MINUTES 206th Session

Council of the National Health and Medical Research Council Tuesday, 1 December 2015 NHMRC Offices, Canberra

Attendance:

Prof Bruce Robinson AM Chair

Prof Kathryn North AM Chair, Research Committee

Prof Ian Olver AM

Chair, Australian Health Ethics Committee

Prof Graeme Samuel AC

Chair, Health Innovation Advisory Committee

Chair, Health Translation Advisory Committee

(via video 3-3.30pm)

Prof Michael Kidd AM Member with expertise in health care training

Prof Brendan Crabb AC Member with expertise in health research & medical

research issues

Prof Sandra Eades Member with expertise in the health needs of Aboriginal

persons and Torres Strait Islanders

Ms Karen Carey Member with expertise in consumer issues
Prof David Story Member with expertise in professional

and post-graduate medical training

Prof Jonathan Carapetis Member with expertise in Public Health

(via video 9.45am - 12.30pm)

Prof Ingrid Scheffer AO Member
Prof Elizabeth Sullivan Member

Prof Chris Baggoley AO Commonwealth Chief Medical Officer (CMO)

Dr Jeannette Young PSM Chief Health Officer (CHO), QLD

Dr Jan Fizzel Representing CHO, NSW

Prof Paddy Phillips PSM CMO, SA (via video 11.30am – 3.30pm)

Prof Dinesh Arya CHO, NT
Prof Gary Geelhoed CHO, WA
Prof Michael Ackland A/g CHO, VIC

A/Prof Tony Lawler Principal Medical Advisor, TAS

Apologies

Dr Paul Kelly CHO, ACT
Dr Kerry Chant PSM CHO, NSW

Observers

Adj Prof Debra Thoms Commonwealth Chief Nurse and Midwifery Officer

Prof Villis Marshall AC Australian Commission on Safety and Quality in Health Care

NHMRC Staff

Prof Anne Kelso AO CEO

Mr Tony Kingdon General Manager

Ms Samantha Robertson Executive Director, Evidence, Advice and Governance

Mr Alan Singh Executive Director, Research Translation
Dr Tony Willis Executive Director, Research Programs

Mr Tony Krizan Executive Director, Corporate Operations and Information

1. WELCOME

The Chair opened the 206th Session of Council at 9am and welcomed attendees to the second meeting of the 2015 - 2018 NHMRC triennium. The Chair acknowledged the Ngunnawal People as traditional owners of the land upon which the meeting was held.

The Chair noted apologies from Dr Paul Kelly, Dr Kerry Chant and Mr Mark Cormack (observer), and noted that Prof Phillip, Prof Lewin and Prof Carapetis will be joining the meeting throughout the day via video conference. The Chair welcomed the observers and confirmed that the meeting was quorate.

The Chair reminded attendees that everything discussed at the meeting was to be held as confidential, and invited members to declare any interest that may be a potential or actual conflict of interest at the start of the session and before discussion of relevant items. Prof Eades noted that she has a conflict of interest with the diabetes guideline at Agenda item 12.

There were no questions on notice for the Office of NHMRC, and Members did not ask for any "for noting" items be raised for discussion.

Council **ADVISED** the Chair that the draft Session Report of the 205th Session of Council was accepted as a true and accurate record of proceedings. There were no questions on notice.

2. CEO REPORT

Prof Kelso provided Council members with the NHMRC CEO Report for October and November 2015. Discussion with Council members included the meeting of the Informal Research and Translation Network, the 9 November 2015 grant announcement and the re-appointment of the Community and Consumer Advisory Group.

Council **DISCUSSED** the CEO Report with Prof Kelso.

3. CHAIR'S REPORT: RESEARCH COMMITTEE

Prof North highlighted a number of issues that were discussed at Research Committee on 20 November 2015 including:

- Strategic Review of the NHMRC Grants Programme getting the balance of funding and disciplines right, in light of falling success rates, noting the time spent by researchers on unsuccessful grant applications. Involving international experts on the review would be helpful, if this were possible.
- Medical Research Future Fund (MRFF) Prof Kelso still the only known member of the Advisory Board. Her involvement will be important in creating synergy between the disbursement strategies of the two research funds.
- The significant amount of MREA funding spent on clinical trials was noted.

In relation to clinical trials, it was noted there are limitations on what can be done through partnerships with pharmaceutical industry and it is important to view the system holistically to avoid further fragmentation of the research sector.

Council NOTED the RC Chair's Report.

4. PRESENTATION ON PEER REVIEW PROCESSES

Dr Willis provided Members with a presentation on NHMRC Peer Review Processes.

Council **NOTED** the presentation.

5. MREA FUNDING RECOMMENDATIONS

Council members discussed the low number of recommended grants in the area of Health Services research. Prof North commented that there had been several Centres of Research Excellence grants funded in the area of Health Services research this year, which offsets the relatively low proportion in the proposed funding recommendations.

Council members discussed the funding recommendations for the Targeted Call for Research into Wind Farms and Human Health, and the potential outcomes of funding this research.

There was discussion on the low proportion of female chief investigators in the Program Grants funding recommendations. Prof North noted that the Women in Science Program is proactive in addressing gender inequity but further progress needs to be made.

It was noted that there is no consumer representative on Research Committee this triennium. However, the comments provided by Community Observers on the peer review process are incorporated as part of the annual review of each scheme and associated improvements to the process for the following round.

Council:

- **SUPPORTED** the funding recommendation listed at Attachments A to D, to a total value of \$120,569,830;
- **NOTED** that relinquished offers will be reallocated to the next ranked highest applicant(s), provided that these replacement offers do not change the overall expenditure;
- ADVISED the NHMRC's CEO to submit the funding recommendations at Attachments A to D to the Minister;
- **NOTED** the summary of community observers' reports at Attachment E;
- NOTED that a detailed breakdown of funded grant data will be tabled at a subsequent meeting; and
- **NOTED** the implications for the MREA, as detailed at Attachments F and G.

Action Item: ONHMRC to provide a list of measures in place to address gender inequity

6. DISCLOSURE OF RESEARCH OUTCOMES DATA FOR ANALYTICS AND REPORTING - PRIVACY CONSIDERATIONS

Mr Tony Krizan introduced the paper and highlighted:

- NHMRC's planned approach to data analytics, and its anticipated participation in a project with IP Australia on Patents Analytics.
- To participate in this project, NHMRC would need to disclose patent information recorded in RGMS and legacy systems to IP Australia.
- NHMRC is sensitive to the privacy issues and will adopt a risk-averse, conservative approach, with road testing of strategies.

Noting the advice from Research Committee that there were no significant concerns about the proposal, Council members agreed that the approach to data analytics was appropriate.

Council **NOTED** NHMRC's proposal to seek the consent of researchers to the disclosure of research outcomes data, including 'road testing' activities.

7. INTERNATIONAL ENGAGEMENT STRATEGY

Dr Tony Willis introduced the item by acknowledging the extensive and diverse range of current international activities supported by NHMRC, including international researcher participation in our main funding schemes. He emphasised that the NHMRC International Engagement Strategy 2015-2019 (the Strategy) aimed to inform NHMRC's future consideration of international opportunities. The CEO noted that this would be the first publicly available International Engagement Strategy for NHMRC.

Council was highly supportive of the Strategy. Members noted that several areas of the document could be improved, including:

- highlighting increased engagement in international committees;
- more positive descriptions of the three tiers;
- expanding on opportunities and responsibilities within our region;
- integration with broader Government international policy (including opportunities to influence these policies); and
- highlighting opportunities for NHRMC to implement a more proactive approach to international relationships rather than being 'responsive'.

Dr Willis noted that negotiations on new agreements are currently being undertaken with India and Vietnam.

The CEO advised that the discussions had been highly constructive, and indicated that the Office of NHMRC would provide an updated Strategy to the next Council meeting.

Council:

- NOTED the draft NHMRC International Engagement Strategy; and
- **ADVISED** the CEO on the draft Strategy, including areas for improvement.

Action Item: ONHMRC to update the NHMRC International Engagement Strategy and bring it back to Council at the next meeting.

8. SUBMISSION TO PRODUCTIVITY COMMISSION INQUIRY INTO AUSTRALIA'S INTELLECTUAL PROPERTY ARRANGEMENTS

Members expressed concern that the focus of the submission was on raising issues for further consideration, rather than prosecuting a strong NHMRC position. Consequently Council advised the CEO not to make a submission to the Inquiry at this time, but noted that this did not preclude NHMRC making a submission in response to the Productivity Commission's Discussion Paper (which is expected in March/April 2016).

Council **NOTED** the draft submission to the Productivity Commission Inquiry.

9. REVIEW OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH, 2007 (THE CODE)

Ms Robertson provided Council with background to the review of the Australian Code for Responsible Conduct of Research, 2007 (the Code). NHMRC is leading the review in collaboration with its co-authors, the

Australian Research Council and Universities Australia. Members noted that a targeted consultation had recently occurred, which resulted in forty-eight comprehensive submissions being received.

As a result of this targeted consultation and NHMRC's discussions with the sector about the application of the Code, it has been decided to make the Code less procedural and more principles-based. To complement this shift, a committee would be established to develop a best practice guide which would provide detail on administering the Code. Council members agreed that a simpler, more principles-based Code was preferable.

Ms Carey, the consumer representative on Council, queried whether there was a role for a consumer on the Code Reference Committee (CoRC). Ms Robertson noted the importance of involving consumers in the review and possibly on the membership of the CoRC. It was also noted that the CoRC membership did not include a member from the State Health Departments, noting the role that clinical researchers undertake in a state hospital setting. Ms Robertson acknowledged that it was important to have representation from this sector and this would be considered as the review progressed.

Council **NOTED** the information provided on the review of the Code.

10. IDENTIFYING STRATEGIC ISSUES AND OPPORTUNITIES FOR NHMRC

Prof Kelso introduced the agenda item and gave a presentation which included the concept of an 'ideal medical research future'. Members expressed their overall support for the approach described in the presentation and made the following additional comments.

There is potential for significant health gains in the Australian community through:

- An increased NHMRC focus on drug and alcohol abuse, gambling and related harms;
- Patient-focused innovation. The introduction of new technology into healthcare must be based on evidence of long-term safety and efficiency;
- Leveraging Australia's strategic advantage in the development of telemedicine. This technology has important potential for addressing health inequities currently existing in Australia; and
- Large scale clinical trials involving many tens of thousands of people.

NHMRC should investigate:

- The sustainability of research institutions, teams and programs over the medium and long-term;
- The level of NHMRC support for health services research;
- Joint NHMRC/ARC grants for Indigenous health research to address the broader socioeconomic issues that link to the health concerns of Indigenous people;
- Setting ratios of medical innovation versus discovery research, and targeted versus investigator initiated research; and
- An overarching plan for 'big data', to include linkage of health records and the use of data analytics.
 'Big data' will be an important factor in enabling clinical trials focussed on better-defined subsets of patients (eg: subgroups based on tumour mutations).

NHMRC should promote:

- Increased co-funding between industry and NHMRC;
- Brokering of partnerships between NHMRC funded researchers and industry to promote translation and commercialisation; and
- Partnerships between researchers and technology companies to drive innovation in health apps and IT platforms - technologies that allow individuals and consumers to control their own health and treatment are of particular value.

Council suggested that a work plan be developed with goals for review at the next Council meeting, and which Council will use to measure its performance over the triennium. Members requested that Prof Kelso's presentation be circulated.

Action Item: ONHMRC to distribute a copy of the CEO's presentation to Council members.

11. DISCUSSION ON THE PROPOSED ACTIVITIES OF THE AUSTRALIAN ACADEMY OF HEALTH AND MEDICAL SCIENCES AND ITS RELATIONSHIP TO NHMRC

The Chair welcomed the President of the Australian Academy of Health and Medical Sciences (AAHMS), Prof Ian Frazer to the Council meeting and noted that he was here to discuss the relationship between the AAHMS and NHMRC.

Prof Frazer thanked the Chair for the opportunity and explained that AAHMS exists as an independent collection of individuals with a wide range of interests across the spectrum of health and medical research, promoting the translation of research into clinical practice.

One of the goals of the Academy is to promote the maintenance of a research literate health workforce. The Academy also aims to provide a form of mentorship to those coming through the system, to encourage those considering an academic medical career and to engage with the Commonwealth and States and Territories on the issues of health policy and delivery of services. Prof Frazer indicated the Academy's willingness to partner with NHMRC and engage on these challenging issues.

Prof Frazer indicated that the Academy is planning a workshop on health and medical priorities in April next year and that NHMRC's participation would be welcomed.

Council **DISCUSSED** the proposed activities of the Australian Academy of Health and Medical Sciences and its relationship to NHMRC.

Action: ONHMRC to put in place a formal mechanism of ongoing contact between NHMRC and AAHMS, in the form of regular meetings.

12. NATIONAL EVIDENCE-BASED GUIDELINE ON SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN TYPE 2 DIABETES

Prof Baggoley and Prof Eades declared an interest for this agenda item. This did not preclude them from participating in the discussion, but they did not participate in the vote.

Prof Jeremy Oates (guideline committee chair, in person) and A/Prof Jonathan Shaw (clinical lead, by video) were in attendance to answer members' questions.

Mr Singh introduced the guideline, noting that a different iteration of the guideline had been submitted for consideration in 2011, at which time NHMRC approval was declined. The current guideline has been updated with a new guideline committee, a new conflict of interest management process, an updated systematic literature review and an independent guideline committee chair.

Mr Singh advised members that the guideline is designed to prevent recurrence of cardiovascular events in adults with type 2 diabetes. It has undergone a 31 day public consultation period (during which 15 submissions were made), an NHMRC commissioned methodological review and local and international expert reviews, and in the view of the Office of NHMRC it meets the 2011 NHMRC standard for clinical practice guidelines.

Mr Singh noted that there is a discrepancy between the target blood pressure of 130/80 in this guideline and the target of 140/90 in the National Heart Foundation's draft hypertension guideline, and A/Prof Shaw was invited to comment. In reply A/Prof Shaw noted that the target of 130/80 is consistent with guidelines spanning the preceding 10 years, and observed that the recently published ACCORD trial, and matched data from the SPRINT trial, offer additional support for this target.

Members voiced concern about the potential risks of pursuing an aggressive target of 130/80, particularly in the elderly, and that warnings in the guideline's supporting material required greater prominence. A/Prof Shaw noted that the guideline committee were concerned that if the risks and harms were overemphasised the benefits of aggressive treatment would be missed; however he did agree to ensure that the current warnings be more prominent in the final guideline.

Council requested the developer to amend the warnings on pages 5 and 6 accompanying the treatment algorithm on page 6 of Attachment B (short form guideline) and Attachment E (guideline recommendations and supporting material).

Council **ADVISED** the CEO to approve the draft guideline (recommendations on pages 2 to 5 of Attachment B).

13. CLINICAL PRACTICE GUIDELINES FOR DEMENTIA IN AUSTRALIA

Prof Samuel declared an interest as a co-funder with NHMRC of the Cognitive Decline Partnership Centre, developer of this guideline. This did not preclude Prof Samuel from participating in the discussion or decision making.

Prof Susan Kurrle (Director of the developing agency) was in attendance to answer members' questions.

Mr Singh introduced the guideline, noting that it comes from the NHMRC partnership centre for dealing with cognitive and related functional decline in older people. It has undergone a 45 day public consultation for which 70 submissions were received, an NHMRC commissioned methodological review and local and international expert reviews, and in the view of the Office of NHMRC it meets the 2011 NHMRC standard for clinical practice guidelines.

Prof Paddy Phillips spoke to the guideline via teleconference. He noted that he had raised four concerns about the title and content of the guideline with the developers, who had agreed to amendments including retitling the guideline as **Clinical practice guidelines** <u>and principles of care</u> for people with dementia. Prof Phillips confirmed that the changes addressed his concerns and that he now supported the guideline.

Members raised a number of issues. Prof Baggoley noted the Commonwealth's concern that some of the guidelines' content could be viewed as aspirational, and as such may raise unrealistic expectations about services not available in Australia. In addition he provided updated advice on dementia services discussed in the supporting material and highlighted the need for ensuring that the relevant Commonwealth, State and Territory regulatory frameworks were referenced.

Dr Young noted that she has provided comments to Prof Kurrle in writing and Prof Ackland advised he would send comments to Prof Kurrle after the meeting.

Concerns were raised about the omission of a recommendation about the use of Souvenaid, a dietary supplement currently marketed in Australia as 'nutritional support for memory function in the early stages of Alzheimer's disease.' Members took the view that a recommendation on the use of Souvenaid in dementia should be made, and Prof Kurrle agreed to convene the committee to do this.

Council requested the developer to:

include updated program information supplied by the Commonwealth in the supporting material;

- consider comments from Queensland and Victoria for inclusion in the supporting material; and
- update the recommendations to reflect Council's advice on Souvenaid.

Council **ADVISED** the CEO to approve the draft guidelines (recommendations on pages 5 to 15 of Attachment B) with one additional recommendation on the use of Souvenaid which members will consider out of session.

14. DRAFT ETHICAL GUIDELINES FOR ORGAN TRANSPLANTATION FROM DECEASED DONORS

Members noted the background information on the development of the draft Ethical Guidelines for Organ Transplantation from Deceased Donors (Ethical Guidelines), undertaken by NHMRC following a joint request from the Organ and Tissue Authority (OTA) and the Transplantation Society of Australia and New Zealand (TSANZ). Members noted the terms of reference and membership for the Expert Advisory Group (EAG) that developed the Ethical Guidelines, which includes representatives from OTA, TSANZ and NHMRC's Australian Health Ethics Committee (AHEC), and members with relevant knowledge of transplantation medicine and consumer issues. Public consultation on the draft Ethical Guidelines took place between 19 January and 6 March 2015 and 18 submissions were received. The EAG addressed issues raised in the public consultation in the final draft of the Ethical Guidelines.

Council members were asked to consider the Ethical Guidelines and provide advice on any issues with the final draft.

Council members raised two issues for AHEC to consider:

- The appropriateness of references to a 'living will'. On page 26 of the draft, the second dot point refers to a 'living will'. Council noted that while this term does not have any legal status, it was a term often used by the community. Council asked AHEC to consider if the term was appropriate in the Ethical Guidelines.
- Whether the Ethical Guidelines should include specific reference to the unique health issues
 experienced by Aboriginal and Torres Strait Islander people in the context of organ transplantation.
 These issues could include reference to the fact that Aboriginal and Torres Strait Islander people have
 increased co-morbidities, less positive outcomes post-transplantation and difficulties associated with
 remoteness.

Council was advised that these issues will now be considered by AHEC at its meeting on 3 December 2015, prior to Council being asked to consider the guidelines out-of-session following this meeting.

Council **NOTED** that it will be asked to consider the final guidelines out-of-session following the AHEC meeting on 3 December 2015.

15. AUSTRALIAN DRINKING WATER GUIDELINES: AMENDMENTS TO CHAPTERS 6 AND 8

Ms Robertson introduced the item. The proposed changes were considered by Council at its 204th Session on 5 June 2015, and released for public consultation. The six submissions received have been considered and the proposed amendments updated as appropriate.

The changes to Chapter 6 provide a hierarchy of documents from which interim guideline values can be determined for chemicals that have been detected in drinking water but do not have a guideline value in the Australian Drinking Water Guidelines (ADWG).

The changes to Chapter 8 clarify the origins and history of *Table 8.2 Chemicals recommended for use in the treatment of drinking water*. While several submissions expressed a preference to have a national body to approve new drinking water treatment chemicals, Ms Robertson noted that the ADWG are not mandated standards and that this decision-making role lies with jurisdictions.

NSW requested a change to the tense of the sentence 'The chemicals in Table 8.2 *were* recommended for use in water supplies...' as it suggests the chemical are no longer recommended. NHMRC agreed to make this change.

Council ADVISED the CEO to publish the amendments to Chapters 6 and 8 of the ADWG.

16. CHAIR'S REPORT: HEALTH INNOVATION ADVISORY COMMITTEE (HIAC)

Prof Samuel provided Council with an overview of the issues discussed at the inaugural HIAC meeting. Of particular interest to HIAC was how NHMRC could assist in increasing commercial literacy in the health and medical research sector.

Prof Samuel also indicated HIAC's focus on translation overlapped with the Health Translation Advisory Committee and suggested that the two committees may need to work collaboratively, including a possible joint meeting.

Members questioned whether NHMRC also had a role in facilitating collaborations between industry and academia; however it was noted that this may be a focus for the MRFF.

Council **NOTED** the HIAC Chair's Report.

17. CHAIR'S REPORT: HEALTH TRANSLATION ADVISORY COMMITTEE (HTAC)

Prof Lewin detailed the discussion from the first meeting of HTAC, including:

- Agreement that NHMRC should develop a description for research translation, rather than a definition:
- The importance of metrics and involving end users;
- Career pathways and training the next generation in translation;
- Moving forward with a second round of Advanced Health Research and Translation Centres (AHRTCs), and the value to AHRTCs of seeking funding from local and state/territory governments; and
- Lessons from the previous triennium's activities, especially the Research Translation Faculty and Partnership Centres.

Prof Kelso noted that Council will be a good venue for linking the work of HTAC, HIAC and Research Committee.

Council NOTED the HIAC Chair's Report.

18. CHAIR'S REPORT

The Chair thanked members for their attendance and noted the useful strategic discussions and the guideline endorsements held at this meeting.

Prof Robinson acknowledged that this would be Prof Ackland's final Council meeting as he will be retiring in February 2016. The Chair thanked him for his service to Council and to Victoria.

Council **NOTED** the Chair's Report.

19. STANDING REPORT ON THE STATUS OF ETHICS GUIDELINES AND PUBLICATIONS AND STANDARDS FOR RESEARCH

Council **NOTED** the update on ethical guidelines.

20. STANDING REPORT ON THE STATUS OF GUIDELINES IN CLINICAL PRACTICE ASND PUBLIC HEALTH

Council **NOTED** the update on current activity in relation to clinical and public health guidelines.

21. INITIATIVES FOR ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH

Council **NOTED** the update on NHMRC activities relating to Aboriginal and Torres Islander health research and researchers.

22. UPDATE ON FUNDING SCHEMES AND STATISTICS OF ANNOUCEMENTS

Council **NOTED** the application data for 2015, the status update on funding schemes and outcome data for 2015 grant announcements.

23. UPDATE ON NHMRC'S CLINICAL TRIALS REFORM WORK

Council **NOTED** the updates provided and the work that NHMRC is doing to transform the clinical trials environment.

24. UPDATE ON THE BOOSTING DEMENTIA RESEARCH MEASURE

Council **NOTED** the progress to date on the Boosting Dementia Research budget measure.

25. JURISDICTIONAL REPORT

Council **NOTED** the information provided.

26. DEVELOPING NORTHERN AUSTRALIAN INITIATIVE

Council **NOTED** the recent developments and next steps in the implementation of the Australian Government's Developing Northern Australia Initiative – Northern Australia Tropical Disease Collaborative Research Programme.

27. OUT OF SESSION PAPERS

Council **NOTED** the outcome of the Out-of-Session activity between the 205th and 206th sessions of Council.

Meeting closed at 3.15pm.