Australian Longitudinal Study on Male Health (MALES)

Technical Report #1

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1. METHODOLOGICAL MATTERS

1.1 Instrument development

Substantial progress has been made on instrument development despite being delayed in starting due to the embargo period after the commencement of the contract.

In accordance with the Detailed Study Plan (Oct 2011), three separate instruments have been developed for participating males targeted at specific age groups (10-15, 16-17 and 18-55 years) (Appendices A, B, & C). Additionally an instrument for parents of the 10-17 year old participants has been developed (Appendix D).

Process

The approach to instrument development is an iterative one in which the first draft instruments will undergo cognitive testing, be revised and then piloted in a dress rehearsal phase, revised again and a final instrument produced for the main data collection.

The draft instruments have been developed through a collaborative process involving experts in areas relevant to male health within and external to the Melbourne School of Population Health.

Adult Instrument (18-55 year old males)

The process has been as follows:

1. Broad domains of inquiry have been articulated based on the parameters outlined in the tender document – DoHA priorities (see Table 1).

2. Working groups have been formed based on those domains. Working groups are led by a member of the Steering Committee with expertise in that area, and draw membership from researchers within and external to the Melbourne School of Population Health (Appendix E lists working groups, leads and members)

3. Working groups met and developed a framework of constructs within the broad domains (Table 1). Selection of constructs was guided by the following principles set out by the Steering Committee

    - Content should be guided by National Male Health Policy, with particular focus on the areas specified in the RTF: health status, health service use, risk and protective factors, and health literacy;
    - The study should complement other relevant data collections – e.g., the Australian Longitudinal Study on Women's Health (ALSWH), the Longitudinal Study of Australian Children (LSAC), and the Australian Health Survey (AHS);
    - Full advantage should be taken of the longitudinal design of the study;
    - The interview/survey instruments for the different age groups should align wherever possible (e.g., assess the same constructs, use equivalent standardised measures);
    - The amount of information sought should be balanced against participant burden;
    - Wherever possible, questions in the interview/survey instruments should come from validated existing measures;
    - The construct must be able to be reliably and validly assessed using a brief measure;
    - Participant burden should be minimized.

4. Working groups then sourced measures and questions to assess constructs.

   To achieve optimal reliability across the age groups, where possible questions and measures were sought that demonstrated validity across the entire age ranges (for example the PHQ9, which screens for depression in adults, has also been validated in young people 12 years and older).

   Where there was no instrument or question that had established validity across age ranges, those that had demonstrated construct validity in the specific age groups were chosen.

   The main sources of questions are:
   - Validated brief scales – i.e. SF12, PHQ9.
   - Other Australian national health surveys (described above)
   - Other health surveys – international population health surveys (e.g. the US Youth Risk Behaviour Survey), or smaller scale Australian studies (RESIDE, HOWRU)
   - Questions developed for MALES specifically. (Note: these are not items requiring psychometric testing but screening questions to rule participants in or out of particular modules, or for collecting specific empirical information i.e. living arrangements of offspring, household expenses and so on)

   The process has been designed to be as inclusive as possible in the first instance with respect to the set of constructs and attendant measures and questions, followed by a refinement and editing phase.

5. Selection of the final set of constructs and questions was undertaken using the following criteria (in no specific order):
   a) How will the data collected be used? That is, what is there a relevant research question?
   b) Is the measure brief?
   c) Is it validated and/or used elsewhere in a high quality study?
   d) Will the results based on data collected from these measures be publishable in high ranking journals?
   e) Is/Are the question(s) too narrow/specific and therefore better asked in a future sub-study?
   f) Is the data policy relevant, that is, does the question provide actionable data for program development/intervention?
   g) Is the data gathered relevant to the research domains delineated in the RTF and proposed in the original tender?

6. Finally, the instrument testing process will be used to determine the final content of the questionnaire. There will be two phases of instrument testing. Phase 1: Cognitive Testing will test the structure and content of individual questions and the questionnaire as a whole. Phase 2: Dress Rehearsal will test the performance of the instruments in the field.

<u>Child and Adolescent Instruments (10-17 year olds)</u>

There has been a slightly different process for developing the instruments for under 18 year old participants. A single working group has been convened, comprising researchers with expertise in child and adolescent health and wellbeing research (Professor George Patton, Dr Lena Sanci, Dr Craig Olsen, and Dr Louisa Degenhardt, in addition to other members of the study team).

Dr Joanne Williams a Senior Research Fellow at the Murdoch Children's Research Institute accepted a 0.4 FTE appointment as an additional research fellow to coordinate the Child and Adolescent instrument development (see Appendix F for description of role). Dr Williams has extensive experience in developing and managing surveys in children and young people.

The Child and Adolescent Working Group followed a similar process of identifying relevant constructs and measures – some of which corresponded to the domains and constructs in the adult instrument, while others focused on child- and adolescent-specific health conditions and risk and protective factors.

Parent Instrument

As parental consent is being sought for participants less than 18 years of age, it has been decided to take advantage of parental involvement and develop a short parent self-complete survey. The advantage of a parent survey is that more detailed and reliable information can be ascertained for a range of areas particularly the young person's health history and the social determinant related variables such as household income and so on.

For both child and adolescent and parent questionnaires the same process of inclusion, sourcing questions, review and elimination as described above was undertaken.

1.2 Instrument Testing

Ethics Approval
Ethical clearance at the University of Melbourne is a two stage process – Melbourne School of Population Health Human Ethics Advisory Group (HEAG) first reviews the submission for compliance with Ethical standards. Once the HEAG approves the submission it goes to the University of Melbourne Health Sciences Human Ethics Sub-Committee (HESC) where final approval is granted. Research activities cannot proceed until HESC approval is in hand.

We sought and received approval from the HEAG for Phase 1 of instrument testing (Cognitive Testing) at the last meeting of 2011 (see Appendix G, ethics application materials, including Application, PLSs & Consent/Assent forms), and will be submitting the project to the HESC at the first meeting for 2012 (21 Feb 2012).

Data Collection
Preliminary consultation with data collection agencies was undertaken in November 2011 following which, a set of specifications for the Phase 1 cognitive testing has been developed (Appendix H). Five data collection agencies have been invited to submit quotes for the Phase 1 instrument testing and, at the time of writing, are preparing their quotes (Appendix I).

We specified that two rounds of cognitive testing take place for each of the four instruments: 18-55 years males, 16-17 years males, 10-15 years males, and parents. There will be one round of cognitive testing of selected questionnaire items with a semi-structured interview examining respondents interpretation of the meaning of questions, the respondent's understanding of the questions, what alternative wording might more accurately convey the question's meaning where uncertainty is identified, and the feelings of the respondent regarding the questions content and relevance. Items to be tested will be selected on the basis of the complexity of the questions, sensitivity of the topics the questions cover, if an extended age range is being used for existing questions, and if the question is newly developed or extensively modified from an existing question.

In the second round of instrument testing, participants will complete the entire questionnaire and then participate in an interview regarding the overall experience of completing the survey, including the time burden and ease or difficulty of providing the information requested, clarity of instructions, sequencing of questions and topics, and so on.

The contracted agency will supply a qualitative report, based on which the instruments will be revised.

The instruments will also undergo statistical review by the Statistical Consulting Centre at the University of Melbourne.

The draft instruments have been circulated to the members of the External Scientific Advisory Group for their advice and input.

1.3 Sampling

Professor Ian Gordon, Director of the Statistical Consulting Centre at the University of Melbourne, has been retained to provide advice on sampling strategies and issues (see Appendix F for a description of the role). Consultation with Professor Gordon is currently taking place.

As proposed in the original tender we will be trialling different sampling methods (Medicare Rolls, Australian Electoral Commission Electoral Rolls and Schools). This will occur at the Dress Rehearsal phase. We have contacted Medicare and the Australian Electoral Commission for preliminary discussion of sampling. The relevant person at Medicare is on leave until February, when further contact will be made.

Mr Pirani, legal counsel for the AEC, indicated in response to our initial enquiry that he had major concerns regarding the appropriateness and legality of using the AER for this project. His concerns were: 1) that DoHA were seeking unauthorized access to the AER via a third party; 2) that the AER would only provide access to a sub-sample of the cohort (over 18's) whereas Medicare would provide coverage of the whole cohort raising questions of statistical validity on which he would have to be satisfied, as well as the issue of the availability of more appropriate alternative source, and; 3) that using the AER to update contact information for Wave 2 was not legally permissible. Professor English in a follow-up phone conversation pointed out that DoHA made no reference to sampling frames in the tender documents and that his letter that described the study did not mean to imply that there would be linkage to the AER to find missing participants. Mr Pirani indicated that further discussions would serve no purpose until he receives a formal application. Applications cannot be submitted without a University HREC approval and thus there is no further action to be taken on this matter at present.

We are also currently seeking advice and exploring options about which state/territory to conduct the sampling trial for schools in.

1.4 Data collection, management and dissemination

No data has been collected at the time of this report. Data collection for the instrument testing phase will be conducted by an independent data collection agency. The tendering process is underway to appoint that agency. This phase of the study will produce qualitative data only for the purposes of refining the instrument. The data will be presented in a technical report to the study team and will not be published or circulated beyond the study team.

1.5 Data Linkage

Membership of the Data Linkage Steering Committee has been finalized and is as follows:

Prof Dallas English (chair)
Prof Jane Pirkis (co chair)
Mr Ian McLean, DoHA
Mr Ross Saunders, DoHA
Prof Louisa Jorm, University of Western Sydney
Dr Phil Anderson, AIHW
Ms Di Rosman, Department of Health, WA
Mr Martin Butler, DoHA

The terms of reference are currently under development and it is anticipated that the first meeting of the committee will occur in the first half of 2012.

2. KEY RESEARCH FINDINGS

There are no research findings to report as no data have been collected as yet.

3. DIFFICULTIES ENCOUNTERED AND STRATEGIES TO ADDRESS THEM

The embargo until 10 August 2011 delayed recruitment of study staff and has had a flow-on effect on instrument development and obtaining necessary ethics approvals.

Consent
In consultation with members of the Steering Committee and members of the relevant ethics committees, it became apparent that the original plan to seek self-consent as a 'mature minor' from participants aged 16 and 17 years was not feasible. While the 'mature minor' approach has been successfully used in the past by members of the study team, there are significant study design differences between those and this study that make it highly unlikely that self-consent for under 18 year olds would be approved for this study. Specifically, those studies that were approved for 'mature minor' consent had an on-site clinician or trained researcher who was able to make an assessment of the maturity or otherwise of the potential participants and exclude participants who were judged not mature enough to give consent. Should using Schools as the means of recruiting young people prove optimal then a 'mature minor' approach may be possible as a member of the research team may be onsite. However, if the Medicare option proves optimal then a survey would be mailed directly to the young person without any prior assessment of their maturity and their ability to make a 'mature minor' consent. For the purposes of trialling the sampling methods in the Dress Rehearsal phase we will be undertaking both methods of survey administration and thus will need ethical clearance for the mail out survey approach. As such we do not believe that the 'mature minor' approach is feasible.

To address this difficulty, the Steering Committee explored the possibility of removing all sensitive and personal questions from the survey, such that it would be deemed minimal risk and thus obviate the need to seek parental consent. However, the group was strongly opposed to this option as it would undermine the scientific value of the data collected, and compromise achieving the study objectives. Another option explored was to retrospectively assess sensitive areas in subsequent waves once participants had reached 18 and could consent for themselves. However the potential for recall bias was deemed to be unacceptable with this option. It was concluded that obtaining parental consent for all under 18 year old participants will be the only ethically acceptable and approvable option. This is likely to impact response rates. However, one benefit of this approach

though is that we will be able to administer the parent self-complete questionnaire for this group and so have more complete and reliable data on important social determinant factors.

Ethics Reporting Cycle

As described above, there are two levels of Ethical Review required for the Instrument Testing Phase: the Melbourne School of Population Health HEAG and the University level HESC. The HESC meets only 10 times per year, with no meetings in January and July. The lack of meeting in January introduced an unavoidable delay in securing approval and subsequent fielding of the instrument testing. We have addressed this by making a concerted effort to have the protocol submitted to the HEAG for the last meeting of 2011, so that any revisions could be made in good time for a strong application to be put forward to the HESC to maximize the likelihood of approval without revision on first presentation to that committee. This meant a very compressed instrument development process, which we were able to achieve due to the commitment of the Working group heads and content area experts who participated in the working groups. We are poised when the HESC reconvenes for 2012 to make a strong submission.

The issue of multiple levels of review is one that we are particularly mindful of for future phases of the study, which will also require review from the DoHA ethics committee. Both the DoHA Committee and the University of Melbourne HESC meet relatively infrequently and the 2012 meeting dates of all three committees are not synchronized (with some requiring submission just days before the prior one meets, or too short turnaround times between committee meeting dates). Thus there is potential for substantial delay to occur is securing approval if submissions are not coordinated and prompt. Our strategy to address this is to plan submissions with adequate lead time and realistic turnaround time between committee meetings.

4. DISSEMINATION/COMMUNICATION ACTIVITIES

We have commenced development of the study identity and branding. We have prepared a Specifications document (Appendix J) and are seeking quotes from a number of qualified graphic designers (Appendix K).

We have commenced development of the study website. The public facing website will be the first stage to go live and we are currently compiling content, and developing the structure of the site (see Appendix L for draft structure).

To date, there have been no communication activities involving participants as they have not yet been identified. However, as part of the process of developing the specifications for graphic design products, we have given consideration purpose-designing products for participants.

5. STUDY MATERIALS

Draft questionnaires for 10 -15 year old Males, 16-17 year old Males, 18-55 year old males and Parents have been developed and are attached (Appendices A-D).

6. PROGRESS TOWARDS STUDY OBJECTIVES AND TIMEFRAMES

The following *study objectives* specified in the Detailed Project Plan have been achieved:

- The External Scientific Advisory Group was convened and met for the first time on December 5 2011 (Appendix M for membership, Appendix N for meeting minutes)
- The instruments have been developed for the different age groups using a process that has ensured that the stated scientific and policy related objectives of the study will be met.
- Preliminary work on developing the sampling strategies has begun.

The *study timeframes* specified in the Detailed Project Plan have been achieved for two important study activities:

- Seeking Ethics Approval (Oct 2011 – May 2012): We have secured HEAG approval for the Phase 1 of Instrument Testing (Cognitive Testing), and will seek approval from the HESC when it reconvenes on 21 Feb 2012.

- Developing the Interview/Survey Instruments (Aug 2011 – Feb 2012): The initial phase of instrument development will be complete on 6 February 2012.

The specified timeframe for Piloting the Instrument (Aug 2011 – Feb 2012) will not be achieved. It is anticipated that the Phase 1 of instrument testing (Cognitive Testing) will commence in March (see OP for provisional timelines). The delay is due to the University of Melbourne HESC not meeting in January 2011, with 21 Feb being the first meeting of 2012. This event is beyond the control of the study.

As described above, the multiple review process, the infrequency of meetings, and lack of synchronicity between the three review committee, make it highly likely that the Ethical Approval cycle will be extended for the Dress Rehearsal and the Wave 1 data collection phases of the study, having a flow-on delay for data collection.

Overall, we have made very good progress in most regards, particularly given the unavoidable delays in appointing staff that were associated with the embargo. We recognise, however, that the timelines are very tight, and will continue to monitor our progress against them very carefully. We will report any slippage to DoHA and make sure that we take appropriate steps to address it. The expertise of our team is enabling us to work as quickly as possible on instrument development; however we are conscious that it is important that we do not trade speed off against quality.

7. DATA MANAGEMENT

In the process of questionnaire development, we have compiled spreadsheets recording the sources and details of each item included the questionnaires that will become the basis of data dictionaries.

8. STUDY GOVERNANCE

We have drafted Terms of Reference for the Consumer and Community Reference Group (Appendix P), and are seeking advice from Anne McKenzie, an expert in community participation at the University of Western Australia, on membership.

We have developed Terms of Reference for the External Scientific Advisory Committee (Appendix Q).

9. APPENDICES & TABLES:

A. Draft Adult Questionnaire

B. Draft 10-15 years Questionnaire

C. Draft 16-17 years Questionnaire

D. Draft Parent Questionnaire

E. Working Groups & Membership

F. Additional Staff Members

G. Ethics Application, PLSs & Consent Forms

H. Cognitive Testing Specifications

I. Cognitive Testing – Agencies invited to quote

J. Study Branding Specifications

K. Study Branding – Agencies invited to quote

L. Study Website Framework

M. External Scientific Advisory Group Membership

N. External Scientific Advisory Group – Meeting Minutes

O. Cognitive Testing Timelines

P. Consumer Reference Group Draft Terms of Reference

Q. External Scientific Advisory Group Draft Terms of Reference