

MINUTES
210th Session
Council of the National Health and Medical Research Council
15-16 March 2017
NHMRC Offices, Canberra

Attendance:

Prof Bruce Robinson AM (day 1 only)	Chair of Council
Prof Kathryn North AM	Chair, Research Committee
Prof Ian Olver AM (A/g Chair, day 2)	Chair, Australian Health Ethics Committee
Prof Graeme Samuel AC	Chair, Health Innovation Advisory Committee
Prof Sharon Lewin	Chair, Health Translation Advisory Committee
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 (day 1 via teleconference)	Member with expertise in professional and post-graduate medical training
Prof Brendan Crabb AC	Member with expertise in health research & medical research issues
Prof Michael Kidd AM	Member with expertise in health care training
Prof Jonathan Carapetis	Member with expertise in Public Health
Prof Ingrid Scheffer AO	Member
Prof Elizabeth Sullivan	Member
Prof Brendan Murphy	Commonwealth Chief Medical Officer (CMO)
Dr Jeannette Young PSM	Chief Health Officer (CHO), QLD
Dr Kerry Chant PSM	CHO, NSW
Prof Paddy Phillips PSM	CMO, SA
Dr Hugh Heggie	CHO, NT
Prof Charles Guest	CHO, VIC
Dr Jodi Glading	Representing Principal Medical Advisor, TAS
Dr Paul Kelly	CHO, ACT
Prof Gary Geelhoed	CMO, WA

Apologies

Professor Anthony Lawler	Principal Medical Advisor, TAS
Professor Bruce Robinson AM (day 2)	Chair of Council

Observers

Mr Mark Cormack (day 2 only)	Department of Health
Mr Graeme Barden (day 1 only)	Department of Health
Prof Helen Zorbas AO	Cancer Australia
Adj Prof Debra Thoms	Commonwealth Chief Nurse and Midwifery Officer
Prof Villis Marshall AC	Australian Commission on Safety & Quality in Health Care
Mr Barry Sandison (day 2 only)	Australian Institute of Health and Welfare

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 Policy & Translation

Dr Tony Willis
Mr Tony Krizan FCPA

Executive Director, Research Programs
Executive Director, Corporate Operations and Information

1. WELCOME

The Chair, Professor Bruce Robinson, opened the 210th Session of Council at 1pm and welcomed attendees to the sixth meeting of the 2015 - 2018 National Health and Medical Research Council (NHMRC) triennium. The Chair acknowledged the Ngunnawal People as traditional owners of the land upon which the meeting was held.

The Chair noted the apology of Professor Anthony Lawler, and noted that Dr Jodi Glading was attending in his place. 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 or regarded 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. The Chair noted the importance of transparency with the operation of Council and reminded Members of the need to be timely with updating their Declarations of Interest (DOI). The Chair suggested that the Secretariat circulate the DOI guidelines to Members to prompt any updates required. Professor Robinson noted that he has recently accepted a board position with Cochlear Limited.

Professor Anne Kelso stated that the CEO of NMRC is required to keep the Minister apprised of her interests. As a matter of process, Professor Kelso has recently advised the Minister of her interests.

For the information of Council members, she will place her interests on Committee Centre.

Council **ADVISED** the Chair that the draft Session Report of the 209th Session of Council was accepted as a true and accurate record of proceedings.

Action item: Professor Robinson to update his disclosure of interests on the Committee Centre.

Action Item: Members to ensure that they update their disclosure of interests on the Committee Centre.

2. CEO REPORT

Professor Kelso provided Council members with a verbal update on the tabled NHMRC CEO Report. The key points included:

- The outcomes from the Women in Health Science (WiHS) Committee meeting on 31 January 2017. Professor Kelso agreed that gender equality in health and medical research is a significant issue needing attention and change and, as a mark of its importance, the WiHS Committee now reports to the NHMRC CEO directly rather than via Research Committee (RC); however, RC and Council will continue to be kept informed of developments. Professor Kelso encouraged Members to pass feedback or input to her directly. Members requested that WiHS should be a standing item on the Council agenda.
- The appointment of a new Minister for Health and Sport, the Hon Greg Hunt MP
- An update of recent NHMRC grant announcements made by Minister Hunt
- The second call for submissions for recognition as an Advanced Health Research and Translation Centre (AHRTC) and the first call for submissions for recognition as a Centre for Innovation in Regional Health (CIRH) closed in December 2016. Shortlisting and interviews occurred in early 2017 and applicants were recently advised of the outcomes under embargo. A Ministerial announcement is expected in the coming weeks.
- The appointment of the new Director of the NHMRC National Institute for Dementia Research (NNIDR), Ms Janice Besch.

Council **NOTED** the CEO Report.

Action Item: WiHS to be included in future Council meetings as a standing item

3. CHAIR'S REPORT

Professor Robinson noted that he had met with Minister Hunt. Professor Robinson noted the Minister was very supportive of NHMRC and reaffirmed his commitment to research. The Minister also indicated support for the Structural Review of NHMRC's Grant Program and noted the importance of NHMRC's work in national health guidelines.

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

4. STRUCTURAL REVIEW OF NHMRC'S GRANT PROGRAM

Mr Alan Singh outlined the Expert Advisory Group's (EAG) development of the proposed alternative grant program structure (the model), including that: the EAG's remit was to address the aims of the review; the public consultation feedback was mixed but a common suggestion was for a hybrid model; and the EAG had debated a number of key issues, e.g., opportunities for early and mid-career researchers (EMCRs), Medical Research Endowment Account (MREA) allocations, collaboration and potential impacts on the sector.

Mr Singh provided an overview of the proposed new grant program structure, which includes:

- four broad schemes, each with a distinct purpose
- consolidated, five year funding under People and Team Grants offering researchers the flexibility to pursue their research. The size of research packages is still being determined but would be sufficient to support researchers through a single line grant
- an emphasis on significance and innovation through Ideas Grants
- proposed strict capping of applications and grants held to reduce peer review burden, with measures to enable re-application in years four and five of an existing grant. This strict capping would not be applied to grants under the Strategic and Leveraging scheme; however, grant specific capping may be considered.

Ms Marion Berry provided an overview of the feedback received from the targeted consultation. She advised that stakeholders mostly agreed with the high level proposed structure and agreed with the need for change. However, they raised questions and made suggestions about elements of the structure including fellowships, the size of research packages, support for Aboriginal and Torres Strait Islander researchers and capping of applications and grants held. Stakeholders all agreed on the importance of communication with the sector and that it would be best not to rush implementation to give the sector time to adapt to the new system.

Mr Singh explained that Research Committee had provided broad, in-principle support for the proposed structure with advice that some elements required further detail and refinement before discussion with the broader sector and implementation. He advised that the Health Translation Advisory Committee (HTAC) and Health Innovation Advisory Committee (HIAC) also recently considered the proposed structure and provided in-principle support. In particular, HTAC provided feedback on the proposed separate clinical trials scheme and agreed that further consultation with the sector should be undertaken on the framework developed by the Clinical Trials Working Group. HIAC advised that the research packages for People and Team Grants should be sufficient to provide support for Australian researchers to be internationally competitive.

Council's key comments on the proposed alternative structure included:

- consumers and the community:
 - the description of the model does not articulate how the proposed structure would assist with better use of the MREA for improved health. This is important to consumers and should be specified in any public document.
 - track record is a nebulous term for consumers. An explanation of track record should be included in any public document, to explain that the full breadth of outputs is considered.
 - consider re-wording the 'knowledge gain' descriptor to focus on the quality of the science.
- People and Team Grants – Consider flexible allocation between the two schemes (rather than a set 25% each of the MREA); however, do not undermine the Team Grants scheme.
- Team Grants
 - support for the proposal that all Chief Investigators (CIs) be equal; however, it would need to be implemented well to support true collaboration.
 - consider providing additional monetary incentive for a fellow to join a team, otherwise researchers may just choose to be on a People Grant and not collaborate.
- Ideas Grants – a significant and exciting change to support innovation and creativity.
- Strategic and Leveraging scheme – cautioned that there may be high application numbers for these grants as they are uncapped.
- Modelling – critical to understanding the impact of the structure and to determine size of packages. Need to ensure that the most high-performing researchers would be supported.
- disadvantaged groups – NHMRC could consider introducing quotas for women researchers and Aboriginal and Torres Strait Islander researchers.
- Aboriginal and Torres Strait Islander researchers – concern that they may be disadvantaged. NHMRC should investigate the impact of the structure on these researchers through modelling and ensure there is support for capacity building to underpin the proposed changes.
- early and mid-career researchers (EMCRs) – it may be difficult for EMCRs to establish independence. Modelling is required to understand the impact.
- specialists – clarification needed on the enhanced Associate Investigator role, including how it would work in practice.
- international competitiveness – the new structure should support Australian researchers to compete internationally. The Team Grant could bring together excellent multidisciplinary researchers who would be internationally competitive.
- industry and philanthropy – the Structural Review may be an opportunity to include guidance in new scheme funding rules, such as in Ideas Grants, on leveraging external funding.
- cohort studies – consider how many cohort studies are needed and their efficiency; also consider a national approach to data registers.
- diversity of workforce – important to increase diversity. NHMRC could consult further with local health networks, Australian Technology Universities and regional and rural universities.
- communication with the sector:
 - important to explain the benefit of the proposed changes for the primary audience (researchers and institutions), but also to explain it for the wider audience.
 - reiterate the complementarity of the Medical Research Future Fund.
- peer review – consider introducing an iterative review process to provide ongoing feedback to researchers.
- implementation – consider potential unintended consequences; be prepared for the key questions; consider the allocation of infrastructure funding.

Council recognised that there will be challenges with implementation but reaffirmed its view that reform of the grant program is necessary. The new model aims to deliver a range of benefits, stemming from a more efficient funding system for the health and medical research workforce. Council considered that the new model will significantly reduce the amount of time researchers spend applying for and assessing grants, with one member suggesting it might, for example, even save a researcher up to one month a year. This will enable researchers to focus more time on their projects, with flow-on benefits to the community on completion and translation of that research. Council considered that the new model presented a significant change, providing greater opportunities for innovative research ideas to be pursued for the benefit of the community.

Council **ADVISED** the CEO to proceed with changing the structure of NHMRC's grant program in accordance with the proposed structure, noting members' suggestions and comments on the details.

5. ART GUIDELINES

Professor Ian Olver provided members with an overview of the process undertaken to revise Part B of the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (ART guidelines).

Members were reminded that, at its meeting on 2 – 3 November 2016, Council requested further advice from AHEC on the following issues: social egg freezing, upper age limits for access to ART services and sex selection for non-medical purposes. Professor Olver provided a summary of AHEC's consideration, and the subsequent changes made to the draft ART guidelines.

Issue 1 – Social egg freezing

Council noted that AHEC discussed the following in considering the inclusion of specific guidance on social egg freezing in the ART guidelines:

- the ethical considerations applicable to the practice of social egg freezing are centred on informed consent and the management of expectations, and are not unique.
- individuals considering social egg freezing require the same information, counselling and consent procedures as any individual considering any ART treatment and, as such, the guidelines in *Chapter 4: Information, Counselling and Consent* of the draft guidelines are applicable.
- it may be helpful to include explicit mention of social egg freezing in the draft guidelines.

Members noted that AHEC approved the inclusion of additional guidelines to address social egg freezing as a form of fertility preservation, detailed on pages 51 – 52 of Attachment 5A of the meeting papers.

Issue 2 – Upper age limit for access to ART services

Council noted that AHEC discussed the following in considering the inclusion of an upper age limit for ART in the ART guidelines:

- although age restrictions might be socially and politically sensitive and, in some cases, illegal, there is a lack of evidence that there are ethical grounds on which to place such restrictions.
- there may be clinical reasons to restrict access to ART services, and these decisions should be guided by evidence-based clinical guidelines.
- the draft guidelines do not include an upper age limit for access to ART services; however, clinics are required to provide individuals with information about risks and success rates, taking into account the age of the individual.

Members noted AHEC's advice that, in light of the above, AHEC had made no changes to the draft ART guidelines on this issue.

Issue 3 – Sex selection for non-medical purposes

Council noted that, in considering Council's request for further discussion on sex selection for non-medical purposes, AHEC had reaffirmed its position that there is an ethical difference between a desire to introduce variety to the existing sex ratio of a family and the desire to design the sex of the offspring based on the preferential selection of a particular sex due to an individual's or a couple's cultural or personal bias, influences or desires. However:

- AHEC also recognises that the motivations of those wishing to use sex selection for non-medical purposes are an important consideration and acknowledges that motivations cannot be easily identified.
- AHEC does not endorse, nor wish to perpetuate, gender stereotyping, or cultural or personal biases based on biological sex.
- AHEC also recognises the role that legislators play in the consideration of socio-political issues and the regulation of ART practices, and agrees that further debate is required before sex selection can be available in Australia for non-medical purposes.

Council noted that AHEC had approved changes to Chapter 8 and Appendix 5 of the draft guidelines to further highlight the ethical, legal, social issues around sex selection for non-medical purposes and promote further debate of this issue within governments and the community. Council noted that the changes meant that sex selection would remain unavailable in Australia for non-medical purposes.

On the issues of sex selection and an upper age limit for access to ART, it was acknowledged that public consultation had drawn out a range of views and that this spectrum was also reflected through the discussions and views of members of the ART Working Party, AHEC and Council. Council, however, in endorsing the draft guidelines recognised the strong ethical framework underpinning the document.

Members **NOTED** that the ART guidelines cover a range of complex issues, and **NOTED** the advice provided by AHEC.

Members **AGREED** to recommend that the CEO of NHMRC issue the revised guidelines.

Action Item: The draft Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017 to be provided to the CEO of NHMRC with the recommendation that they be issued.

Day Two of the 210th Session

6. MEDICAL RESEARCH FUTURE FUND

Council **NOTED** the first disbursements from the MRFF will occur in 2016-17, with \$60.9 million available this year. The Strategy and Priorities developed by the Australian Medical Research Advisory Board (AMRAB) are being considered by the Government within its budgeting processes. There is nearly \$800 million projected to be available over the next four years (2016-17 to 2019-2020).

It is envisaged that AMRAB and NHMRC will work together to ensure complementarity of funding is maintained through collaboration, governance, and shared administration where appropriate. It was recommended that Council should consider and provide advice to the CEO, as a member of AMRAB, to inform discussions on the next round of priorities.

Action item: Include agenda item for next session of Council on consideration of advice to the CEO of MRFF priorities.

7. NHMRC STRATEGIC FUNDING PRIORITIES FOR 2017

Dr Tony Willis presented the item, noting Research Committee's advice to set aside \$20 million of the Medical Research Endowment Account for strategic funding across three priority areas in 2017 – Aboriginal and Torres Strait Islander research, gender equity and health services research. Dr Willis noted that strategic funding for gender equity will be informed by statistical analysis being undertaken by NHMRC in consultation with the Women in Health Science Committee.

Members noted the priorities and discussed the following issues:

- how to assist the translation process to improve Aboriginal and Torres Strait Islander health, for example by ensuring 'mainstream' trials also include Indigenous people at levels representative of their proportion in the total population
- the potential for Aboriginal and Torres Strait Islander research outcomes to improve regional and rural health
- how the strategic priorities will be operationalised, and
- scheme opening times and definitional issues for the Centre of Research Excellence in Primary Health Care.

Council **NOTED** NHMRC's strategic funding priorities for 2017.

8. 2017 MREA INDICATIVE ALLOCATIONS

Mr Tony Krizan presented the MREA Budget for new commitments to commence funding from 2018, as advised by Research Committee to the CEO in February 2017.

The MREA Budget totals \$873.5 million, and includes allocations of \$20 million for Strategic Priorities and \$20 million for new Targeted Calls for Research (TCRs).

Members discussed the proposed allocations, and particularly the selection process for TCRs. NHMRC clarified that a research need can be identified through the following channels:

- NHMRC Council and Principal Committees, the NHMRC Research Translation Faculty (RTF), or community groups
- the NHMRC CEO, Australian Government, or States and Territories through the Australian Health Ministers' Advisory Council (AHMAC).

Members were also advised that the framework for identification and prioritisation of TCRs can be found on the NHMRC website, and that proposals for TCRs can be submitted through the Online Submission Pathway.

Council also discussed strengthening impact reporting for NHMRC funded research, and it noted the extensive work HTAC is doing in this area. Council expressed interest in more information on NHMRC's communication activity in future meetings.

Mr Krizan also advised Council that NHMRC operating on average more than 20% below government benchmark costs for corporate operations.

Council **ENDORSED** the 2017 MREA budget of \$873.5 million for new commitments to commence funding from 2018.

Action item: Bring a report to Council on NHMRC's communications activities and strategy, including efforts to articulate the translation of research into improved health opportunities and systems.

9. DATA STRATEGY

Mr Krizan provided an update on NHMRC's work towards a NHMRC data strategy. The Productivity Commission's draft report on *Data Availability and Use* recommended that research funders report on data sets created from publicly funded research (and whether these are available for reuse or not). Further to this, the draft also included a recommendation that government prioritise research funding based on institutional ability to share data.

The CEO met with the Productivity Commission's Chairman Mr Peter Harris AO to discuss the draft recommendations including that a direction to prioritise funding for research based on institutional ability to share data could have adverse outcomes by overriding the current NHMRC funding criterion of excellence. The CEO also provided clarification on the NHMRC's national leadership in the ethical conduct of health and medical research.

A copy of the CEO's correspondence to the Chairman of the Productivity Commission was provided to Council as an attachment to the paper.

Council **NOTED** the paper. A further update on this work will be provided to Council at the next meeting.

10. RESEARCH COMMITTEE (RC) REPORT

Professor Kathryn North provided Council with an update on the key agenda items from the RC meeting on 22-23 February 2017 which included:

- the Structural Review of NHMRC's Grant Program
- the Beyondblue co-funded Targeted Call for Research and Centre of Research Excellence
- identifying priorities for strategic funding in 2017
- future calls: Global Alliance for Chronic Diseases.

Members discussed the following issues regarding funding schemes:

- Track Record
 - if there is a heavier emphasis on track record as part of fellowship and research support packages, there will be a need for an objective and cohesive way for assessing track records consistently across all schemes
 - it will be important to ensure category descriptors for track record are consistent across fields of research and take into account different career paths and career stages
 - Professor North noted that RC is forming a small working group to increase the consistency of track record assessment across the schemes. Members asked that NHMRC consider including members of HTAC and HIAC in this working group and that CCAG be informed of progress to assure consumers that it is a rigorous approach.
- Partnerships
 - the different models and arrangements that affect how partnerships are formed with co-funding organisations (for example proactive and reactive models)
 - NHMRC noted that we are currently reviewing and updating the partnership page on the website and that HIAC has developed a guide to evaluating industry collaborations in peer review.
- Research Impact
 - how the impact of the research funding is measured is crucial to NHMRC's accountability.

Mr Krizan noted NHMRC activities related to impact and data mining including:

- active negotiations with 'Research Fish' about the potential to use it as a research impact assessment platform
- looking at using ORCID to connect datasets
- developing an NHMRC data portal to go live in 2017
- considering ways to identify clinical outcomes of research.

Professor Kidd advised the Council of his interest due to his role on the Board of Directors for Beyondblue. The Council agreed that there was no conflict in relation to this item.

Council **NOTED** the RC Report.

11. NHMRC INTERNATIONAL ACTIVITIES UPDATE

Dr Willis presented an update on NHMRC's International Engagement Strategy, highlighting progress across a number of the activities.

Members discussed the following issues:

- the ad hoc nature of the activities and plans to shift to a more strategic approach for new activities
- how the activities link in with NHMRC's Corporate Plan
- how NHMRC supports global health in our region
- plans by the Department of Foreign Affairs and Trade to fund health security research.

Professor Kelso noted that global health is important for NHMRC and much of this research is supported through NHMRC's standard schemes. At the same time, NHMRC also needs to be conscious of its remit under the Act. Professor Kelso noted that DFAT was consulting with NHMRC as part of its planning for implementation of the health security research program.

Council **NOTED** NHMRC's upcoming international engagement activities.

12. CORPORATE PLAN

Members were asked to advise on the proposed content of the NHMRC Corporate Plan 2017–2018, which is currently being developed. The proposed approach to this year's plan is to retain much of the existing content of the current plan, including strategic priorities and key activities. The Minister will be consulted about the content of the plan and his approval will be sought for the final plan, in line with the requirements of the NHMRC Act. Members noted that input from Council into a full review of all aspects of the plan will be sought at its October meeting. This will inform the development of a fully revised 2018–2019 plan to set the strategic direction for the 2018–2021 triennium. It was noted that it will be important to consider the priorities of AMRAB when setting NHMRC priorities for 2018–2021.

Council noted the intention to significantly streamline the performance measure section of the 2017–2018 plan, and agreed that specific issues regarding the plan's content would be best dealt with in the context of developing the 2018–2019 plan.

Council **ADVISED** that the proposed content of the corporate plan, as outlined in the agenda paper, was appropriate.

13. PCIC REPORT/INITIATIVES FOR ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH

Prof Sandra Eades spoke to the paper, advising that PCIC has made significant progress over the current financial year. This includes:

- agreement on Targeted Calls for Research (TCRs) in the areas of mental health and ageing well in Indigenous populations
- formation of a TCR expert panel for Indigenous mental health
- commencement of the development of Road Map 3 with the Nous Group. A number of face to face workshops are being planned for the Torres Strait, Sydney, Adelaide, Perth and Darwin as well as an online public consultation.

Mr Singh added that NHMRC engaged four interns from December 2016 to January 2017. They worked on a range of projects including mapping collaboration, and documenting career pathways of researchers.

NHMRC is also working on a survey for Centres of Research Excellence (CREs) to advise on capacity building and measures that might assist with enhancing their work further.

Council members added that stories of success are useful and highlighted the importance of communicating these positive narratives.

Council **NOTED** the PCIC report.

14. INDIGENOUS RESEARCH ETHICS GUIDELINES

The Chair provided background information about the development of the following two revised guidelines:

- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*
- *Keeping Research on Track II.*

Council noted that the scope of the revised guidelines has been broadened to encompass all research and not only health research. Members also noted the proposed questions to accompany the revised guidelines when they are released for public consultation, seeking feedback on specific issues. It was noted that the extra information will be placed on the NHMRC website when the finalised guidelines are released after the expert working committee considers the feedback provided during the public consultation.

The Chair of PCIC, Professor Eades, indicated that PCIC was satisfied with the direction of the document and was looking forward to the public consultation process.

Council **ADVISED** the CEO to release the two revised guidelines for public consultation.

15. AHEC REPORT

Prof Olver, as Chair of AHEC, provided Council with an update on the main agenda items discussed at the AHEC meeting on 17 February 2017. These included:

- *Ethical guidelines on the use of assisted reproductive technology in research* (ART Guidelines)
- review of the Aboriginal and Torres Strait Islander research ethics guidelines
- review of the *National Statement on Ethical Conduct in Human Research*
- NHMRC guidance on payment for participation in research
- NSW draft guidelines for low and negligible risk research, as requested by NSW Health
- Human Research Ethics Committee (HREC) annual reporting to NHMRC.

Council **NOTED** the AHEC Report.

16. NUTRITION GUIDELINES FOR CYSTIC FIBROSIS IN AUSTRALIA AND NEW ZEALAND: EVIDENCE BASED AND CONSENSUS RECOMMENDATIONS

The Chair introduced the item and welcomed Ms Nicole Saxby (Co-chair) and Dr Susannah King (lead methodologist) from the guideline development committee to answer any questions. Mr Singh gave an overview of the guideline's development process, noting it had been subject to independent methodological and clinical review.

The methodological reviewer considered that, in order to meet the NHMRC guideline standard, the recommendations should undergo a full review to make them more actionable, which the developers had subsequently done. Mr Singh noted that as a result, the guideline had, in the view of NHMRC, met the NHMRC's development procedures and requirements.

Professor Gary Geelhoed, as Council spokesperson, noted the significant progress made in cystic fibrosis in recent years, commending the guideline as a complete revision of previous dietitian-led guidelines on this

topic. The developers also discussed their implementation strategy for the guideline, including plans to develop consumer resources by chapter, hold training workshops, and publish a journal article highlighting key recommendations.

Dr Kerry Chant suggested there were some inconsistencies in Chapter 5 regarding the assessment of weight status and nutritional status and tabled a document specifying her particular concerns, which the developers agreed to address (modification 1).

Professor Brendan Murphy expressed concern about Practice Points 4.1 regarding specific staffing ratios, suggesting this may have industrial consequences and be outside the scope of the guideline. The developers agreed to make the section less prescriptive (modification 2).

Professor Sharon Lewin expressed concern about Practice Point 15.4 on dietary supplementation with specific herbal products, suggesting that several of the statements may be inappropriate given evidence was not cited for effectiveness, or specific effectiveness in cystic fibrosis. The developers explained that consumers had requested advice on the use of dietary supplements, but agreed to remove the first three dot points in this section, being those concerning garlic, ginseng, and curcumin (modification 3), as they did not provide advice in relation to practice.

Council **ADVISED** the CEO to incorporate the three modifications discussed above and progress the draft *Nutrition Guidelines for Cystic Fibrosis in Australia and New Zealand: Evidence Based and Consensus Recommendations* for approval.

Action Item: ONHMRC to arrange for the developers to make the required modifications and resubmit the guideline out of session for approval.

17. NUTRIENT REFERENCE VALUES: ADVICE REGARDING RELEASE (SODIUM)

The Chair introduced the item noting this was a third party guideline seeking NHMRC approval. Mr Kelvin King and Ms Susannah van der Straaten from the Australian Government Department of Health (the Developer) and Professor Linda Tapsell, Chair of the Sodium Expert Working Group, were welcomed to the meeting for this item.

Council noted that the NRVs are a set of recommendations primarily used by health professionals to assess dietary requirements. It was further noted that this is the second nutrient to be reviewed under the new Methodological Framework which allows for responsive updating of targeted priority nutrients and that Council at its last session considered updates to the fluoride NRVs.

Ms Samantha Robertson highlighted that this revision includes the removal of the current sodium 'Upper Level of Intake' (UL) as there is no level at which no adverse effect can be observed between sodium intake and blood pressure. Overall NHMRC is confident that its standards on guideline development have been met, including the use of GRADE (Grading of Recommendations Assessment, Development and Evaluation) for assessing the evidence. It was also noted that several submissions were received through public consultation, including one from the Queensland Department of Health.

Professor Tapsell confirmed the scientific rigor of the review and acknowledged that the Suggested Dietary Target (SDT) looks at managing chronic disease risk at the population level and that a UL was unable to be determined as the risk association between sodium and blood pressure does not change as the two factors increase. Council advised that the optics of communication and perception by the public regarding the increased SDT and withdrawal of the UL will be critical at a population level to ensure current public health messaging is retained, noting that the majority of Australians consume twice the sodium SDT and the linear relationship between sodium intake and blood pressure needs to be clearly explained to non-scientists.

The Chair noted that the new recommendation is aligned with the World Health Organisation targets.

The Chair summarised the views of Council and advised that an explicit statement is required in the revised NRV document on the reason for the removal of the UL and increase in SDT, explaining this in consumer-accessible terms. With regard to implementation and population messaging, the Developer should interact with the states and territories prior to release.

Council **AGREED** that this statement and detail on public messaging be provided to Council for consideration out of session.

Action Item: To provide a plain English statement regarding the removal of the UL and increase in the SDT, and demonstrate how this will be presented in the updated NRV report.

Action Item: Outline of the Developers (Commonwealth Department of Health) communication plan with the states and territories to enable consistent messaging prior to release.

18. HEALTH EFFECTS OF WATER FLUORIDATION: ADVICE ON INFORMATION PAPER, QUESTIONS AND ANSWERS, AND NHMRC PUBLIC STATEMENT

Ms Robertson introduced the item, advising that the *Draft Information Paper: Effects of water fluoridation on dental and other human health outcomes* (Information Paper) underwent public consultation from September to October 2016. Thirty submissions and 923 citations were received. Four submissions were from state government health or water supply departments, six from non-government organisations and 20 from individuals. The majority of the latter group were opposed to water fluoridation.

Council **NOTED** feedback on the draft Information Paper from public consultation, with key issues from consumers summarised as follows:

- concern about the effects of fluoride intake on human health
- disagreement over the interpretation of the evidence, with a particular focus on cognitive or intelligence deficits, kidney damage and thyroid problems
- concern regarding the criteria used by NHMRC to search for evidence, particularly where in-vitro or animal studies had been excluded
- perception that the Fluoride Reference Group and NHMRC had conflicts of interest or biased views.

In light of the draft information paper, NHMRC sought Council's advice as to whether the *NHMRC Public Statement: The Efficacy and Safety of Fluoridation 2007* (2007 Public Statement) needs updating. Ms Robertson noted that a revised Public Statement, developed in collaboration with NHMRC's Fluoride Reference Group (FRG) and the jurisdictions, was included in the agenda papers at Attachment G. It was noted that this draft statement will be the subject of consultation with the Jurisdictional Water Fluoridation Working Group before being circulated to Council for approval to release for public consultation. Council's attention was also brought to the draft recommendation, namely that water be fluoridated in the range of 0.6 to 1.1 mg/L. It was noted that Tasmania's legislation and regulations currently permit fluoridation up to 1.2 mg/L but they are looking to amend this to align with NHMRC's recommendation.

Council approval was also sought for the Cochrane Oral Health Group to use observational studies identified in NHMRC's 2016 *Health Effects of Water Fluoridation Evidence Evaluation Report* (EER) to inform an appendix to its 2015 review. This will capture studies excluded from their review and provide a more complete international repository of current research on dental caries and fluoridation.

Council **ADVISED** that the 2007 Public Statement should be updated and noted that a draft will be provided out of session for approval to proceed with its public consultation.

Members **NOTED** that NHMRC plans to release a suite of resources on the health effects of water fluoridation later in 2017, including the final Information Paper, Public Statement and Questions and Answers. This package is intended to assist the jurisdictions provide nationally consistent messaging.

Council **ADVISED** that the Cochrane Oral Health Group be allowed to cite studies in NHMRC's 2016 EER to inform an appendix to the 2015 Cochrane Review: *Water fluoridation for the prevention of dental caries*.

19. PROMOTING SOCIAL AND EMOTIONAL DEVELOPMENT AND WELLBEING OF INFANTS IN PREGNANCY AND THE FIRST YEAR OF LIFE: A NHMRC REPORT ON THE EVIDENCE

The Chair introduced the item and noted that the draft *NHMRC Report on the Evidence* was discussed by the Council of NHMRC in July 2016, prior to targeted consultation. Ms Robertson informed Council that this body of work was initiated by NHMRC's Prevention and Community Health Committee (PCHC) during its 2012-15 triennium. PCHC identified mental health as a priority area, with a particular focus on the role of early caregiving practices in promoting social and emotional development. PCHC was interested in identifying which interventions early in life can improve a child's social and emotional wellbeing and development during infancy, childhood and adolescence, particularly in the context of developing resilience.

The *NHMRC Report on the Evidence* summarises the findings of a comprehensive evidence evaluation which focused on population level interventions delivered during pregnancy or in the first year of life, that might promote infant and child social and emotional development. The report is suitable for use by governments, policy makers, researchers and service providers who work with parents of infants. Ms Robertson informed Council that the Australian Institute of Family Studies has offered to assist NHMRC to produce a webinar to publish on its Child Family Community Australia website. Further, NHMRC will liaise with relevant agencies as part of implementation to encourage uptake and use of the report in policy development and to develop research proposals in the future.

Professor Jane Fisher, Chair of the Mental Health and Parenting Working Committee, joined the item via videoconference. Prof Fisher noted the extraordinary program of work that has produced the report, and the high-quality, comprehensive effort provided by NHMRC's Public Health team.

Professor Elizabeth Sullivan noted the timeliness of this report, particularly with the recent surge in incarceration of young people in Australia, and that the report will be a very useful document for the Australian community.

Ms Robertson asked that Council provide any ideas on implementation and evaluation opportunities to the NHMRC Secretariat.

Council **ADVISED** the NHMRC CEO to release the *NHMRC Report on the Evidence: Promoting social and emotional development and wellbeing of infants in pregnancy and the first year of life* and accompanying *Plain Language Summary*.

20. FUNDING OF NHMRC CLINICAL TRIALS

Prof Gherzi explained the work done by the joint HTAC-RC subcommittee, and the proposal that was to be taken to targeted consultation. Council agreed the work was important and needed; for example it addressed issues raised by consumers in relation to the funding for clinical trials. Several suggestions were made on parties for consultation, such as the Australian Clinical Trials Alliance and affiliated members.

Council also suggested that the CEO consider further changes that could be enabled by implementation of the framework, for example:

- providing advice to researchers on the most efficient trial design to answer particular questions (perhaps through an NHMRC Office for Clinical Trials)

- ensuring trial designs provide the information that could form the basis for regulatory approval, where relevant
- ensuring innovative trial designs are enabled (e.g. rapid assessment trials)
- iterative peer review, or other innovative ways of assessing applications
- using other clinical networks (such as those represented by NHMRC's Advanced Health Research and Translation Centres) to leverage the research and get answers more quickly
- taking a strategic approach to prioritising cohort studies to ensure maximum value from funding
- forming partnerships with states and territories in relation to cohort studies or clinical trials.

Council **NOTED** the draft discussion paper 'A Framework for NHMRC Assessment and Funding of Clinical Trials and Large Studies', and commended the proposed framework.

Action Item: ONHMRC to bring the Framework to the Community and Consumer Advisory Group for discussion.

21. REPORT ON THE STATUS OF GUIDELINES IN CLINICAL PRACTICE AND PUBLIC HEALTH

The Chair introduced the item, noting that advice was being sought from Council on guidelines developed or endorsed by NHMRC and other NHMRC documents that are approaching 5 or 10 years of age in 2017. In particular, Council was asked to indicate if particular products should be reviewed, rescinded or carry a cautionary warning regarding the status of evidence underpinning the document. Where a document is to be rescinded or carry the cautionary warning, this action will be effected at the end of 2017.

Council provided the following advice:

Table 1. Public Health and Clinical Practice Guidelines approaching 5 years of age in 2017

Document	Advice from Council
NHMRC Statement on Cancer Clusters	The information in this document is still current and in use. The document should maintain 'current' status.
DNA Genetic Testing in the Australian Context: A Statement from the National Health and Medical Research Council	Expert advice should be sought as to whether the information for consumers is still current.
Medical Genetic Testing: Health information for you and your family	Expert advice should be sought as to whether the information for consumers is still current.
Clinical Practice Points on the Diagnosis, Assessment and Management of ADHD in Children and Adolescents	It was noted that the Practice Points contain some outdated nomenclature and that newer medication is now available. It was suggested that a statement to reflect the latter be added to the website. NHMRC should also write to the funder, the Commonwealth Department of Health, to advise that Council recommends updating this document.
NHMRC Statement: Is there a role for Thermography in the early detection of breast cancer?	The information contained in this document is still current and relevant. The document should maintain 'current' status.
Infant feeding guidelines - Information for health workers.	This should carry the 5 year cautionary status. Council recommended that the guidelines be considered in the context of a future review of the Australian Dietary Guidelines. It was also noted that consideration should be given to utilising the US Infant Feeding Guidelines.
Patient Blood Management Guidelines Module 2: Perioperative	Seek advice from the National Blood Authority. Karen Carey to approach on behalf of NHMRC.
Patient blood management guidelines module 3. Medical	Seek advice from the National Blood Authority. Karen Carey to approach on behalf of NHMRC.
Patient blood management guidelines module 4. Critical care	Seek advice from the National Blood Authority. Karen Carey to approach on behalf of NHMRC.

Guidelines for the management of absolute cardiovascular disease risk	This should have its status changed to carry the 5 year cautionary warning.
Clinical practice guidelines antenatal care - module 1	Advice to be sought from the Commonwealth Department of Health before its status is changed to carry the 5 year cautionary warning. It was noted that module 2 is currently under review.

Table 2. Public Health and Clinical Practice Guidelines approaching 10 years of age in 2017

Title	Advice from Council
NHMRC Public Statement: Efficacy and Safety of Fluoridation	Updated Statement for consideration at this session of Council.
Evidence-practice gaps report: Volume 1 - A review of developments 2004-2007	This document is still in use. While it will be rescinded, it will still be available on the NHMRC website.

Action item: NHMRC to update status on website where indicated above.

Action item: Advice to be sought from relevant organisations as indicated above.

22. UPDATE ON NHMRC PROJECTS RELATED TO WATER

Ms Robertson introduced the item and advised of the following activities:

- NHMRC is currently scoping a review of Disinfection By-Products produced during chlorination and whether the health guideline values require revision. The committee will report to Council in July 2017.
- the draft microbial Health Based Target framework is undergoing substantial revision and this will be reported to Council in October 2017.
- NHMRC is currently liaising with Department of Health on its role in developing a guideline value for PFAS in water.
- NHMRC has consulted with the jurisdictions on the scope of a review of the recreational water guidelines. This work is currently unfunded and once the scope is agreed the jurisdictions will be approached for funding.

In relation to the fourth dot point above, Council queried whether 'spray parks' and aquatic facilities should be included in the scope of the recreational water guidelines. Council was advised that this will be dependent on the results of the scoping survey and availability of resources.

Council **NOTED** the current activity on NHRMC projects related to water quality.

23. HEALTH INNOVATION ADVISORY COMMITTEE (HIAC) REPORT

Prof Samuel provided Council with an update on the main agenda items discussed at the HIAC meeting on 28 February 2017 which included:

- commercialisation, including a presentation outlining ANU's thinking on commercialisation
- recognising industry-relevant experience
- Development Grants scheme.

Prof Samuel advised that HIAC is currently working on creating a culture of commercialisation for the translation of research into health outcomes. Prof Samuel indicated that Prof Brian Schmidt, Vice-Chancellor of ANU, was invited to the HIAC meeting to present on ANU's approach to commercialisation. Prof Schmidt noted that ANU's focus is on attracting and retaining researchers whose work aligns with the university's strategy and not investing exclusively in past research successes.

Prof Samuel noted that HIAC discussed the need for industry-relevant experience to be carefully considered when examining track record and for diversity to be more highly valued by peer reviewers. Prof Samuel indicated that NHMRC will evaluate the success of the *Guide to Evaluating Industry-Relevant Experience* following the conclusion of the Project Grants scheme Grant Review Panel meetings, including seeking feedback from peer reviewers and universities.

Prof Samuel advised that HIAC is reviewing the fundamentals of the Development Grants scheme in order to best target funding to support commercialisation. Prof Samuel indicated that the success of policy changes to the 2017 Development Grants scheme funding round will be evaluated and will inform consideration of future changes to the scheme.

Council **NOTED** the HIAC Report.

24. HEALTH TRANSLATION ADVISORY COMMITTEE (HTAC) REPORT

Prof Lewin provided Council with an update on the main agenda items discussed at the HTAC meeting on 8 March 2017 which included:

- measuring the impact of NHMRC funded research
- clinical trials
- Structural Review of NHMRC's Grant Program.

Prof Lewin noted that HTAC is working on ways to measure the health impact and social impact of research. Prof Lewin noted that HTAC could use a similar format to the *Guide to Evaluating Industry-Relevant Experience* developed by HIAC.

Council **NOTED** the HTAC Report.

25. UPDATE FROM CHO MEETING

Council **NOTED** the issues discussed at the 2 November 2016 pre-Council meeting between the NHMRC CEO, the Chair of Council and the Commonwealth, State and Territory Chief Health Officers (CHOs). These issues included:

- Clinical Trials Ready
- Water Fact Sheets
- Developing Northern Australia Initiative
- NHMRC Report on the Evidence: Promoting the social and emotional development and wellbeing of infants
- Coal seam gas
- E-cigarettes.

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

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

27. UPDATE ON FUNDING SCHEMES

Council:

- **NOTED** the application data for funding rounds;
- **NOTED** the status update on funding schemes; and
- **NOTED** the outcome data for Grant Announcements.

28. UPDATE ON NHMRC CLINICAL TRIALS REFORM WORK

Council **NOTED** the update on NHMRC's activities to fulfil the requirements of two budget funding measures to expedite clinical trials reforms in Australia, terminating on 30 June 2017.

29. UPDATE ON THE BOOSTING DEMENTIA RESEARCH MEASURE

Council **NOTED** this update on the progress of the Boosting Dementia Research Initiative.

30. OUT-OF-SESSION PAPERS

Council **NOTED** the outcome of the Out-of-Session activity between the 209th and 210th sessions of Council.

CLOSE OF MEETING

The Chair thanked the Secretariat and staff of the Office for their work in preparing the papers and their support for the meeting.

The Chair noted that the next Council meeting would be held in Canberra on 12-13 July 2017.

The meeting closed at 2.45pm.