvement have all resulted in timely and high quality data. However, the overlap of so many objectives and requirements has put some strain on the program. Four main steps in completing the survey cycle are described below. These steps or phases overlap one another with each one being active on one or more two-year survey cycles at any given time (see Appendix B).

Survey Planning

The continuous NHANES has collected health interview and examination data on the U.S. population since 1999. Much of the interview, examination and laboratory content do not change within the two-year survey cycles (see Appendix C). However, every two years new or revised questionnaire material, laboratory assessments, and examination components is considered to reflect changing public health priorities and data needs. Proposal solicitation announcements and research proposal guidelines for new survey content are posted on the NHANES website and presented at professional meetings and meetings with other government agencies. Members of the NHANES user community receive letters inviting them to submit research proposals. Correspondence is sent to dozens of persons who expressed interest in being kept informed of NHANES activities.

The planning process is conducted in stages and often begins two to four years prior to implementation in the field. For example, planning for NHANES 2009-2010 began in 2005. The planning process begins with a formal research proposal solicitation phase. DHANES posts research proposal guidelines on the NHANES website. These guidelines outline the two-stage proposal process that is used to evaluate new survey content.

Initially, interested researchers submit a brief letter of intent which outlines the topic, the public health significance, and the proposed methodology. For the 2009-2010 data cycle, 20 proposals were received in response to these solicitations, ranging from a request to add one question or laboratory analyte, to requests for new health examination components. The letters of intent are evaluated to determine if the proposed topic is safe, feasible, and of sufficient public health significance to include in NHANES. If the letter of intent is acceptable, the proposer is asked to submit a comprehensive research proposal. In some cases, proposers are invited to present their proposed topic. The proposal evaluations are discussed during formal meetings and a decision made to approve or disapprove. If approved, the protocol is fully developed and prepared for field testing prior to use in NHANES. If required, cognitive testing and translation activities are completed prior to field implementation. Similarly, laboratory methods must have been tested and deemed reliable and valid prior to their inclusion in NHANES. All survey protocols, consent forms, and information materials must be approved by the NCHS Ethics Review Board (ERB) prior to use. Finally, DHANES submits the survey content to the Office of Management and Budget (OMB) for annual review and approval.

Preparation for Field Operations

After new survey content has been formally approved, work begins in protocol development and training, and in the design of any structural changes to the MEC. An extensive field operation schedule is prepared to ensure that all aspects of field work are done on schedule and in the correct order (see Appendix D). A significant effort is made to ensure proper community outreach via meetings with county health officials, letters to county staff, and local media to ensure the most favorable reception for the NHANES survey. Additionally, the software and systems groups begin work on the software specifications, design, and development. Once a system is designed it moves to development and then different levels of testing in preparation for pilot tests.

Field Operations

Throughout the course of a year, NHANES contract field staff interview and examine a nationally representative sample of approximately 5,000 people from 15 counties across the United States. One field office team of five people accompanies the MECs in each location to direct field operations. Two MECs are always in operation (with the exception of 2 two-week breaks), while the third is being readied for the next location. A team of approximately 25 interviewers travel from location to location conducting the household interviews in advance of the exams.

Once a participant has been screened into and consented to participate in the study at the household, an extensive personal interview is conducted. Upon completing the household interview the participant is scheduled for an appointment at the MEC about two weeks later. The two highly trained teams of examination, interview, and laboratory staff (15 in each location) conduct the health exams. A crucial piece of this effort is to ensure there is no bias between MEC teams and between health technicians and that the ERB-approved protocol is followed by examination staff, and that every survey participant (SP) is treated fairly, respectfully, and ethically.

After the participant completes the examination at the MEC he/she receives an initial report of findings and is remunerated for their participation in the study. About 12-16 weeks after completing the exam, a participant receives a final report of findings at their house which contains additional and more detailed information. If a participant has any questions they may contact the NHANES medical officer on a toll-free line. A separate hotline is maintained for providing sexually transmitted diseases (STD) results (in English and Spanish), and staff are able to provide to SPs a list of clinics in the participants' local area for those who test positive for STDs. A more comprehensive list of low or no cost clinics or health care providers in the local community is available as well.

Data Preparation and Dissemination

The NHANES data preparation and dissemination process is a multi-stage process consisting of data review, editing, and production of datasets and related documentation, collaborator review, and disclosure review. During NHANES III the data production and dissemination process required about three-and-half years to complete, with periodic additional releases continuing for many more years. For the continuous NHANES

starting in 1999, a large portion of the data are released within one year of the end of a two-year cycle. Most of the remaining data are released within one and a half years. The efficiency improvements over NHANES III are due to improved use of information technology for collecting data and intensive quality assurance / quality control. Note, before data files are released to the public, they are shared with NHANES collaborators for a period of two months, allowing for further scientific review. In addition, the data are reviewed by the NCHS Disclosure Review Board to ensure that the data will not pose a risk of disclosing the identity of a survey participant. Data that pose a risk are not released to the public and instead are available through the NCHS Research Data Center (RDC). The sheer volume and complexity of the NHANES data make the timeliness in data release a remarkable accomplishment.

Important Findings from NHANES

The NHANES data user community is diverse. A search of scientific publications listed in online databases reveals thousands of NHANES references published over the years, including text and reference materials used in medical schools and by public health professionals. The data are widely used by policy makers and planners in Federal, State, and local health agencies. As an example, NHANES is the only source of data for tracking progress towards many of the health objectives in Healthy People 2000 and 2010, the Department of Health and Human Services statement of health objectives for the Nation to improve their health. The NHANES findings cover areas such as chronic disease, immunization, diet and nutrition, infectious disease, and environmental exposures. A number of NHANES findings will now be described.

The NHANES data on overweight prevalence for children and adolescents is critical in the development of Federal nutrition recommendations, dietary guidance and policy. Examples include the U.S. Department of Agriculture National School Lunch and Breakfast programs; eligibility for participation in WIC; the 1995, 2000 and 2005 Dietary Guidelines for Americans and the Obesity Education Initiative of the National Heart Lung and Blood Institute. In public-private partnerships, the data are used by Shape Up America! and the American Health Foundation to promote campaigns for healthy weight and physical fitness. In academic research, the data are used to justify further research on the etiology and treatment of overweight and obesity. NHANES overweight data are pervasive throughout the popular media, in prevention programs, in connection with most chronic diseases, and so on. The data are cited in numerous government reports and is also used to set Federal health goals and guidelines.

When early NHANES surveys showed low iron levels, particularly for women of childbearing age, preschool children and the elderly, the government moved to fortify grain and cereal products with sufficient iron to correct this deficiency. In addition, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) established participant selection criteria using NHANES cut-off values. Now, NHANES monitors the iron level in blood, diet and supplements to monitor iron deficiency and ensure that iron overload isn't a problem, particularly for older Americans. Folate is another example of food fortification to meet a deficiency and, in this case, prevent certain serious birth defects. Again NHANES provides vital information on the safety

and adequacy of this decision and allows trend measures to evaluate whether higher levels have potentially harmful consequences in some population groups.

The National Heart, Lung, and Blood Institute's National Cholesterol Education Program recommends a healthy lifestyle, which includes reducing intake of saturated fat and cholesterol, achieving and maintaining healthy weight, and increasing physical activity for all adults, and regards additional efforts to promote such lifestyle changes to be important for achieving further improvements in the population's lipid levels. During the 1990s, public health messages emphasized low saturated fat and low cholesterol diets, maintenance of healthy weight, and increased physical activity. Furthermore, numerous clinical trials demonstrated the efficacy and safety of lipid-lowering drugs, primarily statins, in reducing coronary heart disease (CHD) risk.

Analysis of NHANES data shows consistent declines in the mean serum total cholesterol levels of adults, in the percentage of adults with serum total cholesterol level of at least 240 mg/dL, and serum total and LDL cholesterol levels between 1960 and 1994. A number of other lifestyle factors have been shown to be related to lipid levels in adults, including dietary intake of saturated fat and cholesterol, excess weight, and level of physical activity, and in both NHANES III and NHANES 1999-2002, data on these lifestyle factors as well as a broad spectrum of other health-related data were collected. The decrease in total and LDL cholesterol in adults between NHANES II and NHANES III was consistent with documented decreases in dietary intake of saturated fat and cholesterol. Between NHANES III and NHANES 1999-2002 data indicated the age-adjusted mean saturated fat intake as a percentage of total calories for adults aged 20 years or older decreased slightly in men and in women. The continued decrease of total and LDL cholesterol levels in older adults is a positive trend. Clinical trial results suggest that a 1% decrease in LDL cholesterol translates into a 1% decrease in relative risk for CHD. NHANES continues to monitor lipids and related lifestyle factors of CHD in the U.S. adult population and additional analyses of these critical population lifestyle factors and lipid data are important.

Immunization is one of the most basic, and yet effective, disease prevention strategies in the U.S. and the world. Immunization policies must be based on the latest and best data possible to target groups at special risk as well as protect society as a whole. Data from NHANES are used to update and improve immunization policies. For example, to better refine immunization policy for CDC's National Immunization Program, serologic testing for several vaccine preventable diseases is included in NHANES. Analysis of antibody levels for tetanus, pertussis, diphtheria, rubella, and measles during NHANES III revealed that several subgroups of the population were at risk due to lower levels of antibody. Analysis of the tetanus and diphtheria data demonstrated that older Americans were at risk for tetanus and diphtheria and needed to be targeted for the vaccine. In October of 2004, the National Foundation for Infectious Diseases started an immunization campaign called "The Power of 10" to raise awareness of the need for a tetanus and diphtheria booster every ten years. They used the data from NHANES III to provide the scientific rationale for the campaign.

Analysis of NHANES III data on immunity to rubella and measles established that immunity was high but that it varied by year of birth. More recent data from NHANES 1999-2004 provided important evidence that rubella transmission was not likely to occur in the U.S. population since immunity to rubella across the population is high enough at 91.3 percent that rubella transmission cannot be sustained. Comparing rubella immunity from NHANES III and NHANES 1999-2004 in different sub-groups of the population by age group and race and ethnicity demonstrated that all population subgroups examined are now at or above threshold immunity levels to prevent transmission of rubella. The increases in immunity between surveys is seen in groups targeted by current U.S. vaccine policy, mainly school-aged children and women of child-bearing age.

NHANES provides national estimates of the prevalence of HPV infection in the U.S. Data collected from NHANES 2003-2004 show prevalence of 26.8 percent in females aged 14 – 59 years – or 1 in 4 women are infected with HPV. The highest prevalence (44.8 percent) was found in the 20 – 24 year-old age group; prevalence then decreased with age. HPV strains 6 and 11 and 16 and 18 that are in the recently approved HPV vaccine, were detected in 3.4% of female participants. Data from NHANES were used to inform the ACIP about the epidemiology of this virus and its subtypes in the U.S. as they developed their recommendation for use of the quadrivalent HPV vaccine.

Biomonitoring documents exposure to environmental toxicants by direct measures of chemicals in blood or other biological specimens from individuals as opposed to measuring chemicals in environmental media and then modeling exposure in individuals. The collection of blood and urine specimens in NHANES provides a unique opportunity for monitoring environmental exposures in the U.S. population. Biomonitoring in NHANES began with the measurement of blood lead levels in 1976 when lead was being phased out as constituent of gasoline. The NHANES data showed that blood lead levels in the U.S. declined dramatically and in parallel to the reductions of lead in gasoline. This information was key to establishing legislation for the permanent removal of lead from gasoline.

A more recent example is the measurement of blood mercury levels for informing policies to reduce environmental exposures, which began in 1999. Humans are exposed to methyl mercury, a neurotoxin, through fish consumption. The fetus is the most sensitive to the adverse effects of exposure, but the extent of exposure in women of childbearing age and hence in the fetus was not known. Data from NHANES 1999-2000 shows that measures of blood mercury in women and children are generally below levels of concern, but the upper distribution of mercury levels in women indicates a narrow margin of safety. These data provided essential information to EPA and FDA for formulation of policies to reduce methyl mercury exposure among women of childbearing age.

NHANES is a complex program of vital national importance. NHANES serves as the hub for a number of related major activities and innovations. To successfully execute all of these efforts there is wide diversity and tremendous depth in the skills of program staff, partners, and contractual staff. Thus, the remainder of this document will cover the program structure, major activities, products, and challenges tied to NHANES. We will

end this document with our view of future opportunities to leverage NHANES and associated programs, to improve the health of America. Finally, please note that throughout the document the discussion moves between the Division of Health and Nutrition Examination Surveys (DHANES) and NHANES. DHANES has overall responsibility as the government division within NCHS that oversees NHANES and the related activities.

PROGRAM STRUCTURE

The DHANES program structure consists of many diverse disciplines in four primary groups, namely, NCHS government staff in DHANES, federal partners, contract field staff, and contract support services. The DHANES staff have primary responsibility for determining the scientific content, building partnerships, securing funding, handling ethical issues, monitoring field operations, reviewing data for quality assurance / quality control, producing public use micro data, and preparing analyses on the data. DHANES staff represents NCHS at professional scientific meetings, associations, and on working groups developing consensus statements and identifying need for health data. The current Federal staff of 53 persons includes epidemiologists, biologists, biomedical engineers, nutritionists and dieticians, environmental scientists, physicians, a dentist, nurses, mathematical and biostatisticians, public health and budget analysts, computer scientists, and administrative and clerical staff. There are vacancies across the Division as staff have left for other jobs or retired. These vacancies remain due to 1) lack of resources to hire additional staff, 2) inability to find appropriate candidates, and 3) difficulty in working with CDC Human Resources staff and processes.

Federal partners play a substantial role in NHANES as they provide scientific guidance and expertise, review field procedures, process and review data, and provide roughly 1/3 of the total budget. Field staff is provided by a data collection contractor (currently Westat) to serve in many different capacities. The data collection contractor also provides statistical design and information technology support. Within DHANES there are about 15 contractors provided by Harris Corporation and Northrup-Grumman/NOVA Research. These staff provide analytic support, data processing, and statistical programming. The next two sections provide additional detail on DHANES and the NHANES collaborators.

Division of Health and Nutrition Examination Surveys (DHANES)

Office of the Director

The DHANES Office of the Director (OD) has primary responsibility for providing leadership for the conduct of NHANES all the related projects and work. This involves planning, directing and coordinating the statistical and research activities of the Division. OD staff lead the development and administration of a research and analytic program, is responsible for monitoring the use of NHANES stored biological specimens, oversee the NHANES genetics program, provide leadership in genetics policy and research, and lead the development of the Community HANES (CHANES) initiative. The OD also participates in the development of policy, long-range plans, and programs of NCHS and provides advice and leads the development of collaborative partnerships within NCHS, CDC, and DHHS and externally with public, private, domestic and international entities on health and nutrition examination statistics and surveys.

Planning Branch

The Planning Branch (PB) is responsible for the planning, design, implementation, and oversight of new questionnaire, examination, and laboratory content. This includes soliciting and reviewing new content proposals; working with collaborators to review the

science, and refine, test and implement proposals; preparing OMB documentation; performing quality control on fielded content; observing field operations in households and in the MEC, and reviewing and helping to prepare data for public release. (Staff in the Planning Branch, and some in the Operations Branch also provide scientific consultation and prepare papers.)

Operations Branch

The Operations Branch (OB) is responsible for overseeing the full lifecycle of field data collection to ensure a continuous, unbiased, and ethically performed study. A portion of this effort is done under contract requiring OB staff to develop and administer the contractual work for data collection, engineering, acquisition and maintenance of the MECs. OB staff also represents NHANES before the NCHS ERB, and handle outreach to county health officials and survey participants. OB provides exam results to survey participants confidentially, and through a medical officer provides interpretation of results. OB staff oversees all aspects of quality assurance for NHANES, and design methodological studies as well. Lastly, OB staff contributes to the CHANES activities with conceptual design, cost modeling, preparing for field operations, and designing data collection methods.

Informatics Branch

The Informatics Branch (IB) is responsible for overseeing the design and development of the survey information technology architecture to support NHANES field data collection. IB contributes to the systems design work, which is prepared by the data collection contractor. As new laws have been enacted with greater responsibilities and requirements for government agencies in relation to security, risk management, project control, and financial performance, IB has taken the lead role in managing this effort. IB is responsible for the data review, production, and dissemination operation. Lastly, IB leads the effort to maintain and improve the NHANES website promoting greater accessibility to NHANES data, documentation, and reports.

Analysis Branch

The Analysis Branch (AB) provides statistical and scientific input for the analysis of NHANES and NHES data. AB staff prepares scientific papers on the prevalence of disease or health-related characteristics, and on the relationships of these variables as observed in the United States population. AB provides expert scientific consultation in public health research and analytic oversight for the DHANES data collection programs. AB also assists in the development, application and dissemination of analytic guidelines and methods of estimation appropriate to the DHANES data collection programs, and participates in study planning and evaluation functions as appropriate.

Collaborators

NHANES is a highly collaborative undertaking. Broad oversight for the survey planning and content is provided through consultation with stakeholders in order to maximize the utility of the survey data. Input on the content of NHANES is provided by numerous agencies within the Department of Health and Human Services (DHHS) including the National Institutes of Health (NIH), Food and Drug Administration (FDA), and CDC; non-DHHS Federal agencies (including the Environmental Protection Agency, U.S.

Department of Agriculture, and Housing and Urban Development); non-government organizations; and individuals (see Appendix E).

NHANES partnerships exist at multiple levels. DHANES staff works closely with collaborators to refine the new content, to ensure it is feasible for inclusion in NHANES, and has been sufficiently tested or validated. Collaborative efforts extend beyond implementation of new content in NHANES. Many collaborators continue to work closely with NHANES staff on data collection issues including the review and editing of data. Collaborators also provide expert observation during data collection and consult on needs that may arise in the field such as additional training for MEC staff and calibration of equipment. Their knowledge, skills, and expertise in a topic area are crucial assets to the program.

Benefits of Collaboration

Collaborators strengthen NHANES by providing financial support, identifying and addressing emerging public health issues, increasing data quality through input of subject matter expertise and consultation, and the sharing of statistical skills and authorship to enhance the contributions of the NHANES data to the scientific community and public health. The collaborator financial contribution is roughly one-third of the overall NHANES budget. By leveraging the NHANES infrastructure, the Federal government operates a very efficient means to collect considerable data. In return, our partners rely upon NHANES to provide high quality data essential for the establishment of policies, and the implementation and planning of research, education, and health promotion programs, as well as the evaluation of those programs. They also benefit from the full range of variables available due to the contributions of others. The richness of the dataset makes NHANES greater than the sum of its parts.

There are numerous examples of the long-standing and more recent partnerships between NHANES and other federal agencies. Here are a few examples of these partnerships:

- DHANES and the USDA Agricultural Research Service collaborate on the NHANES dietary intake interview. This is the only national 24-hour dietary recall. DHANES is responsible for the data collection, while USDA provides the back-end coding and the survey instrumentation. Both groups jointly release the data and analyze the results.
- DHANES and the CDC, National Center for Environmental Health (NCEH) work together to collect specimens and prepare and analyze data for *National Report on Human Exposure to Environmental Chemicals*. This report provides unique information to scientists, physicians, and health officials with the ultimate goal of preventing disease resulting from exposure to environmental chemicals.
- DHANES and the NIH, National Heart, Lung, and Blood Institute developed a blood pressure methodology study to compare mercury based-sphygmomanometer to automated devices. This study, which just recently completed data collection, is the first nation-wide population-based study to determine if automated devices are

comparable to mercury-based devices and can replace them in the exam center and elsewhere

- DHANES and the USDA, Economic Research Service, developed and implemented the Flexible Consumer Behavior Survey (FCBS) which gathers information about nutrition knowledge, attitudes, and beliefs from adults who have completed the medical exam and the 24-hour dietary recall. Assessing such linkages provides critical information on the dietary challenges facing Americans.
- DHANES and the NIH, National Heart, Lung, and Blood Institute and CDC, National Institute of Occupational Safety and Health resumed spirometry testing in 2007. Baseline lung volumes and air-flow rates are assessed; those with airway obstruction undergo repeat testing after inhalation of a short-acting beta-2-adrenergic bronchodilator. In addition, exhaled nitric oxide is assessed, providing a measure of inflammation in the lungs.
- DHANES and NIH, National Center for Diabetes and Digestive and Kidney Diseases developed and implemented questions on gestational diabetes. Women with a history of gestational diabetes (GDM) are at extraordinarily high risk for development of diabetes. NHANES is the only national health survey that collects information about women with GDM. These two groups as well as CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation collaborate on the overall assessment of diabetes and pre-diabetes in the U.S. population.
- DHANES and the Environmental Protection Agency (EPA) added questions to assess asthma medication use among adults 20 years and older and refined questions for all participants on behaviors in response to air pollution.
- DHANES; CDC, NCEH; CDC, National Center for Birth Defects and Developmental Disabilities; NIH, Office of Dietary Supplements; and the Food and Drug Administration are part of a five-way partnership on a folate methods study to determine the most appropriate laboratory method and assay for measuring blood folates. There currently is no gold standard folate measurement and the assay used in NHANES prior to 2007 (Bio-rad) was discontinued by the manufacturer. NHANES specimens are being processed by three different labs using two different assays.

Extensive consultations also occur in meetings with current collaborators and other agencies interested in NHANES. NCHS staff makes numerous presentations throughout the year at major medical and public health professional meetings as well as internal meetings organized by Federal agency research staff. Other mechanisms have been used to gain input on NHANES priorities and future surveillance needs. In September 2003, the DHANES Director held a forum to identify NHANES priorities. The meeting format utilized “Open Space Technology,” a participatory process that is conducive to the exchange of information on diverse topics among groups of interested individuals. NCHS staff and stakeholders attended the forum and interacted to gain insight into

expectations and needs of NHANES stakeholders. Attendees identified the challenges, strengths, and limitations of NHANES, and provided extensive feedback on ways to improve the utility of NHANES to the public health community.

OTHER MAJOR ACTIVITIES

NHANES serves as the core function of DHANES. As described in the first section, NHANES has a long history and many important achievements. NHANES is the gold standard for all other population-based health and nutrition examination surveys. While NHANES is the primary business line of DHANES, there are numerous other efforts underway. These efforts are innovative in nature and include community-based and longitudinal studies, genetics, environmental assessments, and data linkages. These project lines and special projects are now described.

Community HANES

While NHANES serves the needs of the nation as a whole, no comparable program is available to support states, local communities, or special populations such as the underserved or those with health disparities. The Community Health and Nutrition Examination Survey (CHANES) is an initiative to build capacity for health and bio-monitoring at the community level by leveraging the expertise, experience, methods, protocols, information technology, and equipment within DHANES. CHANES can provide rapid access to data with the expected time from the start of a study to data dissemination of less than three years. DHANES has worked on this initiative for several years, built several community-based trailers, developed a conceptual framework, and had discussions or consulted with over thirty different communities in this regard. The information from CHANES is crucial to state and local health policy and program implementation.

In 2003-2004, NCHS helped the New York City Department of Health and Mental Hygiene successfully conduct the first NYC HANES. DHANES produced the study design, developed the information technology, planned the data collection methodology, adapted NHANES protocols, conducted pilot testing and dress rehearsals, and consulted during the field operations. By using comparable methods, NYC identified how the health of the city's population deviated from the health of the Nation thus highlighting their most significant health issues. Objective health estimates of selected conditions such as diabetes, high blood pressure, high cholesterol, and depression were produced allowing NYC to better direct resources to the health needs of New Yorkers.

Similarly, DHANES is currently working with the California Department of Public Health in planning a state biomonitoring program, using the NHANES methods and procedures. We are encouraged by the number and types of requests that we receive to support these community-based efforts. We anticipate more collaborative community-based efforts in the future.

Longitudinal HANES

Collecting data on the same survey participants over time provides insight into the natural history of diseases and the future risk of morbidity and mortality related to factors collected at baseline. NHANES is currently designed as a cross-sectional study design and longitudinal follow-up is limited to linkages of survey participants with the National Death Index, Medicare enrollment and claims data, and Social Security Administration records. An active NHANES longitudinal study has not been done since follow-up of

NHANES I participants (who were examined between 1971 and 1975). Conducted by the Office of Analysis and Epidemiology (OAE) at NCHS, four waves of the NHANES I Epidemiologic Follow-up Study (NHEFS) were done between 1982 and 1992. The vital status for the NHANES I cohort was established through tracing and the collection of death certificates. The data collected in the four waves varied; the first wave included limited health measurements in addition to information taken from hospital medical records and personal interviews. The remaining waves were exclusively medical record abstraction and interviews. Tracing and data-collection rates in the NHEFS were very high. Ninety-six percent of the study population has been successfully traced at some point through the 1992 follow-up. The data from NHEFS have been widely used to study important predictors of health best studied using a longitudinal design. While NHEFS was not conducted by DHANES, the Division has long maintained the desire to conduct another longitudinal follow-up of NHANES participants should the opportunity/resources become available.

OAE continues to match survey participant name and address to the National Change of Address (NCOA) database for participants in NHANES I, III, and 1999-2004. The NCOA is an electronic database of all USPS deliverable addresses and includes address updates for persons who file a change of address card with the Post Office when they move. When this match is conducted, OAE gets back the new address information for only those who reported their move. There is no confirmation that the other individuals previously in the survey continue to live at the last address of record. It is reasonable to assume that most are located at that address, although some unknown number of persons moves without filing a change of address notification with the Post Office.

Analysis Program

DHANES has an ambitious analysis program and has made significant progress towards achieving outlined goals. The program consists of four main goals:

- Foster DHANES research that evaluates the magnitude, impact and risk factors for chronic and infectious diseases, and nutritional, environmental and genetic risk factors in the U.S. population;
- Expand the cadre of research scientists who appropriately analyze NHANES data;
- Explore and expand new approaches to NHANES data analysis; and
- Increase access to NHANES analytic documents and findings to inform and educate researchers, policy makers and the public about NHANES.

Significant progress has been achieved on these objectives. In 2005-07, NHANES staff published 22 NCHS reports, including new types of publications such as the MMWR QuickStats and NCHS Data Briefs. This is a 25% increase since 2002-04. NHANES staff also published more than 25 journal articles using the continuous NHANES data, including three *JAMA* articles and one *Annals of Internal Medicine* publication (2 of the top 10 essential science citation journals in the field of medicine).

DHANES released the NHANES Web Tutorial in the fall of 2006 to expand the scientific user base and ensure that educational tools are available to learn about analyzing NHANES data. Additional content has been added as more modules have been developed, including tutorials for NHANES I, II, and III. The tutorial has received over 90,000 web hits. The tutorial is described in more detail later.

DHANES has also explored novel approaches to NHANES data analysis such as new laboratory and analytic methods. From 2005-2007, reports and presentations were prepared on the effects of measurement error on the prevalence of hypertension; the impact of converted refusals upon survey estimates; investigation of laboratory methods for iron and serum vitamin D; construction of confidence intervals for extreme proportions; small area estimation; and analysis of new analytic datasets. DHANES has worked to increase access to analytic documents, and in essence, serve as a one-stop resource for current and historical NHANES survey data, planning, implementation and analysis documentation and findings. Much of the NHANES legacy documentation has been scanned, converted to portable document format (PDF), and placed on the NHANES homepage.

International Collaboration

The desire to conduct health examination surveys in other countries, based on direct physical measures, has increased. This is especially true in the last ten years. DHANES staff has had a significant consultative role in many of these efforts. In the late 1990's, DHANES staff were actively involved in the planning of nutrition surveys in New Zealand and Australia. In both countries, many of the nutrition measures included in NHANES were successfully adopted for use in the surveys in each of those countries. DHANES has also been involved in the planning and execution of health examination surveys in Korea and even more extensively in Canada. In fact, numerous staff in the division are still involved in these two national health examination surveys modeled after NHANES. These international collaborative efforts have (and will) provide the opportunity to make international comparisons of a variety of critical public health issues, as well survey methods where we have differences. Additional efforts continue to arise. The most recent collaboration is with the European Union (EU). They are proposing to conduct health examination surveys in all of the countries within the European Union during the next decade. DHANES staff are advising public health experts in the EU on the best practices to follow in the conduct of such surveys. Thus, international consultation/collaboration has been, and remains, a significant activity within the division.

Special Projects and Innovations

In addition to the core business lines of DHANES, there are myriad special projects underway that the division leads, facilitates, or contributes to in some way. These projects leverage the national survey to study areas of public health significance that require national probability samples. In effect, they broadly cover the areas of methodological research, surplus sera/urine/plasma, DNA samples, environmental bio-monitoring, nutrition monitoring, and other data linkages.

Methodological Research

DHANES recognizes the importance of conducting methodological research and has conducted multiple projects over the years, but has struggled to maintain this as a core function in the Division. Projects have spanned many diverse areas with the goal of increasing response rates, improving the quality of the data, collecting more diverse data, and providing estimates at the sub-national level.

Examples in the area of survey design and analytic research include optimum selection of primary sampling units; variance estimation and design effects; and multiple imputation. In the area of survey operations examples are remuneration studies; multiple evaluations of response rates and non-response; small area estimation; and use of fixed sites versus MECs. Examples in the area of the science and content of the survey include evaluation of the comparability of various blood pressure measurement devices; evaluation of various folate or other laboratory methods; and additional utilization of previously collected x-rays and ultrasound tapes for alternative research proposals. In addition, almost all the content of NHANES goes through pilot testing and/or cognitive lab testing before implementation in the full survey.

Surplus Sera/Urine/Plasma

Starting in NHANES III (1988-1994), biologic specimens were collected and stored for future research studies. The biologic specimen repository allows NHANES to offer specimens from a representative sample of U.S. population to answer relevant public health questions that were not considered at the time the survey cycle was planned. Since 1991, proposals have been accepted for use of these specimens. Proposals are accepted on a continuous basis and are reviewed for technical merit by a review board that includes laboratory scientists, epidemiologists and medical officers. To date, there have been 43 proposals approved for NHANES III specimens, and 16 proposals for use of the continuous NHANES samples. The data from these proposals have been released for public use. These data are released to the public and have added to the previously released NHANES laboratory data and provide information on emerging public health issues long after the survey cycle has been completed. Researchers who have collaborated on these projects are from CDC, other federal agencies and academic institutions.

DNA Samples

DNA specimens were collected during the second phase of NHANES III (1991-1994), NHANES 1999-2002, and are currently collected as part of NHANES 2007-2008. Genetic information collected from these DNA specimens is used in conjunction with the extensive amount of non-genetic information collected for the purpose of describing the health of the U.S. population. NHANES III DNA samples derived from crude lysates of cell lines have been used for 18 proposals that have generated information on almost 200 genetic variations. Currently five proposals are being reviewed for use of these specimens from the 2008 request for proposals. The genetic data collected in these research studies are used in prevalence and genetic association studies. Additional research is also possible as these data are made available for secondary analyses in the NCHS RDC. To date, 15 proposals have been accepted and approved for secondary data

analysis. Proposals for use of these specimens and secondary data have been received from other CDC Centers, NIH, and academic institutions.

In 2008-2009, it is anticipated that high-throughput genotyping will be performed on the NHANES III and NHANES 1999-2002 specimens generating 1-2 million genetic variants per sample. These data will provide a valuable resource for investigating the effects of genetic variation and health in addition to providing population-based estimates of single nucleotide polymorphisms (SNPs) and other genetic variants in the U.S. A collaborative effort from multiple Centers at CDC, NIH Institutes and academic and commercial institutions are coming together under the Beyond Gene Discovery initiative spearheaded by CDC's National Office of Public Health Genomics to provide resources (both financial and intellectual) for this project.

The genetic data generated from all these efforts builds on the richness of the NHANES demographic and phenotypic data to provide unbiased estimates of genetic variation in the US. The oversampling of the two largest ethnic minorities, non-Hispanic blacks and Mexican Americans, makes this dataset especially unique and beneficial since research efforts in this field have generally not focused on these race/ethnic groups.

Environmental Monitoring

Assessment of environmental exposures has been a component of NHANES beginning with the measurement of blood lead levels in the late 1970s. The major method to measure environmental exposures in NHANES is through biomonitoring, an assessment of exposure to environmental contaminants through measurement of chemicals in blood or urine specimens. In the current NHANES, biomonitoring has expanded to include measurement of over 200 chemicals using the blood and urine specimens that are collected and processed as part of the examination component. Many of these chemicals are processed only due to technological advances in laboratory methods. These methods allow measurement of many different chemicals in small specimen volumes and at very low concentrations.

NHANES environmental biomonitoring data are used to determine which environmental chemicals Americans are exposed to, the extent of exposure, and for chemicals with a known toxicity level, the prevalence of exposure above that level. The effectiveness of programs or policies that are implemented to reduce exposure to specific environmental chemicals is gauged through monitoring trends with these data. Further, the NHANES data establish reference ranges that may be used by state and local public health physicians and scientists to determine whether an individual or group has an unusually high exposure. These data are also useful for setting priorities for research on human health effects from these exposures.

In addition to biomonitoring, NHANES has also included other measures of environmental exposures. These include measurement of personal exposure to volatile chemicals through the use of passive exposure monitors and measurement of environmental chemicals in household dust and water samples, measurement of indoor allergens, and endotoxin from household dust samples. Moreover, NHANES is the only national survey collecting dietary intake data, which in combination with NHANES

laboratory data are essential for the Environmental Protection Agency (EPA) to assess dietary intake of environmental chemicals as part of its safety determination process for such chemicals.

The NHANES environmental exposure assessment components are conducted through collaboration with many groups. CDC's National Center for Environmental Health (NCEH) is the main collaborator for the environmental biomonitoring for whom these data provide the basis for their major report series, the *National Report on Human Exposure to Environmental Chemicals*. Nearly all these laboratory analyses are done in NCEH's state-of-the-art laboratories in Atlanta. The Department of Housing and Urban Development, EPA, National Institute for Environmental Health Sciences of the National Institutes of Health, and the Mickey Leland National Urban Air Toxics Research Center, a private sector organization funded in part by the EPA, have also been collaborators.

Nutrition Monitoring

Nutrition monitoring in the United States is a complex system of coordinated activities that provides information about the dietary, nutritional, and related health status of Americans; the relationships between diet and health; and the factors affecting dietary and nutritional status. The National Nutrition Monitoring and Related Research Act (NNMRRRA) of 1990 (P.L. 101-445) was signed into law on October 22, 1990. The Act called for a 10-year comprehensive plan for nutrition monitoring and related research.

In part due to this attempt for greater planning related to nutrition monitoring, CDC/NCHS and USDA/Agricultural Research Service (ARS) have worked together to collect and report the dietary interview data from NHANES since 2002. The two agencies integrated the Continuing Survey of Food Intakes by Individuals (CSFII), formerly conducted by ARS, forming an expanded dietary interview component in NHANES. The two agencies jointly fund the NHANES dietary interview component, a core component of the survey that all examined persons are eligible to complete. This is a rare, successful example of two Departments working together on an endeavor requiring extreme coordination to achieve the research missions of both Departments more efficiently.

In addition to the dietary interview component, the NHANES nutritional status assessment component includes anthropometry, nutritional biochemistry and hematology data, and extensive interview information on dietary supplement use, alcohol use, consumer behavior related to food purchases, preparation, and expenditures, nutrition assistance and program participation, weight history and behavior, and food security. Moreover, the NNMRRRA requires USDA and HHS to jointly review all nutrition education and dietary guidance information released by either department. The 5-year review and publication of the *Dietary Guidelines for Americans* was mandated in the 1990 Act. Joint agency coordination is continuing and planning has begun for the 2010 *Dietary Guidelines for Americans*.

Most of the NNMRRRA expired in 2003. A variety of legislative proposals have been put forward over the years to reauthorize the original Act and ensure ongoing administration of the joint survey and regular updating of the food composition database. In the current

Congress the issue is being addressed as part of the Farm Bill which includes general language reflecting the ongoing HHS and USDA efforts to maintain and improve nutrition monitoring activities. NCHS' statutory authority to collect data on a wide range of health issues allows us to continue our nutrition monitoring activities even without a law such as the NNMRRRA specifically directing NCHS to do so.

Although there is no formal nutrition monitoring legislation in effect today, NCHS, USDA, and numerous other Federal agencies meet regularly to coordinate survey data collection and research priorities. The National Institutes of Health (NIH) sponsors monthly meetings of the NIH Nutrition Coordinating Committee and the NHANES Interest Group. NCHS and USDA co-plan stakeholder meetings as needed to inform the research and policy communities of survey activities and data products. NHANES is the only source of nationally representative dietary intake and nutrition status data, and formulation of future dietary guidelines, dietary reference intakes, food fortification policies, food program policies, as well as Healthy People 2010 objectives rely upon ongoing NHANES data collection. NHANES nutrition and dietary data are used heavily by private industry as well.

Linkages

NHANES data have been linked with death certificate records from the National Death Index (NDI), Medicare enrollment and claims data from the Centers for Medicare and Medicaid Services (CMS), and Retirement, Survivor, and Disability Insurance (RSDI) and Supplemental Security Income (SSI) benefit data from the Social Security Administration (SSA). Linked data files enable researchers to examine the factors that influence disability, chronic disease, health care utilization, morbidity, and mortality.

Due to the confidentiality NCHS promises its survey participants, no geographic information is available on the NHANES public use data sets. However, many important research questions require the ability to link geography to health and/or the ability to link external data sets which utilize finer geographic detail. Recently, DHANES engaged the Department of Housing and Urban Development (HUD) to geocode NHANES III and NHANES 1999-2004 datasets. This effort utilized the expertise of HUD's "Geospatial One-stop Shop" for this effort. DHANES will continue this effort with HUD for each two year cycle.

All of these linkages must be performed in the NCHS RDC. The RDC is in the unique position of providing secure access to the full range of health and vital statistics information collected by the NCHS data systems, while continuing to protect the confidentiality of respondents and records in a controlled environment. Researchers submit proposals to the RDC to use variables from NHANES or other data sets that have been collected, but due to disclosure avoidance concerns, were not publicly released.

PRODUCTS

Public Use Micro Data

One of the core functions of the Division is the production of public-use micro data sets representing the health measures collected by NHANES examinations and questionnaires. These data are used primarily by private industry, researchers, health practitioners, students, and others in the public health sector for a variety of investigations and analyses of the incidence, prevalence, and interrelationships of numerous health conditions in the general population. DHANES primary goal in this regard is to make high quality data accessible to the public as quickly as possible following the completion of data collection. DHANES released the first set of data files from the 2005-2006 NHANES in November 2007, just 10 months after the completion of data collection.

HES I through NHANES II typically clumped most of the data together into a single file or a few large data files. In contrast, NHANES III and the continuous NHANES moved to smaller datasets covering specific content areas. This change allows for easier manipulation, merging, and maintenance of data. For the continuous NHANES, each two year cycle results in a combined data release consisting of between 3500 and 4000 data items spread across demographics, personal interviews (questionnaires), physical measures (examinations), and laboratory assessments. The number of items per person varies however based on factors such as age, gender, and non-response. These counts do not include data from stored biologic specimens including genetic data and other data held in the research data center.

Publications

Though DHANES staff have various research interests and plans for potential publications, data are not held as proprietary to allow the Division, or any other collaborators providing technical or financial support to achieve their analytic goals before allowing others to access the data. Findings based on analyses of NHANES data inform debate on public health issues, and are frequently cited by researchers, public officials, and lawmakers in support of policies and initiatives.

DHANES staff were at the forefront in developing a new publication series entitled NCHS Data Briefs. NCHS reports currently do a better job of presenting information to technical audiences than to less technical audiences such as those engaged in health policy and programs. The purpose of this series is for NCHS to better address the needs of non-technical audiences, especially those who engage in health policy and health programs. Short reports focused on specific health topics would improve accessibility and likely increase interest in NCHS data among policy and programmatic audiences as well as the general public. The Data Briefs are concise accessible summaries of current public health topics written in non-technical terms with primary display of statistical findings in a graphical form. The Data Briefs are designed for timely publication through Internet release as well print format. Data Briefs are published on the web in PDF format so that the report can be printed. Charts are also available in PowerPoint. DHANES staff wrote the first four data briefs, which were published in November 2007 through January

2008. These publications allowed the division to produce important findings from NHANES 2005-2006 within a year of completion of data collection for that survey cycle. The data briefs presented the latest findings on obesity, total cholesterol levels, hypertension, and HIV infection in the U.S. population. These Briefs received wide media attention. For a list of these and selected other DHANES publications, refer to Appendix F.

Pediatric Growth Charts

The pediatric growth charts consist of a series of percentile curves that illustrate the distribution of selected body measurements in U.S. children. Since 1977, these growth charts have been used by pediatricians, nurses, and parents to track the growth of infants, children, and adolescents in the United States. The 1977 growth charts were developed by NCHS as a clinical tool for health professionals to determine if the growth of a child is adequate. The 1977 charts were also adopted by the World Health Organization for international use.

When the 1977 NCHS growth charts were first developed, NCHS recommended that they be revised periodically as necessary. With more recent and comprehensive national data now available, along with improved statistical procedures, the 1977 growth charts were revised and updated to make them a more valuable clinical tool for health professionals. The 2000 CDC growth charts represent the revised version of the 1977 NCHS growth charts. Most of the data used to construct these charts come from NHANES

Growth charts are not intended to be used as a sole diagnostic instrument. Instead, growth charts are tools that contribute to forming an overall clinical impression for the child being measured. The revised growth charts provide an improved tool for evaluating the growth of children in clinical and research settings. The revised growth charts consist of 16 charts (8 for boys and 8 for girls). These charts represent revisions to the 14 previous charts, as well as the introduction of two new body mass index-for-age (BMI-for-age) charts for boys and for girls, ages 2 to 20 years. The addition of the BMI charts is probably the single most significant new feature of the revised growth charts.

These BMI-for-age charts were created for use in place of the 1977 weight-for-stature charts. BMI is calculated from weight and height measurements and is used to judge whether an individual's weight is appropriate for their height. BMI is the most commonly used approach to determine if adults are overweight or obese and is also the recommended measure to determine if children are overweight. The new BMI growth charts can be used clinically beginning at 2 years of age, when an accurate stature can be obtained.

NHANES Web Tutorial

DHANES, in partnership with the National Cancer Institute (NCI), developed the NHANES Web Tutorial (NWT). The NWT is the first-ever web-tutorial developed for an NCHS survey system. The effort was a collaboration between research analysts, statisticians and programmers, information technology specialists, instructional designers and science writers.

The NWT was developed to meet the growing demands of NHANES data users and to promote broader and more proficient use of NHANES data. After NHANES data were made accessible on the NCHS website in 1998 and PC-based statistical software became available, the NHANES user-base increased dramatically and became more diverse (from graduate student to expert researcher). No matter what level of experience, all NHANES users face similar challenges due to the complexity of the survey design and vast amount of NHANES data that is available. This tutorial teaches users how to: efficiently locate pertinent information on the NCHS website; quickly retrieve NHANES data files and variables to prepare an analytic dataset; and correctly conduct intended statistical analyses with appropriate attention paid to the nuances of NHANES data, given its complex sample design, weighting requirements, and data structure.

The tutorial integrates the vast amount of information on NHANES data with pertinent statistical and programming techniques, and used multi-media web design features to create a user-friendly online learning tool suitable for a wide range of NHANES data users. The tutorial offers analysis tracks in several of the statistical software packages available to analyze complex survey data such as SAS Survey Procedures and SUDAAN. In essence, it serves as a textbook of best practices for analyzing this data and is now part of the accredited CDC online learning courses, offering over nine hours of CMEs or CNEs, or 0.8 CEU credits.

The NWT has received thousands of hits each month, placing the power to get answers on NHANES data and analysis questions in the hands of users 24/7. NWT has been picked up, blogged or featured by a number of academic sites and professional organizations, and has over 900 Google listings. For new NHANES staff, the tutorial has reduced the timeframe for proficiency in NHANES analysis from 3-4 months to 3-4 weeks.

CHALLENGES

DHANES is an ambitious program addressing many important public health needs. The complexity of the program ranges from the operational intensity, contractual arrangements, stakeholder relationships, to intra/inter-departmental agreements. The confluence of these myriad aspects along with new legislative mandates, tight budgets, and retaining a skilled labor force require tremendous dexterity to manage. Over the years, NHANES has remained nimble by responding to uncertain budgets, program shut-down and start-up, the demands of survey operations, emerging public health issues, legislative and legal requirements, stakeholder relationship management, consultation, competition, new methods, and technological changes. This is not meant to be an exhaustive list, but conveys many of the most important issues that DHANES must deal with to conduct NHANES. They will be covered in the following sections.

Budget

The NHANES program receives funding from a variety of sources. The two main sources of funding include direct funding through the NCHS base budget and reimbursable funding from collaborating agencies. Additional support is provided as “in-kind” services such as scientific and technical support, laboratory and data processing, and consultation. In the 2007 and 2008 DHANES budgets, NCHS provided \$18M per year, and an additional \$12M per year came from the reimbursable agreements with our collaborators. However, between field costs, support services contracts, laboratory and reading costs, building new trailers, and DHANES operating expenses, the expenses totaled approximately \$32M. The shortfall was funded with carry-over funding from previous years (see Appendix G). NCHS has special legislative authority to carry reimbursable funding from outside CDC across fiscal years.

The outlook for 2009-2010 is not as clear however. While field costs have not risen beyond expectations, there are a number of issues that are of concern moving forward. In general, the NCHS outlay and reimbursable funds are not increasing, and without an infusion of money the study will be under funded during 2009-2010. Economic conditions cannot be predicted, but do have impact on the field operations. Rising travel and hotel costs generate increases in the field as the field office staff, survey interviewers, and examination staff move from location to location for most of the year, and are essentially in full-time travel status. While collaborator funding appears to be relatively steady we must be mindful that our collaborating departments and agencies may have their own budgetary concerns over the next couple of years. Without, a significant funding increase, fielding NHANES beyond 2010 will be very difficult and it will be impossible to consider IT re-engineering or replacing the fleet of aging trailers.

We have been weighing a number of options to achieve costs savings in NHANES in 2009-2010. There are no options that are desirable to us at this point to save the amount of money we need to keep the program operational, and all options will have implications related to operations, science, with our collaborators, or all of the above. If we eliminate the oversampling beginning in 2009, this would lessen screening by 70% and save approximately \$1M per year. Other changes could be made such as reducing to 12 PSUs, shortening the interview and going to a 3 trailer exam. This would save an additional

\$500k per year, still leaving a deficit, but perhaps a more manageable shortfall for NCHS to cover.

Another option is to continue with the current survey design anticipating that the proposed increases in the 2009 President's budget will come. If those funds do not come, then changes can be made mid-cycle to save money. The only change that would save a significant amount of money is to reduce field staff by eliminating a field team and taking twice as long to examine the same number of people. Aside from the scientific issues with starting an NHANES cycle with one design and finishing with another (or not finishing at all) which might be surmountable, given NHANES' reliance on reimbursable funding, we feel that giving our collaborators anything less than what we initially promised the survey to be at the beginning of the cycle would be unethical. A mid-cycle change likely would bring irreparable damage to the reputation of DHANES and NCHS.

Field Operations

There are numerous challenges in fielding NHANES. These challenges include: a) interaction with survey participants; b) maintaining the MECs; c) field staff fatigue; d) maintaining a high response rate; e) the rigor of cross-country travel; f) an un-yielding schedule; g) and on occasion simultaneous operations in as many as four locations (stands) when there is stand overlap in field office operations. There are numerous conceptual stages to NHANES field operations as depicted in Appendix H. Once in the field, the first step is advance arrangements which consist of securing space for the field office and MEC and meeting with community dignitaries and public health officials to establish strong connections within the community. Continued outreach is maintained in the community throughout the duration of time that NHANES conducts operations in county. After the field office is established, letters are mailed to participants in advance of a visit by a field interviewer. Next interviewers conduct screening at the doorstep and if a person is interested in participating and they (or other household members) screen in, they are asked to participate, review and sign an informed consent document, and then a personal interview is conducted. After the completion of the interview, they are invited to participate in the examination at the MEC. After the participant completes the examination they receive a preliminary report of findings along with remuneration for participating in the study (see Appendix I). There are challenges to obtaining or maintaining the sample persons' participation at each and every one of these stages and a significant amount of staff time and resources are devoted to maintaining high survey response rates.

Survey Participants

There is increased difficulty in screening potential survey participants. This difficulty is manifested in all demographics. Wealthy people, and now even middle class people, are increasingly living in gated communities. This works to our advantage when it is possible to identify a gated community manager willing to work with NHANES. However, more frequently the result is increased difficulty of access and at least an initial rebuff from community management.

It is also becoming increasingly difficult for screened survey participants to participate in the study. Almost all causes of non-participation are variations of increased time

pressures, such as family responsibilities and employment. Travel time to the MEC has increased and in urban areas the travel may be unpleasant. Except for the unemployed, many households work more than the standard forty-hour week, making additional time commitments difficult to keep. Further, there is an increase in the number of languages spoken by participants, resulting in a greater need for translation services. While response rates have declined since 2001, NHANES has been able to maintain a relatively high response rate in comparison to other studies. From NHANES I through NHANES 2005-2006 NHANES has achieved at least an overall response rate of 73% or better (see Appendix J).

Field Staff

As NHANES has been in continuous operation since 1999, a portion of the field staff has been on the road continuously for ten years. (Some staff worked on NHANES III as well.) These staff have made a personal commitment to NHANES and clearly exhibit an *esprit de corps*. However, the travel environment for field staff has become less interesting as NHANES returns to some several of the same survey locations. Natural attrition has taken place at all levels throughout the contract, but it is unclear who is rising through the ranks to succeed a number of the staff that has been working on NHANES since the late 1970s or early 1980s.

There is also increased anxiety regarding the future on NHANES. As the survey continues, seasoned management is beginning to retire. Coupling this with uncertain funding, the rigors of travel, and competition from other large-scale surveys coming on-line, it is becoming increasingly difficult to maintain interest and a competitive advantage for hiring new field staff.

Stakeholder Relationships

Collaboration with stakeholders is of incalculable value. These collaborations add scientific expertise, improve the scope and quality of NHANES data, provide funding, quality assurance / quality control, training, oversight, and data review. In fostering these partnerships challenges do exist. Some of the proposed questions or examination components are not feasible for inclusion in a mobile survey such as NHANES. Time constraints, respondent burden, logistical considerations, safety concerns for participants or staff, and cost are some of the factors that prevent some proposed topics from being included in NHANES. Additionally, some proposers have asked that data they have funded not be publicly released, and this is contrary to NCHS data use and release policies.

Ongoing communication between DHANES staff and stakeholders and a willingness to find common ground, has enabled DHANES to foster many mutually beneficial working relationships with our partners. A challenge facing both DHANES and partners is funding NHANES and other major health survey data collection systems. Just as appropriated funding for NHANES in 2009 and beyond is uncertain, the level of discretionary funds available in collaborating agencies has declined. Efforts to improve data collection efficiency while maintaining data scope and quality are continuing, but if our costs continue to escalate, we may eventually find fewer of our collaborators can afford to participate. Under the current cost sharing of NHANES, with collaborators

funding nearly one-third of the costs, a substantial decline in collaborator funding would be disastrous to the future of NHANES.

Legal and Legislative Requirements

Research Ethics Review

All research involving human participants conducted or supported by the Centers for Disease Control and Prevention must comply with the Department of Health and Human Services Policy for Protection of Human Research Subjects (45 CFR part 46). The NHANES survey protocols are subject to initial and ongoing review by both the NCHS ERB and the NHANES data collection contractor's Institutional Review Board.

Ethics review had been more prominent over the last several cycles of the survey requiring comprehensive documentation of survey procedures. The ERB most recently reviewed and approved NHANES 2005-2006 protocol. Since that approval, the survey has been amended 46 times. The volume of these changes is due to any change in protocol, such as using new outreach materials to improve respondent cooperation. In addition, component changes such as the new exams introduced in the 2007-08 cycle are reviewed by the ERB as amendments. The survey is also subject to an ongoing annual review by the ERB. The NHANES program provides a narrative summarizing response rates, incidents, reports of findings production timeliness, and new findings.

In planning new protocols, the NHANES program must anticipate at least six weeks for ERB review and approval, unless changes to the protocol are minor and receive an expedited review. New protocols must first be cleared by the NCHS Associate Director for Science and then the NCHS Confidentiality Officer. After these clearances the NCHS ERB reviews the proposal, although it rarely approves a new protocol on initial submission. The NHANES program is often asked to respond in writing to questions posed by email from the ERB. Approvals to amendments are usually obtained anywhere from six weeks to four months from original submission.

Confidentiality

Safeguarding the confidentiality of NHANES data is an important concern to DHANES. NCHS operates under the authority and restrictions of Section 308(d) of the Public Health Service Act, the Privacy Act of 1974, and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), which provide, in summary, that no information obtained in the course of NCHS activities may be used for any purpose other than the purpose for which it was supplied. Additionally, this information may not be published or released in a manner in which the establishment or person supplying the information can be identified. DHANES prepared a Privacy Impact Assessment (PIA) for the NHANES, which is posted on the DHHS website. This informs the public about the security controls applied to personally identifiable information (PII) collected by the NHANES. Possible confidentiality and security breaches are handled in accordance with requirements set forth by the Office of Management and Budget (OMB) and must be reported to a centralized reporting system within one hour of receiving the information. The NCHS ERB also monitors these breaches. Policies and procedures related to access privileges for NHANES data, for both in-house (NCHS) and external data users, are

constantly monitored and updated to meet new concerns related to ever-changing technology.

Security

NHANES data are collected under section 308(d) of the Public Health Service Act and subject to the restrictions of this Act, as well as related statutes including the Privacy Act and CIPSEA. DHANES federal and contract staff are subjected to a thorough background check prior to being given access to data, and must sign annual confidentiality agreements informing them of their responsibilities and liabilities under law. The Department (HHS) and the Agency (CDC) each provide minimum standards for physical security of facilities and for configuration of information technology (IT) systems, as well as Rules of Behavior for staff with data access. Over and above these Department- and Agency-wide policies, DHANES imposes an additional layer of security requirements. NHANES data are encrypted at the point(s) of collection and resides in secure databases throughout its lifecycle. Physical data servers are kept in a separate locked enclosure within the secured NCHS facility, accessible only by authorized DHANES staff. On the CDC network, servers are firewall-protected and reside on a separate network subnet, also accessible only to authorized DHANES staff. Access to the non-public data are granted strictly on a need-to-know basis within the Division and is continuously monitored. Any breach of security resulting in loss of data or identification of survey participants would have catastrophic consequences for the program; however, owing to the skill, dedication, and vigilance of DHANES staff, there has never been such an incident in the nearly fifty years of NHES and NHANES data collection.

CPIC / Exhibit 300

Congress and OMB have stated that each executive agency must actively manage its IT program. The goal is for agencies to develop policies and processes that implement systems at acceptable costs, within reasonable and expected time frames, and that contribute to tangible, observable improvements in mission performance. Therefore, Capital Planning and Investment Control (CPIC) processes have been institutionalized throughout HHS, to ensure compliance with the HHS Enterprise Architecture. CPIC uses systematic selection, control, and continual evaluation processes for all IT-related decisions, enabling CDC to translate business priorities into IT investment decisions that increase the business value received from the IT investments. CPIC processes include the Exhibit 300 and earned value management (EVM) reporting.

The OMB-required CPIC reporting places a significant administrative reporting burden on the Division. A variety of information on operations, expenditures, and performance measurements must be assembled from multiple sources and reported using department-provided web-enabled software tools. Updates to various sections are required annually, quarterly, or monthly; in addition unscheduled "data calls" are often issued by CPIC staff to gather up-to-date info on the status of any reportable system attribute, in response to Congressional or Departmental inquiry. Sections of the Exhibit 300 for example require significant planning, including performing cost/benefit analyses of multiple proposed options for system enhancements.

Section 300 of OMB Circular A-11 establishes policy for planning, budgeting, acquisition and management of Federal capital assets. This includes instructions on budget justification and reporting requirements for IT investments such as NHANES. The Exhibit 300 is designed to coordinate OMB's collection of agency information for reports to Congress required by statute (the Federal Acquisition Streamlining Act of 1994 and the Clinger-Cohen Act of 1996) to ensure the business case for investments are made and tied to the mission statements, long-term goals and objectives, and annual performance plans. For IT, the Exhibit 300 is designed to be used as one-stop documents for many IT management issues such as the investment business case, security reporting, Clinger Cohen Act implementation, E-Gov Act implementation, Government Paperwork Elimination Act implementation, modernization efforts, and overall project (investment) management. NHANES has responded with a yearly Exhibit 300 and has received acceptable scores or above for almost all reviews.

Consultation

With the increased requests for consultation and involvement with CHANES studies within the U.S., and with international health examination surveys, there is an increased workload for DHANES staff. While some in the division feel strongly that this is part of our mission, others are concerned that the sheer volume of requests from within (and outside) the U.S. has put a strain on the workload of many staff within the division. It is clear that these other NHANES-like activities would not be as successful without the practical wisdom of our many years of experience conducting such surveys. Our consultative efforts are very much appreciated and acknowledged by these external organizations, and we continue to offer our advice and direct help when possible despite the strains on our own operations.

Competition

NHANES is the only nationally representative large-scale cross-sectional study able to provide a mechanism to study different health issues with physical measurements and laboratory assessments. However, several new studies have come or will be coming on-line posing new challenges for NHANES. For instance, the National Children's Study (NCS) has received enormous attention and funding to conduct a large-scale longitudinal study of children. While the scope is admirable and ambitious, NCS could not have made as much progress without extensive contributions from NCHS and DHANES.

Similarly, the National Heart, Lung, and Blood Institute (NHLBI) and six other components of the National Institutes of Health (NIH) awarded \$61 million over 6 ½ years to conduct the largest long-term epidemiological study of health and disease in Latin American populations living in the United States. This study, the Hispanic Community Health Study, will conduct physical examinations, laboratory assessments, and interviews and follow participants. DHANES consulted early on in this effort and NCHS was asked to be a partner, but due to differences in data sharing philosophies, no partnership was formed.

Studies like the NCS and the Hispanic Health Study leverage the considerable experience, protocols, procedures, questionnaires, technological innovations, and staff from DHANES. It is unusual to think of competition in the federal sector. However,

differing programs and agencies within the same department are competing for ever-increasingly tight resources – both staff and dollars. This new environment provides challenges that require NHANES to be more responsive, open to collaboration, and fiscally sensitive.

FUTURE

From the initial conception and call for a nationwide “health-census” to today, NHANES has kept its core design, but has been forward-thinking and evolved with the times into a complex and multi-faceted program that continues to be relevant. NHANES is the Nation’s backbone for health examination and nutrition statistics, offering a unique opportunity to collect precise health measures, laboratory assessments, genetic material, diet and nutrition, and behavioral information. As former CDC Director Dr. Jeffery Koplan proclaimed, “NHANES is the crown-jewel of the United States public health system.” This endeavor is filled with myriad challenges such as budget uncertainty, national priorities, emerging public health issues, operations, and staffing. Through it all NHANES has responded with data related to – growth charts, blood lead, dietary intake, environmental exposure, folate and neural tube defects, genetics, human papilloma virus, nutrition, obesity, and secondhand tobacco smoke, just to name a few. Data from NHANES have an impact on federal expenditures for food assistance, nutrition education, food safety, public health programs, food safety reviews, and public reporting on many nutrition monitoring and surveillance activities. It should not be taken for granted.

We envision a future in which the Division provides data and services that can support the Nation to an even greater extent than our current activities. First, DHANES must re-engage in methodological research and alternative data collection methods. Critical analysis of survey design, analyzing factors affecting response rates, the potential for blood spots, and investigating new medical technologies are high priorities. With the fleet of MECs aging, it is time to build new trailers with more modern design features and capabilities. And, we must re-engineer the survey information technology architecture and invest in bio-informatics.

With the experience gained on NHANES, the efforts in consulting with diverse communities, and the value in studying the progression of disease, DHANES must become more fully engaged in CHANES and LHANES. This can only be done with NHANES serving as the core, with additional funds, and potentially new design and field strategies. In addition, NHANES is the only nationally representative DNA specimen collection, so the genetics program must be fully funded to support increased throughput and genome-wide associations. While it is the desire of DHANES to expand into new opportunities beyond the core NHANES operation, the reality of the budget situation brings into question whether NCHS will even be able to maintain NHANES in its current form. The public health importance of NHANES is well documented, its design is admired and imitated (or planned or desired to be imitated) throughout the country and world, and it is our hope that NHANES as we know it will continue to operate for years to come.

Over the last several months, DHANES has been considering different approaches to strategic planning taking into account the needs of the Division in developing a plan, and what professionals or organizations might be able to assist the Division. With broad input from NCHS and CDC, the Board of Scientific Counselors, federal partners, academia, state and local governments, industry, and policy makers we look forward to

developing and implementing a strategic plan for DHANES with clear, attainable, and ambitious program priorities.

Appendix A. Survey History

Survey	Years	Age Groups	Survey Emphasis
NHES I	1960 -1962	18-79 years	Growth, development and sensory defects.
NHES II	1963 - 1965	6-11 years	Growth, development and sensory defects.
NHES III	1966 - 1970	12-17 years	Growth, developmental histories, school questionnaires, medical examination including x-rays and laboratory tests.
NHANES I	1971 - 1975	1-74 years	Selected chronic diseases.
NHANES II	1976 - 1980	6 months to 74 years	Detailed personal interview, health examination, nutrition interview, x-rays, laboratory assessments.
HHANES	1982 - 1984	6 months to 74 years	Detailed personal interview, health examination, nutrition interview, and laboratory assessments focused on Hispanic population.
NHANES III	1988 - 1994	2 months and older	Detailed personal interview, health examination, nutrition interview, x-rays, laboratory assessments, and DNA collection.
NHANES 1999-2000	1999 - 2000	All ages	Detailed personal interview, health examination, nutrition interview, laboratory assessments, and DNA collection.
NHANES 2001-2002	2001 - 2002	All ages	Detailed personal interview, health examination, nutrition interview, laboratory assessments, and DNA collection.
NHANES 2003-2004	2003 - 2004	All ages	Detailed personal interview, health examination, nutrition interview, and laboratory assessments.
NHANES 2005-2006	2005 - 2006	All ages	Detailed personal interview, health examination, nutrition interview, and laboratory assessments.
NHANES 2007-2008	2007 - 2008	All ages	Detailed personal interview, health examination, nutrition interview, laboratory assessments, and DNA collection.

Appendix B. Survey Phases and Timeline

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Planning Activities	Solicit proposals for 2005-2006	Pilot test new 2005-2006 components	Solicit proposals for 2007-2008	Pilot test new 2007-2008 components	Solicit proposals for 2009-2010	Pilot test new 2009-2010 components	Solicit proposals for 2011-2012	Pilot test new 2011-2012 components	Solicit proposals for 2013-2014	Pilot test new 2013-2014 components
Tabular Reports¹	2002 data release in 4th quarter	2003 data release in 4th quarter	2004 data release in 4th quarter	2005 data release in 4th quarter	2006 data release in 4th quarter	2007 data release in 4th quarter	2008 data release in 4th quarter	2009 data release in 4th quarter	2010 data release in 4th quarter	2011 data release in 4th quarter
Micro-data Files		2001/2002 release in 1st quarter		2003/2004 release in 1st quarter		2005/2006 release in 1st quarter		2007/2008 release in 1st quarter		2009/2010 release in 1st quarter
Dietary Data²		2001/2002 release in 1st quarter ³		2003/2004 release in 1st quarter		2005/2006 release in 1st quarter		2007/2008 release in 1st quarter		2009/2010 release in 1st quarter
Data Center Access⁴	2001 + earlier years	2002 + earlier years ⁵	2003 + earlier years	2004 + earlier years	2005 + earlier years	2006 + earlier years	2007 + earlier years	2008 + earlier years	2009 + earlier years	2010 + earlier years
Survey	NHANES 2003-2004		NHANES 2005-2006		NHANES 2007-2008		NHANES 2009-2010		NHANES 2011-2012	

¹Release of limited data tables on specific topics of public health significance.

²Additional separate release of NHANES dietary recall data in accordance with DHHS/USDA survey integration plans.

³Without second day recall for 2002 to preserve confidentiality; USDA and HHS will work jointly to develop a bridging methodology to ensure comparability between data.

⁴NHANES variables not released on micro-data files due to disclosure risks. See information on NCHS Research Data Center and the NCHS Policy on Release of Micro Data.

⁵Includes second day recall for 2002

Appendix C. Survey Content



QUESTIONNAIRE COMPONENT MATRIX OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 1999–2008

Component	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Mobile Exam Center (MEC) Questionnaire											
CAPI	12 years and older										
Alcohol Use	20 years and older										
Bowel Health	20 years and older										
Current Health Status	12 years and older										
Depression Screener	12 years and older										
Kidney Conditions—Urology	20 years and older										
Pesticide Exposure	8 years and older										
Physical Activity	12–15 years										
Prostate Conditions	Males 20 and older										
Reproductive Health	Females 12 years and older										
Tobacco Use	20 years and older										
Volatile Toxicants	1/3 sample 12+ years										
Weight History	8–15 years										
ACASI	12 years and older										
Alcohol Use	12–19 years										
Conduct Disorders	12–19 years										
Food Security	12–15 years										
Drug Use	12–59 years*									Age 12–69 years	
Sexual Behavior	14–59 years										
Tobacco Use	12–19 years										
Prostate Conditions	Males 20 and older										Moved to CAPI

*Except where noted otherwise.



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EXAMINATION COMPONENT MATRIX OF THE
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 1999–2008

Component	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
Audiometry	1/2 sample 20–69 years*								Age 12–19 & 70+ years		Age 12–19 only	
Balance	1/2 sample 40–69 years*			Note A								
Bioelectrical Impedance Analysis	8–49 years											
Body Measurements	All ages											
CV Fitness	12–49 years								P.M. participants only			
Dermatology	20–59 years											
Dietary	All ages			Note B								
Dual Energy X-Ray Absorptiometry:												
Body Composition	8 years and older*	Note C						Age 8–69 years				
Bone Density—Hip and Spine	8 years and older											
FCBS Phone Follow-up Module	1 year and older											
Food Frequency	2 years and older											
Hair Collection	1–5 years, females 16–49							Done by mail				
Lower Extremity Disease:												
Peripheral Neuropathy	40 years and older											
Peripheral Vascular Disease	40 years and older											
Mental Health												
CIDI												
Generalized Anxiety	1/2 sample 20–39 years											
Depression	1/2 sample 20–39 years											
Panic Disorder	1/2 sample 20–39 years											
CDISC												
Eating Disorders	8–19 years											
Depression	8–19 years											
Panic	8–19 years											
Anxiety	8–19 years											

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EXAMINATION COMPONENT MATRIX OF THE
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Component	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Parent CDISC:											
ADHD	Parent of 8–15 years										
Conduct Disorders	Parent of 8–15 years										
Depression	Parent of 8–15 years										
Eating Disorders	Parent of 8–15 years										
Elimination Disorders	Parent of 8–11 years										
Ophthalmology:											
Retinal Photo	40 years and older										
Visual Fields	40 years and older										
Oral Health:											
Basic Screening Exam	5 years and older									Note D	
Coronal Caries	2 years and older					Note E					
Dental Sealants	2–34 years										
Denture Questionnaire	25 years and older										
Exclusion qx	13 years and older										
Flourosis	6–49 years										
Incisal Trauma	10–29 years										
Orofacial Pain qx	10–69 years										
Orofacial Pain Exam	13–69 years										
Periodontitis:											
Loss of Attachment	18 years and older*					Note F					
Gingival Bleeding	12–49 years										
Periodontal Bleeding	13 years and older										
Referral/Follow-up	2 years and older*					Note G			5 years and older		
Root Caries	18 years and older										
Saliva	40 years and older		Note H								
Tooth Count	2 years and older*					Note I			5 years and older		

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EXAMINATION COMPONENT MATRIX OF THE
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Component	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Physical Activity Monitor	6 years and older										
Physical Functioning:											
Isokinetic	50 years and older										
20 ft. timed walk	50 years and older										
8 ft. timed walk	50 years and older										
Physician Exam	All ages										
Blood pressure	8 years and older										
Respiratory Health:											
Exhaled Nitric Oxide	6–79 years										
Spirometry	6–79 years										
Tuberculosis	1 year and older										
Vision	12 years and older										

*Except where noted otherwise.

Note A: Increased to full sample, 40 years and older.

Note B: New interview system implemented in 2002. All participants asked to complete a second recall by phone.

Note C: The age range for females in 1999 was 18 years and older.

Note D: Oral health component changed from comprehensive dentist based exam to a simplified oral health screening on ages 5 years and older.

Note E: Added identifying caries status on residual dental roots.

Note F: Age range changed to 13 years and older; LOA measurement positions modified, a third site added.

Note G: Added recommendations to seek care for removable dental prosthetics.

Note H: Discontinued in mid-year of 2000.

Note I: Added counting residual dental roots.



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LABORATORY COMPONENT MATRIX OF THE
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 1999–2008

Lab Test	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Acrylamide	3 years and older*										Age 6 years and older
Albumin (urine)	6 years and older										
Apolipoprotein (B)	1/2 subsample 12 years and older									A.M. participants only	
Arsenic (urine)	1/3 sample 6 years and older										
Bone Alkaline Phosphatase	8 years and older*										
BV/Trichomonas	Females 14–49 years										
Cadmium (blood)	1 year and older										
CD4/CD8	18–49 years/ HIV+ & controls										
Chemistry Panel	12 years and older										
Chlamydia (urine)	14–39 years										
Total Cholesterol	3 years and older*										Age 6 years and older
HDL Cholesterol	3 years and older*										Age 6 years and older
LDL Cholesterol	Subsample 3 years and older*										Age 12 years and older a.m. only
Complete Blood Count	1 year and older										
Cotinine	3 years and older										
C-reactive Protein	3 years and older*									Age 1 year and older	Age 3 years and older
Creatinine (urine)	6 years and older										
Cryptosporidium	6–49 years										
Dust Allergens	1 year and older										
Environmental Phenols	1/3 sample 6 years and older										
Erythrocyte Porphyrin	1 year and older*										Age 3–5 years and females 12–49 years
Fatty Acids	3–11 years, 12 and older, a.m. only										
Ferritin	1 year and older*										Age 1–5 years and females 12–49 years
Fibrinogen	40 years and older										
Folate, RBC	3 years and older*										Age 1 year and older
Folate, Serum	3 years and older*										Age 1 year and older

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LABORATORY COMPONENT MATRIX OF THE
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 1999–2008

Lab Test	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
FSH/LH	Females 35–60 years	[Shaded]										
Fungicides	1/3 sample 6 years and older*	Note A										
Glucose, Plasma	Subsample 12 years and older	[Shaded]										
Glucose Tolerance Test (OGTT)	Subsample 12 years and older								A.M. participants only			
Glycohemoglobin	12 years and older	[Shaded]										
Gonorrhea (urine)	14–39 years	[Shaded]										
Halogenated Phenolic Compounds	1/3 sample 6 years and older*	Note A										
Helicobacter Pylori	3 years and older	[Shaded]										
Hepatitis antiHBs	2–5 years	[Shaded]										
Hepatitis A, B, C, D	6 years and older	[Shaded]										
Hepatitis C Follow-up	All SPs with Hep C											
Herbicides: Substituted Ureas & other Herbicides	1/3 sample 6 years and older*	Note A										
Herpes 1 and 2 Antibody	14–49 years	[Shaded]										
HIV Antibody	18–49 years	[Shaded]										
Homocysteine	3 years and older*	[Shaded]							Age 20 years and older			
Human Papillomavirus (HPV)	Females 14–59 years											
HPV Swab	Females 14–59 years											
Hydroxylated Polychlorinated Biphenyls	1/3 sample 12 years and older											
Immunoglobulin E- Allergens	1 year and older											
Insulin/C-Peptide	Subsample 12 years and older	[Shaded]							Insulin only			
Iodine (urine)	1/3 sample 6 years and older											
Iron	1 year and older*	[Shaded]				Note B						
Latex	12–59 years	[Shaded]										
Lipoprotein (a) (Lp(a))	Subsample 12 years and older											
Lead (blood)	1 year and older	[Shaded]										
Lead dust	Households with 1–5 year olds	[Shaded]										

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LABORATORY COMPONENT MATRIX OF THE
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Lab Test	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
Measles/Varicella/Rubella	6–49 years	[Shaded]										
Metals (urine)	1/3 sample 6 years and older	[Shaded]										
Mercury (hair)	1–5 years, females 16–49 years	[Shaded]				[Shaded]						
Mercury (blood)	1–5 years, females 16–49 years*	[Shaded]				[Shaded]						
Mercury (urine)	Females 16–49 years*	[Shaded]				[Shaded]						
Methylmalonic acid	3 years and older	[Shaded]										
MRSA	1 year and older		[Shaded]				[Shaded]					
Non-dioxin-like Polychlorinated Biphenyls	1/3 sample 12 years and older	[Shaded]										
N-Telopeptides (NTX)	8 years and older	[Shaded]					[Shaded]					
Omega Fatty Acids	3–11, 12 and older a.m. only									[Shaded]	[Shaded]	
Organochlorine Pesticides	1/3 sample 12 years and older	[Shaded]										
Organophosphate Insecticides	1/3 sample 6 years and older*	[Shaded]				[Shaded]						
Parathyroid Hormone (PTH)	6 years and older	[Shaded]										
Perchlorate (urine)	6 years and older*			[Shaded]				[Shaded]				
Perchlorate (water)	1/2 subsample 12 years and older	[Shaded]										
Perfluorinated Compounds	1/3 subsample 12 years and older*	[Shaded]		[Shaded]								
Phthalates	1/3 sample 6 years and older	[Shaded]										
Phytoestrogens	1/3 sample 6 years and older	[Shaded]										
Polybrominated Diphenyl Ethers	1/3 subsample 12 years and older					[Shaded]						
Polychlorinated Naphthalene	1/3 sample 12 years and older									[Shaded]	[Shaded]	
Polychlorinated and Polybrominated Dibenzo-p-dioxins, Dibenzofurans, Coplanar and Mono-Ortho-Substituted Biphenyls	1/3 sample 12 years and older	[Shaded]										
Polycyclic Aromatic Hydrocarbons (PAH)	1/3 sample 6 years and older	[Shaded]										
Prostate Specific Antigen (PSA)	Males 40 years and older			[Shaded]								
PSA Follow Up	Males 40 and older with high results			[Shaded]								
Pyrethroid Pesticides	1/3 sample 6 years and older*			[Shaded]		[Shaded]						
Other Pesticides	1/3 sample 6 years and older*	[Shaded]				[Shaded]						

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LABORATORY COMPONENT MATRIX OF THE
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Lab Test	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
Selenium	3–11 years*					Age 40 years+						
Surplus Sera	6 years and older					Reduced # of vials						
Syphilis	18–49 years											
Thyroid Function Testing	1/3 sample 12 years and older					Age 12 years +						
TIBC	1 year and older*					Note B						
Toxaphenes	1/3 sample 12 years and older											
Toxoplasma	6–49 years	Note D										
Transferrin Receptor	1–5 years, females 12–49 years											
Triglycerides	Subsample 3 years and older*					Age 12 years and older, A.M. only						
Vitamin A/E/Carotenoids	3 years and older*					Age 6 years and older						
Vitamin B6	1 year and older											
Vitamin B12	3 years and older*					Age 1 year and older						
Vitamin C	6 years and older											
Vitamin D	6 years and older*					Age 1 year and older						
VOC (blood)	Subsample 20–59 years*					1/2 sample age 12 years and older						
VOC (water)	Subsample 20–59 years*					1/2 sample age 12 years and older						
VOC Exposure Monitor	Subsample 20–59 years											
White Blood Cell/ DNA	20 years and older											

*Except where noted otherwise.

Note A: In 1999, the subsample was ¼ for those aged 12–59 years. In 1999–2002, the subsample was ½ for those aged 6–11 years.

Note B: Age range changed to 3–5 years and females 12–59 years.

Note C: Analyzed retrospectively from Surplus Sera 2001–2004.

Note D: Analyzed retrospectively from Surplus Sera 1999–2000.

Note E: In 2001–2002, the subsample was ½ for those aged 6–11 years.



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QUESTIONNAIRE COMPONENT MATRIX OF THE
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 1999–2008

Component	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Survey Participant (SP) Questionnaire											
Acculturation (ACQ)	12 years and older	[Blue bar]									
Allergy (ARQ)	1 year and older	[Blue bar]									
Audiometry (AUQ)	20 years and older*	[Blue bar]									
Balance (BAQ)	40 years and older	[Blue bar]									
Blood Pressure (BPQ)	16 years and older	[Blue bar]									
Cardiovascular Disease (CDQ)	40 years and older	[Blue bar]									
Demographics (DMQ)	0 years and older	[Blue bar]									
Dermatology (DEQ)	6 years and older*	[Blue bar]									
Diabetes (DIQ)	1 year and older	[Blue bar]									
Diet Behavior and Nutrition (DBQ)	0 years and older	[Blue bar]									
Dietary Supplements & Medications (DSQ)	0 years and older	[Blue bar]									
Digit Symbol Substitution Test (CFQ)	60 years and older	[Blue bar]									
Early Childhood (ECQ)	0–15 years	[Blue bar]									
Health Insurance (HIQ)	0 years and older	[Blue bar]									
Hospital Utilization & Access to Care (HUQ)	0 years and older	[Blue bar]									
Immunization (IMQ)	0 years and older	[Blue bar]									
Introduction & Verification (IVQ)	0 years and older	[Blue bar]									
Kidney Conditions (KIQ)	20 years and older	[Blue bar]									
Medical Conditions (MCQ)	1 year and older	[Blue bar]									
Miscellaneous Pain (MPQ)	20 years and older	[Blue bar]									

*Except where noted otherwise.



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QUESTIONNAIRE COMPONENT MATRIX OF THE
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 1999–2008

Component	Age Range	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	
Occupation (OCQ)	12 years and older*								Age 16 years and older			
Oral Health (OHQ)	2 years and older*								Age 18 years and older			
Osteoporosis (OSQ)	20 years and older											
Physical Activity & Physical Fitness (PAQ)	2 years and older											
Physical Functioning (PFQ)	1 year and older											
Respiratory Health & Disease (RDQ)	1 year and older											
Sleep Disorders (SLQ)	16 years and older											
Smoking and Tobacco Use (SMQ)	20 years and older											
Social Support (SSQ)	60 years and older*								Age 40 years and older			
Tuberculosis (TBQ)	1 year and older											
Vision (VIQ)	20 years and older*								Age 12 years and older			
Weight History (WHO)	16 years and older											
Family Questionnaire												
Consumer Behavior (CBO)	0 years and older											
Demographic Background/Occupation (DMQ)	0 years and older											
Food Security (FSQ)**	0 years and older											
Health Insurance (HIQ)	0 years and older								Found in SP Quest			
Housing Characteristics (HOQ)	0 years and older											
Income (INQ)	0 years and older											
Pesticide Use (PUQ)	0 years and older								Found in MEC Interview			
Smoking (SMQ)	0 years and older											

*Except where noted otherwise.

**Adult and Child person-level food security data collected after the dietary recall.



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ACRONYMS AND ABBREVIATIONS USED IN THE
NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)

ACASI	Audio computer-assisted self interview
ADHD	Attention deficit hyperactivity disorder
BV	Bacterial vaginosis
CAPI	Computer-assisted personal interview
CD4	T lymphocyte helper cells
CDISC	National Institute for Mental Health's Computerized Diagnostic Interview Schedule for Children
CIDI	World Health Organization's Composite International Diagnostic Interview
CV Fitness	Cardiovascular fitness
FCBS	The Flexible Consumer Behavior Survey module
FSH/LH	Follicle stimulating hormone/Luteinizing hormone
HDL	High density lipoprotein
HPV	Human papillomavirus
LDL	Low density lipoprotein
MEC	Mobile examination center
MRSA	Methicillin resistant staphylococcus aureus
NTX	N-telopeptides of bone type I collagen
PAH	Polyaromatic hydrocarbons
PSA	Prostate specific antigen
Qx	Questions
RBC	Red blood cell
SP	Survey Participant
TH	Thyroxin
TIBC	Total iron binding capacity
TSH	Thyroid stimulating hormone
VOC	Volatile organic compounds
WBC/DNA	White Blood Cells/Deoxyribonucleic acid



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Appendix D. Survey Operations Timeline

Advance Arrangements

Timeline	Schedule and Procedures
4-6 months to location start date	Meet with county/city officials to introduce survey and gain cooperation and support, identify liaisons, build medical referral list, share survey plan, and identify issues concerning participation
90 days to location start date	Final negotiations for Field Office and MEC sites; obtain permits/zoning.
70 days to location start date	Request endorsement letters.
45 days to location start date	Mail 1 st round of public officials' letters to introduce community leaders to NHANES.
10 days to location start date	Mass campaign effort to local print, television and broadcast media outlets
7 days to location start date	Mail 2 nd round public officials' letters providing site information not available during the first mailing (clinic address, local phone numbers and date of Open House). Advance letters are also mailed to all sampled households.

Field Activities

Timeline	Schedule and Procedures
Field Office set up start	Field office opens and the press campaign is handed off to field manager. Physical office setup and segments reviewed.
Interviewing start	Interviewers arrive at the site 3 days after the field office opens. Case assignments are made and interview debriefing started.
MEC set up	Complete MEC setup and calibrate equipment.
Media / Dry Run Day	Invite media and public officials to open house. Provide tours and test equipment in the afternoon with volunteers.
Exams start	NHANES survey participants begin examinations at the MEC about 2-3 weeks after the start of interviewing.
Field Office / MEC shut down	Staff adjudicate records and complete the shut down procedures to complete work in a location. Final shipment to labs is completed. Rental property returned and utilities turned off.

Appendix E. Collaborators

Department	Agency	Center/Institute/Office
Department of Health and Human Services	Centers for Disease Control and Prevention	1. National Center for Birth Defects and Developmental Disabilities
		2. National Center for Chronic Disease Prevention and Health Promotion
		3. National Center for Environmental Health
		4. National Center for Infectious Diseases
		5. National Center for HIV, Viral Hepatitis, STD, and TB Prevention
		6. National Immunization Program
		7. National Institute for Occupational Safety and Health
	Food and Drug Administration	8. Center for Drug Evaluation
		9. Center for Food Safety and Applied Nutrition
	National Institutes of Health	10. National Institute of Aging
		11. National Institute on Alcoholism and Alcohol Abuse
		12. National Institute of Allergy and Infectious Disease
		13. National Institute of Arthritis and Musculoskeletal and Skin Disease
		14. National Cancer Institute
		15. National Institute of Child Health and Human Development
		16. National Heart, Lung, and Blood Institute
		17. National Institute of Diabetes and Digestive and Kidney Diseases
		18. National Institute on Deafness and other Communication Disorders
		19. National Institute of Dental and Craniofacial Research
		20. National Institute on Drug Abuse
		21. National Institute of Environmental Health Sciences
		22. National Eye Institute
		23. National Institute of Mental Health
		24. Office of Dietary Supplements
Environmental Protection Agency		25. Office of Pesticide Programs
Department of Agriculture		26. Agricultural Research Service
		27. Center for Nutrition Policy and Promotion
		28. Economic Research Service
Department of Housing and Urban Development		29. Department of Housing and Urban Development

Appendix F. Selected Publications by DHANES Staff

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http://www.cdc.gov/nchs/data/series/sr_11/sr11_248.pdf

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7. Advance Data No. 347. Mean Body Weight, Height, and Body Mass Index, United States 1960-2002: <http://www.cdc.gov/nchs/data/ad/ad347.pdf>
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MMWR articles

1. Prevalence of Chronic Kidney Disease and Associated Risk Factors --- United States, 1999--2004: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a2.htm>
2. Folate Status in Women of Childbearing Age, by Race/Ethnicity --- United States, 1999--2000, 2001--2002, and 2003--2004:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5551a2.htm>
3. Correctable Visual Impairment Among Persons with Diabetes --- United States, 1999--2004: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5543a2.htm>
4. Surveillance for Dental Caries, Dental Sealants, Tooth Retention, Edentulism, and Enamel Fluorosis --- United States, 1988--1994 and 1999--2002:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5403a1.htm>

5. Prevalence of Overweight and Obesity Among Adults with Diagnosed Diabetes --- United States, 1988-1994 and 1999-2002:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5345a2.htm>
6. Children and Teens Told by Doctors That They Were Overweight --- United States, 1999--2002: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5434a3.htm>
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<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5420a5.htm>
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<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5401a3.htm>
10. Prevalence of Overweight and Obesity Among Adults with Diagnosed Diabetes --- United States, 1988--1994 and 1999--2002:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5345a2.htm>
11. Blood Mercury Levels in Young Children and Childbearing-Aged Women --- United States, 1999-2002: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5343a5.htm>
12. Surveillance for Elevated Blood Lead Levels Among Children --- United States, 1997-2001: <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5210a1.htm>
13. Trends in Intake of Energy and Macronutrients --- United States, 1971-2000:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5304a3.htm>
14. Lower Extremity Disease Among Persons Aged greater than/equal to 40 Years With and Without Diabetes --- United States, 1999--2002:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5445a4.htm>
15. Mobility Limitation Among Persons Aged greater than/equal to 40 Years With and Without Diagnosed Diabetes and Lower Extremity Disease --- United States, 1999--2002: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5446a4.htm>

Health E-Stat Web releases

1. Prevalence of Overweight, Infants and Children less than 5 years of age: United States, 2003-2004:

http://www.cdc.gov/nchs/products/pubs/pubd/hestats/overweight/overwght_child_under02.htm

2. Prevalence of Overweight and Obesity Among Adults: United States, 2003-2004:
http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese03_04/overwght_adult_03.htm
3. Prevalence of Overweight Among Children and Adolescents: United States, 2003-2004:
http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese03_04/overwght_child_03.htm
4. Supplemental Analyses for Estimates of Excess Deaths Associated with Underweight, Overweight, and Obesity in the U.S. Population:
http://www.cdc.gov/nchs/products/pubs/pubd/hestats/excess_deaths/excess_deaths.htm
5. Iodine Levels, United States, 2000:
<http://www.cdc.gov/nchs/products/pubs/pubd/hestats/iodine.htm>

Appendix G. Budget Chart

	2007	2008	2009	2010	2011	2012
NCHS Funds	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00	\$18.00
Reimbursable Funds	\$12.30	\$10.10	\$11.80	\$11.20	\$11.20	\$11.20
Carryover Remaining	\$7.10	\$5.85	\$1.65	\$0.00	\$0.00	\$0.00
Income	\$37.40	\$33.95	\$31.45	\$29.20	\$29.20	\$29.20

Field Costs	\$27.80	\$28.63	\$29.49	\$29.98	\$30.18	\$30.38
Lab Readings Costs	\$1.50	\$1.70	\$1.80	\$1.85	\$1.91	\$1.97
Support Contracts	\$1.70	\$1.77	\$1.82	\$1.88	\$1.93	\$1.99
Trailers	\$0.35		\$0.70			
IT Infrastructure Upgrade			\$1.00			
Division Operations	\$0.20	\$0.20	\$0.21	\$0.22	\$0.22	\$0.23
Expenses	\$31.55	\$32.30	\$35.02	\$33.92	\$34.24	\$34.57

Cumulative Balance / Deficit	\$5.85	\$1.65	-\$3.57	-\$4.72	-\$5.04	-\$5.37
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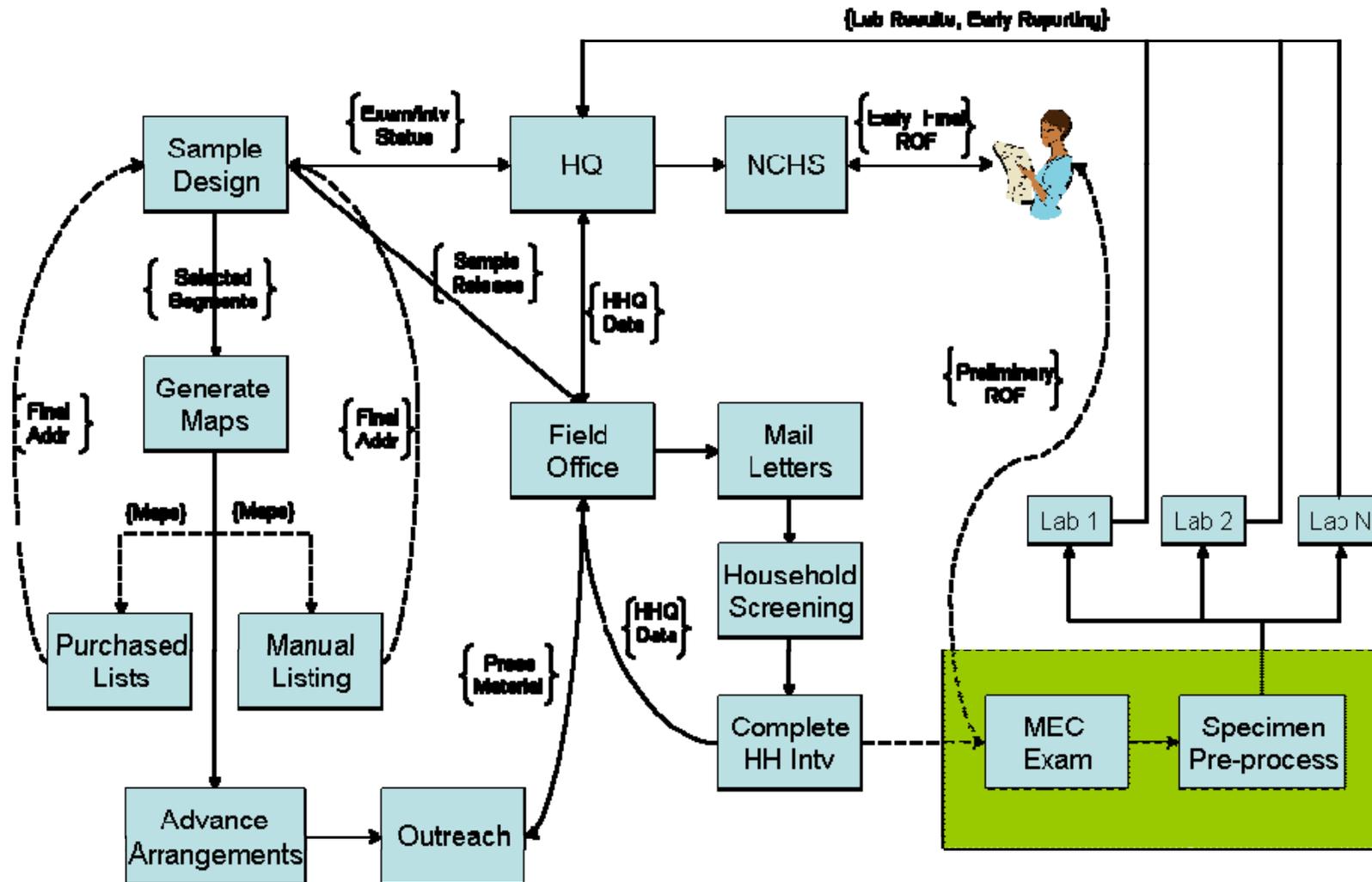
Additional Funds to Make Whole	\$0.00	\$0.00	\$3.57	\$4.72	\$5.04	\$5.37
Cumulative Total Additional Funds Needed			\$3.57	\$8.30	\$13.34	\$18.71

Note: All figures in millions; * NHANES field operations end in 2012 by current contract terms

Assumptions

1. No changes made to operations, sample size, or over-sampling.
2. NCHS provides \$18M from 2007 – 2012.
3. Re-imbursables constant at \$11.2M from 2010 and beyond
4. Field costs increase 3% per year beyond 2007.
5. Lab costs increase by 3% per year beyond 2008.
6. New support contracts to be negotiated with an increase of 3% beyond 2009.
7. New trailers built in 2007(1), 2009(2).
8. Proposed IT infrastructure upgrade costs \$1M in 2009, and then produces \$400K (2010) and ~\$700k savings each year thereafter. Savings are subtracted from field costs.
9. Division operations increase by 4% a year from 2009 forward.
10. Additional funds added each year to make study whole.

Appendix H. Field Operations Workflow



Appendix I. NHANES 2007-2008 Remuneration Schedule

Remuneration Category	Payment
SPs 16+ who agree to fast and be examined at pre-selected time	\$100
SPs 16+ who refuse to fast and be examined at pre-selected time	\$70
SPs 12 – 15 who agree to fast and be examined at pre-selected time	\$50
SPs 12 – 15 who refuse to fast and be examined at pre-selected time	\$30
SPs under age 12	\$30
Non-SP parents of SPs under 16 years (one time payment)	\$20
Dietary phone follow-up	\$30

SP Transportation Allowance

Mileage	Cities	Rural Areas
<15 Miles	\$30	\$25
16 – 30 Miles	\$45	\$45
31 – 59 Miles	\$55	\$50
>60 Miles	\$70	\$65

Appendix J. Sample Size and Response Rate

