

Technical Report # 2

March 2013

Table of Contents

Executive Summary	4
1. Methodological Matters – Pilot Testing	5
1.1 Cognitive Testing.....	5
1.1.1 Testing of the study questionnaires	5
1.1.2 Cognitive testing sample design	5
1.1.3 Data collection	6
1.1.4 Ethics approval	7
1.1.5 Quality assurance.....	7
1.1.5.1 Field preparation and recruitment	7
1.1.5.2 Data collection and interviewing	7
1.2 Dress Rehearsal.....	9
1.2.1 Comparison of sampling and recruitment methods	9
1.2.1.1 Review of recruitment options	9
1.2.1.2 Evaluation of recruitment strategies.....	10
1.2.3 Dress Rehearsal sampling design	13
1.2.4 Data collection for Dress Rehearsal	15
1.2.5 Dress Rehearsal printing and mail-out logistics.....	17
1.2.6 Ethics approval	19
1.2.7 Quality assurance in data collection	19
1.2.7.1 Field preparation and monitoring	19
1.2.7.2 Respondent contact management	20
1.3 Tendering and procurement process.....	20
1.3.1 Procurement of services for Cognitive Testing	21
1.3.2 Procurement of services for Dress Rehearsal	21
1.4 Data Linkage	23
2. Key Research Findings.....	25
2.1 Findings from Cognitive Testing	25
2.1.1 Overall performance of questionnaires	25
2.1.2 Performance of selected questions.....	26
2.2 Findings from Dress Rehearsal	29
2.2.1 Response rates	29
2.2.3 Sample characteristics	31
2.2.3 Pre-notification and reminder	34
2.2.4 Performance of questionnaires	34
2.2.5 Performance of contact forms and consent process	35
2.2.6 Contact data file.....	35
2.2.7 Other findings	36
2.2.8 Conclusions	37
3. Questionnaire revision	37
3.1 Questionnaire revision following Cognitive Testing.....	37
3.2 Questionnaire revision following the Dress Rehearsal.....	39
4. Difficulties encountered and strategies to address them	40
4.1 Sampling and Mail-out Issues.....	40
4.1.1 Medicare enrolment contact data - issues and challenges	40
4.1.2 Medicare mail-out process - issues and challenges.....	41
4.2 Dress Rehearsal response rates	41

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

4.3 Redesign of materials and protocols to improve response	45
4.4 Timeline	46
4.5 Budget	47
4.6 Ethical issues	47
5. Governance.....	47
5.1 Governance groups.....	47
5.2 Contribution of governance groups.....	48
6. Dissemination and communication activities.....	48
6.1 Development of a study brand	48
6.1.1 The process	48
6.1.2 The brand concept.....	49
6.1.3 The brand essence.....	49
6.1.4 The branding material	50
6.2 Development of a study website	50
6.2.1 The process	50
6.2.2 The long-term view	51
6.3 Other communication activities	51
7. Study Materials produced and used.....	52
8. Data management	54
8.1 Data coding	54
8.2 Data processing and cleaning rules.....	55
8.3 Data capture and storage	56
8.4 Data Book.....	57
9. Achievement of timeframes and objectives.....	58
10. Works cited.....	58

Executive Summary

The Australian Longitudinal Study on Male Health (Ten To Men) is a new longitudinal study of Australian men and boys between the ages of 10-55 years aimed at identifying the factors that contribute to the poorer health outcomes in Australian males in general, and in particular sub-groups of men. The Department of Health and Ageing has funded the University of Melbourne to conduct this study.

This technical report is the second in a sequence of reports describing the progress of the design and implementation of Ten To Men. While Technical Report #1 describes the first phase of questionnaire development including the process of sourcing and developing appropriate questions for the questionnaires, this second report details the design, implementation and findings of the pilot testing phase of the study.

The pilot testing phase of the study is drawing to an end and a great deal of knowledge has been gained over the course of that process. Chapter one describes the design and operational considerations for the Cognitive Testing and Dress Rehearsal. That chapter also includes activities related to Data Linkage. Chapter two outlines the key research findings, the most significant of which were that Schools and the AEC were not feasible recruitment options for the study and that the response rate for the DHS Mailout recruitment was significantly lower than anticipated. However, the questionnaire performed well in field. Chapter three describes the iterative process of review and revision of the study instruments, which are currently undergoing their final review before Wave 1. Chapter four discusses the difficulties and issues encountered in the pilot testing phase, the implications of these for Wave 1 and the approaches taken to addressing these. The most serious of these is the low response rate seen in the Dress Rehearsal which raises questions about the viability of this method for Wave 1 and has implications for budget and timelines. That chapter outlines the response of the study team to that information is engaging in a process of consultation, investigating options for improving the response rate, alternative recruitment strategies, and so on. It also concludes that based on those activities the target of recruiting 58,000 males will be difficult to meet with the resources available. Chapter six explains the activities of the various Study Governance bodies, including their roles in reviewing options for Wave 1 in the light of the Dress Rehearsal results. Chapter seven describes the communications activities undertaken in the past 12 months, including the development of the Ten To Men brand, website and presentations made by the study team. Chapter eight describes the development of the data dictionary for the Dress Rehearsal and the development of the framework around data governance for the study. In the final chapter the study materials developed over the course of the year are described.

Overall 2012 and early 2013 have been a very productive year and to the extent that the pilot testing has provided invaluable information on how the study instruments and methods perform in the field it has been a success. The low response rates were unanticipated by every researcher associated with the project, again showing the importance of undertaking rigorous pilot testing. However, since becoming aware of this issue the governance bodies of the study and affiliated researchers have been committed to reassessing the study methods and materials in order to ensure the success of Wave 1 data collection in 2013.

1. Methodological Matters – Pilot Testing

This chapter describes the methodological considerations involved in the development of the study instruments, sample design and data collection for the pilot testing.

Two pilot tests were undertaken to support decision making around questionnaire development and design as well as the recruitment methodology. The first pilot, Cognitive Testing, focussed on the content and performance of the study questionnaires. The second pilot was a Dress Rehearsal of different recruitment and data collection methods and field testing of the instruments.

1.1 Cognitive Testing

1.1.1 Testing of the study questionnaires

Cognitive Testing was undertaken in March and April 2012. The aim of the Cognitive Testing was to ascertain information on the design, length and flow of questions in the study questionnaires and assess the appropriateness of questions for specific age groups. The latter focussed on issues of potentially sensitive questions, reliability of questions, and how well newly developed questions were understood by participants in each age group.

Four questionnaires were developed by the University of Melbourne:

1. an interviewer-administered questionnaire for the boys of 10 to 15 years (15 pages; 67 questions);
2. a self-complete paper-based questionnaire for adolescent males between 16 and 17 years (18 pages; 93 questions);
3. a self-complete paper-based questionnaire for adults 18 to 55 years (34 pages; 154 questions); and
4. a self-complete questionnaire for parents of the young boys and adolescents (10 pages; 60 questions).

All questions in the questionnaires were sourced by the study team and research experts affiliated with the study. Major Report #1 describes this process in detail.

Following a minor tender process, Roy Morgan Research was contracted to undertake the Cognitive Testing. Prior to the cognitive testing interviews Roy Morgan Research assisted with the design of the questionnaire forms. This included contributing suggestions for amending wording, sequencing, layout and formatting of the questionnaires, and subsequent editing and layout work to produce clearer, more user-friendly versions of the questionnaires to use in the cognitive testing interviews. Language and instructions were reviewed to ensure the questions were appropriate for their particular format (self-complete paper-based questionnaire, or interviewer-administered face-to-face questionnaire). The interviewer-administered questionnaire for the 10-15-year-old participants also required the development of a number of show-cards to use during the interview.

1.1.2 Cognitive testing sample design

Potential participants targeted by age group were recruited from the Roy Morgan Research Single Source data base.

The target sample for recruitment was 56 interviews (see Table 1.1 for details). In addition to age group targets, the desired demographic profile of participants was for lower socio-

economic status and educational attainment. A total of 60 interviews were completed, over-achieving quotas for adults and parents, but under-achieving for adolescents.

Table 1.1: Cognitive Testing - target sample and achieved sample

Questionnaire	10-15 years males	10-15 years males	16-17 years males	18-55 years males	18-55 years males	Parents of boys aged 10-17	Total
Age Group:	10-12 years	13-15 years	16-17 years	18-29 years	30-55 years	No age limit on parents	
Target Round 1	5	5	5	4	4	5	28
Target Round 2	5	5	5	4	4	5	28
Target Total	10	10	10	8	8	10	56
Completed Interviews	11	9	7	10	10	13	60

1.1.3 Data collection

Cognitive Testing interviews were conducted from Friday 30 March 2012 to Monday 16 April 2012. Cognitive testing of the questionnaires comprised two phases. Phase 1 was designed to assess participant responses to a selected list of questions. This list contained questions that had been newly developed for the study to be tested for efficacy and comprehension and questions that had been previously used and validated in other studies but not in the target age groups. Participants completed a shortened version of the questionnaire that included those questions, followed by a face-to-face interview focused on the participant's understanding and interpretation of the questions of interest.

Phase 2 was designed to evaluate the overall performance of the questionnaire. Participants completed the entire questionnaire and follow-up interviews sought feedback on the overall experience of completing the full questionnaire, including appropriateness of questions, order of questions, overall comprehension of the questionnaire, and problems (e.g. confusion, discomfort, concerns etc.) the participant may have experienced while completing the questionnaire.

Interviews were conducted following interview guidelines developed in conjunction with Roy Morgan Research. Interviewers were instructed to provide minimal assistance to participants during the questionnaire completion stage, to instruct the participant to answer the question with their best guess, and to mark questions that participants had problems with for discussion later. During the questionnaire completion stage the interviewer remained in the room with the participant and noted any indicators of concern or confusion as well as recording any comments or queries from the participant. A note taker was present for most interviews to assist with capturing the follow up discussion with participants. Members of the study team from the University attended a number of the cognitive testing interviews to gain first hand feedback on the questionnaires and to monitor the cognitive testing process.

Incentives were provided to all participants: participants aged 10-17 years received a \$50 Coles Group & Myer Gift Card, and participants aged 18 and over (including parents of 10-17-year-olds) received \$75 cash.

Written informed consent/assent was obtained following the requirements of the University's Human Research Ethics Committee.

1.1.4 Ethics approval

The University of Melbourne has a two stage ethics approval process. At the first stage the local School of Population Health Human Ethics Advisory Group (HEAG) reviews the application in detail and makes a recommendation to approve, following which the University Health Sciences Human Ethics Subcommittee (HESC) reviews and gives approval. This structure is designed to reduce burden on the HESC, and to ensure that all applications undergo a thorough review. It does however significantly lengthen the time required to gain approvals, particularly as the HESC meets only 10 times annually.

For Cognitive Testing ethics approval from HEAG was received on 2 February 2012 and approval from HESC was provided on 12 March 2012. Appendix 2 contains copies of approval letters.

1.1.5 Quality assurance

1.1.5.1 Field preparation and recruitment

Whilst the content of all questionnaires was provided by the University of Melbourne, following extensive consultation with the Steering Committee of the Australian Longitudinal Study on Male Health, further revision and improvement of the survey instruments was needed in field preparation of Cognitive Testing. The questionnaire development process continued with the Roy Morgan Research team working in conjunction with the Ten To Men study team at the University of Melbourne. This process included suggestions and discussions on amending wording, sequencing, layout and formatting of the questionnaires, and subsequent editing and layout work to produce clear, user-friendly versions of the questionnaires ready for cognitive testing. Language and instructions were adjusted as appropriate to ensure the questions worked for their particular format. For the interviewer administered questionnaire for the 10-15-year-old participants the development of a number of showcards to use during the questionnaire completion stage was also required to improve the quality of response of the youngest participant group.

A targeted recruitment approach was chosen to source participants for the Cognitive Testing as the most effective and efficient method of recruiting participants in the narrowly defined age bands within the limited timeframe. This involved calling past respondents to the Roy Morgan Single Source, a large national syndicated survey which has a sample of approximately 50,000 people, nationally, each year. From this list, households in the greater Melbourne area, with men and children in the target age groups were selected for contact. Calls were made to potential participants by selected members of the trained CATI interviewing team.

1.1.5.2 Data collection and interviewing

A soft launch approach was taken for the start of fieldwork, with a small number of interviews conducted on the first few days of interviewing. This allowed the project team to assess the interview process, identifying any potential issues prior to commencing the main fieldwork period with a larger interviewing team.

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

A set of follow up questioning guidelines for each survey instrument were developed by Roy Morgan Research in collaboration with the University of Melbourne, detailing specific questions to be discussed in the Phase 1 interviews and areas to probe for these questions, as well as more general points to cover in the Phase 2 testing.

An intensive interviewer briefing session was held on Tuesday 3 April, with attendance by a member of the study team from the University of Melbourne. This session covered an overview of the study, the cognitive testing process and guidelines, and the content of the questionnaires. Questions which had been identified for testing in the Phase 1 interviews were discussed in more detail, including the background to some of these questions and some of the ways in which the questions may be interpreted by participants. Approaches to use in the follow up interviews when discussing the more sensitive questions were raised, along with ways to encourage participants to discuss their thoughts. This briefing session provided the interviewers with valuable insight information on the study as well as strategies to collect high quality and unbiased data.

As requested by the University of Melbourne, all interviewing for the Cognitive Testing was conducted at the Roy Morgan Research offices in Collins St, Melbourne. This provided a controlled and professional environment in which to conduct the interviews.

Interviews were conducted by highly experienced members of the Roy Morgan Research Customised Research team, with experience in conducting similar cognitive testing interviews for other social and government surveys. A total of ten researchers conducted the 60 interviews.

On arrival for an interview, a rigorous consent process was used, following the requirements of the ethics protocol. The participant (and their parent, if the participant was under 18) were met by their interviewer and taken through the consent process (detailed in the section below). Once consent had been obtained, the parent and child were taken to separate rooms to complete their questionnaire. Parents of participants were not present during interviews with their children.

Interviewers were instructed to provide minimal assistance to participants during the questionnaire completion stage, and instead instruct the participant to answer the question with their best guess, and mark the question for discussion later. During the questionnaire completion process the interviewer remained in the room with the participant, and noted any indicators of concern or confusion, as well as recording any comments or queries from the participant.

A note taker was present for most interviews, to assist with capturing the follow up discussion with participants. Interviews were not recorded by audio or video, in accordance with the application to the University's Human Research Ethics Committee. Notes were typed up for analysis after the interview.

Members of the study team from the University attended a number of the cognitive testing interviews, to gain first hand feedback on the questionnaires and to monitor the Cognitive Testing process.

A services information sheet was produced by the University of Melbourne study team, with a list of suggested contacts for further support on a number of issues which may be raised by some of the sensitive content in the questionnaire. It included contact details for Lifeline, Kids Helpline, drug and alcohol services, sexual health, domestic violence, health and mental health services and was offered to any participant in case a participant felt they needed professional support.

At the end of the field work period, a debriefing session was held with members of the interviewing team and attended by members of the study team at the University of Melbourne. Feedback on the Cognitive Testing of the questionnaires was discussed by topic, focusing on the questions which were deemed to need improvement. Appendix 1, the Final Report from Roy Morgan Research, describes the methodology of the cognitive testing in detail.

1.2 Dress Rehearsal

The Dress Rehearsal was conducted from late July to December 2012, with field work occurring from October to December. Following a major tender process, Roy Morgan Research was contracted to conduct the Dress Rehearsal.

The aims of the Dress Rehearsal were to:

- compare sampling and recruitment methods commonly used in large scale population studies;
- trial different recruitment protocols aimed to increase response rates;
- trial the study materials and questionnaires developed for the study; and
- assess logistical and operational issues.

1.2.1 Comparison of sampling and recruitment methods

1.2.1.1 Review of recruitment options

To identify the optimal recruitment option for the study a review of other comparable population studies the effectiveness of their recruitment strategies was conducted. Effectiveness was assessed based on the achieved response rate. The review included consulting investigators of other studies and a literature review of population-based studies, cohort studies, longitudinal studies and cross-sectional studies in health within Australia and between 1975 and 2012.

Three potential recruitment strategies were identified as feasible in principle: Medicare Australia enrolments for males aged 10-55, Australian Electoral Roll enrollees for males aged 18-55, and Schools for males aged 10-17.

A review of the literature found numerous studies had used the Australian Electoral Roll to recruit participants, however a large number of these were RCT's recruiting control group participants via the electoral roll, and thus not comparable with Ten To Men due to the difference in study design, scope and specific content related to a medical or health condition. Other studies using the AER were cross-sectional health studies which focussed on specific health conditions. Across these studies, response rates varied widely with figures reported between 19.5% and 80% response, with a substantial number grouped around 30% - 50%. However, none of the studies using the Australian Electoral Roll had a broad population health focus or was as large in scope as Ten To Men.

Three large Australian population health studies used Medicare enrolments to recruit their participants; one recruiting women only, one recruiting parents of newborn babies and four-year-old children, and a third recruiting participants aged 45 and older. Their response rates varied between 17.9% and 57.2%.

With respect to schools, the literature search identified numerous studies for adolescents that had used schools for recruitment, however almost all of these had collected the data in

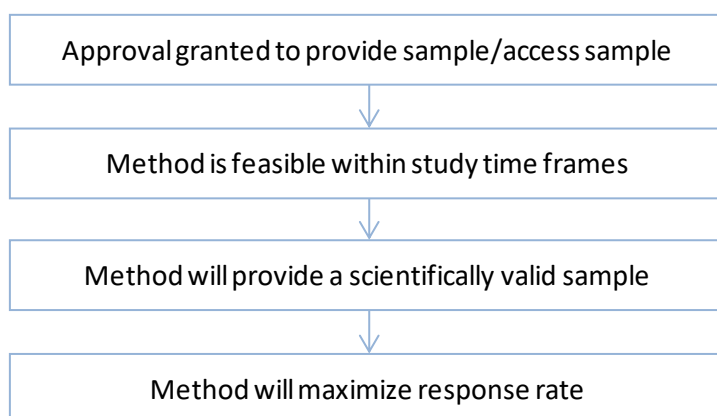
schools, either using paper questionnaires or clinical examinations or a combination of both. While these studies reported high response rates for the data collection (i.e. 88%-95%) they are not comparable with the data collection protocol for Ten To Men in which schools would be used only to distribute the study documents and the data collection then taking place in the participant's home. Only three cross-sectional studies were located using a similar data collection protocol. All three achieved lower response compared to the in-school studies, ranging between 7% and 49%. Again, these studies were smaller in scope and recruited more specific participant groups (twins and children with chronic health conditions) making direct comparison difficult.

In general, the literature review demonstrated the limitations of relying on the results of other studies as the sole basis on which to make design decisions for Ten To Men. Response fractions achieved in other studies varied substantially for both within and across recruitment strategies. Overall, no other population-based study in Australia was comparable in scope to Ten To Men. Most commonly they did not include the broad age range of participants being enrolled (10-55-year-olds), they were not longitudinal in design, or they differed to varying degrees in research design and/or recruitment protocols.

1.2.1.2 Evaluation of recruitment strategies

Following the identification of the three potential sampling approaches (Medicare Australia, Australian Electoral Roll and Australian Schools), an evaluation process was undertaken. That process can be described as a criterion-based hierarchical evaluation. It involved evaluating the potential sampling frames against a set of four criteria which are ranked hierarchically. The evaluation criteria were determined and structured in a hierarchy such that if a method failed to fulfil a criterion it was ruled out at that point and not evaluated against subsequent criteria. The criteria were selected as the minimal set of conditions which a method must meet to be firstly a viable sampling approach, and secondly the preferred approach. Figure 1 shows the criteria and hierarchy defined for evaluating sampling approaches.

Figure 1: Evaluation criteria and Hierarchy



The evaluation process occurred over the course of the pre-field implementation of the Dress Rehearsal from May to September 2012.

Stage 1 Evaluation – Approval to provide sample

In the first stage of evaluation, following University of Melbourne Human Research Ethics Committee approval the respective bodies holding the respondents' contact data were contacted and approval was sought to collect data through their mechanisms.

For recruiting through Australian schools, applications were submitted to the Victorian and South Australia Education Departments as well as the respective Catholic Education Offices representing Catholic schools in these two states. The aim was to approach eligible boys/adolescents in schools and distribute study material; however, data collection would not occur on-site in the schools. Instead adolescents would complete a paper-based questionnaire at home and return it by reply-paid mail to the study, and parents of boys aged 14 or under would return a contact form to request an interview for their son which would be held in their home.

For recruiting through the Australian Electoral Commission (AEC), an application for an extract from the electoral roll of males aged 18-55 for health research Approval was sought for both the Dress Rehearsal and Wave 1.

For recruiting through DHS/Medicare an application for a DHS mail-out to males aged 10-55 on the Medicare Enrolment database was submitted and approval was sought for both the Dress Rehearsal and Wave 1.

The findings from this first evaluation stage are summarised in Table 1.2.

Table 1.2: Summary of approval for sample process by institution

Sample Frame	Response to application
Victorian Catholic Schools	Denied
South Australian Catholic Schools	Approved
South Australian Government Schools	Approved
Victorian Government Schools	Approvable only with major protocol changes
Medicare Enrolments	Approved
Australian Electoral Roll (AER)	Still under review as at 1 October 2012

Reasons given by the Catholic Administrative bodies in Victoria for refusal of approval were that some of the content in the questionnaire was incompatible with the Catholic ethos and/or normalised behaviours (for example, sexual orientation, drug use and antisocial behaviour). Additional concerns were raised about the qualifications and training of interviewers.

Given this result, Victorian Catholic Schools were not evaluated further on subsequent stages.

Stage 2 Evaluation – Feasibility of method within timeframe

The second evaluation stage looked at whether the recruitment method was feasible within the study timeframes. The study must be conducted in a timely manner, and thus the provision of the sample extract must occur within a specified timeframe. For Dress Rehearsal the critical cut-off date for receipt of sampling approval and data was 1 October 2012.

Medicare, South Australian Schools and Victorian Government Schools all responded within the feasible study timeframe, however, the AEC failed to meet the required study time-frames, due to initial delays in processing the application and then repeated requests for further information and clarification of scope and methods of the study and qualifications and decision-making process of the University of Melbourne Ethics Committee. By the 1 October 2012, no final ruling on the application had been forthcoming from the AEC. Overall, 14 weeks had passed since the application was lodged until this date without an indication as to whether

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

the application would be successful. Thus, the AEC was not evaluated further on subsequent stages.

Stage 3 Evaluation – Scientific validity of method

The next stage of the evaluation considered whether the method would provide a scientifically valid sample.

Three other major longitudinal population health studies have used Medicare enrolments for recruiting participants: The Longitudinal Study on Australian Women's Health, The Longitudinal Study of Australian Children and 45 and Up. All three studies achieved samples that were, after weighting, comparable with the characteristics of the ABS population statistics and have generated many peer-reviewed publications.

Although numerous studies use schools to recruit their participants, they were smaller in scope and complexity and also collected data in the schools. Drawing implications from such studies for the sample quality for Ten To Men is therefore not valid. Moreover, although the Victorian Government Department of Education and Early Childhood Development approved the application to recruit through schools, they requested major changes to the recruitment protocol. Instead of distributing study materials to potential participants in randomly selected classes within randomly selected schools, they requested that an advertisement for the study would be posted in school newsletters and other locations inviting interested parents to contact the study to enrol their son. This change in sampling approach would generate a non-random sample and introduce a high self-selection bias. It would also represent a completely different sampling approach to that used for the adult sample, which would make it impossible to combine the under-18 cohort with the adult cohort for analytical purposes. Such a change in protocol would undermine the validity of the sample, and as such, Victorian Government Schools were considered to have denied approval.

Thus, Victorian schools (Government and Catholic) would not be available for sampling under-18 participants in Dress Rehearsal. Since significant changes to the questionnaires and protocols were unlikely for Wave 1, this introduced the risk of having no representation from an entire state, one which represents 25% of the total national sample. Therefore, drawing a national sample through Schools was deemed unfeasible in terms of providing a scientifically valid sample.

Stage 4 Evaluation – Maximisation of response rate

In the final stage of evaluation, selection of a feasible recruitment method would be determined by how well the method would maximise the response rate of the study. As only one sampling method remained in consideration at this stage of the evaluation, it was not possible to evaluate comparative response rates in this stage.

Summary

Of the three potential sampling frames evaluated, the Medicare Australia enrolment was the only feasible sampling approach for Ten To Men. In 2011, 22.5 million individuals were represented on the Medicare enrolments database. Medicare Australia enrolments have been used in a number of established national and state-based longitudinal health studies including the Longitudinal Study on Australian Women's Health, the Longitudinal Study of Australian Children, and 45 and Up in NSW confirming that it is a viable and valid recruitment method. Those studies have achieved response rates that vary between 17% for 45 and Up to 57% (LSAC and Women's Health). There are additional benefits to using Medicare enrolments.

Most particularly that it allows all members of the cohort to be sampled in the same manner. Also, potential participants may be more comfortable being approached about participating in a health study via an organisation that is health related, rather than electoral or educational avenues, and the Department of Human Services is experienced in and supportive of the conduct of this type of research. There are some potential disadvantages to using Medicare enrolments. In the main these involve having the DHS mediate the recruitment process and the inclusion of DHS material in the mail-out which may deter some potential participants. A more detailed discussion of challenges presented by recruiting through Medicare enrolments is presented in Chapter 4.

1.2.3 Dress Rehearsal sampling design

Using Medicare enrolments as the sole sampling frame, the sample for the Dress Rehearsal was set at 1250 adult males, 500 15-17-year-old males, 500 10-14-year-old males and 500 parents of the 10-14-year-old males. It was decided that 15 year old males should be grouped with the 16-17-year-old males rather than with the 10-14-year-old boys as this was considered more appropriate for their developmental stage. For adult males three age groups were targeted: 18 to 25 years, 30 to 35 years and 50 to 55 years. 18-25-year-old males were oversampled to compensate a potentially lower response rate for this group.

Based on the review of comparable studies, a 20% response fraction was used to calculate the sample size for the Dress Rehearsal. Table 1.3 outlines the proposed sample (number of contacts to be drawn) and the target completion rate expected.

Table 1.3: Dress Rehearsal Medicare Sample per target group

		Sample	Target Completions
Adults (18-55)	Total	1250	250
	18-25 years	500	100
	30-35 years	375	75
	50-55 years	375	75
Adolescents (15-17)	Total	500	100
Boys (10-14)	Total	500	100
Parents		500	100

The Australian Standard Geographical Classifications was used to stratify the sample based on metropolitan/major cities, inner regional and outer regional areas in Victoria and South Australia. Areas classified as remote and very remote were excluded from the sample frame. A specified ratio between the geographic areas was set to allow oversampling of outer and inner regional areas: 65% metropolitan, 25% inner regional and 10% outer regional.

Postcodes were selected as the primary sampling units. 3 postcodes were selected in each State, one in each geographic region (major city/metropolitan, inner regional, and outer regional). For feasibility reasons the selection rules were as follows:

- For the inner regional and outer regional postcodes in each state, only postcodes with an area less than or equal to 200km² as per 2006 postcode boundaries were eligible;
- For outer regional postcodes, if the distance to a major travel point was too large the postcode was excluded;
- Postcodes were chosen at random.

Applying these rules the study sampling statisticians at the University of Melbourne selected the following postcodes in Victoria: Coburg (3058), Wandong (3758) and Nicholson (3882); and in South Australia: Greenacres (5086), Buckland Park (5120) and Monash (5342).

Table 1.4 shows the sampling plan provided to the Department of Human Services to draw the sample from Medicare enrolment data.

Table 1.4: Sampling plan provided to DHS by the University of Melbourne

Postcode	10-14-year-olds	15-17-year-olds	18-25-year-olds	30-35-year-olds	50-55-year-olds
Victoria					
3058 Coburg	164	164	163	122	122
3759 Wandong	60	60	62	47	47
3882 Nicholson	26	26	25	18	18
Total VIC	250	250	250	187	187
South Australia					
5086 Greenacres	164	164	163	123	123
5120 Buckland Park	60	60	62	47	47
5432 Monash	26	26	25	18	18
Total SA	250	250	250	188	188
TOTAL	500	500	500	375	375

There are some challenges associated with using postcodes as sampling units. Postcode boundaries are periodically modified by Australia Post and whether the most recent postcodes are used in a data set depends on how frequently that data set is updated. 2011 Census data was used to identify the number of in-scope males residing in a postcode using 2011 postcode boundaries. The Medicare database may not be as up-to-date resulting in discrepancies between the Medicare enrolment data and Census data in the number of in-scope males identified as living in a postcode. Additionally, the DHS has a policy of excluding any individual from the sample frame who has not had a medical contact in the 12 months prior to extracting the sample. This policy is designed to lessen the likelihood of including a deceased person in the mail-out. These two factors mean that for a given postcode the required target number may not be met, as was indeed the case for some postcodes selected for the Dress Rehearsal. Table 1.5 shows the respective enumeration of in-scope males by age group in the selected postcodes in 2011 Census and the Medicare enrolment data extracted for the Dress Rehearsal.

Table 1.5: Comparison of 2011 Census data and DHS data on number of in-scope males for Dress Rehearsal postcodes

Postcode	Boys 10-14 years		Adolescents 15-17 years		Adults 18+ years	
	2011 Census	DHS Database	2011 Census	DHS Database	2011 Census	DHS Database
3058 Coburg	740	692	411	355	5464	2919
3758 Wandong	86	70	55	33	291	168
3882 Nicholson	31	20	28	14	97	64
5086 Greenacres	436	383	24	180	24	1414
5120 Buckland Park	48	88	43	66	43	293
5342 Monash	59	32	28	9	28	61

Given that the number of in-scope males available in a specific postcode in the Medicare data was lower than the Census data on which the postcodes were selected, the following guidelines were developed for sampling when a shortfall occurred.

1. The sample for outer regional postcodes should be drawn first followed by inner regional and then metropolitan areas.
2. If the number of available contacts in one area is less than the target sample then all males in that age group and postcode will be selected into the sample and the remaining target number will be drawn from the subsequent geographic area.

Another potential issue was participants transitioning from one age group to another over the course of the study. The time gap between the drawing of the sample, the dispatch of invitations, and interviewing means that a participant could have a birthday during this time and might move up to the next participant group. In order to ensure an accurate sample for the specified age groups, the following additional rules for drawing the sample were implemented:

- Adult sample: only select men who were born between 1 January 1957 and 30 September 1994;
- Adolescent sample: only select boys who were born between 1 January 1995 and 30 September 1997;
- Boy sample: select boys
 - o who are born between 1 January 1998 and 30 September 1998 (i.e. study invitation addressed to boy aged 14 years); and
 - o who are born between 1 January 1999 and 30 September 2002 (i.e. study invitation addressed to parent of boy aged 10-13 years).

Due to factors described above the final DHS sample frame had fewer in-scope males in several postcodes and age groups, and the selection guidelines described above were applied resulting in a final sample described in Table 1.6.

Table 1.6: Final sample drawn by DHS

Postcode	10-14-year-olds	15-17-year-olds	18-25-year-olds	30-35-year-olds	50-55-year-olds
Victoria					
3058 Coburg	173	202	163	141	122
3759 Wandong	60	34	62	36	47
3882 Nicholson	17	14	25	10	18
Total VIC	250	250	250	187	187
South Australia					
5086 Greenacres	164	175	163	123	123
5120 Buckland Park	60	66	68	53	47
5432 Monash	26	9	19	12	18
Total SA	250	250	250	188	188
TOTAL	500	500	500	375	375

After final checks of the sample contact data against the Death Register on the day of the mail-out, one adolescent was removed due to being deceased.

1.2.4 Data collection for Dress Rehearsal

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

To evaluate recruitment strategies the Dress Rehearsal tested the efficacy of using a pre-notification and reminders in regards to maximising response rates. For reminders; no reminder, a reminder letter, and a full reminder packet were compared.

Recruitment protocols differed between adult males and the two younger age groups.

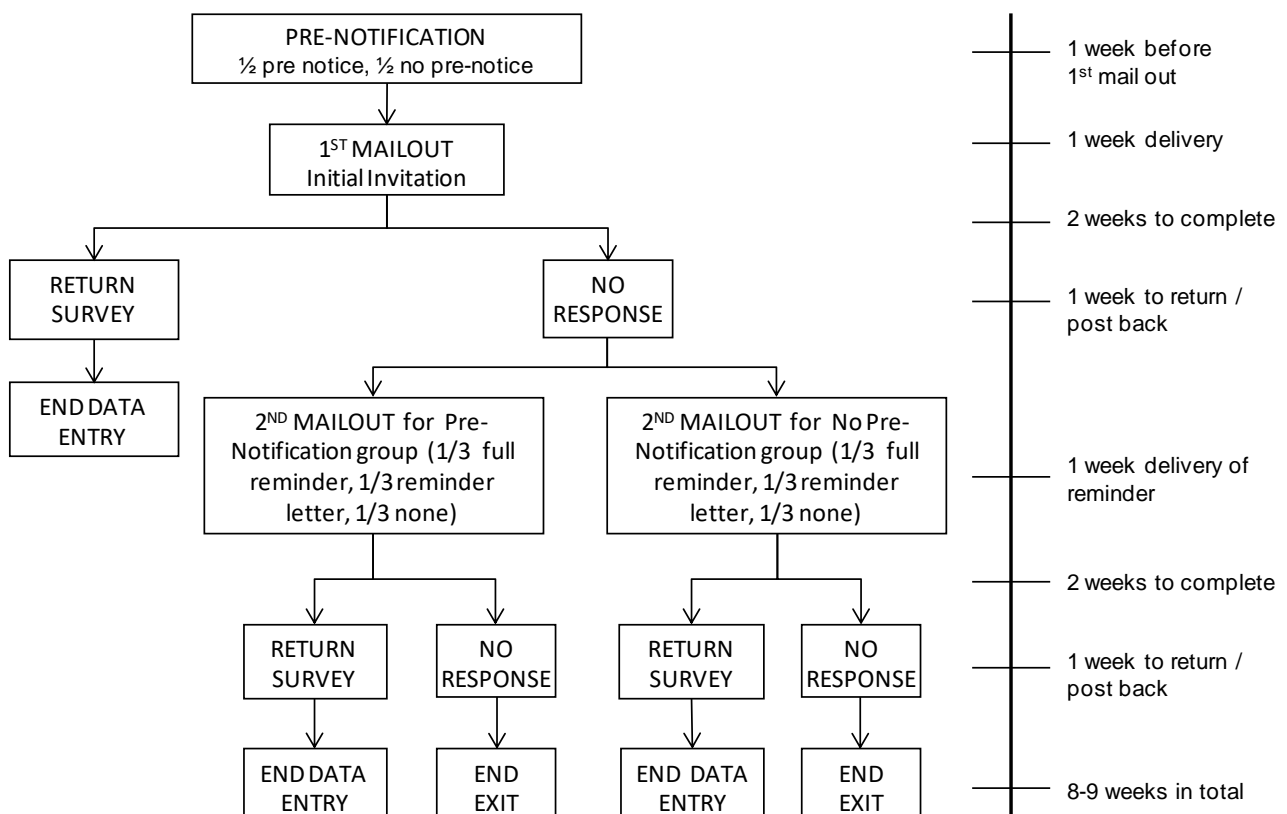
Adult Male Protocol

One half of the sample was sent a personalised pre-notification letter advising that the survey packet would soon be arriving.

One week later the entire sample was sent a study packet inviting them to participate. The study packet included a personalised study introduction letter, a study information brochure (PLS), a consent form, paper questionnaire and personal information sheet. Two post-paid reply envelopes were supplied with instructions to return personal information sheets and consent forms in one envelope and the completed questionnaire in the other.

Four weeks after the initial study packet was mailed, one third of the participants were sent a full reminder packet (including the same content as in the initial mail-out), one third were sent a reminder letter and the remaining third did not receive a reminder. Reminders were only sent to participants who had not returned a completed survey at the date the reminder was scheduled. Figure 2 provides an overview of the participant invitation and reminder process and integrated timeline:

Figure 2: Adults recruiting and data collection process.



Adolescent Protocol

For adolescent males (15-17 years) no pre-notification letter was sent, the entire sample was mailed a study packet inviting them to participate. Packets went directly to the adolescent male and contained a 15-17 Years Pack and a Parent Pack. The 15-17 Years Pack included a study introduction letter, an information brochure, an assent form, a questionnaire and a

personal information sheet, and a services information sheet. The Parent Pack included an introduction letter for parents, a parent information brochure and parent consent form. Two post-paid reply envelopes were provided for the adolescents to return their completed questionnaire in one and their personal information and parent and self consent/assent in the other. The reminder was sent to all non-respondents four weeks after the initial mail-out and all reminders were in the format of a full packet.

Boys Protocol

No pre-notification was used in this group. Parents of 10-14-year-old boys were mailed the study packet inviting their son to participate. The packet included a Boys Pack and a Parent Pack. The Parent Pack contained a personalised study introduction letter, a Parent information brochure, a sample consent form and a contact form for the parent to get in touch with the research organisation to organise an interview. The Boys pack included a letter for the eligible boys and a Boys information brochure. Again, four weeks after the initial mail-out a reminder packet was sent following the same protocol described above.

After returning the contact form or calling the study hotline, an interview time was scheduled and an interviewer visited the parent and child at their home or another place determined by the parent or child. The interviewer brought with him/her the full study pack containing study brochures for the parent and boy, parent consent form, boy assent form, parent paper survey, tablet with the CAPI boys interview, a hard-copy of the boy questionnaire and show cards required in the interview. Show cards were designed to make it easier for the boy to select his answer to a question and to protect the privacy of the boy's responses, as the child could nominate response numbers rather than stating his response aloud.

On the day of the interview, the interviewer was instructed to review all forms and materials with the parent, respond to questions and collect the signed consent and assent documents. Ideally, no adult except the interviewer would be present during the interview, to protect the boy's privacy. However, if the boy requested to have a parent present or a parent insisted on being present, the interviewer would accommodate the request.

Prior to commencing the interview, parents were asked to assist with some of the questions about the boy's height, weight and waist measures. Thereafter they were handed the Parent questionnaire to complete while the interview was being conducted with their son.

Copies of all Dress Rehearsal documentation including pre-notification, invitation, and reminder letters, study brochures, and Dress Rehearsal questionnaires are available in Appendix 3.

1.2.5 Dress Rehearsal printing and mail-out logistics

The Department of Human Services (DHS) is the custodian of all Medicare Australia enrolment data. Since the selected recruitment methodology for Dress Rehearsal was a mail-out of survey invitations using Medicare Australia enrolments the printing and mail-out of Ten To Men documents had to follow DHS protocols. This required close collaboration between the survey organisation Roy Morgan Research and the DHS.

The DHS does not release contact data to an external party. This introduced considerable complexity into the printing and mailing process in terms of allocating participants to comparison groups and tracking data. For boys and adolescents this was not an issue, however for adult males the objective of Dress Rehearsal was to test different pre-notification and reminder protocols. This required assigning adult males to one of six different combinations of pre-notification and reminder messages:

Group 1: pre-notification, invitation pack and reminder letter

Group 2: pre-notification, invitation pack and full packet reminder

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

- Group 3: pre-notification, invitation pack and no reminder
- Group 4: no pre-notification, invitation pack and reminder letter
- Group 5: no pre-notification, invitation pack and full packet reminder
- Group 6: no pre-notification, invitation pack and no reminder

Each participant's group assignment had to be documented and reported back to the study team. The challenge was to ensure that each participant received the correct documents following the group that they were assigned to. As Roy Morgan Research did not have access to the sample information DHS was required to use unique ID numbers and numeric barcodes for each individual in the sample. These IDs were generated by Roy Morgan Research and included a unique set of numbers plus a reference number for each of the documents they were printed on, i.e. consent form, questionnaire, contact information sheet.

For the pre-notification mail-out the DHS project team allocated one of the above group numbers to each participant in the extracted sample and allocated a unique ID number from a list supplied by Roy Morgan Research to each participant. DHS then provided a complete sample list including those additional numbers (group and ID) to their mail-house, and a de-identified list was returned to Roy Morgan Research so they could add group number information for each unique ID to their Respondent Management System.

For the reminder mail-outs Roy Morgan Research provided the DHS project team with a list of IDs for individuals who should not be sent reminders, this included all individuals who had responded and all participants who were assigned to the 'no reminder' groups. Based on this list DHS could identify all participants who were to be sent reminders and, using the group assignment numbers, which type of reminders to send.

Logistical issues with under 18 participants.

DHS regulations stipulated that for individuals aged 15-17 all mail-outs go directly to the individual and not to a parent/guardian. As parental consent was required for adolescents to participate in the study, the invitation pack had to include documentation for the parent as well as documentation for the adolescent. This added complexity to the printing and mailing process as separate sets of documents for parents and adolescent had to be printed and plastic wrapped as two 'packs'. Documents for the parent and the adolescent had to include the same unique participant ID in order to ensure that parent consent was received. A high level of monitoring and checking was required to ensure the correct parent and adolescent packs were matched and packaged into one pack for mailing.

The mail-out for boys generally followed the same procedure as the adolescents. Differences were that for boys under the age of 14, DHS regulations require that any mail is addressed to a parent, and if the boy is 14 the mail-out is addressed to the boy. Also, the DHS mandated that where a boy is listed on two Medicare cards showing different addresses (i.e. separated parents) both cardholders must be sent the study materials.

Responsibilities for printing the study documents were shared between the Roy Morgan Research printer and the DHS printer/mail-house. All documents that included participant names were printed by the DHS mail house and any anonymous or generic documents, i.e. the questionnaire booklet and study brochures, were printed by the Roy Morgan Research printer. The rationale for this division was so Roy Morgan Research could maintain a high level of quality control over the printing of the questionnaire booklets to ensure they met the required standards for error free scanning and data processing, as well as oversee the inclusion of barcodes and reference numbers documents in order to be able to match the various documents pertaining to a single participant for data processing and verifying consent.

Appendix 4 contains the printing and mail-out methodology document developed by Roy Morgan Research to provide detailed instruction to the DHS on the methodology, and the final printing specifications.

1.2.6 Ethics approval

Approval was sought for both the Dress Rehearsal and Wave 1 in a single project application on the rationale that there would be no new protocols or materials introduced in Wave 1 and thus the ethical considerations would be the same for both data collections. However, separate applications were made for Adult males and males under the age of 18 on the rationale that research in minors involves additional protections and also as there were mode differences in the data collection for the youngest age group (10-14 years).

The University of Melbourne has a two stage ethics approval process. At the first stage the local School of Population Health Human Ethics Advisory Group (HEAG) reviews the application in detail and makes a recommendation to approve, following which the University Health Sciences Human Ethics Subcommittee (HESC) reviews and gives approval. This structure is designed to reduce burden on the HESC, and to ensure that all applications undergo a thorough review. It does however significantly lengthen the time required to gain approvals, particularly as the HESC meets only 10 times annually. In all the ethics approval process for Ten To Men took three months (April - July 2012).

An amendment was submitted and approval granted to conduct an extension phase of the Dress Rehearsal to conduct a further phase of pilot testing (a Drop and Collect recruitment method) in January 2013.

Approval letters are provided in Appendix 2.

1.2.7 Quality assurance in data collection

A range of protocols were developed for various aspects of the Dress Rehearsal and communicated to the research services organisation to ensure high quality of delivery.

1.2.7.1 Field preparation and monitoring

Roy Morgan Research consulted extensively with the study team on reviewing the study questionnaires, including the flow and wording of questions and the formatting of consent forms, contact forms and questionnaires. They were responsible for setting up the questionnaires and contact forms as scannable forms and ensuring that the printing quality met the standards required for error-free scanning and data processing. With their extensive experience in this field of work and their in-house quality assurance protocols RMR were able to deliver a high quality outcome.

Roy Morgan Research also established a call centre team (Team 1800) and a team of interviewers to interview the 10-14-year-old boys. Both call centre staff and the interviewers received intensive training before the start of fieldwork. Members of the study team were present as observers in all training sessions and training met the quality expectations of the study team.

During field work Roy Morgan Research provided regular updates on the progress of the data collection which included updates on response rates, contacts and enquiries by respondents

as well as procedural issues. Information was exchanged in a timely manner and acted upon quickly as required.

1.2.7.2 Respondent contact management

A comprehensive contact management protocol was established for the Dress Rehearsal data collection. It was expected that after mailing out the survey invitations to participants some would require further information and would contact either Roy Morgan Research or the University of Melbourne study team. Study materials, i.e. invitation letter and information brochure were designed to direct participants to Roy Morgan Research as a first point of contact for questions. This was particularly important for the parents of the boys so that interest for interviews could be established with the parent who made contact. The study website also included a link for participants to contact the Roy Morgan Research project team.

Roy Morgan Research trained their Team 1800 call centre staff to respond to and document enquiries from respondents and supervise the field interviewing team. The main responsibilities of Team 1800 with regard to participants were answering their queries, collecting participant's contact details, documenting and if possible solving complaints, converting refusals, providing details of health service organisations if needed or requested. With regard to interviewer supervision the Team 1800 staff were required to inform interviewers about changes in participant's contact details, provide technical CAPI support, and advise on duty of care issues if necessary.

Two 1800 phone lines were established by RMR, one for participants and one for interviewers. During fieldwork, the Ten To Men 1800 lines were staffed from 8am to 9pm, 7 days a week (EST). The respondent phone line was staffed for two further weeks after the field work period.

All calls were managed and documented via a web-based Respondent Management System (RMS). The call log was designed to capture the type of caller (parent, adolescent, adult), the reason(s) for the contact and the outcome. For each participant contact as many contact details as possible were acquired or confirmed.

In conjunction with Roy Morgan's respondent management system the study team at the University developed an internal contact management protocol. A detailed contact management manual was written to document roles and responsibilities within the project team, protocols to process participant's requests and complaints as well as reporting requirements between Roy Morgan Research and the study team.

Participants could also contact Roy Morgan Research and the University of Melbourne by sending an email to tentomen@roymorgan.com or info@tentomen.org.au. Protocols for processing emails followed the same principles as for telephone contacts.

Appendix 5 contains the Roy Morgan Research contact management manual. Appendix 6 contains the Ten To Men study team contact management manual.

1.3 Tendering and procurement process

For both the Cognitive Testing and the Dress Rehearsal an external research organisation was contracted to recruit participants and undertake data collection. The University of Melbourne has strict processes for contracting external companies to provide their services to the University to ensure the probity of procurement. Dependent on the value of the services

the contract has to be treated as a purchase order (up to \$150,000), a minor tender (between \$150,000 and \$400,000) or a major tender (over \$400,000). The process for procuring services varies substantially between these three scenarios and gains considerably in level or review, time required and complexity as the value of the purchase increases. The University of Melbourne flowchart for decision rules when purchasing external services is attached in Appendix 7.

1.3.1 Procurement of services for Cognitive Testing

The contract value for Cognitive Testing was within the range of a purchase order. Cognitive testing of study questionnaires is a specialised task and only a small number of research services organisations were identified as potential service providers. In all 5 organisations were invited to submit a proposal for the cognitive testing and 4 quotes were submitted.

Organisations were required to respond to a list of response criteria in writing and submit a detailed costing sheet for their proposal. The response criteria covered the following items: the suggested methodology for cognitive testing, expected timelines, data security, recruiting of participants, progress monitoring, experience and ethical considerations.

Following receipt of proposals a selection panel met to evaluate the submissions on 3 February 2012. The evaluation was guided by an evaluation form which outlined the key selection criteria and asked the panel members to rate each criteria on a scale from 1 to 4, where 1=excellent, 2=good, 3=average and 4=inappropriate. The evaluation panel consisted of the Chief Investigators Jane Pirkis, Dallas English, the Study Coordinator Dianne Currier, Ten To Men research fellow Maree Brinkman and an external reviewer: Ben Edwards, Executive Manager of Longitudinal Studies at the Australian Institute of Family Studies.

Following the evaluation, two companies were shortlisted and a final reference check determined the successful candidate who was offered a service agreement based on the University of Melbourne's Standard Services Agreement.

Relevant documents from the process of engaging a service provider for Cognitive Testing are attached in the Appendix 7.

1.3.2 Procurement of services for Dress Rehearsal

Following the initiation of a joint tender for Dress Rehearsal and Wave 1 services which had to be suspended (see Section 4.3 below for details), a tender process was initiated for Dress Rehearsal services only.

The cost of services for the Dress Rehearsal was estimated to potentially exceed \$400,000, therefore it was thought prudent to instigate a major tender process from the outset.

The major tender process involves three meetings with the Major Tender Board. The first meeting is to review the specifications, response criteria, costing documentation, evaluation criteria and establish the overall budget available for the contract. If the Board finds these documents in order the invitation to tender can be issued. Tenders are submitted directly to the Board, and a second meeting convened to open the tender and record the details including overall cost. The proposals are then released to the study team for evaluation and selection of a preferred candidate. A recommendation and justification for choice of candidate is then submitted to the Board who at a third meeting approve, after which commissioning and contracting can take place. The Board meets every two weeks, with a one week prior to

meeting date deadline for submission of documents. In all, depending on the length of time the tender is open for, the process, should approval be forthcoming at each step, takes approximately 6-8 weeks.

The Ten To Men study team researched and compiled a list of appropriate qualified and resourced research services organisations to respond to the tender. The identification of eligible organisations and subsequent invitation to tender was made in consideration of the following capacity and experience criteria:

- A multi-state presence and established multi-state monitoring and management systems;
- Organisational capacity to recruit participants and collect the data in multiple modes (including face-to-face interviews and by mail) and to process and report on the data in a short time period;
- In-house capacity to produce the study documentation, information systems, participant support systems and so on; and
- Experience in the field of health and social research and with dealing with sensitive matters.

Based on the study team's experience and investigation of the research organisations currently operating in Australia, five organisations were identified as suitable and invited to respond to the request for tender. Of these five organisations two submitted their responses and were evaluated. Three organisations elected to not submit a response due to either limitations in their business capacity at that time or because the requirements of the tender did not align with their business model.

In order to minimise the burden of responding to the tender a pre-submission process was conducted to allow bidders to seek clarification and receive responses to their specific questions. Briefly, the tender opened on 22 June 2012 by invitation. A formal tender briefing meeting was held on 2 July 2012 at the University of Melbourne, School of Population and Global Health offices. Nominations to attend this briefing had to be made to the Contact Officer by close of business (5:00 p.m.) on 29 June 2012. Tenderers were requested to submit their questions to the Contact Officer in preparation for the meeting by close of business (5:00 p.m.) on 29 June 2012. Tenderers had the opportunity to ask additional questions at the briefing once the submitted questions have been addressed. Additional questions were accepted in writing until the 10 July 2012. All additional inquiries and responses were circulated to all tenderers by 13 July 2012 (not disclosing confidential information). After this date no further questions were accepted. Tenders had to be submitted no later than close of business (4:30 p.m.) on 20 July 2012.

The tenderers were required to provide a detailed response on a list of specified response criteria. The response criteria concerned the following areas: essential criteria (tender contact details, organisational profile, and financial security information), information on capacity and resources management, IT systems, time management, quality control, data processing, and experience. Further, tenderers were asked to complete a costing table which was designed to allow comparisons between tender submissions. The response to selection criteria and the completion of the costing table were informed by a comprehensive tender specifications document including all relevant information on recruiting and data collection processes.

After the receipt of proposals the selection panel met on 12 July 2012 to evaluate the submissions. The selection panel comprised the Chief Investigators Jane Pirkis, Dallas English, the Study Coordinator Dianne Currier, and two external research experts, Mark Wooden (Professorial Research Fellow and Director, HILDA Survey) and Margaret Kelaher (Associate Professor, Melbourne School of Population & Global Health).

The proposals were evaluated using a structured evaluation form regarding the quality and scope of response to tender, capacity to undertake the work required in the tender, experience in the field, their pricing and cost/value ratio, and the quality and relevance of listed referees. Each of the five evaluation categories was given a weighting. Reviewers were instructed to score the responses of the service providers regarding the evaluation categories on a scale from 1 to 5, where 5=excellent, 4=very good, 3=good, 2=fair and 1=unsatisfactory, provide a rationale for their rating and indicate their overall preferred agency.

All relevant documents used in the selection process of the service provider for the Dress Rehearsal are attached in the Appendix 7.

1.4 Data Linkage

Linkage with routine population databases is a central element of the design of the Ten To Men study. By undertaking data linkage with routinely collected population datasets including Medicare Benefits Schedule, the Pharmaceutical Benefits Scheme, hospital and ambulance data, disease registers and others, researchers will better be able to achieve the aims of the study.

Modern cohort studies such as Ten To Men are increasingly making use of linkage with external data sets to increase their usefulness for answering research questions of policy relevance. For example, in Australia, the 45 and Up study, which is conducted in NSW has made extensive use of linked data and as a result, has been able to address a wide variety of important questions that could not possibly be examined using the traditional longitudinal study in which all the information is collected directly from the participants.

Linking data from other sources to primary questionnaire data will allow a broader range of research questions to be explored in greater detail, particularly those concerned with service use. It will improve the quality of data in certain domains, as participants may not necessarily be the most reliable source of information. Poor recall of past health conditions, undesirable diagnoses, incomplete knowledge or recall of diagnoses, medications and dates are only some response behaviours that can lead to loss in data quality. Finally, undertaking data linkage enhances the ability of the study to track health related events and outcomes over time. The study will re-contact participants every three years to collect primary data. However between waves it will be possible to periodically update health event information from linked datasets. This will allow a more detailed trajectory of disease onset, course, treatment, and outcome to be established.

Conducting this data linkage will extend the breadth and depth of the study dataset in important ways, including:

1. Providing detailed and more accurate information on a variety of health outcomes;
2. Providing up to date information over time allowing tracing of course of development of health conditions, treatment, and outcomes;
3. Providing detailed and more accurate information on encounters with health services.

The later is of particular interest as males are documented to have lower engagement with health services. Linkage to detailed service use data will allow researchers to identify characteristics of males related to level of service use that may be then targeted in future policy or program initiatives to improve engagement with services. It will also allow an examination of research questions related to how use of services impacts on health behaviours and health outcomes.

Development of the Ten To Men Data Linkage Protocol

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

Data linkage is a complex and evolving area with multiple stakeholders including Commonwealth and Jurisdictional data custodians, state based linkage authorities, integrating authorities, and so on. The Data Linkage Steering Committee comprises a strong representation of stakeholders and researchers and has provided invaluable guidance on establishing best-practice data linkage protocols for the study and advice on preparation of key ethics applications particularly the forthcoming March application to DoHA for approval for linkage to MBS, PBS and other Commonwealth held data. A draft protocol has been written for the study and is currently under review by the Data Linkage Steering Committee. That protocol (Appendix 8) sets out key platforms, including as a project by project integration rather than the creation of enduring linked datasets, the use of the AIHW as the first choice Data Integrating Authority for Commonwealth held data, the requirement for consent to linkage as part of consent to join the study, the use of the SURE system for accessing linked data sets (www.sure.org.au), and the identification of the set of potential datasets with which linkage will be sought in a phased manner (Table 1.7-1.9).

The AIHW has agreed, informally, to act as the Integrating Authority for integration of study data with Commonwealth held data, and to hold the linkage spine.

Table 1.7: First phase: Commonwealth held data for which approval for linkage is being sought

DATA CUSTODIAN	DATA HELD
Department of Human Services	Medical Benefits Schedule Pharmaceuticals Benefits Scheme Repatriation Pharmaceutical Benefits Scheme Department of Veterans' Affairs Service Use
AIHW HELD	National Death Index National Diabetes Register/National Diabetes Service Scheme

Table 1.8: Future Phases: Commonwealth, Jurisdictional and other datasets for which linkage may be sought

DATA CUSTODIAN	DATA SET *
Department of Human Services	Organ Donor Register Australian Hearing Services Australian Childhood Immunisation Register Bowel Cancer Screening Register
DoHA	Residential aged care Community Aged Care Package (DoHA) Home and Community Care (DoHA) Aged Care Assessment Team (DoHA)
AIHW ADMINISTERED – APPROVALS AND/OR IDENTIFIERS TO BE SOUGHT FROM STATES	Australian Cancer Database National Hospital Morbidity Database National non-admitted patient emergency department care database National Outpatient care database National Perinatal Statistics Database Disability information (NMDS)
Department of Veterans' Affairs	Australian Veterans' Home Care Files
National Blood Authority	Australian Bleeding Disorder Register

DATA CUSTODIAN	DATA SET *
State & Territory Health Departments and other State-based organisations*	Public hospital admissions/inpatient data Emergency Department Ambulance data Mental Health (services, ambulatory, community) Drug and alcohol services/surveillance Registries of births, deaths, marriages Notifiable and infectious diseases/conditions Registries (Cancer and others) Aged Care Disability Services Maternal and Child (Perinatal, immunisation, child health) Dental Pathology, radiotherapy, radiology – radiology Private hospital admissions
ANZDATA	Australian and New Zealand Dialysis and Transplant Registry

* For State and Territory Health Departments and other state-based organisations the Data Sets described are by type of dataset rather than the names of actual datasets as these vary by state.

Table 1.9: Datasets currently under Development

Data sets for which work development of Statistical Linkage Keys is currently underway or has just been completed. Approval processes currently unknown.

DATA CUSTODIAN	DATA SET
AIHW	National Community Mental Health Care Alcohol and other Drug Treatment Services

2. Key Research Findings

2.1 Findings from Cognitive Testing

2.1.1 Overall performance of questionnaires

Length of questionnaire

The completion time for questionnaires varied for the different age groups consistent with the differing length of the age-specific instruments. Table 2.1 details the completion time for each questionnaire. Feedback from interviews indicated that only adult participants found the questionnaire too long. However, given the specific testing environment it can be expected that reaction to the length of the questionnaire would be much stronger in a field situation.

Table 2.1: Approximate time taken to complete questionnaire by participant group

	Shortest time taken	Longest time taken*	Average time taken*
10-15 years males	25 minutes	45 minutes	34 minutes
16-17 years males	27 minutes	44 minutes	35 minutes
18-55 years males	40 minutes	60 minutes	52 minutes
Parents of boys aged 10-17	10 minutes	25 minutes	18 minutes

* Excluding incomplete questionnaires

Question order

The placement of sensitive questions in the questionnaire is an important consideration. In the adult questionnaire, participants found the order of questions generally well balanced. In particular, the placement of questions about relationships and sex, and intimate partner violence approximately two-thirds of the way through the questionnaire was far enough into the questionnaire for the participant to feel more comfortable answering such personal questions, and thus more likely to continue.

Likewise, in the 16 to 17 years questionnaire there were no issues with question order. Some participants did indicate they found some questions repetitive however the questions referred to were, in the main, lists of response items in longer measurement scales.

In the 10 to 15 years questionnaire the question order worked well, with a few exceptions. The separation of the non-suicidal self-harm and suicide questions was an issue, as was their relatively early position within the questionnaire. Further, the order of the questions on drug taking behaviours were asked in ascending order of seriousness, and it appeared inappropriate to be asking the younger/more innocent participants about serious drugs and behaviours when they had already indicated not yet having tried alcohol or tobacco.

There were no issues with the order of questions in the Parent questionnaire.

Sensitive Questions

The testing context is not an accurate reflection of how participants would act if completing the questionnaires in their homes as per the overall study design. Participants may give more positive responses, and social desirability may play a stronger role. To capture information on how future participants might react to the potentially sensitive questions, cognitive testing participants were asked how they think people 'like them' would handle these questions, or how they themselves might have reacted to these questions if they were being asked by an interviewer, or being asked to fill in a self-complete questionnaire at home. None of the participants said they were upset by the sensitive questions, but several indicated that they had doubts that people would answer the questions on partner violence, self-harm and illegal drug-taking honestly.

General Comments

Some participants felt the questionnaire, particularly the adult questionnaire, was so long as to occasionally discourage completion. However, relatively few thought that the questionnaires would be too much of a burden for respondents. The option of completing the questionnaire online was discussed and tended to be positively received, particularly when answering sensitive questions which may require privacy from other members of the family or household.

2.1.2 Performance of selected questions

Questions were classified as having no issues, minimal issues, moderate, or major issues. A classification of 'moderate' indicated that the question required minimal clarification or rewording in order to address the issues. However, where a major issue was identified a serious review of the question was recommended. Table 2.2 details questions that showed either moderate or major issues.

Table 2.2: Question performance in cognitive testing

Question	Gravity of issue
Fruit & Vegetables	moderate
Drinks	major
Eat Breakfast	moderate
Eat Specified Foods	major
Nutritional Supplements	moderate
General Health (Self Assessment)	moderate
Pain	moderate
Health Conditions & Symptoms	major
Weight & Height	moderate
Hours of Sleep	moderate
Restless Sleep	moderate
Injury	moderate
Depression Scale	moderate
Usual Walking Pace Outdoors	moderate
Number of times/total times activity per week	major
Sedentary Behaviour	major
Minutes of physical activity over past 7 days	major
Skin Colour	moderate
Time in Sun	moderate
Alcohol	moderate
Illicit Drugs	moderate
Form of Sexual Relationship (Monogamous or Other)	moderate
Sexual Identity (Self-Perception)	moderate
Behaviour Within Relationship	moderate
Relationships & Sex (Minors)	moderate
Fatherhood	moderate
Structure that contains household	moderate
Housing problems currently experienced	moderate
Raise \$2000 for an emergency	major
Work & Work Environment (Adults)	moderate
Clubs, Groups & Organisations	major
Religion & Spirituality	moderate
Masculinity	moderate
Experienced Discrimination	moderate
Checkups with GP	major
Health Concerns/Questions – First Seek Information	moderate
Health Concerns or Questions – Use of Internet	major
Looked Up Health Information or Advice	moderate
Attitudes to Own Health	moderate
Age at last birthday	moderate
Live in One or More Homes	moderate

Question	Gravity of issue
Worked for Pay in Last 12 Months (Minors)	moderate
Parental Tobacco & Alcohol	moderate
Online Friends	moderate
Support Networks	moderate
Bullying – Experienced or Committed	moderate
Antisocial Behaviour	moderate
Screen Time (Minors)	major
Health Services Utilised by Son	moderate
Medication prescribed by doctor	moderate
Living Environment (Parent)	moderate
People 18 and Over Usually Living with Parent	moderate
Children Usually Living With Parent	moderate
Journey to School (transport)	moderate

In summary, issues can be grouped into three categories: those related to timeframes, those related to ambiguous response categories and those related to complex formats.

For a number of questions the timeframe given in which a condition, event or activity occurred, led to confusion. For example, participants were asked how often they drink specific drinks each day, or how often they eat specific food each week. These specific behaviours could vary and therefore led to different responses depending on the time of responding. For other questions using the reference to a “usual day” or “usual week” was challenging for participants who do not follow a specific routine during the time of surveying, such as people on holidays or the unemployed.

For other questions response categories or question wording were found to be ambiguous and open to different interpretations. This occurred at different levels of severity. It was most apparent in the questions on ‘fast food’, ‘consumption of drinks’ and ‘club participation’. For example, on the consumption of soft drinks it was difficult for participants to decide what counted as a soft drink and how to define such things as energy drinks or other products marketed as wellness drinks such as ‘Up and Go’. The same issue was noted for take away/ fast food categories. Incomplete lists of drink and food categories combined with varying individual definitions for these made it difficult for the participant to respond to these questions.

Some question formats were too complex either in their format/layout or in the level of detail of response sought. Examples are the questions on physical activity, sedentary behaviour and screen time. These questions asked participants to calculate the minutes or hours per usual work/non-work day or the number of times an activity was done for 10 minutes or more during a usual week and aggregate the total time per week. Participants found calculating the exact time challenging and others struggled with the definition of a usual day or week as they had irregular schedules.

For most of the questions showing major issues, more than one of the above problems were identified.

2.2 Findings from Dress Rehearsal

The Dress Rehearsal field work phase concluded on 7 December 2012, and data processing and analysis are underway at the time of preparing this report. The Dress Rehearsal provided invaluable information and experience in terms of the logistic and operational aspects of the study conduct. Preliminary findings on overall response were disappointing and indicate that a substantial revision process will be required to optimise the study materials and design before commencing fielding Wave 1.

2.2.1 Response rates

For every age group the response fraction was considerably lower than the anticipated 20% with an overall response of 6.1%. Table 2.3 gives an overview of response fractions by age group.

Table 2.3: Crude Response Fractions by Study and Age Group

Study Group	Number Approached	Response Fractions		
		Response Fraction % (95% CI)	Number Contacted	Response Fraction % (95% CI)
Boys	500	7.4% (5.1%-9.7%)	480	7.7% (5.3%-10.1%)
Parents of boys	500	7.0% (4.8%-9.2%)	480	7.3% (5.0%-9.6%)
Adolescents	499 #	5.2% (3.3%-7.1%)	478	5.4% (3.4%-7.4%)
Adults*				
Overall	1250	5.6% (4.3%-6.9%)	1210	5.8% (4.5%-7.1%)
18-25 year olds	500	2.8% (1.4%-4.2%)	480	2.9% (1.4%-4.4%)
30-35 year olds	375	6.1% (3.7%-8.5%)	358	6.4% (3.9%-8.9%)
50-55 year olds	375	8.8% (5.9%-11.7%)	372	8.9% (6.0%-11.8%)

One adolescent removed as deceased after drawing of sample but before dispatch of initial mail-out

Response fractions did not vary substantially between the three age sub-groups (adults, adolescents and boys). The lower response in adolescents reflects, in part, a high level of invalid consent forms returned by this group (21%). Had the consent forms been completed as required by protocol the response fraction in adolescents would have been 6.9%.

The response rate for the age sub-groups among adults varied noticeably, with young adults (18-25 years) having a substantially lower response fraction (2.8%) than the oldest males (50-55 years – 8.8%). This variation between age groups causes the overall response rate for adults to be below that of the boys as well as adolescents (after accounting for 'invalid consent').

When comparing response fractions for the three streams across states, no difference was evident for adults in Victoria and South Australia, while adolescents showed a small difference in responses by state, with slightly higher responses in South Australia. For boys, however, response fractions were substantially higher (more than double) in Victoria than South Australia. While the difference could be attributable to sampling variance, it may be the case that there was a State-based difference in the likelihood of recruiting boys to join the study. Table 2.4 gives an overview of response fractions for each stream by state.

Table 2.4: Crude Response Fractions by Study Group and State

Study Group	Response Fractions			
	Number Approached	Response Fraction % (95% CI)	Number Contacted	Response Fraction % (95% CI)
Boys	500	7.4% (5.1%-9.7%)	480	7.7% (5.3%-10.1%)
Victoria	250	10.0% (6.3%-13.7%)	239	10.5% (6.6%-14.4%)
South Australia	250	4.8% (2.2%-7.4%)	241	5.0% (2.3%-7.7%)
Adolescents	499	5.2% (3.3%-7.1%)	478	5.4% (3.4%-7.4%)
Victoria	249	4.4% (1.9%-6.9%)	243	4.5% (1.9%-7.1%)
South Australia	250	6.0% (3.1%-8.9%)	235	6.4% (3.3%-9.5%)
Adults	1250	5.6% (4.3%-6.9%)	1210	5.8% (4.5%-7.1%)
Victoria	624	5.6% (3.8%-7.4%)	605	5.8% (3.9%-7.7%)
South Australia	626	5.6% (3.8%-7.4%)	605	5.8% (3.9%-7.7%)

Comparing responses across regional areas shows that response fractions in the capital city/metro areas were, in all three study groups, somewhat higher than in the other regions, though the differences were not remarkably strong.

Whilst small, the sample size for boys and adolescents in outer regional areas was expected to at least result in one to two respondents in these groups. However, no boys and adolescents from outer regional areas joined the study in the Dress Rehearsal. Due to the small sample size it is unclear whether this is an issue of concern in Wave 1. It appears however more likely than not that recruitment of boys and adolescents may prove to be more difficult in outer regional areas than in inner regional or city areas. The raw figures do not indicate any particular issues with response fractions for adults in outer regional areas. However, the small sample size involved meant a relatively large confidence interval which may mask such an issue. Table 2.5 provides sample statistics and response fractions by study stream and region in Dress Rehearsal.

Table 2.5: Crude Response Fractions by Study Group and Region

Study Group	Response Fractions			
	Number Approached	Response Fraction % (95% CI)	Number Contacted	Response Fraction % (95% CI)
Boys	500	7.4% (5.1%-9.7%)	480	7.7% (5.3%-10.1%)
Capital city/metro	337	8.6% (5.6%-11.6%)	323	9.0% (5.9%-12.1%)
Inner Regional	120	11.6%	116	6.9% (2.3%-11.5%)
Outer Regional	43	6.7% (2.2%-11.2%)	41	0.0%
Adolescents	499	5.2% (3.3%-7.1%)	478	5.4% (3.4%-7.4%)
Capital city/metro	377	5.6% (3.3%-7.9%)	364	5.8% (3.4%-8.2%)
Inner Regional	100	5.0% (0.7%-9.3%)	94	5.3% (0.8%-9.8%)
Outer Regional	22	0.0%	20	0.0%
Adults	1250	5.6% (4.3%-6.9%)	1210	5.8% (4.5%-7.1%)
Capital city/metro	835	6.5% (4.8%-8.2%)	804	6.7% (5.0%-8.4%)
Inner Regional	313	3.2% (1.3%-5.1%)	307	3.3% (1.3%-5.3%)
Outer Regional	102	5.9% (1.3%-10.5%)	99	6.1% (1.4%-10.8%)

* There were no boys or adolescents recruited from outer regional areas; i.e. a response fraction of 0.0%:

2.2.3 Sample characteristics

Additional analysis on the distribution of respondents by socio-demographic characteristics provides an overview of the sample composition. Tables 2.6 to 2.8 show the proportions of respondent in each participant group by education level, marital status (adults and parents only), country of birth, language spoken at home, and household income (adults and parents only). The majority of adult participants are married or in a de facto relationship, are employed, born in Australia, speak English at home, have a University degree and belong to the upper income category. A very similar composition was found in the boys and parents sample. For the adolescents, less demographic information was available, as there was no parent questionnaires conducted for this group and some of the socio-demographic information could not be asked reliably of the adolescent. However, those questions asked consistently in boys and adolescents showed the same trend. The majority of adolescents lived in one home only, were born in Australia and spoke English at home.

Overall this analysis shows that in Dress Rehearsal the sample is skewed towards the higher socio-economic population. This finding was also confirmed by interviewer feedback. Whether this finding is related to the mail-out data collection method or a random effect within the small sample remains unclear.

Table 2.6: Socio-demographic characteristics for adults (=70)

Socio-demographic characteristic	Adults Number (%)
Marital Status	
Never married	16 (23)
Widowed	0 (0)
Divorced	4 (6)
Separated but not divorced	1 (1)
Married/de facto	47 (67)
Missing	2 (3)
Country of birth	
Australia	53 (76)
Elsewhere	16 (23)
Missing	1 (1)
Main language spoken at home	
English	64 (91)
Other language	5 (8)
Missing	1 (1)
Highest education level	
Less than secondary school	0 (0)
Year 7	1 (1)
Year 8	0
Year 9	2 (3)
Year 10	3 (4)
Year 11	5 (7)
Year 12	9 (13)
Trade certificate/apprenticeship	12 (17)
Diploma	7 (10)
University degree	23 (33)
Other	4 (6)

Socio-demographic characteristic	Adults Number (%)
Missing	4 (6)
Employment status	
Employed (%)	55 (79)
Unemployed, looking for work (%)	8 (11)
Unemployed, not looking for work (%)	7 (10)
Missing (%)	
Before Tax Household Income (2011/12 Financial Year)	
\$200,000 or more (%)	1 (1)
\$80,000 - \$199,999 (%)	36 (51)
\$40,000 - \$79,999 (%)	18 (26)
\$20,000 - \$39,999 (%)	8 (12)
\$1 - \$19,999 (%)	2 (3)
Nil income (%)	1 (1)
Negative income (%)	0 (0)
Don't know (%)	3 (4)
Missing (%)	1 (1)

Table 2.7: Socio-demographic characteristics for adolescents (n=26)

Socio-demographic characteristic	Adolescents Number (%)
Country of birth	
Australia	26 (100)
Elsewhere	0 (0)
Missing	0 (0)
Main language spoken at home²	
English	25 (93)
Other language	1 (4)
Missing	1 (4)
Number of homes lives in	
One home only	25 (96)
Two or more homes	1 (4)
Highest education level	
Year 8	2 (7)
Year 9	9 (33)
Year 10	7 (26)
Year 11	6 (23)
Year 12	0 (0)
Missing	2 (8)
Did paid work in last 12 months?	
Yes	16 (62)
No	10 (38)
Missing	0 (0)

Table 2.8: Socio-economic characteristics for boys (n=37)

Socio-demographic characteristics	Boys Number (%)
Gender of responding parent	
Female	30 (81)
Male	4 (11)
Missing	3 (8)
Marital Status of Parents	
Never married	1 (3)
Widowed	0 (0)
Divorced	3 (8)
Separated but not divorced	5 (14)
Married/de facto	26 (70)
Missing	2 (5)
Country of birth	
Australia	31 (84)
Elsewhere	6 (16)
Missing	0 (0)
Main language spoken at home	
English only	34 (92)
Other language	3 (9)
Missing	0 (0)
Number of homes lives in	
One home only	31 (84)
Two or more homes	6 (16)
Highest education level	
Year 3	7 (19)
Year 4	6 (16)
Year 5	8 (22)
Year 6	5 (14)
Year 7	8 (22)
Year 8	3 (8)
Missing	0 (0)
Parent's Highest education level	
Year 10	1 (3)
Year 11	1 (3)
Year 12	3 (8)
Trade certificate/apprenticeship	4 (11)
Diploma	8 (22)
University degree	15 (41)
Other	2 (5)
Missing	3 (8)
Employment status	
Employed	28 (76)
Unemployed, looking for work	2 (5)

Socio-demographic characteristics	Boys Number (%)
Unemployed, not looking for work	5 (14)
Missing	2 (5)
Before Tax Household Income (2011/12 Financial Year)	
\$200,000 or more	2 (5)
\$80,000 - \$199,999	17 (46)
\$40,000 - \$79,999	9 (25)
\$20,000 - \$39,999	3 (8)
\$1 - \$19,999	1 (3)
Nil income	0 (0)
Negative income	0 (0)
Don't know	3 (8)
Missing	2 (5)

2.2.3 Pre-notification and reminder

Due to an error made by the DHS project team in sending the assigned form of reminder to groups 2 and 4 (described in chapter 3.5.1) the full range of comparisons between different combinations of pre-notification with reminder formats could not be conducted. However, valuable information about the relative contribution of pre-notifications and reminders was collected.

- Firstly, the 'no pre-notification/no reminder' combination performed very poorly overall, suggesting that utilising a pre-notification and/or a reminder of some form is a better approach.
- Secondly, the response rates for those who received a reminder letter (with pre-notification) tended to be similar to, or just below, the response rate of those who received a full reminder pack (without pre-notification). As the reminder letter/pre-notification letter combination can be produced at significantly lower cost, this method would be the preferred method of the two.
- Finally, where a reminder was used, regardless of the reminder type it seemed to account for around 20% of total responses in the sub-groups. This further strengthens the case for use of reminder letters rather than full packs.

2.2.4 Performance of questionnaires

Overall, the questionnaires appeared to have performed well with regard to completeness of data in all three study groups. The data verification team of Roy Morgan Research reported that none of the questionnaire formats required extensive verification or cleaning at the input stage of the processing of data. Most of the incomplete data can be rectified by using the appropriate cleaning rules. Data quality checks (e.g. illogical/inconsistent responses and missing data analysis) performed by the study team of the University did not show any serious issues with any questions in the questionnaires. Only a relatively small number of questions seem to require some additional work in terms of wording and physical formatting.

This is a positive result as it suggests that the low response rates are unlikely to be caused by issues with the ease of use or sensitive content of the questionnaires. Overall, it appears that

once individuals decided to participate they could complete the questionnaires easily and well, bearing in mind that in general the adult participants had fairly high education levels.

2.2.5 Performance of contact forms and consent process

Issues were identified with the Information Sheet and Consent/Assent forms particularly for the adolescents. Seven adolescent participants (representing 21% of all returns in this stream) failed to provide 'valid consent' which meant that their data could not be used in Dress Rehearsal. These comprised:

- three instances of the assent form being returned blank, when all other required documentation was received in good order;
- two instances of the assent form including a printed name but not a signature, when all other documentation received in good order;
- two instances of non-receipt of parental consent, when all other documentation received in good order.

This level of data loss would be unacceptable in Wave 1. To minimise data loss by 'invalid consent' in adolescents we are exploring the following options:

- reviewing the requirements for valid consent (e.g. consent by printed name instead of signature);
- simplifying the consent 'paperwork' (e.g. by combining the adolescent assent and parent consent requirements into a single document) and/or streamlining the contents of the mail-out packs;
- developing a 're-contact' procedure to notify respondents of missing/incomplete consent elements and to attempt to obtain these elements (where contact details available via the information sheet);
- improving instructions to complete the study documents.

Other issues in documents returned by adults and adolescents related to:

- writing an incorrect date on consent/assent forms (approximately 27% of adolescents and 12% of adults wrote what appeared to be their date of birth, rather than the date of signing the form);
- writing information into the wrong fields in an information sheet (e.g. school name written in school address field and vice versa) or leaving fields blank (e.g. postcode).

In both groups, adults and adolescents, there is clearly scope to improve both the quality and quantity of data obtained via the information sheet, and reduce processing times, by improving the structure of these documents. This could include:

- adjusting the visual appearance of the form and/or providing better explanation of the reason for asking particular questions where missing data was more prevalent (e.g. Medicare number, alternative contacts);
- including 'screener' questions (e.g. 'Are you currently working?') to help clarify whether missing data in the following question (e.g. 'Work telephone number') means 'not applicable' or 'did not answer';
- reduce the quantity of information requested on this form and revise the layout of the form to reduce the time required for verification.

For the boys and parents of the boys the above issues were not apparent, since in this stream the interviewer walked the parent and boy through the consent process and had the opportunity to check the information sheet for completeness.

2.2.6 Contact data file

Overall, there did not appear to be any significant quality issues associated with DHS contact data.

While the number of items 'returned to sender' will underestimate the total number of invalid addresses (i.e. some items are simply discarded by the recipient rather than returned), the figures for returned mail in each stream were in the range expected for Medicare data:

- Adults – 40 (3.2%)
- Adolescents – 21 (4.2%)
- Boys – 20 (4.0%)

There were no instances of incorrect age reported to us by recipients or evident in relation to completed questionnaires which means that the algorithm used by DHS to exclude boys and adolescents who have a close birthday and might therefore move between groups worked as designed.

One instance of wrong gender was reported to us by a recipient. The issue was reported to DHS who confirmed that this was an isolated issue related to incorrect recording of the title of this individual.

Four enquiries were received from parents of adolescents, advising that the study pack had been sent to an address at which (it was claimed) the child had never lived. In each case, however there was a connection between the address and the recipient (e.g. a grandparent, an ex-partner etc.), which would suggest that this information had indeed been supplied to the DHS at some point.

Overall, there does not seem to be a sample quality-related barrier to using a Medicare enrolments sample in Wave 1.

2.2.7 Other findings

Some protocol issues that were expected to create challenges, such as the inclusion of co-cardholders (introduced by DHS policy) and the separation protocol for personal information from study questionnaires (as required by the University HREC), did not create any significant issues.

There were a small number of instances in which respondents returned all documents in a single envelope and two instances where the envelope containing the questionnaire failed to arrive while the envelope with the consent and contact information was received. We are unable to tell if this was due to loss during transit or if the questionnaire was never mailed.

Sending the study invitation to both cardholders raised the possibility of conflicting views between co-cardholders with respect to the child's participation arising. However, this did not occur in Dress Rehearsal, although given the relatively small sample in the Dress Rehearsal this situation may arise Wave 1.

Of the 37 interviews conducted with boys, 12 (32%) were with boys listed on more than one Medicare card and for 5 of these the co-cardholder made contact with Roy Morgan Research. Though a small sample size, it may be worth noting that the boys with co-cardholders were somewhat over-represented in the interviews actually conducted (22% of the boy sample resulting in 32% of conducted interviews). It could well be that having two contact persons at recruiting the boy was valuable. Our assumption is that with a greater number of targeted postcodes and available interviewers in Wave 1 the inclusion of a co-cardholder may actually

help increase the response rate for boys. However, at the same time the extra mail-out to co-cardholders means increased recruiting costs.

2.2.8 Conclusions

Overall, the Dress Rehearsal indicated that the current methodology is capable of being implemented according to the design. Most aspects of the methodology were implemented well. However, the involvement of three different organisations with different organisational cultures and operating procedures complicated the production process and resulted in some data loss in the Dress Rehearsal. Some contributory factors to issues experienced in the application of the Dress Rehearsal protocol were clarity and frequency of communication, the geographical distance between the mail house and the project teams of Roy Morgan Research and the University of Melbourne, institutional barriers within DHS to monitoring of the mail-out by the Roy Morgan Research and the University of Melbourne, time pressures and the complexity of the protocol. All of these factors contributed to the error in the reminder protocol. While the study was still able to glean useful information about the relative contribution of pre-notifications and reminders, the full range of comparisons of combinations of effects initially planned could not be made. Valuable lessons were learned regarding establishing clear communication and monitoring processes between all organisations involved.

The key learning from the Dress Rehearsal is, however, that response rates under the existing methodology fell well short of the targeted 20%, which raises the larger question of whether a DHS mail-out methodology is an appropriate strategy for Wave 1.

3. Questionnaire revision

3.1 Questionnaire revision following Cognitive Testing

Following the cognitive testing a number of working meetings were conducted to review all four questionnaires, discuss changes in wording and format, identify question to eliminate, and source replacement questions for seriously underperforming questions.

The following actions were taken:

1. To reduce participant burden due the length of the questionnaire and/or because cognitive testing indicated questions were not performing, the following questions were deleted:

<u>Adult</u>	<u>Adolescents</u>	<u>Boys</u>	<u>Parents</u>
Some Injury questions	Sugar drinks and take away food	Sugar drinks and take away food	Nativity of other biological parent
Sleep disordered breathing	Peanut allergy	alcohol use	Housing problems
Walking pace	2 nd acne question	Online friends	Financial problems
Sugar drinks and take away food	Parental alcohol use	MOS Social Support	
Some sexual activity questions	Peers anti-social behaviour	Self-harm intent	
Sexual satisfaction scale	Online friends	Social Phobia and Separation Anxiety	
Sexual difficulties	MOS social support		
Housing problems and heating	Self-harm intent		
	Masculine appearance		
	Community participation		

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

<u>Adult</u>	<u>Adolescents</u>	<u>Boys</u>	<u>Parents</u>
Masculine appearance Anxiety scale	Health information Separation anxiety		

2. Wording and/or layout was modified, but no substantive changes to content made for a number of questions, as the following table indicates.

<u>Adult</u>	<u>Adolescents</u>	<u>Boys</u>	<u>Parents</u>
Health conditions and symptoms Injury Physical activity Hours outdoors Fruit and Vegetables Supplements Over the counter medications Masculinity Income Physical activity at work Discrimination Health literacy	Pain Health literacy Sexual identity Bullying (victim and perpetrator) Physical activity Age Screen time Masculinity	Aches and Pain Bullying Screen time Health information	Health conditions and Symptoms Injury Medical services Household Income

3. New questions were added to cover constructs where cognitive testing showed poor performance of existing questions, or on the advice of the External Scientific Advisory Group. These were:

Adult Questionnaire:

- Sedentary behaviour (*Sourced from Longitudinal Study on Women's Health*)
- Skin tone/type (*Sourced from National Sun Survey*)
- Child living arrangements (*Sourced from LSAC*)
- Financial stress (*Sourced 45 and Up*)
- Community participation (*Sourced from LSAC*)
- Under-employment (*sourced from HILDA*)
- Household composition (*Sourced from parent questionnaire*)

Adolescent Questionnaire

- Disability (Source Washington Group Questions; same as in Adult questionnaire)
- PedsQL General Well Being Scale (adolescent report)
- Additional lifetime health conditions (Source from Parent questionnaire)
- Injury (Sourced WHO; same as in Adult questionnaire)
- Puberty question (Modified from Pubertal Development Scale)
- Social support (Sourced from Victorian Adolescent Health Cohort Study - HOWRU)
- 12 month prevalence suicidal behaviour (Sourced from Youth Risk Behaviour Survey)
- Life events checklist (Source: Patton et al 2003)

Boys Questionnaire

- PedsQL General Wellbeing Scale (child version)
- 12 month prevalence to suicide questions (Sourced from Youth Risk Behaviour Survey)
- Social support questions (Sourced from Victorian Adolescent Cohort Study – HOWRU)

Parent questionnaire

- PedsQL General Wellbeing Scale (parent report) (Sourced from Validated Scale)
- Financial problems (Sourced from 45 and Up)

4. There was some minor reordering of questions to allow a better flow and faster completion of the questionnaire.
5. Finally, a free text section was included at the end of the questionnaire for participants to write any additional information or comments they would like to share with the study.

3.2 Questionnaire revision following the Dress Rehearsal

Overall the questionnaires seem to have performed well in the Dress Rehearsal. However, the low response rate achieved in Dress Rehearsal indicates that there are barriers to engaging males in participating when they receive the study materials unsolicited in the mail. While Dress Rehearsal could not provide any information on the reasons for non-participation, it is likely that one factor is the contents and presentation of the invitation packets, including the length of the questionnaire. In this light, a further round of questionnaire review was undertaken.

The questionnaire review process has been structured as follows and is currently underway:

1. The study team to reviews the questionnaires;
2. The study team recommends questions for deletion, or revision to shorten and provide justification;
3. The Chief Investigators review the study team recommendations and make the final decision on questionnaire content;
4. The study team revise the questionnaires;
5. Repeat steps 2 to 4 if necessary.

As part of the revision process questions may be reworded, reformatted or deleted. Decisions on question changes are made on the basis of a set of criteria which apply for all questions in the questionnaires. These include:

1. A question must be short measure of the health construct that it measures;
2. A question must be relevant to proposed age group;
3. A question must be appropriate for a baseline questionnaire, for example
 - a. Necessary to rule people in and out of follow-up groups and data analysis (e.g. health outcomes and pre-existing conditions);
 - b. Be a known mediating factor or exposure associated with future health outcomes;
 - c. Necessary to characterise the cohort (e.g. demographics, social status, mood state etc.);
4. Novelty - a question or construct is not covered, or under-researched in other population health studies;
5. A question or group of questions is relevant to issues important in the male health field and/or identified in the National Male Health Policy;
6. Health outcomes included must show a reasonable level of prevalence/burden of disease in the population/age group.

All questions in the current questionnaires will be reviewed according these criteria, and those which fulfil at least one will be exempt from deletion, but may be further improved by

rewording or reformatting. If questions do not meet the set standards it will be flagged by the study team as a candidate for deletion and then discussed in a team meeting with the Chief Investigators, who will then make the final decision.

The revision process will also be informed by analysis of the Dress Rehearsal questionnaire data that is currently being finalised. A full report on that analysis will be included in a future report, but briefly the analyses of Dress Rehearsal questionnaire data include:

- Assessment of the characteristics of respondents;
- Assessment of the proportion of missing data for individual survey items;
- Assessment of trends in item response fractions by page number and topic;
- Assessment of the performance of questionnaire skip logic;
- Checks for implausible values and inconsistent responses; and,
- Assessment of the performance of specific item formats.

Appendix 9 contains the analysis plan for the Dress Rehearsal with full details of analysis to be undertaken.

4. Difficulties encountered and strategies to address them

4.1 Sampling and Mail-out Issues

4.1.1 Medicare enrolment contact data - issues and challenges

Medicare enrolment data and the policies around its use for research raised a number of issues concerning the composition of the sampling frame and logistics.

Firstly, it is expected that a small number of incorrect addresses will appear in the sample. With addresses being updated by medical practices and GPs when a medical encounter occurs, the number of incorrect addresses should be minimised and DHS reported that their usual level of 'Return to Sender' mail is approximately 2%.

Secondly, although the DHS undertakes regular updates of postcodes and addresses, there are likely to be discrepancies between Medicare contact data and Census data.

Thirdly, as described above, any individual who had not made a claim related to medical services in the prior 12 months was excluded from the sample frame. The study obtained data on the age and regional distribution of numbers of males excluded and found that between 20% and 30% of contacts could be excluded from the sample (in some sub-samples this could even reach rates up to 39%). These excluded groups, for example males who do not see a doctor on a regular basis, are undoubtedly of interest in a population-based national study on male health.

Finally, for boys aged 13 years or younger the invitation has to be addressed to the parent or guardian of the boy who is listed on the Medicare card the boy is listed on as well. Boys however can be listed on more than one card and those cardholders may reside at different addresses (e.g. if parents are divorced or separated). The DHS requests that when a boy is listed on two Medicare cards and the cardholders do not reside at the same address both cardholders must receive any information sent in relation to their son. This means in addition to the parent/cardholder who resides in the selected postcode as described in the original protocol, study information must also be sent to the co-cardholder who was not initially

selected and may live in a different out-of-scope postcode. This requirement introduces additional expense in terms of printing and mailing, but also logistical issues around refusals and scheduling interviews for which additional protocols had to be developed.

Although there are challenges in using Medicare enrolment data in terms of coverage, quality and feasibility, Medicare enrolment data remains the optimal source of contact data for a mail-out survey. One significant advantage of using Medicare data lies in being able to quantify the limitations and thus being able to establish procedures to mitigate these. Subsequent discussions with the DHS have raised the possibility that a waiver might be possible for the 12 month 'no contact' rule and a mechanism for accomplishing this has been identified. Additionally the DHS mail-out manager has suggested an application to send different letters/materials to out-of-scope co-cardholders should be made to the EREC which, in his opinion, should have no objection.

4.1.2 Medicare mail-out process - issues and challenges

There were errors made by the DHS project team which resulted in some data loss in the Dress Rehearsal. The first error involved two groups receiving the wrong reminder format, and therefore instead of having 6 combinations of pre-notification, invitation, reminder type to compare there were only four (see Chapter 1.2.4 for more information on the mail-out process). The second involved what appeared to be some anomalies in the randomisation of adult males to the different groups – such that certain ages and states were over-represented or under-represented in some groups. This impacted on our ability to discern what were age and region related effect and what are effects of the pre-notification, invitation, reminder combinations. Despite these errors there were a sufficient number of combinations to elucidate useful information about the effectiveness of reminders and of full-pack versus a reminder letter, and to observe that the invitation only group performed worst overall. Additionally, weighting was applied to mitigate the second issue, although it could not overcome it entirely and there remains some uncertainty in interpreting the data. The issue in the first instance appears to be largely due to organisational barriers in the DHS with respect to mail-outs. The study team and sub-contractor were in regular contact with the DHS project team and travelled to Canberra to meet and discuss the processes. However, despite the good working relationship and supportive attitude of the DHS project team toward the study, the complexity of the Dress Rehearsal trial design and institutional barriers to having any external personnel participate in quality control activities resulted in the misallocation of reminders error occurring. With respect to the issue of insufficient randomisation, the causes are still being investigated.

While these issues will not arise again, as no subsequent mail-out will have comparison groups, they did alert the study team, sub-contractor and DHS that communication needs to be improved, and the DHS has committed to seeking permission from their privacy office to the effect that if study or sub-contractor personnel sign the relevant non-disclosure documents they will be permitted to participate in quality checking in the mail-house.

4.2 Dress Rehearsal response rates

As reported in Chapter 2.2 the Dress Rehearsal achieved lower than expected response rates. There are several implications of these low response rates the most significant being related to costs of conducting Wave 1 (discussed below in section 4.4 Budget), and representativeness of the study cohort.

Lack of representativeness due to low response rates is a criticism levelled at many current studies. We argue, as do some members of our External Scientific Advisory Group, that representativeness *per se*, is largely inconsequential for longitudinal studies. In terms of participants, the validity of a longitudinal study is much more affected by attrition over time than by poor initial recruitment. However, low initial response can mean that the people recruited are relatively homogeneous (e.g. people with higher socioeconomic status), and if some of the determinants of health and wellbeing have different effects for various subgroups of the population, there might be insufficient variation in the study data to identify this. The credibility of the study would suffer from such low response rates, regardless of their impact on validity, and the study team is exploring other means of recruitment that might give higher response.

The reasons for this lower than anticipated response cannot be directly ascertained as the privacy regulations governing DHS administered mail-outs do not permit follow up contact with non-responders. Since becoming aware of the Dress Rehearsal results we have undertaken consultation with a number of researchers on the issue. Professor Annette Dobson, Chief Investigator for the Longitudinal Study of Australian Women's Health, whose team has had extensive experience in recruiting longitudinal cohorts, advised that in a recent recruitment for a cohort of young adult women using the same DHS mail out protocol as the Dress Rehearsal resulted in an ~6% response rate. Roy Morgan Research, who conducted the Dress Rehearsal and who run a number of large national data collections advised that they had observed steady declines in response rates and greater efforts required to recruit participants for their nationwide Morgan Poll. Professor Emily Banks, Scientific Director of the 45 & Up Study expressed the opinion that recruitment of a cohort that included many younger males for a general omnibus health study via mail out would have to approach a very large number of individuals to collect a large cohort. Professor Mark Wooden, Study Director of HILDA was of the opinion that the results reflect a societal change in which mail-out surveys could compete in a time-poor, information-saturated culture.

The general view of the Study Steering Committee and Scientific Advisory Group was that the Dress Rehearsal response could not have been foreseen, but again clearly indicated that the mail-out model was not as effective as it once was. Moreover, a number of reports in the literature have noted that longitudinal studies – whatever their methodology – have been faced with declining response rates for over a decade^{1,2}. Overall, the feedback we obtained strongly suggests that the research environment has changed and that more intensive recruiting efforts are required and/or larger numbers of potential participants must be approached to achieve the Ten To Men target sample.

The other main implication of the low response rates is that based on the results of the Dress Rehearsal, the study does not have sufficient resources to recruit a cohort of 58,000 men and boys using the current method.

In this context the study embarked on a two-pronged process to set out the options for Wave 1 data collection.

1. A reconsideration of the recruitment/sampling methods in general; and
2. Exploring ways to rework the current protocol and materials to determine if they can be sufficiently improved to make the mail-out approach viable.

Review of Sampling and recruiting methods

As part of the process of consulting with individuals and advisory groups, the study canvassed opinion and sought advice on alternative sampling and recruitment approaches. Table 4.1 details the options canvassed and a brief assessment of their strengths and weaknesses.

Table 4.1 Sampling and recruitment options

PROBABILITY SAMPLING			
Option	Response rates	Implication for data quality and meeting study aims	Benefits/Risks
Medicare Mail out random stratified sample	<u>Longitudinal Studies</u> - Historically with other large population studies (1996 – 2009) response rates were b/w 18% and 57% - ALSWH baseline recruitment 1996 , response rates vary by cohort from 35.5% to 53.5% - LSAC recruitment in 2003/2004 : response rate b/w 50.4% and 57.2% (incl. non-contactables) Followed up with phone contact though. - 45 and Up recruitment from Feb. 2006 to Dec. 2009 : 17.9% - Contemporary response data of pilot studies in 2012 show response rates b/w 4%-8%	High validity: - Same sample frame across all participants 10 to 55 - Random selection based on postcode - Can enumerate the sample frame and quantify non-response	Benefits - Cost effective - All participants follow same sampling approach - Control over sample frame - Random sample - Information on composition of sample frame available Risks - Low response rate - Sample frame limitations: no contact, difference from census Medicare data and Census data - Capacity of DHS mailing house - DHS legal obligations with minors (Co-cardholder protocols, confidentiality of data, mail-out protocols etc.) - Potential for unreliability in keeping timelines for mail-out - Less quality control by Study
Household Sampling with Drop & Collect Field workers to door knock, distribute survey packets and collected completed materials or schedule interviews.			
	<u>Longitudinal Studies</u> - HILDA. 66% households 92% adults within those households for initial recruiting 2000. Unknown for 2011 top up. - <u>AusDiAB</u> 1999-2000. 49.6% of eligible households. <u>Cross-sectional Studies</u> - National Drug Strategy Survey 2010. 50.6% households responded. - National Health Survey 2011/12. 73.7% of households responded. - National Survey of Mental Health and Wellbeing 2007. 51% of households responded.	Validity high to moderate - Door knocking based on census areas SA2s/SA1s etc. - Cluster effect in Wave 1, cluster effect may remain higher in adults as the study progresses	Benefits - Higher response - Random sample - All participant groups follow the same approach Risks - More pronounced cluster effect - More labour intensive and costly
Household sampling with Telephone Survey Contact based on white pages phone numbers and RDD mobile phones; Phone interview conducted			
Telephone	<u>Cross-sectional Studies</u> - AIHW 2009 Vaccination Study 35% - Liu et al 2011 Pilot Young women reproductive health. 74% & 88% qualified as eligible, landline and mobile	Validity high to moderate - Random sampling - Would have different modes of data collection for different age groups	Benefits - High Response rates - Random sampling - Biases documented to some extent Risks - High cost - CATI not feasible for 10-14 years olds

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

	<p>respectively. Adjusted for eligibility unknowns 54% and 45%.</p> <ul style="list-style-type: none"> - Holden 2005. Mates 78% of eligible males. - NSW Pop Health survey. 2009 52-63% - <u>Xue et al 2008 CAM National survey 15%</u>. <p><u>Longitudinal Studies</u></p> <ul style="list-style-type: none"> - Martin et al 2007. Florey Study of Male Ageing – SA. 70% for interview, 41% attended clinical assessment. 		- Consenting with minors a potentially non-approvable for Ethics
--	---	--	--

NON-PROBABILITY SAMPLING			
Convenience Sampling with Schools			
<p>Advertising through schools' newsletter, interested parents/adolescents contact the study to request materials.</p>	<p>No studies report doing this. Might be an adjunct to in school data collection. Has the same limitations with respect to recruitment, plus the additional burden of the schools approval process.</p>	<p>Low validity:</p> <ul style="list-style-type: none"> - Mixed sampling approach for adults and under 18 years - Participants 10 to 17 only - High <u>self selection bias</u> - Cannot calculate a response rate as no denominator. 	<p>Benefits</p> <ul style="list-style-type: none"> - Cost effective if high level of clustering <p>Risks</p> <ul style="list-style-type: none"> - 3-stage approval process, high <u>self selection bias</u> - Clustering effect - Long field time - Resource intense approval process - Not receiving approval in some states (<u>Vic Gov</u>); not being able to recruit in a state - Uncertain response rate, likely to be low - Uncertain sample characteristics - Mixed sampling approach for groups may sacrifice data quality
Convenience sampling using Media			
<p>Convenience sampling – Advertise the study in the media and invite men to participate</p> <ol style="list-style-type: none"> To call and organise participation and select preferred mode To do online (not suitable for boys) 	<ul style="list-style-type: none"> - Garret 2011 – 622 young people – 9 months advertising, online, newsletters - (66%) reported hearing about the study through a website or an electronic newsletter/ email - Big Drink Debate UK 2008 – recruited 22,780. Big media campaign, distributing questionnaires in local papers, <u>doctors</u> offices, town and <u>cit</u> centres. Online option. (<u>cross sectional and anonymous</u>) 64% female, 68% 25-54. 	<p>Low validity :</p> <ul style="list-style-type: none"> - Purely self-selection - We don't know what we get - We don't know anything about the non-respondents - Cannot calculate a response rate as no denominator. 	<p>Benefits</p> <ul style="list-style-type: none"> - Respondents who join will be motivated and thus more likely to stay with the study long term <p>Risks</p> <ul style="list-style-type: none"> - Might not achieve quota - Cannot calculate costs or estimate time as do know what the uptake will be - Self-selection bias - Not representative of Australian men - Resource intense - Costs for advertisements unclear
<p>Opportunity sampling/ snowball sampling using</p>	<ul style="list-style-type: none"> - UNSW advertising to all students 	<p>Low validity:</p> <ul style="list-style-type: none"> - Purely self-selection 	<p>Benefits</p>

community organisations, interest groups	multiple methods – 4.4% (~2200 students) - Healthy Dads, Healthy Kids 107 men responded, 53 enrolled in trial. - Other literature – in studies recruiting small targeted samples advertising in media is often part of the strategy.	- Cannot calculate a response rate as no denominator.	- Respondents who join will be motivated and thus more likely to stay with the study long term Risks - Might not achieve quota - Cannot calculate costs or estimate time as do not know what the uptake will be - Self-selection bias - Not representative of Australian men - Resource intense - Costs for advertisements unclear
--	--	---	--

General opinion was opposed to non-probability approaches to recruiting due to the low validity and uncertainty around costs and timelines. For probabilistic methods telephone interviewing was ruled out as the complexities of gaining parental consent seemed insurmountable within the timeframe, and the costs were very high. Ultimately it was decided that the Drop and Collect method was the strongest option on the rationale that while it was a more costly method of recruitment it would likely achieve a higher response, it was compatible with the broad range of age groups and mixed mode of data collection, and would overcome the issue of failing to ‘cut through’ and engage prospective participants with the study. The University commissioned Roy Morgan Research to conduct a small pilot study to provide information on response, using the same study materials as the Dress Rehearsal. That study is currently underway.

4.3 Redesign of materials and protocols to improve response

It was initially planned to conduct focus groups to examine the study materials and protocol to gain feedback on elements which might deter individuals from participating. In January 2013 an ethics application was made and approved to conduct the focus groups. To date, however, the focus groups have not been held as the consensus that emerged in consultations and advisory group meetings on the issue was that the likely main barrier to participation was establishing initial engagement with the study – achieving ‘cut through’ – and that until this was established the actual content and format of the study materials was largely irrelevant. It was also felt that the combined expertise of the study’s Advisory groups and the sub-contractor could do much toward improving the study materials. The option is still available to conduct focus groups should the need be perceived.

Instead it was decided to trial an alternative method for recruiting participants, the Drop and Collect method. This method is considered much more effective in terms of achieving initial engagement and is currently being trialled.

Other measures explored include the use of incentives, making study materials simpler and more appealing, decreasing the questionnaire length to reduce burden, developing a communication campaign to raise awareness of the study. In terms of incentives, given the budget constraints there is a limit to the size of incentive that could be offered, with pre-incentives being unfeasible. Feedback from the Dress Rehearsal interviewers indicated limited interest in the iPad raffle incentive in boys and parents. The question of incentives is currently on hold pending the outcome of the current pilot and decisions about overall recruitment

strategies. The other options are being pursued, with revisions of PLSs underway, and a further round of questionnaire review. The utility of a communications campaign is currently being explored with a view to identifying the most cost-effective activities that can be undertaken within the current timeframe and resources.

Despite the disappointing response results, the Dress Rehearsal was an invaluable exercise in terms of informing the research team of community responsiveness to the proposed design. We have no doubt that the current phase of review and redesign efforts will result in a robust design and valid methodology for conducting a successful Wave 1 data collection and meeting the study aims. Clearly the results of the Dress Rehearsal have implications for the timelines and budget which are discussed below.

4.4 Timeline

Initial timelines proposed that the instrument development and pilot testing be completed by February 2012. This timeline was overly ambitious given the delay in hiring study personnel due to the embargo on announcing the award of the tender, and that the study questionnaires had to be developed from scratch and cognitively tested, the multiple approvals required to test recruitment strategies, and the lengthy tender process in place at the University of Melbourne to ensure probity in sub-contracting arrangements (described above). To attempt to minimise the time between the completion of the Dress Rehearsal and commencement of Wave 1, and because the services required for DR and W1 were essentially the same, it was decided to seek tenders for both the Dress Rehearsal and Wave 1 at the same time. This process took place in April/May 2012. However, when the tenders were received, they were both substantially higher than the available funds. The reasons for this were the lack of certainty around recruitment methods, response rates and so on which would not be known until after the Dress Rehearsal, all of which resulted in the bidders being conservative in their costing estimates. Despite negotiations with the tender board to permit the study team to enter negotiations with the bidders in an effort to bring the costs within range, the Board decided that the tender should be aborted, and a new revised tender be requested. While this did cost time, the process did produce some valuable information on potential shortfalls in budget and the need to review the study protocols. A new tender was submitted for the Dress Rehearsal only (see Section 1.2.3), which was successful in appointing a sub-contractor to conduct the Dress Rehearsal. Due to the less complex nature of the Dress Rehearsal stand alone tender the tender process was compressed, and the Dress Rehearsal commencement was delayed by only a few weeks. The overall length of the Dress Rehearsal was longer than the original proposed timeline due to the trialling of recruitment approaches and materials in order to optimise the data collection protocols for Wave 1.

At the time of the abandoned tender it became apparent that Wave 1 would not commence in September 2012 as originally proposed and discussions began with the DoHA project team in May 2012 regarding revised timelines for Wave 1.

The disappointing response results uncovered in the Dress Rehearsal have had an impact on timeline. Instead of minor revisions to protocols and materials and going immediately out to tender for Wave 1 data collection as anticipated, a serious reconsideration of the options for Wave 1 had to be undertaken (described above in section 4.2). The addition of a further pilot study, and the lessons learned regarding the risks of going to tender with too much uncertainty resulted in the tender process being pushed back to March/April 2013. It is anticipated that a sub-contractor will be appointed in early May and Wave 1 pre-field work commenced shortly thereafter and data collection finalised in late 2013. This is within the timeframes that had been under discussion with the Department of Health and Ageing since May 2012.

4.5 Budget

As mentioned above, the abandoned tender provided early indications that the available budget might be inadequate for the proposed data collection protocol. At that time alterations were made to the protocol to reduce costs without compromising the scientific validity of the study or its ability to meet its stated aims. These included reducing the number of boys to be interviewed, not including a parent survey for adolescent males, and not offering the online version for Wave 1.

These measures however are not sufficient to address the budgetary implications of the low response rate revealed by the Dress Rehearsal. To reach the proposed sample size of 58,000 at the response rates seen in the Dress Rehearsal, a substantially increased number of eligible participants would need contacted and invited to participate. That number is not achievable within the available budget. There are a number of measures that can be taken to offset this shortfall – for example reducing the size and thus printing, postage and data processing costs of the questionnaires, simplifying and reformatting collateral study documents, opting for the less costly reminder option, simplifying the document matching and collating processes and so on. All of these will be implemented should the mail-out option be pursued in Wave 1. However, while these will reduce the costs associated with the data collection, they will be insufficient to make up the shortfall caused by the low response rates.

Should the Drop and Collect method currently being trialled be adopted, the proposed sample of 58,000 will not be achievable as Drop and Collect is an overall more labour intensive and thus costly method of recruiting. However, based on current estimates it will yield approximately the same number of enrolments as the mail out method given the response rates.

When it first appeared that there may be some shortfall in the budget the study team initiated negotiations with the University on the possibility of exempting the sub-contractor payment sections of the budget from a portion of the University infrastructure and support services levy. This is a complex and difficult process and is currently still underway. Any funds recouped will be devoted to increasing data collection.

4.6 Ethical issues

There were a number of issues raised at the HEAG that required several rounds of revision before a recommendation to approve was granted. These concerned the content of the questionnaires – primarily the inclusion of sensitive questions on drug use, alcohol, mental health, and antisocial behaviour for both adults and minors, the issue of confidentiality and the possibility of subpoena of study data on illegal activities, the distress and safety protocols, and the risks related to returning documents containing identifiers and completed questionnaires in a single return envelope. In none of these areas was the study proposing to introduce protocols or include materials that had not been previously used in Australian research. A number of the provisions requested by the HEAG potentially impinged on the study's ability to collect valid data. The study revisited those issues with the HESC and ultimately proposed amendments to bring the study in to line with general research practice, which were approved.

5. Governance

5.1 Governance groups

In accordance with the commitments in the Detailed Project Plan the study governance structure has been functioning as designed. The Study Steering Committee met fortnightly during the questionnaire design and testing phase, and then on an ad hoc basis to address methodological issues as they arose (meeting four times in 2012). Terms of Reference were developed and approved by the study External Scientific Advisory Group (Appendix 10). The Group met twice in 2012. Terms of Reference were developed and approved for The Data Linkage Steering Committee (Appendix 11). The Committee met three times in 2012. Work is underway to convene the Community and Consumer Advisory group including drafting terms of reference, developing selection criteria for membership and identifying key peak bodies and community groups to target for recruitment. The Technical Advisory Group is largely comprised of members of the Study Steering Committee, and met late in 2012 to discuss options following the Dress Rehearsal. At the request of the Department an update document was produced for the Minister's Male Health Reference group in August 2012.

5.2 Contribution of governance groups

1. Questionnaire Development

The Study Steering committee was closely involved in the questionnaire development process, with most members leading or contributing to working groups described above. Members of the broader Technical Advisory Group also participated in working groups in areas of their expertise. The Study Steering Committee also played a major role in the process of revising draft questionnaires in terms of debating and deciding on priority areas, overall content and length and assessing the validity of the proposed items and measures. The External Scientific Advisory Committee reviewed the questionnaires and offered input on priority areas, under-research areas, optimal length and format, and selection of measures.

2. Post-Dress Rehearsal

The Study Steering Committee/Technical Advisory Committee and the External Scientific Advisory Group met in December and January to review the preliminary Dress Rehearsal response data and consider the implications for Wave 1 and options going forward (see section 4.2 above for an account of those discussions).

3. Data Linkage

The Data Linkage Committee focussed on determining what the requirements for linkage for the study were and how current best-practice in data linkage could be built into the studies protocols. This included advising on the use of an Integrating Authority, the use of SURE, the writing of consent and plain language statement documentation, and identifying relevant Commonwealth and Jurisdictional held datasets for linkage with study data. The committee also reviewed the draft documentation being prepared for submission to the Department of Health and Ageing Ethics Committee in March 2013.

6. Dissemination and communication activities

6.1 Development of a study brand

6.1.1 The process

The University contracted a professional creative agency named STREAMER DESIGN + COMMUNICATION to help developing a study brand that engages the different stakeholders of the Australian Longitudinal Study on Male Health. In this context it was important to create a brand that conveys integrity, trust and professionalism while at the same time being inclusive, open, inviting and non-judgemental.

After meeting with the study team for a comprehensive discussion to better understand the study aims and challenges driven by its scale and complexity, STREAMER ran a number of creative workshops. First, an audience mapping workshop was held to identify the target audience for the study and workshop communication strategies to improve audience reach. Six male participants were recruited from outside Melbourne University for this workshop. Second, a brand essence workshop was held to build the framework for the creative process, the development of a branding hierarchy and name. Members of the study Steering Committee were among the participants in for this workshop. Outcomes of these two workshops were used to develop the brand concept. During the development of the brand concept STREAMER repeatedly sought feedback from external and independent males to test the validity of the brand concept to the study audience.

6.1.2 The brand concept

The brand name 'Ten To Men' quickly captures the sense of the study being about males. It alludes to the full age range nicely as participation starts at the age of 10. The rhyme 'Ten To Men' is easy to remember and easy to say.

Interestingly when developing the brand name, including the word 'health' as part of the main name changed and limited branding opportunities. The word 'health' as a centre of the brand name could alienate the target audience and could put them off the study as a whole. In the context of this study health needs to focus more on males' lifestyle and wellbeing rather than solely on ill-health which is the common interpretation of health.

These findings led to the development of an emotional, engaging and unbiased logo that only uses the catchy phrase 'Ten To Men', but that is locked up with the official study name 'The Australian Longitudinal Study on Male Health'.

Brand imagery uses key messages explored through engaging typography and illustrations that suggest motion in time. The idea of time is introduced by using shapes of mechanical cogs and wheels that are interlocking with one another. These can be explored in different ways across different communication and marketing means. The concept of movement is expanded through the use of symbols for different modes of transport, which each will be linked to different subsets of males based on life stages.

6.1.3 The brand essence

The study brand is an aspirational brand that will engage through the experience of doing something good for the future generations of Australian men. The brand communicates this 'community feel' in a way that individuals, and especially young people, have a chance to arrive at these ideas for themselves, without hard selling this message.

In order to talk to a broad audience of men about male related issues it is impossible to avoid stereotyping completely. The goal was to describe the Australian male in a creative and stylish way without being confrontational. The challenge was to find a way to do this without excluding certain groups of males.

An important concept and underpinning essence of the brand is therefore the idea of time in combination with health. Making time an inherent part of the brand, in a way that it will emotionally engage with people as they move through the study over a period of time will help creating a strong bond of identification and therefore improve retention rates. As the study

continues over time and with future study data becoming available this idea of time will be explored by using life stages as identifiers for participants and the interested community/stakeholder. People can transition from one life stage into another as the study continues and they can learn about themselves and others throughout these stages.

6.1.4 The branding material

A series of graphics and documents were developed as a suite of brand elements.

Table 6.1: List of brand elements

Elements	Description
- Brand name and tagline	- Defines spelling, font, formatting and use in different scenarios and for different purposes
- Brand logo	- Delivered with study tagline (to be used for sponsoring, merchandising, branding) and without study tagline (to be used in letters, presentations and other documentation where the study name is present). - Delivered in high, medium and small resolution - Designed in colour, grey, black and white
- Additional graphics	- Drawings to complement the logo format
- Brand colours	- Defined rgb and cmyk codes for the three basic brand colours
- Presentation template	- Defined header, section and content slides
- Report template	- Defined cover and body pages with header and footer settings
- Letterhead	- Defined header and footer settings for first and following pages

A style guide was also developed and delivered by STREAMER to explain the rules for using the brand elements correctly. It is important when establishing a new brand that the brand elements are used consistently and with continuity. This will increase the recognition value of the brand over time and help creating a strong brand. A copy of the Ten To Men style guide is attached in the Appendix 12.

6.2 Development of a study website

6.2.1 The process

The development of the Ten To Men study website was designed in two stages. In the first stage the creative agency STREAMER DESIGN + COMMUNICATION was contacted to design the graphical illustrations of the website wire frames and layers to be used in the later stage of web development (1 May 2012). The design was informed by the aims of the website and its future use:

- To engage the audience of 10-55 year old respondents, researchers, the general public, media, funders, academics, stakeholders;
- To consider appropriate language at the top level navigation of the site (to engage and help people find their way);
- To present the key messages in a clear but creative and visual way;

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

- To design the site in three main phases, allowing for it to be expanded and developed over a long period of time;
- To ensure that areas of the site can be updated and managed by the University of Melbourne;
- To ensure that three main groups can access the site (participants, researchers, and researchers);
- To develop a navigation that is flexible enough to grow into a full scale operational robust site, with social media links;
- To consider the University of Melbourne branding and banners, as part of the Study branding (note that we will advise on this in detail once we have a confirmed brand);
- To ensure that the design and tone of the site is inclusive and engaging and professional;
- To ensure that the public, respondents and researchers can easily find what they need; simple navigation, minimal scrolling, no deep hierarchies.

The wireframe designs were delivered to the University on 29 May 2012.

The second stage concerned the website development. Since the development and programming of a website involves a different set of skills, quotes were sought from three web design companies, one of which was STREAMER. This time, a company called F2Foote Francis convinced with their proposal and was contracted on 14 August 2012.

After provision of the background material to F2 the agency developed the website frame using Joomla! Templates, CMS Integration and additional web components. Through a process of reviewing and refinement between F2 and the study team at the University of Melbourne a draft website was accepted by the study team as the structured frame of the Ten To Men website.

F2 provided two members of the team with 4 hours of training in Joomla! and content uploading. The web content was sourced and compiled by a member of the study team and uploaded by the administration officer.

Following a final test of its functionality, the website (www.tentomen.org.au) was launched on 28 September 2012.

6.2.2 The long-term view

It is planned that the website will develop a significant position for maintaining the study cohort, disseminate news and findings to the public and collaborate with other researcher. In this context it is considered to extend the current pages dedicated to participants and researcher. For example in the future it could be possible for participants to login to a secure part of the respondent website to manage their personal study account and update their details. In the context of disseminating data and communicating with the research community it would be beneficial to manage the process of application to access to Ten To Men data and add on studies through mechanisms of the study website. Similar activities are organised successfully on the websites of other longitudinal population health studies, e.g. ALSWH: <http://www.alsw.org.au> and HILDA: <http://www.melbourneinstitute.com/hilda>.

The timeline for this part of the website development project will be revisited once Wave 1 data collection is complete.

6.3 Other communication activities

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

A number of presentations were held to disseminate information on Ten To Men in the research community in order to create awareness and increase the profile of the study. These included:

1. Presentation at the School of Population Health Seminar
Melbourne School of Population and Global Health
Hunting and gathering: Finding and following 58,000 males to investigate their health
Jane Pirkis, Dallas English, Dianne Currier, Marisa Schlichthorst
Thursday, 22 August 2012
2. Annual workshop: Australian Longitudinal Study on Male Health (Ten To Men) –
Maximising the Utility of the Study
Population Health Congress 2012
Adelaide Convention Centre
Sunday, 9 September 2012
Associated Event 2:00pm - 5:00pm
3. Poster presentation
Population Health Congress 2012
Adelaide Convention Centre
Ten To Men - The Australian Longitudinal Study on Male Health: Wave1
Jane Pirkis, Dallas English, Dianne Currier, Marisa Schlichthorst and Rachel Koelmeyer
Wednesday, 12 September 2012
4. Ten To Men – The Australian Longitudinal Study on Male Health
Victorian Male Health Gathering
International Men's Day
Hemisphere Conference Centre, Moorabbin
Dianne Currier
Monday, 19 November 2012
5. Conference Presentation:
First National Sexual & Reproductive Health Conference
Hilton on the Park, Melbourne
Panel Session 1: "What we know - and don't know: a symposium about Australian data on sexual and reproductive health"
Ten To Men - and the Sexual and Reproductive Health of Australian Men
Marisa Schlichthorst
Wednesday, 21 November 2012, 1.00-2.30pm.
6. Keynote Presentation
45 and Up Study Collaborators' Meeting
SMC Conference and Function Centre, Sydney
Hunting and gathering: Finding and following 58,000 males to investigate their health
Dallas English
12 October 2012

7. Study Materials produced and used

For the Dress Rehearsal the study team designed comprehensive study packets including all important and by the ethics committees required information for participants. Tables 7.1 to 7.3 provide a detailed list of the survey packet contents and document sizes for each respondent group. Appendix 3 contains copies of all materials.

Table 7.1: Content of mail-out packs to adults

Mail-out documents	Document size
Adult Pre-Notification included: <ul style="list-style-type: none"> • Medicare letter (personalised) • Pre-notification letter (personalised) 	<ul style="list-style-type: none"> • 1 page • 1 page
Adult initial pack included: <ul style="list-style-type: none"> • Medicare letter (personalised) • Fly sheet with study branding and words 'Adult Pack', and die cuts to show ID/barcode of following item (Study Introduction Letter) • Introductory letter (personalised, with Adult questionnaire ID & barcode) • Study Information Brochure - Adults • Services Information Sheet • Return Envelope • Return Envelope • Questionnaire booklet (including consent form and personal information sheet) 	<ul style="list-style-type: none"> • 1 page • 1 page • 1 page • A4 tri-fold • 1 page • DL • C4 (folded to C5) • ~34 pages
Adult reminder letter included: <ul style="list-style-type: none"> • Medicare letter (personalised) • Reminder letter (personalised) 	<ul style="list-style-type: none"> • 1 page • 1 page
Adult reminder pack included: <ul style="list-style-type: none"> • same content as the initial invitation pack 	<ul style="list-style-type: none"> • See above

Table 7.2: Content of mail-out packs to adolescents

Mail-out documents	Document size
Adolescent Pack comprises following elements in clear plastic wrap: <ul style="list-style-type: none"> • Fly sheet with study branding and words 'Young Person's Pack', and die cuts to show ID/barcode of following item (Study Introduction Letter) • Study Introduction Letter (personalised, with Adolescent questionnaire ID & barcode) • Study Information Brochure - Adolescent • Services Information Sheet • Food Drink Card • Return Envelope • Return Envelope • Questionnaire booklet including personal information sheet and assent form (rear page showing through plastic wrap – i.e. can see Adolescent questionnaire ID/Barcode) 	<ul style="list-style-type: none"> • 1 page • 1 page • A 4 tri-fold • 1 page • 2 pages • DL • C4 (folded to C5) • ~32 paged
Parent Pack comprises following elements in clear plastic wrap: <ul style="list-style-type: none"> • Fly sheet with study branding and words 'Parent's Pack' (or similar) and die cuts to show ID/barcode of following item (Study Introduction Letter) 	<ul style="list-style-type: none"> • 1 page

Mail-out documents	Document size
<ul style="list-style-type: none"> • Study Introduction Letter (personalised, with Parent ID number & barcode) • Study Information Brochure – Parent • Consent Form, with Parent ID number/barcode also on back page (showing through plastic wrap) 	<ul style="list-style-type: none"> • 1 page • A 5 8 pages • 1 page

Note: The mail-out for the reminder pack followed the same rules for printing as the initial mail-out.

Table 7.3: Content of mail-out packs to boys/parents

Mail-out documents	Document size
<p>Boy Pack comprises following elements in clear plastic wrap</p> <ul style="list-style-type: none"> • Fly sheet with study branding and words 'Boy's Pack' (or similar) and die cuts to show ID/barcode of following item (Study Introduction Letter) • Study Introduction Letter (personalised, with Boy ID number & barcode) • Study Information Brochure – Boys • Assent Form with Boy ID Number/barcode also printed on rear • Services Information Sheet 	<p>Printing responsibility</p> <ul style="list-style-type: none"> • 1 page • 1 page • A4 tri-fold • 1 page • 1 page
<p>Parent Pack comprises following elements in clear plastic wrap</p> <ul style="list-style-type: none"> • Fly sheet with study branding and words 'Parent's Pack' (or similar) and die cuts to show ID/barcode of following item (Study Introduction Letter) • Study Introduction Letter (personalised, with parent ID number & barcode) • Study Information Brochure – Parent • Contact Form, with parent ID number/ barcode • Return envelope DL • Questionnaire booklet including consent form 	<ul style="list-style-type: none"> • 1 page • 1 page • A5 8 pages • 1 page • DL • ~18 pages

8. Data management

8.1 Data coding

A data dictionary was developed to describe the attributes of question items captured in the Ten To Men study questionnaires. Considerable thought was given to establishing a data dictionary that would:

- Be user-friendly to data users;
- Provide a thorough description of the variable attributes;
- Be compatible with commonly-used data management and analysis software;
- Provide flexibility for coding additional waves of data collection.

To establish a data dictionary that met these criteria the Ten To Men study team consulted with other large longitudinal studies as well as considered data coding and manipulation conventions for commonly used data management and analysis software.

A first important step was to establish a standardised method for naming the variables. Supported by a review of naming conventions used in other longitudinal studies the following conventions were applied to name the variables:

- a. The length of variable names was limited to 10 characters for data elements and 11 characters for derived variables;
- b. The characters in the variable name represented the following:
 - **1st character:** wave indicator starting with 'a' for the baseline wave of data collection;
 - **2nd and 3rd characters:** topic indicator, indicative of the domain and construct for the variable; for example, 'hd' for 'diagnoses' within the 'health status' domain;
 - **4th – 9th characters:** describe the variable attribute; for example, 'cobown' for the participant's 'own country of birth';
 - **10th character:** identifies the study group to whom the variable applies and/or the informant who provided the data. For example, 'b' stands for variables included only in the 'boys' questionnaire, 'f' for variables included only in '15 to 17' year olds, 'u' for variables included in all 'under 18 year olds', 'a' variables included only in 'adult' questionnaires, and 'p' for all variables answered by a 'parent';
 - **11th character:** indicator for derived variables.

The selected naming conventions make it easier to decipher related variables in the data dictionary by sorting the variable list by their name in alphabetic order. The 10th character in the naming convention also helped to easily identify the subgroup for which a variable was collected given that not all data elements were included in all of the study questionnaires.

Secondly, for Dress Rehearsal it was important to collect useful information about the origin of missing responses. This information was used in the evaluation of the performance of study questionnaires and specific variables. Guided by the codeframe used in the HILDA study different codes for a range of missing response data were defined for the Ten To Men Dress Rehearsal, i.e. -1 for 'not asked', -2 for 'not applicable', -3 for 'don't know', -4 for 'refused or not answered', -5 for 'invalid multiple response', -6 for 'value implausible', -7 for 'unable to determine value' and -8 for 'no questionnaire or interview completed'.

A data dictionary has been produced for Dress Rehearsal and a simplified version is attached in Appendix 13.

8.2 Data processing and cleaning rules

Data processing and cleaning was required for the scannable self-complete paper questionnaires in adults and adolescents. The standard procedure for processing scannable self-complete questionnaires used by Roy Morgan Research included the following steps:

1. **Grading:** Returned questionnaires were physically inspected to assess their level of completeness and whether the pen marks on the survey would be captured by the scanner. Where necessary, RMR staff would overwrite the marks on the questionnaire to ensure the data will be captured as intended by the respondent;
2. **Scanning:** The questionnaires were scanned to capture the data included on the form;
3. **Verification:** Fields flagged for verification during scanning were manually checked. All write-in fields were checked at this stage, along with fields that were identified to have invalid multiple responses. A set of rules was applied to handle these data issues;
4. **Data cleaning:** Matters which could not be resolved at verification stage were referred to the data cleaning team for further investigation. Pre-defined rules for data cleaning were applied to resolve any issues. At this stage the data cleaning team also applied

the defined missing value codes, ensured that the data was coded as specified in the data dictionary and did logic edits. Where available ABS standard code frames were applied, i.e. for country of birth, occupation and language spoken at home.

The aim in Dress Rehearsal however was to gain an understanding of the performance of the questionnaires and therefore less data cleaning and more documentation and coding of response issues than usual was required. For this reason specific data verification and cleaning rules had to be established for Dress Rehearsal.

For this purpose, the Ten To Men study team worked with Roy Morgan Research to establish data verification and cleaning rules that allowed the Ten To Men study team to identify when respondents had not answered the questionnaire in the manner intended to allow refinement of the questionnaire for Wave 1. This meant that rules which inferred a response were generally not applied. Instead, missing data codes for invalid multiple responses, implausible responses and unreadable responses were applied. Variables of particular interest were captured as multiple response items so the patterns of response could be identified. Logic edits to recode contradictions were not applied; rather, the contradictions were retained in the dataset so that the particular subset of respondents who were providing contradictory data could be identified.

8.3 Data capture and storage

With the exception of the boys, where data was directly captured as electronic files in the CAPI, questionnaire data was originally captured on paper-based forms and then converted to an electronic data file via scanning by Roy Morgan Research. At the end of the field work period, the electronic files were transferred by Roy Morgan Research to The University of Melbourne following the specified rules below:

1. .csv files, Microsoft Excel files, SPSS data files and Stata data files of the response data from each stream of participants;
2. Image files of consent and assent forms, information sheets and selected pages of the self-complete scannable questions (pages with free text comments); and
3. Microsoft Excel files of the identifiable information for each participant (captured from consent and assent forms and information sheets. These files also include a column with the unique identifier which can be used to link response data with the respondent's personal information. This link is important for follow up or if a respondent wishes to withdraw from the study.

The following policies and legal obligations are the grounds for developing principles for data storage and access for the Ten To Men study:

- The National Statement on Ethical Conduct in Human Research;
- The Australian Code for the Responsible Conduct of Research;
- Australian Privacy Legislation;
- University of Melbourne Regulations pertaining to the Management of Research Data and Records;
- Contractual obligations under the contract between The University of Melbourne and Commonwealth Department of Health and Ageing, governing the conduct of the Ten To Men study; and
- Conditions mandated in the ethics approval governing the conduct of the Ten To Men study.

To comply with the above policies and legal obligations the following rules have been established for Ten To Men:

- The data collected from the 2012 Dress Rehearsal will be stored securely with restricted access to the data for authorised personnel only;

TEN TO MEN: THE AUSTRALIAN LONGITUDINAL STUDY ON MALE HEALTH

- Any personnel with access to the data must have signed a Deed Poll of Non-Disclosure in relation to Commonwealth Confidential Information and Personal Information Policy;
- Response data will be separated as soon as possible after data collection from personal/identifying information and stored separately from;
- In general staff will only have access to either response data or personal/identifying information. The minimum number of staff required to maintain the dataset will have access to both;
- Original data records will be retained in its central storage for the duration of time that The University of Melbourne is the custodian of this data;
- The data will be stored in a manner that is durable and maintains the integrity of the data;
- Procedures will be implemented to protect against loss of data;
- Data will only be retained for participants with valid consent;
- Any destruction of the data will be authorised by the appropriate member of the study team and conducted in line with documented study procedures and in a manner that maintains the confidentiality of the data;
- A record of the data, personnel who have access to the data and its location will be maintained;
- Procedures for managing the data will be documented;

The data storage policies for Ten To Men are based on the principle of data separation, whereby response data is always separated from personal data. Three categories of data files were classified:

1. Personal/identifiable Information: Data from which the identity of a specific participant can reasonably be ascertained. This includes the study consent and assent forms and information sheets and any identifiable information derived from these original records;
2. Re-identifiable response data: Questionnaire data from which identifiers have been removed and replaced with a code, which may allow re-identification of the participant but which will maintain the confidentiality of the participants' identity;
3. Potentially identifiable response data: Questionnaire response data from which identifiers have been removed and replaced with a code that allows the re-identification of the participant, but where the nature of the data collection or data provided may still allow identification of the participant.

Data from the 2012 Dress Rehearsal is stored separately to the Ten To Men project-related data on a password protected partition of a secure server of the University of Melbourne. Within this partition, data will be stored in three separate folders following the above categorisation of data. The access to each folder will be carefully monitored and is restricted to specific personnel. All paper-based data is stored in a locked cupboard in a fireproof area and building. Personal/identifiable information and questionnaire response data are stored in separate cupboards with separate keys.

8.4 Data Book

A data book has not been produced for data collected in Dress Rehearsal since this data is not part of the research data that is to be released to the public. It is only used for testing purposes. However, intensive analysis of question performance and missing value analysis is on the way to inform the further revision of the study questionnaires for Wave 1.

A data book including tables on frequencies and missing data by question will be produced for all data collected in Wave 1.

9. Achievement of timeframes and objectives

As described in the Timelines section above (4.3) in May 2012 re-negotiation of overall study timeframes was commenced and is currently ongoing.

The following objectives have been achieved:

- Ethical Approval for Cognitive Testing
- Ethical Approval for the Dress Rehearsal
- Ethical Approval for Wave 1
- Development of questionnaires
- Cognitive Testing of questionnaires
- Review and finalisation of questionnaires
- Development of study collateral documents
- Development of study brand
- Development and going live of study website
- Development of the study data dictionary
- Appointment of subcontractor for Dress Rehearsal
- EREC approval for Medicare mail-out
- Testing of feasibility of AEC and Schools based recruiting
- Conduct of Dress Rehearsal
- Development of Wave 1 mail-out sampling plan
- Conduct of Annual Workshop
- Production of a Major Report
- Production of the 2012 Annual Report

10. Works Cited

1. Morton, L, Cahill, J, Hartge, P. Reporting Participation in Epidemiologic Studies: A Survey of Practice. *American Journal of Epidemiology*. 2006.163:197–203
2. Galea, S and Tracy M. Participation Rates in Epidemiologic Studies. *Annals of Epidemiology*. 2007. 17 (8): 643-653