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1. Introduction from the Chief Investigators

The past year has been a busy and productive one for the Ten To Men team. Much has been accomplished in developing the study infrastructure in preparation for the commencement of Wave 1 data collection in the coming months. As would be expected in the establishment phase of a new large-scale research enterprise, there have also been challenges, both anticipated and not, that have been encountered and resolved over the past twelve months.

The instrument development phase has been concluded, with the development of four instruments that have been extensively tested and refined over the course of field-testing and internal and external expert review. These instruments have been designed to collect a wide range of data on individual and social/environmental factors relevant to male health, and provide the foundation for the ongoing assessment of outcomes and relationships between risk and protective factors over the lifetime of the study.

Pilot testing of the instruments, recruitment, field logistics and data processing procedures has been extensive. The first phase of in-field pilot testing was a full scale Dress Rehearsal using the mail-out recruitment method. The Dress Rehearsal provided a great deal of valuable operational information and data for questionnaire evaluation however, it also revealed that there were unanticipated issues related to achieving a feasible response rate. A period of review and consultation of the Dress Rehearsal findings resulted in a decision to conduct a small-scale pilot test of an alternative recruitment strategy – household recruitment, more often referred to as the “drop and collect” method. Response rates were much improved using the drop and collect method however the higher cost of this method of recruitment has implications for the size of the cohort achievable. Evaluation of the comparative advantages and disadvantages of the mail-out and drop and collect methods is currently underway, and will inform the design decision for Wave 1.

A great deal has been achieved in terms of establishing the study infrastructure to support the aims of the study over the long-term. A detailed assessment of the data management and storage needs of the study has been completed and the decision making and implementation phase will be shortly underway. Data linkage protocols have been developed and are currently under review by the Department of Health and Ageing. The sampling plan has been finalised for Wave 1 data collection and participant safety and contact management protocols have been developed.

Ten To Men has been increasing its visibility among the male health community through presentations at conferences and the launch of the study website. Presentations have been received with great interest and the study has found great support among stakeholders in the wider community. Building on this, work is in progress to convene the Consumer Reference Group which will provide valuable input from those on the ground as well provide an avenue for information about the study to be circulated widely.
As we prepare to embark on the data collection for Wave 1 much has been accomplished. Responding to the challenges that have arisen over the course of the past year has ensured that the instruments, data collection protocols, and so on that we take to Wave 1 are the best possible options and provide a solid foundation for a long-lasting and high-quality study that will make significant contributions to the knowledge base on male health.
2. Study Personnel & Committees

Study Team
A new research fellow, Ms Rachel Koelmeyer, joined Drs Dianne Currier and Marisa Schlichthorst and Mr Robert Lukins on the Ten To Men study team. Rachel holds a Bachelor of Science (Honours) degree, with a major in Biochemistry and Molecular Biology, and a Masters in Public Health, with a specialisation in Epidemiology and Biostatistics. Rachel has over 10 years of experience working in health research, including as a research assistant in laboratory-based medical research projects, as a Clinical Trials Manager of investigator-initiated clinical trials and as a Research Officer, managing national social research projects.

Steering Committee
The Study Steering Committee met several times to contribute their knowledge and experience in crucial areas of study design and operational issues. This included playing 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 Steering Committee also had a major role in reviewing the Dress Rehearsal results, considering the implications for Wave 1 and offering advice on options going forward.


Sampling Working Group
A sampling working group was established to develop the detailed sampling plan for the study. The members of the working group are: Professor Ian Gordon (Director of the Statistical Consulting Centre at the University of Melbourne), Professor John Carlin (Director of Clinical Epidemiology & Biostatistics Unit at the Murdoch Childrens Research Institute), Matthew Spittal (Ten To Men Study Steering Committee), Suzanne Manova (Geospatial mapping expert, based at the McCaughey VicHealth Centre) and Dallas English, Jane Pirkis, Dianne Currier and Marisa Schlichthorst from the Ten To Men study team.

The group met regularly over the past year and concluded the development of detailed sampling plans in March 2013. Professor Ian Gordon developed the detailed sampling plan, more detail on which are provided below.

Technical Advisory Group
This group’s expertise was drawn upon in the development and refinement of the questionnaires, and in evaluating the Dress Rehearsal results and discussion of options for Wave 1 in the light of those results. Members of this group were also involved in evaluating tenders for provision of services for data collection for the Dress Rehearsal.

External Scientific Advisory Group
The External Scientific Advisory Group has met twice in the past 12 months, and members have provided additional advice to the study team on specific issues via email. Sally Goodspeed stepped down as Chair and Professor Emily Banks agreed to take the role. Mr Steve Biddulph has resigned from the group due to other commitments. A replacement is currently being sought.

Membership of the External Scientific Advisory Group comprises: Sally Goodspeed, Ben Edwards, Melissa Wake, Emily Banks, Rob Moodie, John McDonald, Annette Dobson, Osvaldo Almeida, and John Glover.

Data Linkage Steering Committee
The Data Linkage Steering Committee has met twice in the past twelve months. Professor Emily Banks joined the group. Ross Saunders has resigned from the group on his retirement. Additional representation from the Australian Institute of Health and Welfare has been included on an informal basis. 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 state/territory held datasets for linkage with study data. The committee also reviewed the draft documentation prepared for submission to the Department of Health and Ageing Ethics Committee in March 2013.


Community and Consumer Reference Group
Work is underway recruiting for this group. A target list of relevant organisations and individuals has been compiled and recruitment will commence in the coming months. There will be an application process to ensure the right mix of representation is achieved on the group. The first meeting of the group is being planned for October 2013, to be held in conjunction with the Ten To Men Annual Workshop and the Australasian Men’s Health Gathering in Brisbane.

3. Key Activities and Outcomes

Dress Rehearsal
During the pre-field phase the options of recruiting via Schools and the AEC options were both ruled out due to unfeasibility relating to inability to gain approvals and timeliness. The Department of Human Services Ethical Review Committee gave approval for the study to conduct a mail-out using contact information from the Medicare Enrolments database. Following a competitive tender process, Roy Morgan Research was commissioned to conduct the Dress Rehearsal. Pre-fieldwork including refining the study questionnaires, formatting collateral documents, training interviewers and liaison with DHS project and printing teams occurred from July to September 2012. Field work took place in October and November 2012.

A great deal of information and insight was gained from the Dress Rehearsal with respect to the effects of using reminders and pre-notifications and on improving study documentation,
and logistical issues involved in conducting a mail-out using Medicare contact data. However, the Dress Rehearsal results revealed an unexpectedly low overall response fraction of less than 10%. Analysis of the dress rehearsal data indicated that the questionnaires performed well with mean proportion of missing data ranging between 0.6-5.7% across the four study instruments. There were no indications that participants were distressed by the more sensitive content of the questionnaires, and these had no higher levels of missing data than any other questions in all four instruments.

**Drop and Collect Pilot**
The unexpectedly low response rates revealed in the Dress Rehearsal were a cause for concern and prompted a reconsideration of recruitment methods. Following consultation with the relevant study committees and the Department of Health and Ageing a decision was made to pilot test household recruitment using a "drop and collect" method of recruitment. Roy Morgan Research was commissioned to undertake a brief pilot. The Drop and Collect Pilot used the same questionnaires and making only minor modifications to other study documents. Four postcodes were selected (three in Victoria and one in South Australia, two regional and two metropolitan) and following a pre-determined household selection pattern interviewers approached selected houses. Eligible males residing in that household were invited to participate and if they agreed males aged 15-55 were left a copy of the questionnaire or an interview time was made for boys aged 10-14. Interviewers made up to three attempts to contact selected households and up to two attempts to call back and collect completed questionnaires. The pilot occurred in January/February 2013. Results were encouraging with a 64/87 (74%) of confirmed in-scope households accepting a questionnaire/invitation for interview. Among the confirmed in-scope households who accepted a questionnaire/invitation for interview 6/12 (50%) of boys, 1/3 (12.5%) of adolescents and 33/71 (46.5%) of adult males providing useable information.

**Data management and analysis**
A comprehensive data dictionary was produced for the four questionnaires and data management and security protocols developed and implemented. The pilot studies provided the opportunity to test these, and all performed well with only minor adjustments indicated for the main data collection.

Given the small sample size in the Dress Rehearsal no analyses of prevalence or association were undertaken, although we provided a description of the sample. However, a detailed analysis plan was written to assess the quality of the dataset and the performance of the questionnaire including missing data, implausible values, functioning of skip questions and so on. The questionnaires performed well in most analyses, and results of the analysis were included as part of the questionnaire revision process. Detailed results of the Dress Rehearsal questionnaire analysis will be presented in the June 2013 Major Report.

**Ethics**
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).
Submission was made in April 2012 and final approval obtained in July 2012. The long approval process was a result of the two-stage ethics approval process at the University of Melbourne, as well as the size and complexity of the project.

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. A further amendment will be made when protocol decisions are finalised for Wave 1.

**Sampling**
With the ruling out of the Electoral Roll and Schools as recruitment options, sampling work focussed on the Medicare mail-out method of recruitment. For that method, postcodes were selected as the sampling unit, and some initial work was undertaken to evaluate the potential effects of clustering. Following the January 2013 release of the new ASGS remoteness classifications, which are the basis for oversampling regional males, work progressed quickly and a sampling plan based on postcodes was produced in February 2013. With the introduction of the possibility that a Drop and Collect recruitment method will be adopted, a sampling plan was developed for that method based on SA1s and SA2s.

**Data Linkage**
A data linkage protocol has been developed for the study. The protocol sets out key features, including 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.

In March 2013 submission was made to the DEC for Phase 1 of the data linkage. Phase 1 covers the major datasets for which DoHA is the data custodian – MBS, PBS, and other Commonwealth held data.

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

**Annual Workshop**
In September 2012 the inaugural Ten To Men Annual Workshop was held in Adelaide as a pre-conference event at the 2012 World Population Health Congress. Attendance was modest, however multiple universities (including one international university), and male health research organisations were represented including: Flinders University, University of Otago Canada, University of Western Australia, University of Queensland, MindOUT – National LGBTI Health Alliance, Andrology Australia, Men’s Health South Australia.

The first hour of the session was a presentation by members of the study team (presentation slides attached). Co-chief investigators Jane Pirkis and Dallas English, Study Coordinator Dianne Currier, and Research Fellow Marisa Schlichthorst contributed to the presentation. Following the presentation there was an hour of discussion.

Attendees were enthusiastic at the prospect of the wealth of data and new knowledge the study will generate, supportive of the University of Melbourne’s efforts in implementing the
study, and unanimously agreed that this is an extremely important undertaking that will have long term benefits for Australian males and the country as a whole. For the Study Team the workshop provided useful feedback on the study design and implementation to date, a valuable opportunity to make contact with other researchers in the area, and a number of interesting suggestions to be considered in the planning for Wave 2.

In 2013 the Workshop will be held in October as a satellite event to the Australasian Men’s Health Gathering in Brisbane.

Other conferences & Presentations & information dissemination activities:

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. 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

3. 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

4. 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.

5. 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
   Friday, 12 October 2012
6. Presentation
   Minister’s Male Health Reference Group
   Park Royal Hotel, Melbourne
   Jane Pirkis
   Friday, 19 April 2013

Study Website
The phase 1 of the study website went live in 2012. It is located at www.tentomen.org.au. Work is currently underway for phase 2 which is building a dedicated participant area, where participants will be able to update personal information and access participant specific information. Phase 3 development will occur later in 2013 and involves the researcher area including requests for access to study data and so on.

Timelines
The unexpected results of the Dress Rehearsal and the decision to conduct further pilot testing in order to determine the optimal recruitment method introduced delay into the timelines for commencement of Wave 1. It is now anticipated that Wave 1 will commence in May 2013, with data collection occurring between July and November 2013.