

# A National Biomedical Risk Factor Survey for Australia: Issues for consideration

Diana Hetzel

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Enquiries about or comments on this publication should be addressed to:

PHIDU, The University of Adelaide, South Australia 5005  
Phone: 08-8303 6239 or e-mail: [PHIDU@publichealth.gov.au](mailto:PHIDU@publichealth.gov.au)

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# A National Biomedical Risk Factor Survey for Australia:

## Issues for consideration

National population health surveys containing a component of physical measurement have been used both in Australia and overseas to add to the information about the state of health of a population and to complement research into particular issues, diseases or directions in health policy.

Such a survey has been proposed recently for Australia, with initial planning and costing undertaken by the Australian Institute for Health and Welfare (AIHW) over the last two years. However, given the Institute's identified need for an investment of at least \$3 million, additional planning and development has been agreed by the Commonwealth Department of Health and Aged Care and AIHW for the scope of a survey, the cost and the likely value of its results. The National Public Health Partnership has endorsed this approach.

This short paper will outline some of the issues that require consideration as part of the decision-making about these types of surveys in general, and will report briefly on some of the models that have been used overseas.

### **1.0 The primary reasons for undertaking biomedical risk factor surveys**

From an examination of the use of surveys of this type that have been undertaken in the United States, Canada, New Zealand, the United Kingdom and Australia, the following purposes have been identified. Biomedical risk factor surveys have been used for:

- The monitoring within a population of certain high priority health goals and targets relating to the prevention of various diseases or conditions at one point in time, and over time if surveys are repeated regularly;
- The provision of baseline data related to particular health issues or policies;
- The contribution to particular research questions about health and related conditions and their treatment or eradication;
- The surveillance of infective agents or other factors that impact negatively on the population's health or may do so in the future;
- The collection of information at a population level - to assist in the development of policy and planning of services or determining need, to assess the degree of success of health promotion or illness prevention strategies or to contribute to a greater understanding of health and illness.

The primary purpose of the proposed AIHW survey was to monitor disease risk patterns, by collecting national information on risk factors and their distribution, assessing trends in risk factors by comparing results with previous survey data and validating self-reported health conditions, health status and behaviours.

One issue requiring clarification is whether the purpose of a biomedical risk factor survey for Australia is primarily to monitor the health of the population, or if it will also contribute to an understanding about the population's health and well being and its genetic, biologic and social determinants. Such decisions will impact significantly on the areas to be covered by the survey - the nature of the questions and any biologic markers or measures to be included, components of survey design and sampling, any sub-populations of interest, extent of consent required and other significant legal and ethical issues, consumer response rates, extent of funding, organisational infrastructure needed to support a survey and subsequent issues of survey design, data and sample storage, record linkage and trend analysis.

It will be important to consider carefully, which of these purposes, monitoring alone or with the ability to contribute to the knowledge base as well, is the impetus for a national survey of this kind. It will also determine the perceived value of any survey for those who have the responsibility for deciding whether such a survey should proceed.

## **2.0 A national biomedical risk factor survey and its place in the longer term direction of national population health information development**

There has been a considerable investment by governments and others in the collection of health information and concomitant biomedical and other measures to date in Australia, although one of those studies is now ten years old. The International Diabetes Institute (IDI) has received significant funding recently for a major study into the prevalence of diabetes and cardiovascular disease (AUSDIAB) and associated risk factors, which is currently underway. A number of physical measures that were included in the AIHW survey proposal are being gathered as part of the AUSDIAB survey.

The National Public Health Information Development Plan has been published and its stated purpose is 'to identify the action needed to improve public health information in Australia'. A biomedical risk factor survey is included as one of its components (Recommendation 1.1.1). However, it is not clear how widely this particular direction has been canvassed with a range of other interested parties, beyond the NPHP and NPHIWG.

There are a number of broader questions to be considered.

What are the longer-term policy questions or issues that should form the basis of a national population health survey that includes physical measures?

What health issues are important to consider now, and which are likely to emerge as significant for our nation over the next ten or twenty years?

What are the significant gaps in information currently that a survey of this kind could help to remedy?

Are there certain population groups that should be considered as a priority for inclusion?

What are the directions for future population health surveying and collection nationally, and how does a national biomedical risk factor survey program fit within a longer-term view?

It is also not yet apparent how priorities for population health, which would be included in a survey of this kind, might be determined across the Department of Health and Aged Care and in partnership with other jurisdictions. For example, to what extent are State and Territory health agencies interested in participating in the survey direction, design and funding? Will they be supportive of national directions solely, or will they wish to raise local issues for inclusion and to fund possible State estimates? What are the interests of other public health practitioners, community and professional organisations, and researchers from tertiary educational institutions? Are other divisions within the Commonwealth Department of Health and Aged Care interested in and supportive of a survey? Are there areas that overlap with the interests of other sectors? Are there emerging health issues that ought to be considered for inclusion?

An agreement to the investment of a significant amount of health funding in a national biomedical risk factor survey requires support from a range of parties who have an interest in health policy issues. There is an urgent need to undertake discussions with the State and Territory health authorities and a range of other stakeholders. This is necessary in order to determine the level of interest in a survey, the perception of its value and importance, views on priority issues for inclusion (and the criteria for deciding which issues will be included), funding options and the preferred process for its development, should it proceed.

A wide level of commitment to the undertaking of a survey and its objectives will be essential before the issue can proceed successfully through AHMAC processes and beyond. Furthermore, all stakeholders will need to be committed fully in order to be able to respond positively to the likely community interest that will be generated once the survey is agreed and publicised.

### **3.0 The content of a national biomedical risk factor survey**

The planning work undertaken by the AIHW resulted in a focus on issues that are generally recognised as contributing to significant mortality and morbidity within the Australian adult population. Its recommendations for topics for inclusion are cardiovascular disease, diabetes mellitus, communicable diseases and nutrition.

The report of the workshop (AIHW March 1998) indicated that the participants gave priority to the areas above and, after discussion, excluded genetics and cancer from the survey. Participants identified a range of biologic markers for inclusion, and canvassed the possibilities of including children and young people as subjects, using collected sera for further research, linking results with data held by AIHW and the Australian Bureau of Statistics (ABS) and conducting the survey in rural and remote communities or for high-risk sub-populations.

Over two years have now passed since the initial AIHW workshop and there have been a number of new areas of interest identified. To date, there has not been a broad scoping exercise regarding the content and design of a national survey. Those with expertise in areas such as child and youth health, Indigenous health, disability or the health of recent immigrant populations, for example, have not yet been consulted. Other significant health issues such as substance use, injury and violence, oral health, respiratory disease and the emerging interest in autonomy and control and other psychosocial contributors to health and illness might be considered for possible inclusion.

Further discussion is now needed about the areas for inclusion if such a survey were to be conducted. There are other health issues, such as nutritional deficits in Indigenous people, environmental health effects of various contaminants, risk factors for mental health, childhood antecedents of adult disease and other population health determinants that could be considered. An examination of the biologic markers that have already been collected in overseas surveys suggests that there may be value in including markers such as fibrinogen, homocysteine and others, and in considering some physical measures of respiratory status and other fitness indicators. Furthermore, there are convincing arguments for considering the inclusion of children and young people in surveys such as these.

Communication with Canadian authorities who are currently planning their own national biomedical risk factor survey, indicates that a substantial amount of planning and research is needed, in order to ensure that the significant investment of money required for surveys of this kind is realised in valuable and useful results which lead to better health strategies for the population, and that wide support is built for the survey from the start. A similar process is needed for Australia.

#### **4.0 Other sources of population health information to determine risk factor prevalence**

There are a number of current initiatives that should be examined to determine whether they could contribute to the collection of information that is to be covered by a national survey of risk factor prevalence.

Such approaches include a possible expansion of the BEACH survey, linkage to the IDI Diabetes Prevalence Survey (AUSDIAB), the use of CATI methodology for surveying and its link to clinic services for sampling and physical examinations, and the options of funding studies using surveying and blood samples which are already collected in significant numbers elsewhere (for example, through blood donation or via private pathology laboratories). These options may prove not to be suitable after detailed examination, but nevertheless, deserve consideration at this stage. There are also a number of regional surveys underway or seeking funding from sources such as the NHMRC that may be worth considering as elements in building a picture of risk factor prevalence. Data management issues will also need to be considered in detail.



## **5.0 Legal and ethical considerations for consumer involvement**

There are a large number of legal and ethical issues that emerge once a survey with biologic blood and other physical markers is proposed. These need careful attention and discussion, and some may require legal opinions to reduce the likelihood of future legal claims and liability.

Consumer involvement in a survey of this kind will be critical in determining its success, given the response rates that are needed to ensure that sampling is representative of the population(s) of interest. Significant investment will be required to encourage consumer participation and support at every stage of the survey. Initial discussions with colleagues in New Zealand indicate that their most effective strategy to encourage participation in The NZ National Nutrition Survey involved local community newspaper stories about the survey, with a local interviewer being photographed. The interviewer then took the newspaper article with them to remind participants of the survey, and the interviewers found it very effective. Marketing to the community also took many other forms, and a part time communications person was employed to organise television and radio interviews, local newspaper stories and photographic opportunities.

Consumer confidentiality and privacy concerns will require a concerted effort and a planned strategy to allay fears of data collection, storage, security and access to researchers for analyses. Consumer anxieties are also likely to be heightened when biomedical sampling, particularly of blood, is initially raised in the public domain. The benefits of the survey and aspects of the methodology will need to be asserted and discussed fully.

Issues of the extent of the consent to be sought from participants will be largely determined by the nature of the survey, its content and the age groups who will be asked to participate. All the usual provisions regarding informed consent will be required and explicit information about every aspect of the survey should be clearly outlined. Languages other than English and the use of interpreters, literacy levels, and the ability to understand and to give one's own consent will need to be thought through carefully. Cultural considerations will also be important.

A number of issues regarding information for participants are immediately apparent. All participants should be given the opportunity to receive results from the survey, but this will not be straightforward. For example, if a testing procedure reveals a result that indicates that the person's sample is abnormal or indeterminate, what level of reliability and sensitivity does this represent? What does an abnormal result mean for the person's physical and mental well being, and future health? Who will be responsible for talking to the person and explaining the results? To whom should the information be given – the subject or his/her general practitioner, or both? What about people who do not have a general practitioner? What about the case of a young person under the age of 18 years and what is the duty of care to a young person whose legal guardians refuse to disclose an abnormal result? What about the psychological impact of

transmitting a false positive result to a person and subsequently discovering that it has been made in error? What about the need to notify certain conditions to State or Territory public health authorities, and the inability then to maintain a person's confidentiality?

Specific problems are related to aspects of the final survey design. For example, if sera are to be stored for future research or surveillance purposes, will they be identifiable? For how long will samples be stored and how securely will they be stored? Will they be available for DNA testing or research into genetic markers or diseases? What about pre- and post-test counselling if viral or genetic markers are tested? Who will do this? Will permission for linkage to administrative or clinical databases be sought? Will there be any attempts to incorporate longitudinal cohorts within the sample range? Many other issues such as these will require elucidation, discussion and possible ethical approval.

Many of these issues will require consideration under various State, Territory and Commonwealth legislation, and some will require specific ethical approvals. Consumer consultation and involvement will be a critical element of planning a survey of this kind.

## **6.0 Logistical issues for biomedical sampling and physical measures**

The desire to sample blood and possibly other physiological substances such as saliva and urine as part of a national survey brings with it a significant number of complex issues that will require discussion and resolution, and will influence the cost of the survey significantly. Some of these that relate to blood sampling are outlined in Attachment 1.

Standardisation of sample collection and of physical measures will be required as well as a detailed discussion of the processes to be used. A range of standard protocols exist for sample collection and the measurement of factors such as blood pressure, but these will need to be examined in detail and expert advice sought as to the level of standardisation that should be employed.

It will be more difficult to decide on the process of whom should take the samples and perform the measurements, and when and where the samples are taken (eg. in the home, at a clinic, at a mobile testing centre). Options include:

- training one specially recruited team of collectors employed by the surveying body which travels from site to site;
- using regional teams of people who receive training and service their local area;
- contracting collection to organisations who have staff already employed and trained for venesection, and have accredited processes for blood collection, transport and testing, eg. private pathology services, blood transfusion services.

All collectors will require training to some degree, strict supervision and adherence to protocols, and monitoring to ensure to quality assurance and inter-collector reliability throughout the survey.

## **7.0 Issues of linkage to a National Health Survey (ABS)**

To date, the development of a national biomedical risk factor survey has been driven by the desire to link such a survey with a National Health Survey (NHS) run by the ABS. There are a number of advantages to linking the two surveys. Response rates for ABS Health Surveys have been high, at about 90% or so, and linkage will result in the gathering of a raft of demographic, socioeconomic and health data in a way that has not previously been attempted on this scale. This will allow a broad picture of the population's health to be achieved.

However there are a number of factors to be considered. To date, the ABS has not undertaken a survey of this kind, involving a wide range of blood samples and physical measures. Given the complexities of such a process and a relative lack of familiarity with these aspects of data collection, there will need to be a detailed process negotiated if this option is followed.

There is interest in chronic disease risk factor surveillance following work on an integrated framework for chronic disease prevention by DHAC. A need for a chronic disease risk factor surveillance system has been identified to support this work, possibly incorporating both biomedical and behavioural risk factor surveillance. By 2004, it will be timely to repeat the National Nutrition Survey, so there is a possibility of uncoupling a biomedical risk factor survey from the ABS NHS and attaching it to a National Nutrition Survey. This would give a biomedical survey the detailed nutrition questions that are lacking from the NHS (there are only six questions about nutrition in the NHS).

Linkage with the National Health Survey will also not be easy from a practical perspective. The Survey is a continuous, multi-stage population survey over twelve months, collecting an extensive range of data (which will contribute to the background information required for a biomedical risk factor survey). How many collection points will be required? What time delay between interview, and the taking of physical and blood measures will be acceptable? Will collections for rural and remote populations be attempted? Will the ABS employ the collectors of the biomedical and other measures, or will another organisation do so?

It may be that the ABS National Health Survey is not the best vehicle to which to link a survey of this kind. There may be alternative ways of proceeding that would offer a more practical approach given the logistical difficulties outlined above. Are there other strategies that would be operationally more efficient, such as the collection of all information by a team (including a nurse) or the use of CATI procedures to establish convenient appointments for respondents to attend local 'clinics' for examination? Are there additional opportunities for self-administered mail back questionnaires or are there other research areas that

utilise attitudinal measurement scales? In addition, sampling size and other sampling issues should not necessarily be pre-determined by the requirements of the ABS NHS for the survey. Sample size, for example, should be determined by the nature of the outcomes that are sought.

It may be important to consider selecting an agency or agencies, or a team of people with proven experience in all aspects of a survey such as this, from data collection, processing, analysis and publication. Opportunities for contracting aspects of the survey administration should be considered.

A final issue for consideration is that of data analysis and research opportunities once the survey has been conducted. There are stringent legislative provisions that guide the ABS and its release of data. This may restrict access to confidential data for record linkage, for a longitudinal sub-sample or for further research interests into stored sera for example. There is also a precedent for information to be made available only at extra cost, in addition to that paid initially for the data to be collected. However, there is a recent agreement between the ABS and the Australian universities regarding access to NHS data at no extra cost. Experience overseas suggests that health survey bodies make data available widely and at reduced or no cost.

Significant effort will need to be invested in the analysis of the data once it has been collected, in order for the financial investment to be realised. There may be opportunities for researchers with a wide range of interests to assist in the analysis, if they are allowed access to the data. This should lead to a quicker output of information from the survey and improved dissemination of the findings. There may also be opportunities to undertake record linkage with other administrative collections if consent and privacy issues are dealt with, and there may be ways of commencing a population based longitudinal cohort within the survey as well.

## **8.0 Biomedical risk factor survey experience overseas**

### **8.1 United States of America (USA)**

The USA has an extensive and sophisticated program of surveys and data collection systems under the auspice of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention. Some NCHS data systems and surveys are ongoing annual systems while others are conducted periodically. NCHS has two major types of data systems: systems based on populations, containing data collected through personal interviews or examinations; and systems based on records, containing data collected from vital and medical records.

They include:

National Health Interview Survey

National Health Interview Survey on Disability

- State & Local Area Integrated Telephone Survey (CATI-equivalent)
- National Immunization Survey
- National Health and Nutrition Examination Survey (NHANES)
  - NHANES I Epidemiologic Followup Study
- National Survey of Family Growth
- National Health Care Survey
  - Ambulatory Health Care Data (NAMCS/NHAMCS)
  - Hospital Discharge and Ambulatory Surgery Data
  - National Home and Hospice Care Survey
  - National Nursing Home Survey
- National Employer Health Insurance Survey
- National Mortality Followback Survey
- National Maternal and Infant Health Survey
- National Vital Statistics System
  - Birth Data
  - Mortality Data
  - Fetal Death Data
  - Linked Births/Infant Deaths

Since 1960, the National Center for Health Statistics (NCHS) has been responsible for producing vital and health statistics for the United States. NCHS has legislative authority under the Public Health Service Act to collect statistics on the extent and nature of illness and disability of the population; environmental, social, and other health hazards; determinants of health; health resources; and utilization of health care. The National Nutrition Monitoring and Related Research Act of 1990 directs the Departments of Health and Human Services and Agriculture to strengthen national nutrition monitoring and to implement a plan to assess the dietary and nutritional status of the U.S. population on a continuous basis. The National Health and Nutrition Examination Survey (NHANES) is the cornerstone of the National Nutrition Monitoring and Related Research Program, providing data needed for nutrition monitoring, food fortification policy, establishing dietary guidelines, and assessing government programs and initiatives such as the Healthy People 2000 and 2010 objectives of the Department of Health and Human Services.

The goals of NHANES follow:

- to estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors;
- to monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- to monitor trends in risk behaviors and environmental exposures;
- to analyse risk factors for selected diseases;
- to study the relationship between diet, nutrition, and health;
- to explore emerging public health issues and new technologies; and
- to establish a national probability sample of genetic material for future genetic testing.

The NHANES has been a program of periodic surveys conducted by NCHS. Examination surveys undertaken since 1960 have provided national estimates of health and nutritional status of the US civilian non-institutionalized population, using nationally representative samples. NHANES has taken a new direction beginning in 1998. The major differences from previous Health and Nutrition Examination Surveys are that NHANES is now being implemented as a continuous, annual survey, and that it will be linked to related Federal Government data collections conducted on the general United States (US) population, in particular, the National Health Interview Survey (NHIS) and, potentially, the US Department of Agriculture's food consumption surveys. The Program also has permanent ongoing funding under federal legislation enacted in 1992.

Previously, researchers needed to use the entire 4 or 6-year sample in order to make even the broadest statistical estimates, because data were only representative of the entire population if one used the entire sample period. Researchers sometimes had to wait as long as 10 years after data collection before gaining access to data based on the entire 6-year sample. From 1998, NHANES has collected data from a representative sample of the U.S. population, newborns and older, every year. The new design has also allowed increased flexibility in survey content.

NHANES is linked to NHIS at the Primary Sampling Unit (PSU) level (i.e., the same counties, but not necessarily the same individuals, will be in both surveys). NHANES will also be linked to NHIS with regard to questionnaire content of the household interview, for selected topics. Links to Medicare and National Death Index records permit longitudinal/historical studies of disease.

These interrelationships with existing surveys and databases follow the Department of Health and Human Services' Survey Integration Plan. In addition, USDA's Continuing Survey of Food Intakes by Individuals (CSFII) will be merged with NHANES in year 2000. Work is underway to conduct additional research and development of a computer-assisted dietary interview method by USDA in collaboration with NCHS.

The NHANES I Epidemiologic Followup Study (NHEFS) is a national longitudinal study designed to investigate the relationships between clinical, nutritional, and behavioral factors assessed at baseline NHANES I, and subsequent morbidity, mortality, and institutionalization. The NHEFS population includes the 14,407 participants who were 25-74 years of age when first examined in NHANES I (1971-75). NHEFS is a collaborative project involving NCHS, the National Institute of Aging, other components of the National Institute of Health, the Substance Abuse and Mental Health Services Administration, and other Centers in the Centers for Disease Control and Prevention. NHEFS provides data on mortality, morbidity, and hospital utilization as well as changes in risk factors, functional limitation, and institutionalization between NHANES I and the followup recontacts.

The first wave (1982-84) of data collection was conducted for all members of the NHEFS cohort. It included tracing the cohort; conducting personal interviews with subjects or their proxies; measuring pulse rate, weight, and blood pressure of surviving participants; collecting hospital and nursing home records of overnight stays; and collecting death certificates of decedents. Continued follow ups of the NHEFS population were conducted in 1986, 1987, and 1992 using the same design and data collection procedures developed in the 1982-84 NHEFS, with the exception that a 30-minute computer-assisted telephone interview was administered rather than a personal interview, and no physical measurements were taken. The 1986 NHEFS was conducted on members of the cohort who were 55-74 years of age at their baseline examination and not known to be deceased. The 1987 and 1992 NHEFS was conducted on the entire non-deceased NHEFS cohort.

In the USA, NHANES has a long history of successful and useful data collection activities with high response rates. The burden on the public is kept minimal, participation is voluntary, and there is no paperwork burden on businesses or health care providers. The technology innovations that are planned for NHANES will result in rapid and accurate data collection, data processing, and publication of results.

The NHANES program has been very successful in recent years in setting the stage for national policy directions, consumer guidelines' development, research priorities and contribution of material for research activities. In 1997-1998, there were over 200 publications based on the NHANES and published in peer reviewed international journals. This only represents those where NHANES was identified in the title or as a key word, those in English and those in the journals contained in certain computerised databases. The subject of these publications reflects the full range of diseases and conditions across all ages of participants, preventive strategies, health promotion, and epidemiological and statistical methods.

The number of people examined in a 12-month period is about the same as in previous NHANES, about 5,000. NCHS first conduct a pilot test followed by two dress rehearsals prior to the main study. The purpose of the pilot test is to resolve timing and training issues and check the automated data collection systems and equipment. The dress rehearsals are used for further training of technicians and other staff for the main survey. As in the previous NHANES people are screened using sample selection. This is followed by detailed household interviews. Sample persons are invited to receive physical examinations and health and dietary interviews in mobile examination centers (MEC's). Home examinations consisting of a subset of exam components will be offered to those sample persons who are unwilling or unable to come to the MEC for the full examination. Various medical tests and procedures will be conducted to enable analysis of the relationship between health and nutrition status and disease risk factors, to measure the prevalence and comorbidity of diseases and disorders, to establish reference standards, and to monitor secular trends in health and nutrition status.

In NHANES III conducted from 1988 to 1994, blood specimens were collected from participants aged 12 years and older and stored frozen in liquid nitrogen or as cell cultures. As a result of needing to collect more sample volume to accommodate out-of-range results that have to be repeated, large numbers of surplus serum samples have been stored frozen. This means that both cell cultures and frozen white blood cells are available to researchers with funded research programs.

Though participants in the survey signed an extensive consent form, specific mention of genetic testing was not included. Given the scientific importance of this resource to the US, a proposal to develop a plan to make DNA available to the research community for de-identified testing was approved by the NHANES Board in 1996, and de-identified samples for DNA research are also available to funded researchers, after an extensive process of approval and scrutiny.

NHANES is currently soliciting proposals for new content for 2001. Proposals can address the addition of survey questions or laboratory analyses of blood, urine and potentially specimens from other sources. Proposals for inclusion of examination components and other physical measures are not being considered, as the program is already extensive.

## 8.2 Canada

There has been a recent and significant increase in interest in population health surveys in Canada. After the 1978 Canada Health Survey, there was a hiatus of almost a decade in large-scale household interview surveys. The main recent surveys are the 1985 module in the (telephone) General Social Survey, 1986 postcensal survey on disabilities and the 1987 and 1990 Ontario health surveys. There have also been a number of more focused surveys on topics such as smoking, health promotion and fitness.

The Canadian Government approved permanent multimillion dollar funding for a biennial National Population Health Survey in 1992, which is longitudinal and includes a set of core population health status measures. Most recently, Canada has progressed steadily towards a comprehensive plan for national population health information, which includes significant innovations in record linkage and a framework and philosophy to bind the various strategies into a coherent infrastructure incorporating a cost-effective approach and staged development.

Planning is at a very early stage for a biomedical risk factor survey, and the Canadians are just starting to develop a process for its design. A paper has been commissioned from the Institute for Clinical Evaluative Sciences in Toronto. This is a survey of major physical measures' surveys, particularly those run at the national level. There is considerable consultation being planned with key stakeholders, and Statistics Canada is keen to begin refining the list of physical measures and their rationales that will be the focus of the survey. The first step



being taken is the compilation of the scientific and health information and policy rationales that underpin a survey of this kind and then questions of feasibility and operational considerations will be examined. They are planning to spend from \$5 to 10 million, and the final amount of funding will depend on the strength of the rationales/needs for different kinds of measures. For example, if there is a constituency for measuring pulmonary function, this is a discrete and rather costly measure, but one that is much more feasible now with CAPI and portable spirometry. They have not yet considered sample design issues.

### 8.3 United Kingdom

The Health Survey for England is a series of annual surveys about the health of people in England. The survey provides regular information on various aspects of population health and monitors some national health goals and targets.

The Health Survey was first proposed in 1990 to improve information of morbidity by the (then) newly created Central Health Monitoring Unit within the Department of Health. This information is used to underpin and improve targeting of nationwide health policies. The survey was carried out in 1991-1993 by the Office for Population Censuses and Surveys which is now part of the Office for National Statistics. From 1994 onwards, the survey has been carried out by the Joint Survey Unit of the National Centre of Social Research and the Department of Epidemiology and Public Health at University College London.

The Health Survey is designed to be nationally representative of people of different age, sex, geographic area and socio-demographic circumstances. The 1991 and 1992 surveys had a limited population sample of about 3,000 and 4,000 adults respectively. For 1993 to 1996, the adult sample was boosted to about 16,000 to enable analysis by socio-economic characteristics and health regions. In 1995 for the first time, a sample of about 4,000 children was also introduced. For the 1997 Health Survey, the sample was about 7,000 children and 9,000 adults.

The aims of the Health Survey for England are:

- to provide annual data about the nation's health;
- to estimate the proportion of the population with specific health conditions;
- to estimate the prevalence of risk factors associated with those conditions;
- to assess the frequency with which combinations of risk factors occur;
- to examine differences between population sub-groups;
- to monitor targets in the health strategy; and
- (from 1995) to measure the height of children at different ages, replacing the national study of health and growth.

The Health Survey combines questionnaire answers and physical measurements as well as other objective measures such as analysis of blood samples and lung function tests. The Health Survey for England contains a 'core' which is repeated

each year and each survey year has one or more modules on subjects of special interest. The 'core' includes:

- questions on general health and psycho-social indicators
- smoking
- alcohol
- demographic and socio-economic indicators
- questions about use of health services and prescribed medicines - the focus for
- these may vary from year to year to suit the modular content of the survey.
- blood pressure
- measurements of height, weight and blood pressure

The modules may be about a single topic, several topics or about population groups. The modules to date have been:

1993	cardiovascular disease
1994	cardiovascular disease
1995	asthma accidents disability
1996	asthma accidents special measures of general health (Euroquol, SF36)
1997	children and young people
1998	cardiovascular disease
1999	ethnic groups
2000	older people, social exclusion
2001	disability, asthma, accidents.

From 1993 to 1994 when cardiovascular diseases were the main focus, the surveys included physical measures and the taking of a blood sample. The response rate for the first stage interview was 71% and blood samples were obtained from 51% of the initial sample. A range of blood analyses was performed and a small sample was stored for possible future analysis with participant consent.

For 1998 where cardiovascular disease is the main focus, the following blood analyses were undertaken:

- total cholesterol
- HDL cholesterol
- fibrinogen (a clotting agent - raised levels can contribute to cardiovascular disease and stroke)
- haemoglobin
- ferritin
- C-reactive protein.

For the years in which asthma was included, blood samples were analysed for Immunoglobulin E (IgE - the antibody responsible for the immediate type of immune response - a raised level of IgE is found in people with an atopic

predisposition) and house dust mite specific IgE. Cotinine (a metabolite of nicotine) levels have also been included in the survey to measure for smoking and are particularly useful in assessing passive smoking. Cotinine levels can be obtained from either a blood sample or a saliva sample.

#### 8.4 New Zealand (NZ)

Experience in New Zealand with biomedical risk factor surveying is reflected in the 1996/97 NZ Health Survey that was linked to the 1997 National Nutrition Survey. The cost of the National Nutrition Survey (NNS) was \$NZ 3.5 million over three years in contracts, excluding costs to the Ministry of Health for staff time, and the cost of the National Health Survey was \$NZ 750,000. The NNS was run by the University of Otago under contract.

The linkage with the NZ Health Survey was the result of financial pressures preventing separate funding of the NNS. It was the best way to ensure that both surveys occurred. Those who were involved with the surveys do not recommend a linkage in the future. It reduced the response rate in the second survey due to the multiple dropout opportunities (NNS was 50.1%). There are some advantages though, now having a linked data set to dredge for further information. It was believed it may save money, although no analyses were done to confirm this.

Blood sampling was crucial to the NNS. It has provided good data for blood cholesterol and iron deficiency. It provides some validation for the nutrient information where available. For example, dietary inadequacy of iron was very high from the 24-HDR data, yet blood samples showed iron deficiency anaemia was not an issue for nearly all of the female population. Biological markers are the way of the future and are a natural adjunct to the dietary information. A large number of different assays were investigated for inclusion in the NNS, however, due to financial and logistical constraints, only a limited number occurred. Urine samples and bioimpedance were also considered, but eventually rejected.

The results of the NNS have shown three key nutrition issues in NZ - obesity and overweight, food security and calcium inadequacy. These are all now priorities within the Ministry for policy work, but given a number of constraints, and the size of the issue, obesity is progressing first.

## **ATTACHMENT 1**

### **Logistical issues for biomedical sampling**

1. Collection of blood and other samples
  - Occupational health and safety training of staff, if recruited for the survey
  - Equipment and location of venesection clinics, or in-home sampling?
  - Informed consent will be complex– especially if genetic or DNA testing
  - Sample identification using at least 2-3 indicators- e.g. name, date of birth, code, Medicare number
  - Documentation of participant demographics and GP, linkage of information to sample needs to be established, bar-code identification would be useful for database entry - (using light pens)
  - Appropriate tubes (preferably Vacutainer type) with anticoagulant, determine volume of blood required, blood mixing apparatus available, possible piggy backing of tests to a single tube but an original sample is required for viral studies and for archiving of samples
  - Appropriateness/usefulness of viral markers needs to be established e.g. Hepatitis A antibody disappears in some cases, accurate vaccination history (if available) will be relevant,
  - Biological false positive rate for each test to be considered
  - Sample stability for reliability of test result - sample-test turnaround time including transport time for rural and remote areas.
2. Transport of blood samples
  - Validated temperature controlled storage and transport of specimens needed
  - Sample receipt and identification during transport
  - Must meet requirements of International Air Transport Authority standards and their equivalents for road and rail transport re regulations for unscreened blood samples, depend on the volume of samples (i.e. for samples above and below 50 mls. there are different costs and regulations).
3. Testing of Blood samples
  - Need establishment of normal ranges
  - Define sensitivity and specificity of test, technique or kit standardisation
  - One laboratory only per test and/or per state to ensure laboratory standardisation?
  - Establish confirmatory test and decision protocol for reactive results.
4. Verification of test results
  - Accreditation of laboratory: National Accreditation of Testing Authorities
  - Approved and acceptable results, in line with Royal College of Pathologists Quality Assurance Program or similar performance program.

## 5. Test interpretation

- Clinical outcome management protocol, standard letters, information leaflets for participants and their doctors need to be developed
- Pre-test counselling for viral or genetic testing required
- Should an opportunity for public education of health risks be taken during interview?
- Ethical approval and consideration of how to achieve fully informed consent should be addressed (particularly for DNA testing)
- Problems of ownership of samples and data –(particularly relevant for stored sera – eg. gene patenting issues from the US arm of Human Genome Project)
- Duty of care to notify outcomes needs to be addressed
- Need to establish management protocols and follow-up for biological false positive or indeterminate results especially where participants might be concerned eg. viral markers. Follow-up and repeat testing with later generation screening tests should be offered. Liability due to stress from false notification needs to be assessed.
- Tracing of participants will be an issue throughout the study, particularly if longitudinal - strategies using Medicare database, electoral role, death notification etc. should be considered.

## 6. Notification of test results

- Development of standard letters and protocols
- Relevance of findings with health management information should be given to participant -? Liability if study outcome for some is poor health but those groups/ individuals not advised of risk minimisation behaviour.
- Notification by mail or phone of positive viral markers is undesirable- should be briefed in person by a trained counsellor or GP with information tools. Best handled through GP to ensure follow-up. E.g. notification letters should not be sent to be received on a Friday when counselling is not available over a weekend. Links with established services and resources for HIV, Hepatitis C etc should be made.
- Issues of poor participant traceability can be even within one week of sample collection (Australian Red Cross Blood Service new donor and Lookback experience).

## 7. Counselling and follow-up

- Trained staff required for viral notification
- Consider notification also under state public health legislation
- Confidentiality especially of positive viral markers.

## 8. Sample Archiving and repository establishment

- ? Archiving of samples - plasma, DNA - cost, site - monitoring of alarmed freezers at appropriate temperature, stability of sample storage prior to archiving should be established

- Where to site archive (one or many)? Ongoing maintenance costs for storage, define ownership, decision making process and approval for any further testing
- Consider liability issues of non - de-linked samples and performance of new screening tests without consent
- Value of national plasma sample archive for future screening of new viruses- de-linking will remove liability of notification (if participant informed) but less use as a longitudinal study.
- Should specimens be linked or de-linked? - Ongoing liability and responsibility to inform of later test results from archiving - follow-up issues, ethics to resolve uncertain test results with evolution of newer, better tests.