Ethical considerations arising from National Health Measurement Surveys

With particular reference to the Australian Health Measurement Survey (AHMS) program

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This process resulted in the preparation of a Business Case for the Australian Health Measurement Survey program (AHMS), which was undertaken by an Inter-Governmental Steering Committee (drawn from Commonwealth, State and Territory health and information agencies), assisted by a scientific Reference Group. Their expertise and contribution to the developmental process is hereby acknowledged.

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ABSTRACT

The purpose of this paper is to identify a range of ethical considerations* that arise during the design and implementation of national health surveys that incorporate physical and biochemical measures. These include, for example, the gaining of informed consent, the nature of survey sampling, and the storage of biochemical samples.

These cross-sectional surveys are able to provide important information on the prevalence of various health conditions and distributions of physical, mental and biochemical characteristics of the population, as well as providing data on the relationship between risk factors and selected conditions, and social and environmental determinants of health. In Australia, a program of national health measurement surveys that will collect a range of measures (physical and biochemical characteristics) is proposed, the Australian Health Measurement Survey (AHMS) program.

The ethical, legal and social issues that arise are numerous. A number of broad policy issues emerge that require discussion. In order to ensure that survey programs are conducted within an ethical framework, these issues must be identified and discussed with communities and others, and broad agreement reached about the most appropriate ways to proceed.

(* This paper is not intended to be a comprehensive review of all the ethical issues that may arise in the context of the AHMS program, nor of the methods that might be used in their resolution. The purpose of the paper is to raise some issues as part of the development of the AHMS Program in the hope that those who have the ultimate responsibility for its design and implementation might address them).

1. INTRODUCTION

National sample surveys, which include physical and biochemical measurement, can provide important information on the prevalence of various health conditions and distributions of physical, mental and biochemical characteristics of the population, as well as data on the relationship between risk factors and selected conditions, and social and environmental determinants of health. Survey programs of this nature are now being conducted in many countries around the world, and the information that is collected is an important resource to support policy development and health planning. A program of national population health surveys using self-reported information and a range of more objective measures (physical and biochemical characteristics) is proposed for Australia, the Australian Health Measurement Survey (AHMS) program.

There are a large number of legal and ethical issues that emerge once a survey with biochemical and other physical measures is proposed. These include, for example, the gaining of informed consent, the nature of survey sampling, and the storage of biochemical samples. These need careful attention and discussion, and some may require legal opinions to reduce the likelihood of future legal claims and liability.

Community involvement in a survey of this kind is critical to its success, given the response rates that are needed to ensure that results are representative of the population(s) of interest. Significant investment is required to encourage participation and support at every stage of the survey. Consumer confidentiality and privacy concerns require a concerted effort and a planned strategy to address issues of data collection and usage, storage, security and access by researchers and others for analyses. Consumer anxieties are also likely to be heightened when biomedical sampling, particularly of blood, is raised in the public domain. The use of languages other than English and of appropriate interpreters, literacy levels, and the ability to understand and to give one's own consent must be considered carefully. Cultural and religious considerations, particularly regarding the taking of samples or physical measurements, will also be important. The benefits of these surveys and aspects of their methodologies need to be asserted and discussed fully.

It is apparent that the ethical, legal and social issues that arise from a survey program of this kind are numerous, and will be determined largely by the survey design and its implementation. In order to ensure that the program is conducted within an ethical framework, these issues must be identified, discussed and broad agreement reached with the community about the most appropriate ways to proceed.

2. AN OVERVIEW OF NATIONAL HEALTH MEASUREMENT SURVEYS

2.1 Background

Monitoring and forecasting the population's health and health determinants are prerequisites for knowledge-based health policy and the development of health care at national, regional and local levels. National health measurement surveys are characterised by the collection of subjective information through questionnaires, and the gathering of more objective information via measurement of height, weight and body mass; factors in saliva, blood and / or urine; lung function; mental health and cognitive state; or childhood development. These surveys are also referred to as 'health examination surveys' in some countries.

From an examination of the use of surveys of this type that have been undertaken around the world, the following purposes have been identified:

- 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 as 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; and
- 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 and to contribute to a greater understanding of health and illness.

Survey programs of this nature have been conducted for many years in the USA, some European and Asian countries, the United Kingdom and, more recently, in New Zealand, and serve as the base to support health policy, health research and prevention strategies in those countries.

2.2 Experience in countries other than Australia

Numerous countries such as Korea, Latvia, Pakistan, Greenland and Canada have conducted single national health measurement surveys. The majority focused on cardiovascular health and included measures of body dimensions, blood pressure and analyses of blood samples.

A number of international, collaborative surveys across countries have been established. Examples of these include CINDI (Country-wide Integrated Non-Communicable Disease Intervention) and MONICA (Multinational

Monitoring of Trends and Determination in Cardiovascular Disease). The current WHO initiative, Stepwise Approach to Surveillance (STEPS) of non-communicable disease risk factors, also uses standardised questions and measurement protocols at three levels of monitoring, depending on available resources, across developing and more developed countries worldwide (Bonita et al. 2001).

However, some countries have now established, or are developing, ongoing programs of population health surveys using physical and biochemical measures. The key design features of these programs are summarised in Table 2.1. Of these, the programs in the US and the UK are the most sophisticated, and survey results and analyses have been highly valued for use by policy-makers and researchers. Each conducts their survey on an annual, rolling basis and includes a wide range of physical and biochemical measures. Both of these programs survey children, offer interview and measurement in respondents' homes (or in mobile clinics), have a longitudinal component for follow-up of participants, some linkage to administrative data and store collected samples for further research.

A number of countries are now favouring the survey design used by the UK Health Survey for England (HSE), which has a core content component (measured at every survey), and special interest modules (measured less frequently or opportunistically). The core content is designed to monitor general health, common risk factors and the socioeconomic determinants of health over time. Special interest modules examine particular health-related questions on an occasional or rotating basis in order to examine certain issues in greater depth. The Scottish, New Zealand, and the US NHANES survey have also adopted this model (see Table 2.1).

The degree to which ethical matters have been addressed in the development of these programs is seldom detailed and is often not able to be verified. However, there are a variety of ethical clearances that are in place regarding some significant issues such as consent for measures to be taken and for the storage of samples, data linkage and access to samples by researchers (see Table 2.2).

Table 2.1: Programs of population health measurement surveys - Examples from countries other than Australia

Country and survey program	Frequency	Inclusion of children	Sample size (per survey)	Location	Physical and biochemical measures	Linkage to admin. data *	Sample storage
USA **National Health and Nutrition Examination Survey (NHANES)**	Annual continuous[1] (from 1999); previously a series of multi-year surveys (since 1960)	✓ from 2 months old (since 1988)	7 000 per annum	Mobile centre or in the home	**Core measures**: Blood pressure, height, weight, body dimensions, analyses of blood and urine **Measures on sub samples**: include ECG, audiometry, balance testing, bioelectrical impedance, cardiovascular fitness, body composition, bone densitometry, dermatology exam, lower extremity disease exam, muscular strength testing, oral health, vision testing, TB skin test, spirometry, allergy testing	✓	✓
England **Health Survey for England (HSE)**	Yearly (from 1991)	✓ from 2 yrs.	20 000 (16 000 adults & 4 000 children 1998)	Home	**Core measures**: Blood pressure, height, weight, body dimensions **Measures related to individual survey topics**: Cardiovascular disease (blood) Asthma / accidents / disability (blood, saliva, spirometry)	✓	✓
Scotland **Scottish Health Survey**	Triennial (from 1995)	✓ from 2 yrs.	13 000 (1998)	Home	**Core measures**: Blood pressure, height, weight, body dimensions, lung function, blood analyses **Measures related to individual survey topics**: Cardiovascular disease (blood)	✓	✓

[1] From 1999, each annual sample is representative of the population; previously the total multi-year survey was required to achieve a representative sample.

Country and survey program	Frequency	Inclusion of children	Sample size (per survey)	Location	Physical and biochemical measures	Linkage to admin. data *	Sample storage
Singapore **National Health and Morbidity Survey**	5-7 years (from 1992)	×	4 700	Clubs and community centres	**Core measures:** Blood pressure, ECG, height, weight, body dimensions, blood analyses **Every survey focused on**: Diabetes and cardiovascular disease	n.a*.	n.a.
Germany **National Health Examination & Interview Survey**	6-8 years	×	11 600	Health clinic or home	**Core measures**: Blood pressure, height, weight, body dimensions, blood and urine analyses, mental health exam., tests of function, nutritional status	n.a.	n.a.
New Zealand **NZ Health Monitor program** (secured funding – to be run from 2001/2)	Continuous (10 year cycle program) (National Nutrition Survey 1996/7 then every 5-10 yrs.)	✓	7 500 (5 000 for nutrition and mental health surveys)	Home	**Core measures**: Height, weight, body dimensions, bio-impedance, blood pressure, blood analyses **Measures related to individual survey topics**: Child nutrition (1st survey) Mental health Disability	✓	To be deter-mined
Finland **Health 2000**	Five-yearly (from 2000) Previous survey 1978/9	×	10 000	Home or mobile clinics	**Measures:** Height, weight, body dimensions, bio-impedance, blood pressure, tests of physical and mental functioning, vision and hearing, oral and dental health, ECG, spirometry, Blood, saliva, urine, and faecal analyses	n.a.	✓

n.a.* = Details not available in English

Table 2.2: Overseas Population Health Measurement Surveys – Ethical Issues

Country and its national survey	Formal ethical approval	Consent for:
USA **NHANES**	NHANES Institutional Review Board	Written, informed consent from each participant (12 years or older) for both the in-home interview and the health examination, and permission from parent or guardian for child under 18 years – general consent for participation and for information to be released according to legal provisions relating to confidentiality and privacy. No specific consent for DNA testing of anonymised stored samples – currently under review by NHANES. *No release of information to anyone other than the respondent, except as required by law (public health notified diseases and child physical abuse notification)*
UK **Health Survey for England**	Ethical approval obtained from the North Thames Multi-centre Research Ethics Committee (MREC) and from all Local Research Ethics Committees (LRECs) in England**.**	Written, informed consent for: Blood pressure results to be sent to GP (adult and child under 16 years) Sample of blood to be taken (adult 18+ years) Sample of blood to be taken (child 11-17 years) Blood sample results to be sent to GP (adult 18+, child 11-17 years) Blood sample for storage and unspecified testing (not of viruses) (adult 18+, child 11-17 years) Blood sample result to be sent to respondent.
FINLAND **Health 2000**	n.a.	Each participant is asked to sign a document that allows the National Public Health Institute to use his or her data in medical research. Several biological samples are stored for later analyses, concerning e.g. cancer research.
NEW ZEALAND **Child Nutrition Survey**	Auckland Ethics Committee for pilot	Informed consent from adult guardians and children, as well as assent. Consent for possible storage of samples, and for samples to be destroyed at the end of the survey. Consent for sending abnormal results to GP.

n.a.* = Details not available in English

2.3 Experience in Australia

There have been several national population based studies conducted in Australia that have included the collection of physical and biochemical measurements. The key features of these surveys are outlined in Table 2.3. Many smaller surveys, usually focused on particular geographic areas or special populations of interest, have also included physical and biochemical measurements but only 'national' population based surveys are described below. The National Heart Foundation's Risk Factor Prevalence Study surveys of capital cities have been repeated over time and provide a time series of data on cardiovascular health.

With the development of several survey programs overseas that include physical and biochemical measurement, there has been an increasing interest in Australia for establishing a similar, coordinated national program. The first Australian proposal began as a single biochemical risk factor survey to repeat, and build on, the information obtained from the 1989 National Heart Foundation survey. The proposal has since developed to follow the model adopted by the UK and USA, that of a coordinated national program of periodic population health measurement surveys to cover a range of public health issues over time. An outline of the proposed Australian Health Measurement Survey (AHMS) program is described in Section 2.3.1.

Table 2.3: National population health surveys using physical and biochemical measurement in Australia

	Survey design	Sample size	Physical and biochemical measures
National Heart Foundation: Risk Factor Prevalence Study	Three cross-sectional surveys in all capital cities in 1980, 1983 and 1989	5 000 to 10 000 adults (aged 20+)	Related to cardiovascular health: blood, blood pressure, fasting glucose (only first two) and body measurements
Aust. Council for Health, Physical Education and Recreation Inc.: Australian Health and Fitness Survey	Cross-sectional national survey of schoolchildren in 1985	8 500 students aged 7 to 15 years	Related to cardiovascular health: blood, blood pressure and body measurements
Environmental Protection Authority: National Survey of Lead in Australian Children	Cross-sectional national survey in 1995	3 000 children (aged 1-4)	Related to blood lead levels: blood
ABS: National Nutrition Survey	Cross-sectional national survey in 1995 (undertaken on a sub-sample of the ABS NHS)	13 800 children and adults (2+)	Body measurements, and blood pressure (16+)
International Diabetes Institute: Australian Diabetes, Obesity and Lifestyle Study (AusDiab)	Cross-sectional national survey in 1999	10 000 adults (aged 25+)	Related to cardiovascular disease and diabetes: blood, oral glucose tolerance test, body measurements, bioimpedance, spot urine and ECG; (foot screening, sensory tests and retinal photography in a sub-sample)

2.3.1 Outline of the proposed Australian Health Measurement Survey program

The proposed AHMS program has been developed as a program of cross-sectional surveys that include a component of physical and biochemical measurement, and will examine a range of disease outcomes and risks. The broad aim of the program is the collection of population health information at a national level – specifically designed to assist in the development of health policy and service planning, to assess the degree of success of health promotion or illness prevention strategies and to contribute to a greater understanding of health and illness in Australia.

The AHMS program will be nationally representative of people of different age, sex, geographic area and socioeconomic circumstances. It will combine questionnaire responses and physical and biochemical measures (such as measurement of height and weight; analyses of samples of blood, urine, and saliva; and tests of function). The program of surveys allows for the inclusion of a wider range of content areas than a single 'stand-alone' survey. The design contains a 'core' of measures, which is likely to be repeated at each survey, with one or more modules on subjects of special interest undertaken opportunistically, and utilises a similar model to that which has been implemented successfully in the UK and the USA.

A number of national health policy areas have been identified as important for inclusion in the AHMS program, such as chronic disease comorbidities, onset of risk factors in childhood, overweight and obesity, mental health, lack of physical activity and nutrition, in addition to risk factors for cardiovascular disease and diabetes mellitus. The survey will provide national prevalence estimates for a range of chronic diseases and conditions across relevant age groups.

Two frameworks, *The National Health Performance Framework* (devised by the National Health Performance Committee (NHPC 2001) and AHMAC endorsed) and *Preventing Chronic Disease: A Strategic Framework*, (devised by the National Public Health Partnership (NPHP) (2001) and AHMAC endorsed) provide a mechanism to ensure national data collection develops in a coordinated way to fill information gaps in Australia. The AHMS program offers an important opportunity to collect information to fill some gaps highlighted by these frameworks.

The AHMS program is recommended to commence in association with the Australian Bureau of Statistics' (ABS) National Health Survey (NHS), which collects health information by personal interview. The first survey of the AHMS program would be conducted in association with the NHS in 2004/5, preceded by a dress rehearsal in 2003/4. The program is, in effect, in two parts. The first of these comprises the subjective measures undertaken in the

NHS. The second includes the physical and biochemical measurement undertaken in the AHMS. It is proposed that the survey be repeated after six years, with the possibility of more frequent (e.g. three yearly) surveys once the initial results have been analysed and their contribution to policy development, program planning and research assessed.

The proposed objectives of the AHMS program are:

- to determine the prevalence of selected disease outcomes and risk factors / determinants in the Australian population and selected population groups, as a basis for policy and strategy development;
- to monitor trends in the prevalence of identified disease outcomes and risk factors / determinants in the Australian population and selected sub-population groups;
- to examine the relationships among selected diseases and risk factors / determinants; and,
- to validate self-report of selected risk factors / determinants using biological measures, in order to assess the validity of time trends in health indices obtained using self-report.

Information from the surveys will be used:

- to generate reliable evidence over time to be used for population health planning and the evaluation of several major disease prevention and control activities, including the National Health Priority Area (NHPA) strategies;
- to examine the relationships among selected diseases and risk factors / determinants to assist in focusing research efforts and policy developments;
- to provide the infrastructure for "opportunistic" testing of issues of concern (for example, lead or other pollutants) that may arise in the future; and,
- to validate the self-report measures that are collected in face-to-face health surveys and potentially provide weights for adjustment of those surveys.

Future opportunities for consideration within the AHMS program exist for administrative data linkage to cancer and death registries, possible sample storage and for the inclusion of a longitudinal component to allow follow-up of some participants over time, all subject to participant consent. These issues have been considered for the initial AHMS, but require considerable community consultation and ethical debate, and have been excluded from the proposed first AHMS at this time.

3. ETHICAL CONSIDERATIONS

The development of national health measurement surveys gives rise to a significant range of ethical, legal and social issues. In order to ensure that such programs are conducted within an ethical framework, these issues must be identified, discussed and broad agreement reached about the most appropriate ways to proceed.

3.1 An ethical framework for research in Australia

Ethical considerations are essential to good research, and ethical inadequacies in a research program are as significant as scientific inadequacies (NHMRC 1999). In Australia, research involving human participation must be conducted in accordance with agreed ethical considerations as set out in the National Statement on Ethical Conduct in Research Involving Humans (NHMRC 1999). In addition, international codes and agreements are also pertinent, such as the World Medical Association's Declaration of Helsinki (amended October 2000). Research involving human participation is also subject to a variety of legal requirements at Federal, State and Territory levels. All research must comply with any relevant Commonwealth and State/Territory legislation (NHMRC 2000).

Ethical principles serve to identify good, desirable or acceptable conduct in all spheres of human activity. There are four basic ethical principles that have been identified as the basis of ethical conduct in research involving humans (Gillon 1994; Beauchamp & Childress 1994; NHMRC 1999).

These principles are:

- Integrity of researchers – a commitment to the principles as set out in the Joint NHMRC/AVCC Statement and Guidelines on Research Practice 1997;
- Respect for autonomy – the obligation to respect the autonomy of others, in so far as this is compatible with equal respect for the autonomy of all potentially affected;
- Beneficence and non-maleficence – the obligation to maximise possible benefits and minimise possible harms. Researchers exercise beneficence in assessing the risks of harm and benefits to participants, in respecting the rights and interests of participants and in reflecting on the cultural and social implications of the research;
- Justice – the obligation to act fairly and to address the question of who ought to receive the benefits of research and bear its burdens.

Above all, research must be so designed that respect for the dignity and well being of participants, takes precedence over the expected benefits to knowledge (NHMRC 2000). However, there are instances where research has

not been designed nor conducted in accordance with these goals. As an example, there is a long history in Australia of Aboriginal and Torres Strait Islander (ATSI) communities' very different experience with research conducted by the non-Indigenous community. These research experiences have been exploitative, highly intrusive and disempowering, and have not served the interests of Indigenous people (McAullay et al. 2002).

These precedents are reflected in the drafting of the NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (1991), and a number of other research ethics guidelines that have been developed by Indigenous research bodies and organisations in consultation with their communities. Any research must be inclusive of Indigenous community interests and researchers must honour culturally different values, needs, practices and perspectives (Atkinson et al. 1994). Significant issues include the importance of consultation (aimed at producing relevant research), community involvement, cultural appropriateness, consent, data and information ownership and the appropriate dissemination of research findings (McAullay et al. 2002). Most importantly, research needs to be relevant to identified health needs of Aboriginal and Torres Strait Islander communities, aimed at producing new knowledge, and of potential benefit to Indigenous health. Aboriginal and Torres Strait Islander communities are "particularly concerned about the use of information about Indigenous persons – particularly, what information is collected, by whom, how is it used, who owns the data, who has access and under what circumstances" (ABS & AIHW 1997).

The recent advances made in relation to articulating ethics issues and processes for conducting ATSI health research have been significant. These have been largely steered by ATSI community representatives, and may serve as a good model for broader community consultations around ethical issues in health research. The processes in place around ATSI research ethics might be adapted for broader community consultations, particularly, for the 'special' consultative needs of other marginalised groups such as those who have drug and alcohol use problems, homeless people, those with mental health problems, and culturally and linguistically diverse peoples.

3.2 The nature of the AHMS program

The process of conducting a national health survey using physical and biochemical measures leads to ethical issues arising at each step in the process. For example, the initial steps of priority / agenda setting determining the need for a survey, and the allocation of funds to support its development have ethical dimensions that ought to be considered. The design of the survey program and the selection of special groups for inclusion in the sampling frame require ethical review. The choice of content areas and their measurement have ethical implications, as do issues surrounding the

feedback to participants of results. Informed consent and its scope, confidentiality and privacy of information must be considered, as well as the possible storage of samples and their future use.

Participants in the AHMS program and the Australian community as a whole ought to be assured that each of these areas has been examined in detail and ethical considerations addressed, through a consultative process that allows for greater community involvement in identifying the ethical challenges that it sees as most important.

3.3 Survey processes requiring ethical consideration

3.3.1 Subject recruitment

Participants in a survey program can be recruited in ways that can have ethical implications. This is particularly true if subjects are coerced into participating or are given false expectations. It may be unlikely that such coercion or deception would be overt; rather, it may be subtle and more difficult to detect. For example, the use of any incentives to encourage participation ought not precede the gaining of informed consent, as this may impair the voluntary character of that consent (NHMRC Statement, S1.10).

The recruitment of special groups will require additional consultative processes. This is particularly relevant for groups such as Indigenous peoples. The survey design may present Indigenous Australians with more difficult choices about participation. Additional information and consultation processes will be needed to facilitate decisions about whether or not to participate. Particular attention will also be required in the development of survey protocols if seeking the involvement of children through their parents, to ensure that coercion does not occur to any extent.

3.3.2 Informed consent

During the recruitment phase, survey subjects should be clearly informed of the intent and activities required for participation. They should also be advised of possible consequences of participating in the survey (for example, that they may receive information about aspects of their health if they agree to do so). Participation in the survey will be voluntary and subjects should be informed that they can cease their participation at any stage of the survey. 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. 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 very important for many groups in the community.

The ethical and legal requirements of consent have two components: the provision of information and the capacity to make a voluntary choice. The requirements for obtaining consent are outlined in the NHMRC Statement 1999 (refer to S1.7). The onus is on researchers to ensure that each subject understands the implications of participating in the survey, is competent to consent and is exercising a voluntary choice. Informed consent is essentially a process.

In some circumstances and in some communities, consent is not only a matter of individual agreement, but also involves other properly interested parties (for example, community elders in Indigenous communities). In such cases, researchers need to obtain the consent of all parties before commencing (NHMRC Statement, S1.9). In the case of research that involves Indigenous individuals or communities, the Interim NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (NHMRC 1991) should be consulted.

When subjects are recruited, they should be informed of the benefits and risks of participation, details of the survey activities and any possible use of data of all kinds being collected. As part of the survey, some measures may involve the taking of samples of blood, saliva or other physiological substances. In the NHMRC Statement 1999, Section 15.4 outlines the requirement for consent where human tissue samples are collected for research purposes. The collection of biochemical samples requires that the subjects be told, in lay language, of the purposes and risks of the sample taking, and the uses to which the samples will be put, as well as other information. Any information that is provided to participants must be provided in plain and accessible language. In addition, the NHMRC Statement 1999 (S15.3) identifies the need for the institution responsible for the conduct of the survey to have policies in place that conform to relevant legislation and are consistent with the NHMRC Statement regarding tissue sampling. Such policies need to consider the source, nature and cultural or religious sensitivity of the sample, the original purpose for its collection, and the objectives of the research. Issues such as the access of other parties who may purport to have an interest in the information (for example insurance companies, police, family members) will require the development of protocols regarding data access and protection.

A number of questions arise about the extent to which a researcher must go to inform participants of the unknown or unplanned use of samples, particularly if a decision were to be made to store and bank samples for future use in possibly unspecified research. What is the long-term responsibility of the researcher, or agency, to keep the participants informed of the use of their samples? What are the limitations of conducting additional analyses that are unrelated to the original survey purposes? To what extent does the initial informed consent cover any later research? Are the rights of participants disregarded when unspecified research is conducted on samples collected for

another purpose? Is there a duty to inform participants of the results of subsequent research? Is there a duty to inform participants of the subsequent disposal of the sample in the future? These issues are significant and complex and the rights of participants must be ensured and safeguarded.

One dilemma is whether a generic consent to undertake research on a sample given by a participant originally, is adequate consent to conduct a specific test on stored samples in the future. The obvious strategy of obtaining fresh consent has at least three major problems: (a) subjects may be very difficult to contact if follow-up has not been maintained or they are deceased, (b) a high proportion of non-consent either due to inability to re-contact or to refusal may bias the results, (c) for certain samples, multiple measures may emerge of interest and a process of very specific informed consent would generate an almost continuous stream of consent requests to the participant. Failure to obtain a new informed consent will expose a researcher to (a) allegations of unethical behaviour, and/or (b) a difficult situation if the measure information may be of clinical relevance to the participant, yet the participant was not counselled about the test before samples were taken and tested (Schulte et al. 1997).

The banking and future use of samples also raises questions of the ownership of samples, and access to the samples and results by other researchers. Protocols to protect samples and to deal with possible requests for access from nonscientific interests, such as employers, police or insurance companies also needs to be addressed. For some communities, for example for Maori people, there may be a cultural requirement not to store samples, and to return any unused portion of a sample to its owner.

In Australia, issues relating to sample storage, access and future use are dealt with in the NHMRC Statement 1999, which addresses such practices in paragraphs 1.7 to 1.12 and 15.4 to 15.8. The effect of these paragraphs is that later use of collected tissue for research without consent would not comply with the National Statement, unless an institutional ethics body reviewing the AHMS program waived the consent requirement pursuant to paragraph 15.8. This is a key issue that would need to be resolved, for example, by providing participants with adequate information about how the samples will be used. The issue of sample storage in the AHMS program has been discussed but will not be undertaken at this time.

The issue of genetic testing has been the subject of NHMRC attention and relevant advice is contained in the NHMRC Guidelines for Genetic Registers and Associated Genetic Material (1999) and Ethical Aspects of Human Genetic Testing – an Information Paper (NHMRC 2000).

For consideration:
What procedures will be needed to ensure that consent is informed, voluntary and that the participant is capable of giving consent?
Who on the survey team will be responsible for the gaining of informed consent?
How will the giving of consent be recorded?
Will survey information and consent forms be available in languages other than English?
What are the cultural and religious issues associated with the survey design that may influence consent?
What processes are the most appropriate for Indigenous peoples?
Will the use of interpreters be offered?
What about literacy issues?
What about subjects with communication difficulties or other disabilities?
What procedures will be in place to gain consent on behalf of children? How will the assent of children be gained? How will researchers determine if a child is able to consent on their own behalf?
Will there be any people who are excluded from participating? On what grounds should those decisions be made?
What are the ethical implications of sample storage for future research, and how might this affect consent procedures?

3.3.3 Confidentiality and Privacy

Confidentiality refers to an obligation that arises from a relationship, often contractual, between two parties in which one has given information to the other. The recipient is under an obligation not to use that information for any purpose other than that for which it was given. Legally, confidentiality is protected by the right of the person who provided the information to compel the recipient of the information to comply with their obligation (NHMRC 2000).

Privacy refers to a person's interest in exerting effective control over the collection of, access to, use of, or disclosure of any personal information that has been collected or could be collected by another person (NHMRC 2000). In Australia, privacy is legally protected within the jurisdiction of the Commonwealth and in some States and Territories, by statutory codes of conduct that must be followed by public authorities. The Information Privacy Principles, in Section 14 of the *Privacy Act 1988 (Cth)* set standards to ensure privacy of personal information. The NHMRC has produced guidelines that reflect the Principles as they relate to health research (Guidelines Under Section 95 of the Privacy Act 1988, March 2000). The AHMS program and its processes must comply with these guidelines to ensure an ethical duty to participants is observed.
Exceptions to obligations of confidentiality and to the statutory codes concerning privacy include when:

- the information provider consents to the release of the information;
- the law authorises or compels release; and / or
- the information is released in the public interest (NHMRC 2000).

Protocols for the survey will require consideration of confidentiality and privacy issues for possible sharing of information within the research team, for access to any long-term storage of samples and other data (if proposed at a later time), and for any administrative data linkage (if proposed at a later time). There will also need to be protocols developed for access to data by other researchers, non-scientific interests and possible family members of participants. Issues of consent, confidentiality and privacy from subsequently deceased persons will also require consideration.

For consideration:
What mechanisms need to be in place at each stage of the survey to ensure that measures to protect confidentiality and privacy of participants comply with NHMRC guidelines and legal provisions?
How will these provisions affect the objectives of the survey?
To what extent will identified data be maintained and its protection ensured?
What processes should be followed for de-identification of data?
How will the privacy and confidentiality of participants who subsequently die be managed, particularly in the case of consent for future access to data or samples for additional research, if this is approved?
How will the confidentiality and privacy of participants be ensured during the collection of measures?

3.3.4 Interpretation and communication of test and survey results

Several questions are pertinent to the sharing of information from a survey, including when to inform, whom to inform, how to inform, and maintaining the confidentiality of the information. The traditional paradigm that epidemiological research is concerned with data about group risk rather than individual effects is less appropriate in a survey of this kind. Participants are contributing to the research through their individual results, many of which may have particular and identifiable meaning for their own health status, and may represent opportunities to access treatment or preventive interventions.

When to inform?
There are three levels of need for information sharing which are likely to emerge in the implementation of the survey.

i) The most urgent level of need will be where an emergency arises during the interview or measurement phase of the survey and transportation of a participant to a health facility or other service is required. Information regarding the health status and testing results if available should be given to

the participant (or ambulance officer, if more appropriate) to transmit to the appropriate personnel at the receiving facility.

ii) For the majority of measures performed as part of the survey, standard interpretations of the findings exist. For these measures, there is general scientific agreement regarding threshold levels. Consequently, these findings should be shared with the participant, subject their agreement. When the health status of the participant is known to be at risk, the information should be shared as a matter of priority.

The participant should be given information on possible next steps that might be pursued to obtain further evaluation of the findings and their implications. Subjects whose measures are in the normative range should also be informed of the results, but not as rapidly as those with abnormal findings. Protocols will be required to set out standard interpretations of measures, consistently worded information and agreed approaches to the transmission of results to participants, with suggestions of further sources of assessment, such as general practitioners. The issue of consent from participants for the receipt of results will also need to be considered (see later).

iii) For some measures performed as part of the survey, there may be no clear interpretations of the findings or agreed-upon critical levels. In such cases, it will be difficult to interpret the findings for a participant. Such a measure might be included in the survey because of the need to determine its distribution in the general population, but there may be no clear guidelines as to reportable levels. It should be considered whether or not to report these findings to participants on a measure-by-measure basis.

Who to inform?

Another ethical issue is who should be informed and there are a number of aspects to consider. In a survey of this kind, there is a probable duty of care to inform participants of results. Therefore all participants should be given the opportunity to receive results from the survey (with their consent), unless this is specifically contraindicated, either by the expressed wish of the person not to receive results, or because there are known circumstances that indicate such information would be harmful to a person's emotional well being. In general, subjects should be provided with their results and some immediately useful information in exchange for their participation. The survey might represent an opportunity to provide participants with information about strategies to address certain aspects of their health risk.

Additional complications arise if measures include genetic or DNA testing, or survey samples are made available for this type of testing at a later date. Is there a responsibility for the survey team to inform participants or their family members of a possible risk identified by the testing? Should pre- and

post-test counselling be offered in these circumstances? How practical might that be several years after completion of the survey?

The family of a participant is often an interested party, not only in the case of any DNA testing, but also when previously unrecognised risk factors are found. Clearly, the family would share the burden of caring for an ill family member. However, the greater duty of care is clearly owed to the participant, and it is probably sound ethical practice to inform only the subject and allow him or her to determine whether family members should be informed. An exception to this is when the subject is a child.

Other aspects should be considered. If an environmental health measure indicated a high exposure in a participant, what duty would exist to notify an employer or a relevant environmental health authority or to alert the participant to possible methods of exposure? To what extent should the results of measures be made available to parents if a young person is unwilling for this to occur? What extent of effort should occur to ensure notification of an abnormal result to a participant's medical practitioner with the consent of the participant?

How to inform?

It is important that a subject is not 'diagnosed' by participating in a general population health survey of this kind. Rather, a subject should be informed that a finding is abnormal and that medical advice and follow-up should be sought. There are several reasons why a 'diagnosis' should not be used. There may be additional circumstances of which the survey team is unaware that contributed to the finding. Additional tests may be required to determine the status of the person more accurately, and information should be imparted in such a way that clarifies it as a risk, not as a diagnosis.

The receipt of information about one's personal health and the presence of new or existing risk factors can be a source of immediate anxiety, psychological distress and depression (Shaw et al. 1999). The receipt of a positive result on testing for risk factors in the majority of studies is normally associated with psychological distress, anxiety and depression in the first four weeks following, but only in a minority of cases are such effects evident for longer than this. Results from studies using experimental designs show that presenting results to participants and providing post-test emotional support prevents or reduces some of the mood disturbance following positive results. The ability to provide counselling for participants in the survey may be limited, but survey team members who are responsible for feeding back results should be aware of these issues.

There are wider issues involved in the communication of results of the survey, especially for particular population sub-groups or communities. Gathering and interpreting data are unlikely to be independent from social

and political contexts. Where there are current debates over health risks, communicating the results of such data cannot be separated from the use of the data (Nelkin et al. 1989). Dissemination of risk information can have implications for citizens' and employees' rights to privacy, confidentiality and nondiscrimination, and researchers should be aware of the social power of this type of information.

For consideration:
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? Will any re-testing be offered?
What does an abnormal result mean for the person's physical and mental wellbeing, 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?

3.3.5 Special considerations for the involvement of children

The inclusion of children and young people in a survey program of this kind will advance knowledge about their health and wellbeing. However such research should only be conducted where:

- the research is important to the wellbeing of children and young people,
- their participation is indispensable to the research,
- the study method is appropriate for children and young people, and
- the circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person (NHMRC Statement 1999, S4).

The gaining of consent to the participation of children and young people also involves special consideration. Consent must be obtained from a child or young person whenever he or she has sufficient competence to make this decision, and either

- the parent / guardian in all but exceptional circumstances, for a child; or
- any organisation or person required by law.

Refusal to participate on the part of a child or young person must be respected (NHMRC 1999), and such a refusal will override parental

permission. Thus where children are not able to give their own consent, in addition to consent from a parent or legal guardian, the assent of a child must also be gained. Assent refers to a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent. All information given to a child must be age and developmentally appropriate, and accessible (i.e. in a language that the child understands).

There is research evidence that surveying children can present certain methodological challenges, but considerable work has been undertaken in the area of questionnaire development and pre-testing with children of varying ages, from four years and older (Borgers et al. 2000; Scott 2000). The recommendations from these studies should be used when the interviewing of children is undertaken, and appropriate design of questionnaires adopted.

The benefits and possible harms associated with the taking of measures, particularly physiological samples such as blood, and the communication of results should be considered carefully. The use of microtechniques for the collection and assaying of samples should be investigated, as well as strategies to minimise any adverse effects of sample collection (e.g. the use of anaesthetic creams). The decision to allow blood sampling for a purpose such as this, which is non-therapeutic, must be the child's, and it is inappropriate to insist on the taking of blood or other samples, if a child indicates either significant unwillingness before the start or significant stress during the procedure.

4. COMMUNITY INVOLVEMENT

There is a significant responsibility to involve community members in the identification of ethical issues and in finding satisfactory solutions to resolve them. A range of strategies can be employed to undertake this, from consultation with consumer organisations and community representatives, to the use of focus groups and cognitive testing, to pilot testing of the survey processes.

Consumer involvement in a survey of this kind is critical in determining its success, in order to achieve the response rates that are needed to ensure that the results are representative of the population(s) of interest. Significant investment will be required to encourage consumer participation and support at every stage of the survey. Consumer confidentiality and privacy concerns will require a concerted effort and a planned strategy to ensure issues of data collection, disposal or storage, security and access to researchers for analyses are handled ethically. Consumer anxieties are also likely to be heightened when biochemical sampling, particularly of blood, is raised in the public domain. The benefits of the survey and aspects of the methodology will need to be asserted and discussed fully, and community confidence gained if the AHMS program is to achieve its objectives and benefit the Australian community.

4.1 Identified processes for the resolution of ethical issues

There are a number of community consultation processes about ethical issues that are being or have been undertaken in Australia and overseas, which will assist in identifying different models of consultation with communities. Most have been implemented because of the rising community interest in genetic information and related research. These include the current Australian Law Reform Commission (ALRC) and Australian Health Ethics Committee's (AHEC) Joint Inquiry into the Protection of Human Genetic Information; the US National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health's (NIH) Report of the First Community Consultation on the Responsible Collection and Use of Samples for Genetic Research; and the various consultations being undertaken by the Wellcome Trust and the UK Medical Research Council prior to the establishment of BioBank UK (Ethical aspects and public consultation on Public Perceptions of the Collection of Human Biological Samples, March 2002). It is likely that a range of concerns will also emerge from consultations with communities in Australia regarding the AHMS program.

There are a number of ways to proceed. Clearly each of the issues identified above requires careful thought and discussion. Existing Australian ethical guidelines will provide direction in some areas (NHMRC 1991). Advice can

also be sought from researchers and agencies in Australia and overseas who have experience in the conduct of surveys of this kind. The determination of the most appropriate solutions will be part of the more detailed planning of the survey, which will be required if agreement in principle is gained from AHMAC.

A continuing process of consultation with consumer organisations, ethnic and Indigenous groups, and community representatives will be required to explore community attitudes and social, cultural, ethical and spiritual concerns about issues, and to determine the way(s) to proceed with the survey program's development and execution. Ultimately the final survey will need to be placed before an Institutional Ethics Committee (as outlined in the NHMRC Statement 1999) for consideration and final ethical approval.

4.2 Aboriginal and Torres Strait Islander communities

Consultation is a key component of Indigenous involvement in research. A research proposal must be formulated in partnership with Indigenous communities and their consultative organisations, and underpinned by the principle of self-determination. The act of developing a research proposal independently of the Indigenous community has the effect of disempowering the participants from the outset (Atkinson et al. 1994), leading to research that will have been structured through non-Indigenous cultural perspectives and practices. There also needs to be a commitment to ongoing consultation throughout the life of a research proposal, not solely at its outset. Consultation should also produce consent at both the community and the individual level if a proposal is to be supported.

Equity in research implies that Indigenous community participation in the conduct of the research. What opportunities exist for community participation? Where are the opportunities to employ Aboriginal and Torres Strait Islander people throughout the research process? What possible barriers and difficulties may there be, and how might they be resolved?

Issues of dissemination of research findings are also fundamental and include ownership and publication of findings, consent for the further use of biological samples, storage of such samples, and destruction of identifiable data (McAullay et al. 2002). Agreements need to cover the ethical use of information of all types, including community feedback, publication of research findings (including academic publication) and release of findings more widely via the media, for example.

Indigenous participants in the survey program must be assured that each of these areas has been examined in detail and ethical considerations addressed. There is a responsibility to involve community members in the identification of ethical issues and in finding satisfactory solutions to resolve them. A range

of strategies can be employed to undertake this, from consultation with Indigenous organisations and community representatives, to the use of focus groups and cognitive testing, to pilot testing of the survey processes.

Community 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 participation and support at every stage of the survey. Confidentiality and privacy concerns will require a concerted effort and a planned strategy to ensure issues of data collection, storage, security and access to researchers for analyses are handled ethically. Issues of blood sampling may also raise concerns, given the impact of the Human Genome Diversity Project on certain Indigenous communities (Dodson 2000). A continuing process of consultation with Indigenous groups, and their community health representatives will be required to explore community views about the full range of ethical issues, and to determine the ways to proceed. Ultimately, any proposed survey should also be subject to the usual processes of ethical oversight by an appropriate Indigenous Ethics Committee(s) before it can commence.

5. CONCLUSION

The development of a national health measurement survey program for Australia (the AHMS program) offers a significant opportunity to undertake consultations with a wide range of interested people and communities about the considerable ethical and social issues that will arise as a result of running a survey program of this kind. There are many pertinent issues to consider and a number of different consultative approaches will be required, given the diversity of interests and communities. All aspects of the AHMS program will need to be discussed fully and community confidence gained, if the program is to achieve its objectives and benefit the Australian community.

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