Ethical considerations for a proposed program of National Population Health Surveys using objective measures for Australia

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Ethical considerations for a proposed program of National Population Health Measurement Surveys using objective measures for Australia

The purpose of this paper is to identify a range of ethical considerations that arise as part of the design and implementation of a proposed program of national population health surveys using objective measures, the Australian Health Measurement Survey (AHMS) program. A number of broad policy issues emerge that require discussion and resolution.

1. Introduction

National probability sample surveys 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 providing data on the relationship between risk factors and selected conditions, and social and environmental determinants.

A program of national population health surveys using self-reported information and a range of objective measures (physical, mental and biochemical characteristics) is proposed for Australia, the Australian Health Measurement Survey program (AHMS). The ethical, legal and social issues that arise from a survey program of this kind are numerous, and will be determined largely by the final 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 about the ways to proceed.

2. An ethical framework for research

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).

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; 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.

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).

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).

3. The nature of the survey program

The process of conducting a national population health survey using objective measures leads to ethical issues arising at each step in the process. For example, the design of the survey program will raise ethical issues peculiar to it. The selection of special sub-population groups for inclusion in the sampling frame requires ethical consideration. 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. The possible storage of samples and their future use also raise significant ethical concerns.

Participants in the survey program and the Australian community as a whole must be assured that each of these areas has been examined in detail and ethical considerations addressed.

4. Survey processes requiring ethical consideration

4.1 Subject recruitment

Participants in the 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 difficult choices about participation. Additional information will be needed to assist them to decide about participation. Particular attention will also be required to survey protocols if seeking the involvement of children through their parents, to ensure that coercion does not occur to any extent.

4.2 Informed consent

During the recruitment phase, survey subjects should be clearly informed of the intent and activities required for participation and of possible consequences of participating in the survey (for example, that they may receive information about aspects of their health). Participation in the survey will be voluntary and subjects should be informed that they may 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.

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.

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. These are currently undergoing revision.

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 biological samples requires that the subjects be told, in lay language, of the purposes and risks of the research, and the uses to which the samples will be

put, as well as other information. 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 purpose 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) need further discussion.

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 is made to store and bank the 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.

A major 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). These issues need further discussion and resolution.

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 or even nonscientific interests, such as employers, police or insurance companies. 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 needs to be resolved, for example, by providing participants with adequate information about how the samples will be used.

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?

4.3 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 survey 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 approved), and for any administrative data linkage (if approved). 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?

4.4. 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.

Whom to inform?

Another ethical issue is who to inform 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, 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 is 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?

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 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 parents/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, in addition to consent, 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.

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.

6. Consumer involvement in survey design and implementation strategies

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 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. Consumer 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. 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, and community confidence maintained if the Australian Health Measurement Survey program is to achieve its objectives and benefit the Australian community.

7. Suggested processes for the resolution of ethical issues

There are a number of ways to proceed. Clearly each of the issues identified above requires careful thought and discussion. Existing Australian ethical guidelines provide direction in some areas. Advice has also been sought from researchers and agencies in Australia and overseas who have experience in the conduct of surveys of this kind. Some issues, such as the possibility of sample storage and banking for future research, have substantial ethical implications and have been referred to the Australian Health Ethics Committee of the NHMRC for policy advice.

The determination of the most appropriate solutions will be part of the more detailed planning of the survey, which will be required if funding and agreement in principle is gained from AHMAC. Ultimately the final survey will need to be placed before an Institutional Ethics Committee (as outlined in the NHMRC Statement 1999) for their consideration.

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