

ME/CFS Australia (Victoria) Submission to Strategic Review of Health and Medical Research

Thank you for the opportunity to comment on the Strategic Review of Health and Medical Research.

We welcome the emphasis of the current review on chronic illness and associated burden of disease. Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a severely debilitating and poorly understood chronic illness that strikes people young and lasts for years or decades. It is conservatively believed to affect over 100,000 Australians and the associated burden of disease is consequently high.^{1,2} The illness is classed by the World Health Organisation (WHO) as a neurological condition, and it is known to be triggered by infection.^{3,4} The economic costs in Australia are estimated at approximately \$4 billion dollars annually.⁵

Much ignorance and prejudice surrounds ME/CFS and who have it. This continues to be a significant barrier to quality biomedical research and medical treatment.

ME/CFS Australia (Victoria) makes the following input:

Why is it in Australia's interest to have a viable, internationally competitive health and medical research sector?

ToR 1. A viable, internationally competitive health and medical research sector is vital to the quality of life for Australians due to its relationship with medical care and consequent reduction in burden of disease.

We highlight that both the personal and economic costs of chronic illness are so high that even modest medical progress would bring significant returns, likely to be well beyond the medical research costs. For example, most people with ME/CFS are unable to maintain full time employment, 20%-40% are unable to work at all, and the costs to personal and family life are incalculable.^{6,7,8,9} If only a proportion of such people could be returned to good health, the economic and personal benefits would be huge.

How might health and medical research be best managed and funded in Australia?

ToR 2. ME/CFS Australia (Victoria) supports an increase in both Federal and State government investment in health and medical research. Whilst we understand the need for well coordinated national research, we also support the maintenance of multiple channels of funding, including philanthropic organisations and different levels of government. The availability of multiple sources of funding may lead to a more diverse approach in medical research, which we consider important.

ToR 7. ME/CFS Australia (Victoria) strongly supports the enhancement of community and consumer participation in medical research. Community involvement is one way of ensuring that scientific research is balanced to account for consumer concerns and derives maximum public support and benefit from funding investments. In the case of ME/CFS, it would help improve trust between patients and the scientific/medical professions, which on some occasions has been lacking.

What are the health and medical research strategic directions and priorities and how might we meet them?

ToR 12. ME/CFS Australia (Victoria) strongly supports greater consideration of the nation's burden of disease profile in identifying research priorities, particularly in cases where there is a very low existing level of research and a comparatively high disease burden. The negligible level of ME/CFS research in Australia has resulted in a higher disparity between medical research and burden of disease for ME/CFS than for almost any other chronic illness.^{2,10} We highlight the following points:

1) The current 'operating model' for public health research, which relies mostly on patient groups to raise the profile of their illness, and to facilitate early studies to develop scientific capacity, has inherent weaknesses from a public policy perspective. Importantly, the nature of an illness greatly affects the ability of those affected to do this. In the case of ME/CFS, people are severely disabled from the outset and they face much ignorance and discrimination. Until now, mental illness has faced similar barriers. Reportedly, some cancers with high survival rates may be over funded at the expense of others where, with higher death rates, not many people are left to fight.¹¹ In short, if people are 'too sick', 'too dead' or 'too stigmatised', their ability to effectively advocate for and facilitate medical research may be limited.

Thus, we see the need for mechanisms within the health and medical research sector to identify the most overlooked illnesses, with little research and a relatively high burden of disease, and to more actively facilitate and encourage scientific and medical interest in these areas. For example:

- Assessment processes for research proposals could incorporate meaningful weighting to proposals that address such areas of neglect.
- Methods for raising the profile of various illnesses to stimulate interest within the scientific and medical communities should be developed/improved. For example, convey areas of high unmet research needs to scientists, better education and addressing areas of major ignorance.
- Expanding the criteria for targeted calls for research.
- Provision of small scale seed/pilot funding to smaller studies to build capacity in these areas of research.

2) In relation to burden of disease and fundamental scientific research, the 1998 Wills review states, "Australia is a small part of the global research community and fine-tuning the content of fundamental research would achieve little compared with concentrating on fields where Australia can be world leading."¹²

We point out that fields where Australia is 'world leading' and areas of disease burden are not mutually exclusive. For example, the NHMRC Zerhouni international review states that Australia's research strengths include the fields of Immunology, Neuroscience, Infectious Disease and Cancer.¹³ The first three of these are almost certainly relevant to ME/CFS, which is classified by the WHO as a neurological illness³, and it is also known to be triggered by infection.⁴ ME/CFS may also be a risk factor for cancer.¹⁴ Australia is therefore uniquely placed to make an international contribution in fundamental research for ME/CFS, an area neglected globally. Yet, as stated above, the extremely low level of research into ME/CFS is extraordinary, given it's high burden of disease.

We therefore advocate that priorities within Australia's areas of fundamental research expertise should give far greater consideration to 'closing the gap' between chronic illnesses with a relatively high disease burden and extremely low levels of medical research. Mechanisms such as those suggested in point one would be helpful in this respect.

Notably, the Wills review recommended that burden of disease be a significant driver of 'priority driven research'.¹² We support the further implementation of this recommendation.

3) Reading the assessment processes for NHMRC project grants (attachment 1), it appears this process does not give sufficient weight to potential outcomes for patients.¹⁵ The degree of emphasis on scientific status seems misguided by comparison.

We propose that potentially significant outcomes for patient health ought to be a criteria under the category “Significance of Expected Outcomes”, and that such criteria be given sufficient weighting to affect assessments. We appreciate that it is often not possible to forecast the impact of scientific study on patient health, but would argue that in some cases the potential may be very clear, and this ought to be recognised and expedited. We support general advances in scientific knowledge and recognise the contribution of such basic science toward patient outcomes, but note that the process already provides a high level of support in this area.

Conversely, we suggest that matters of scientific status, such as potential invitations to plenary presentations, should not be considered under “Significance of Expected Outcome” (attachment 1). Matters of scientific recognition are already covered extensively under “Track Record”.

Whilst we understand the importance of track record in demonstrating competence and ability, we are concerned that the degree of emphasis on scientific reputation may create a dynamic where it is difficult for other scientists with new or alternative ideas to achieve success in the funding process.

ToR 13. We note that research into ME/CFS is neglected on a global basis. Given Australia’s areas of research expertise, Australian researchers are ideally positioned to make further international contributions of significance in this area.

How can we optimise translation of health and medical research into better health and wellbeing?

ToR 8. ME/CFS Australia (Victoria) supports better translation of scientific knowledge into medical practice for ME/CFS patients, particularly given the ignorance patients commonly face within the medical profession.

Discussions of translational research seem, for obvious reasons, focused on the role of practical translation of existing research knowledge into better treatment for patients.

We highlight that better health and wellbeing of patients can also be better served by the orientation of some biomedical/clinical research more directly towards the aetiology and treatment of specific illnesses and patient outcomes. This is particularly important for illnesses where there is no cure or very effective treatments, and thus less to be gained from research to practice translation. For example, excellent Australian research has shown that a number of infectious illnesses can trigger ME/CFS in a small but significant percentage of patients.⁴ One would think that this might have led to investigations of a range of early intervention strategies in the acute phase to prevent onset of ME/CFS. Instead, much medical research continues to focus on descriptive research of downstream symptoms, fatigue in people without ME/CFS, symptom management techniques, predisposing factors, all of which have led to little in the way of effective prevention or treatment.

Additionally, it is important that there is more effective follow up of initial promising research findings.

ToR 9. The new Australian Health Survey currently being undertaken by the Australian Bureau of Statistics (ABS) should include a sufficient sample size to identify illnesses at the level of WHO ICD codes. The survey could potentially provide much unanticipated health information on various illnesses. For example, the use of pedometers for measuring activity levels in this survey would likely be very relevant to ME/CFS research where self reporting of activity is usually subjective.

References

1. Health Policy Unit, Royal Australian College of Physicians (RACGP) 2002, 'Chronic Fatigue Syndrome Clinical Practice Guidelines 2002', *Medical Journal of Australia*
2. Begg et al 2007, *The burden of disease and injury in Australia 2003*, Australian Institute of Health and Welfare, Canberra. <http://www.aihw.gov.au/publication-detail/?id=6442467990>. [Annex Table 3: Disability-adjusted life years (DALYs) by age, sex and cause, Australia 2003].
3. World Health Organisation 1994, *International Classification of Diseases (ICD) 10*, viewed March 2012 <http://apps.who.int/classifications/icd10/browse/2010/en#/G90-G99> [G93.3 - Postviral fatigue syndrome/Benign myalgic encephalomyelitis]
4. Hickie et al 2006, 'Post-infective and chronic fatigue syndromes precipitated by viral and non-viral pathogens: prospective cohort study', *British Medical Journal*
5. Productivity loss based on Reynolds et al 2004, 'The Economic Impact Of Chronic Fatigue Syndrome', *Cost Effectiveness and Resource Allocation*, assuming similar percentage productivity losses per person with ME/CFS in Australia in 2010. Direct health costs per person based on Lloyd et al 1992, 'The Economic Impact of Chronic Fatigue Syndrome', *Medical Journal of Australia*, indexed by ABS Health CPI. Prevalence estimate 0.7% Australian population (RACGP 2002).
6. Reynolds et al 2004, 'The Economic Impact Of Chronic Fatigue Syndrome', *Cost Effectiveness and Resource Allocation*.
7. Jason et al 2008, 'The Economic Impact Of ME/CFS: Individual and Societal Costs', *Dynamic Medicine*.
8. Lin et al 2011, 'The Economic Impact Of Chronic Fatigue Syndrome In Georgia: Direct And Indirect Costs', *Cost Effectiveness and Resource Allocation*.
9. Bombardier and Buchwald et al 1996, 'Chronic Fatigue, Chronic Fatigue Syndrome, And Fibromyalgia: Disability And Health Care Use', *Medical Care*.
10. National Health and Medical Research Council 2011, 'NHMRC Research Funding Datasets Based On Burden Of Disease and Health Issues', viewed March 2012 <http://www.nhmrc.gov.au/grants/research-funding-statistics-and-data/funding-datasets/chronic-fatigue-syndrome>.
11. Stark 2011, 'Breasts monopolising cancer spotlight', *The Age* 9th January 2011. The following quotes from the article illustrate the issue: "THE breast cancer lobby's 'pink steamroller' is diverting public awareness and funding from ovarian cancer and contributing to the disease's low survival rates, a leading specialist has claimed. 'You can't dress up ovarian cancer. Your tits are in your face so it [breast cancer] is a very out-there topic. The majority of women with the disease go on to survive and talk about it and lobby for it. The majority of women with ovarian cancer die within five years, and usually for the last two of those years they're too unwell to be out there lobbying for it,' Dr McNally said."
12. Wills 1998, *The Virtuous Cycle Working together for health and medical research*, Commonwealth of Australia.
13. International NHMRC Review Panel 2008, *An International Perspective On The National Health And Medical Research Council's Research Strategies*, National Health and Medical Research Council. [page 7]
14. Jason 2006, Causes of Death Among Patients With Chronic Fatigue Syndrome, *Health Care for Women International*.
15. National Health and Medical Research Council 2011, *NHMRC Project Grants Funding Rules for funding commencing in 2013*

NHMRC Project Grant Category Descriptors

The following category descriptors are used to score an application against each of the assessment criteria: 1) Scientific Quality, 2) Significance or Innovation and 3) Track Record, relative to opportunity. The process of consistently referring GRP members to these descriptors is vital to ensuring equity, thoroughness and process consistency both within and across all GRPs. The Category Descriptors provide GRP members with indicators that can be sampled to guide appropriate scoring of each application.

APPENDIX A

Worthy of Funding

Category	Scientific Quality	Significance of the Expected Outcomes OR Innovation of the concept	Track Record – relative to opportunity
7 Outstanding by International Standards	the proposal: <ul style="list-style-type: none"> has objectives that are well-defined, highly coherent and strongly developed is a near flawless design is without question highly feasible 	the planned research: <ul style="list-style-type: none"> addresses an issue of utmost importance to human health will translate into fundamental outcomes in the science and/or practice of clinical medicine or public health or fundamental changes in health policy will likely be the subject of invited plenary presentations at international meetings, often with relevance across several fields is highly innovative and introduces advances in concept will almost certainly result in highly influential publications. 	relative to opportunity, the applicant team: <ul style="list-style-type: none"> in the main, comprises the most outstanding researchers in the country for their peers/cohort is highly recognised for their contribution to their field of research members have very strong records of other research-related achievements members have strong international reputations or are well on the way to developing them members hold leadership positions in highly regarded scientific or professional societies has a track record that is highly relevant to the proposed research
6 Excellent	the proposal: <ul style="list-style-type: none"> is clear in its intent and logical is excellent in design is apparently highly feasible 	the planned research: <ul style="list-style-type: none"> addresses an issue of major importance to human health could be the subject of invited plenary presentations at international and national meetings is innovative with respect to the question being addressed and the approach to it is very likely to result in highly influential publications. 	relative to opportunity, the applicant team: <ul style="list-style-type: none"> has a record of achievement that places them in the top 10% of peers/cohort members are recognized for their strong contributions to their fields of research members have good and growing international reputations members have clear positions of leadership, or are emerging leaders, in their field members hold leadership positions in well regarded scientific or professional societies members have track records that are very relevant to the proposed research

Worthy of Funding

Category	Scientific Quality	Significance of the Expected Outcomes OR Innovation of the concept	Track Record – relative to opportunity
5 Very Good	the proposal: <ul style="list-style-type: none"> has clear objectives raises only minor concerns regarding study design will likely be successfully achieved 	the planned research: <ul style="list-style-type: none"> addresses an issue of considerable importance to human health could be the subject of invited plenary presentations at national specialty meetings may contain at least one innovative idea may result in several influential publications 	relative to opportunity, the applicant team: <ul style="list-style-type: none"> has a record of achievement, that places them well above average for their peers/cohort members are well recognized for their contributions to their fields of research members have growing national reputations and their research appears frequently at national meetings members have track records in fields relevant to the proposed research
4 Good	the proposal: <ul style="list-style-type: none"> is sound in terms of its objectives contains several areas of concern in the experimental design raises some concerns about successful completion. 	the planned research: <ul style="list-style-type: none"> addresses an issue of some importance to human health may have some novel aspects, while others underpin or extend existing knowledge. may result in some strong or influential publications 	relative to opportunity, the applicant team: <ul style="list-style-type: none"> members have solid records of achievement members have made contributions to their fields of research contains one or more CIs with an existing or emerging national reputation, albeit in a niche area members have track records that are consistent with the proposed research
3 Marginal	the proposal: <ul style="list-style-type: none"> is satisfactory in terms of its objectives, but may not be successful with all of them has a number of areas of significant concern contains several study design problems or flaws 	the planned research: <ul style="list-style-type: none"> addresses an issue of some concern to human health has relatively little novelty is not particularly innovative 	relative to opportunity, the applicant team: <ul style="list-style-type: none"> members have published a number of works in a field relevant to this application in the last 5 years, but many have been less productive than might reasonably be expected is deficient in some areas of expertise that will be required to successfully complete the proposed research members have limited track records in the field of the proposed research

Not Worthy of Funding

This table shows the percentage of applications received in 2010 and 2011 which were assessed to be in the fundable categories (4-7):

Category	7	6	5	4
2010	-	9.96%	25.12%	34.45%
2011	0.1%	8.40%	37.50%	49.50%