

## • **Strategic Review of Health and Medical Research**

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Submission on behalf of Monash University by

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

Article 25 of the United Nations Universal Declaration of Human Rights espouses the right to a standard of living adequate for health including medical care and necessary social services, together with in Article 27, the right to share in the benefits of scientific advancement. The Australian Government devotes substantial resources to the provision of health care making it one of the largest service sectors in our economy (9% of GDP and 17.6% of the Federal government budget). The Australian populace both in response to surveys, through their interest in the mass media and at the ballot box have consistently demonstrated that they view health services as important and that they expect not only that these services be of high quality but that they also improve in nature over time, providing new therapies, improved diagnostics and better health outcomes. Improvement in health care is achieved by harnessing the results of medical research.

Notwithstanding the fact that the majority of medical research is performed overseas, it is important for Australia to have a viable, competitive health and medical research sector (HMRS) for the following reasons:-

- 1) Australia has a moral responsibility as a wealthy country (13<sup>th</sup> of 20 by 2011 GDP in the G20) to participate in the collective activity of medical research for the benefit not only of its own citizenry but also for humankind in general. To take advantage of the work of scientists of other nations without contributing a fair share is inconsistent with our views of Australia's place in the world and of the behaviour fitting for an advanced nation. In particular as a regional leader we have a further responsibility to use our intellectual capital and our scientific infrastructure to contribute to the solution of health problems that affect our close neighbours.
- 2) Discoveries in health cannot be blindly applied within the Australian health system. The genetic makeup of our population, the environment in which they live, the way our health system functions and the economic circumstances that operate all affect the way a new health innovation may be implemented. The questions of best use of and the appropriate mix of therapeutic and diagnostic modalities must all be trialled and tested in Australian conditions by the medical research sector. A sector that is highly trained and using current research methodologies is essential. Similarly, research into the functioning of our current health system to identify best practice and ensure consistency of performance across a large country in a variety of practice settings is also extremely important and relies on the HMRS.
- 3) The HMRS is integral to the training of skilled health professionals who base practice on best available evidence and who utilise the habits of life-long learning to continually improve practice quality. Numerous studies demonstrate the importance of integrating research into education to achieve the highest quality in graduating practitioners. The world's most respected and best

universities are also those in which research is of prime importance and the continuing production of practitioners of the highest quality depends on a high quality HMRS.

4) Scientists of the HMRS are members of one of the new knowledge industries in which highly skilled professionals generate new knowledge. The technologies of modern laboratory science are directly transmissible to other areas of scientific enquiry that support diverse sectors of our economy such as the food and agribusiness sector, biotechnology, ecology and environmental activities and even to some degree mining, in the areas of processing and bioremediation. Because of its strength the HMRS is a major training site for scientists who can then work in a large number of different sectors. In addition, the HMRS takes advantage of the skills of mathematicians, IT professionals, engineers and chemists to form multidisciplinary working groups that develop solutions of practical importance and economic value. This in turn enhances capacity and skill level in our workforce.

5) The discoveries of the Australian HMRS is a source of great national pride. The achievements of Nobel Laureates and other high achieving researchers contribute to our sense of identity and of what we believe it means to be Australian. It increases our national self-esteem and promotes the status of Australia on the international stage.

What are the features of a viable and internationally competitive HMRS?

A viable, internationally competitive HMRS is based on the collective efforts of a number of institutions including universities, hospitals, both public and private, medical research institutes and biotech and pharmaceutical companies. Each of them has a particular role to play within the enterprise but we would like to note the pivotal role of universities. Universities not only engage in internationally competitive advanced research, they also train medical and other health practitioners, scientists and technical staff. By virtue of the training system, they are closely linked to both the private and public hospital system. The establishment of Advanced Health Science Centres across Australia will link the universities to hospitals and MRI's and we fully support the funding of such entities with a focus on improved health outcomes. Universities are locations that are highly conducive to the conduct of cross-disciplinary research involving Engineering, science, arts, economics etc. Particular opportunities attend the recruitment of mathematical modellers, quantitative economists and information technologists to build systems science approaches to improving our health system.

Other features of an internationally competitive HMRS is a broad discipline spread from basic sciences through to clinical and public health research to enable a fertile discovery base that supports active translation into improved clinical practice. A large number of basic scientific disciplines including biochemistry, cell and molecular biology, microbiology, the technologies of functional genomics, immunology and others melded with disciplines such as bioinformatics provide the environment for identification of new ways to improve health. This broad discipline base needs support along with the more applied medical research sector.

The following additional points are also relevant to this question: -

#### NATIONAL AND REGIONAL HEALTH NEEDS

- There are still many health inequities in Australia, particularly the continuing health gap between Aboriginal and Torres Strait Islanders and other Australians. Health research originating overseas is unlikely to address their needs or develop solutions that are workable in an Australian context. This can only come from locally performed research, informed by knowledge that is both national and international in character.

- As mentioned above, Australia not only has its own health needs that require Australian based and focussed research, it also must consider International health issues and contribute to the health of our region by properly referenced research. This research can be done in partnership such as the previous partnership of NHMRC with The UK-based Wellcome Trust and the Ministry of Research, Science and Technology and Health Research Council of New Zealand which was a major program, focusing on the health problems of developing countries in South and South East Asia and the Pacific region and aimed to promote collaborative research and training in these regions with Australia and New Zealand. Such programs address regional issues with the added bonus of also increasing the quality and skill of our national scientific workforce.

#### RESEARCH EXCELLENCE AND THE EDUCATION INDUSTRY

- The Excellence in Research for Australia (ERA) initiative has shown that Medical and Health Researchers in general operate either well above or above world standard confirming that we have the capacity within Australian Universities to conduct excellent research of the highest international quality. This has allowed Universities to attract some outstanding overseas researchers as conditions and funding slip in other countries due to the Global Financial Crisis and changes in policy. This builds the quality of our skilled workforce and improves the level of training to our students and health practitioners. It makes us able to attract increased levels of international funding and improves the standing of our universities.
- Medical research is an important and large component of national research activity that leads to the high international ranking of our research-intensive Universities. The international rankings of universities are an extremely important marketing tool and are likely to increasingly determine which universities are eligible to train international students. The higher education market is currently a major earner for Australia (currently attracting more than 250,000 international students, the third most in the world) and is one of our few successes in the export of services as opposed to goods. Our competitive standing in this valuable export industry would be compromised if Australia's research output declined with a consequent fall in university ranking.

#### WORKFORCE- Clinical, Health Educational and Research Leadership

- In the Australian healthcare system teaching hospitals provide the nucleus of expertise and understanding from which new knowledge spreads to private specialist, general practitioners and other health professionals. They fulfil this role by attracting opinion leaders who typically develop this role through medical research leadership. These individuals attract new staff from amongst the brightest graduates and play a major role in developing the high standing and prestige of these institutions. This in turn feeds into high quality patient care.
- In our health system considerable latitude is provided to clinicians to suggest or choose diagnostic and treatment strategies. For this reason students must be provided with critical evaluation skills that will allow them to provide appropriate advice and explain reasons to patients. This capability is largely confined to those with a medical research background. This is a principal reason why Universities seek to expose students to teachers who are accomplished in research as well as clinical practice.

- Virtually every area of medicine & healthcare, ranging from blood transfusion to water quality, is subject to rapid and continuous change. New information must be evaluated and where appropriate assimilated into healthcare at an ever increasing rate. Individuals with a medical research background are those primarily involved and capable of undertaking this task. Very few without strong research involvement have the credibility to contribute to this activity. Researchers are overwhelmingly represented amongst those providing information to government and industry on health related matters.

#### ECONOMIC BENEFIT

- The 2010 Intergenerational Report and the Australian Institute of Health and Welfare review of “Australia’s Health 2010” [1] articulated the unprecedented problems we face as our population ages. Our nation is becoming more obese and our risk profiles for diabetes, cancer and mental health disorders have never been greater. This will undoubtedly lead to an unsustainable, increase in health costs. Investment in research is needed to mitigate our future projected and unexpected health and economic challenges.
- Medical research brings economic benefits to Australia. The development of the HPV vaccine and the bionic ear, the commercial trials of new drugs and the products developed by CSL are widely appreciated examples. Another example from the applied area of clinical research is the ASPREE trial of low dose aspirin, funded by the US National Institutes of Health, is expected to bring over 30 million dollars to Australia over the next 5 years.

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

We have commented in the previous section on the features of a viable HMRS including the need for a diverse range of disciplines and skills situated in a broad range of institutions. Such a structure has the potential to be uncoordinated and care needs to be given to any redesign of the current system as it risks abandoning such important principles as merit-based funding, the primacy of the peer review process and increases the risks attendant on trying to “pick winners”. Nevertheless there are opportunities to structure the way research is performed so that critical mass is built for any particular project. The use of networks and partnership centres offers promise as long as criteria of researcher quality are paramount. Merely linking everyone with a declared interest and spreading the money around will lead to loss of quality and poorly focused research.

The level of funding of the HMRS does not compare particularly well with major countries overseas. Studies on optimal level of science funding such that good science is funded and poor science is not suggests that the appropriate level is somewhere around the 33% level, significantly above current HMR funding levels of 21%. Nevertheless there is little prospect of significantly increased Federal government funds in the current economic climate. Therefore funding increases if they are to come must be sourced from elsewhere. This could include state government, the private sector including superannuation funds, industry, philanthropy and international sources. The government should consider alterations to tax legislation and incentives of various sorts to encourage such funding. One interesting new development has been the introduction of partnership centres in which funding is obtained both from agencies such as the NHMRC and State or private sources and the funds are used to address problems of mutual interest to both funders. This model may be able to be deployed more widely with international and charitable institutions.

Notwithstanding some problems related to the processes of grant submission, the NHMRC in general has been competent in its management of the HMRS in Australia. Its processes focus on encouraging excellence by the peer review system, it has engaged in long-term strategic planning to focus on important health problems, it has attempted to develop sustainable support of research careers and it provides authoritative advice to government. Its processes work reasonably well given the low level of funding applied to administration. There is overlap between the areas funded by NHMRC and ARC and at present support of the sector can be compromised by failure to coordinate between the two agencies. This is particularly important in the case of funding of basic biological sciences that may have health implications.

The balance between people support and project support is a difficult one to get right. However at present it is clear that the tenuous nature of the career paths in the HMRS is such that it fails to recruit sufficient practitioner fellows who can combine basic and clinical research. In addition, careers in HMRS are insufficiently attractive to students choosing courses at university. This needs to be addressed as a matter of urgency. Issues that need examination include the duration of support of fellows and the age until which fellows are supported, the appropriate number of fellows to be supported at each level from early career researcher onwards and the balance between clinical and non-clinical fellows.

### **RESEARCH FUNDING**

- Alternative funds need to be considered. Government needs to engage the business world and implement a national investment in HMR. In Europe some countries are thinking of placing a levy on business profits, to be used to establish an investment bank. An HMR investment bank may be worth considering. Perhaps additional income could be generated from pharmaceutical companies selling products in Australia in a similar manner to the mining tax.

- There needs to be better tax incentives for industry and philanthropy to donate or invest in medical research. The Private sector may under such a scheme not actually ‘donate’ but be able to ‘invest’ in long-term research with translational outcomes.
- Grant schemes that partner with industry such as the NHMRC development/partnership grants and the ARC linkage grant scheme should not curtailed but rather expanded. Clarity within the ARC about their willingness to invest in health linkage projects would be welcome as there is considerable uncertainty presently and decisions are made without consultation with the NHMRC.
- Consideration should be given to more investment in “Partnership Centres” where 50% is funded by other stakeholders (Super funds, Govt, Insurance companies etc).
- **RESEARCH FUNDING MANAGEMENT BODIES - NHMRC and ARC**

#### *GOVERNANCE AND POLICY:*

- ARC and NHMRC report to two different government departments creating opportunities for a disconnect between schemes. Joint discussions so that ramifications of changes to ARC schemes on HMRS are necessary. Funding body rules such as ARC limiting NHMRC grantees to only one ARC grant application stifles the ability of researchers to form partnerships and collaborate.
- An examination of the need for both agencies may be worthwhile. Some countries e.g. Switzerland have one governing body for all research funding.
- Consideration should be given as to who are the appropriate stakeholders in NHMRC decisions and policies. Is it government, the HMRS, the health consumer, the taxpayer? How should the wishes of stakeholders be incorporated into NHMRC decisions including grant awards? These are difficult issues but a closer connection to the end user of the products of health research may strengthen the political consensus that supports HMRS funding. Increased community and consumer participation in development of policies and potentially even funding decisions is worthy of consideration; although care must be taken so factional interests do not hold that research captive.
- Commonwealth and State Government health departments seem disengaged from the research process, a notable difference to the situation in both Europe and North America. At present research is considered largely the province of the NHMRC, regardless of how closely aligned to the strategic needs of the healthcare system. The problem is compounded by frequent refusal to allow researchers to gain access to data, regardless of the importance of the public health issue or the appropriateness of the arrangements to manage confidentiality. Examples of the restrictions are the refusal of the electoral commission to approve most applications for randomised population samples and the refusal of the Australian Bureau of Statistics to provide causes of death.

#### *GRANTING BODIES, GRANT ROUNDS AND GRANTS MANAGEMENT SYSTEMS:*

- Consideration should be given to the merging of RGMS and RMS to create a National Grants Management System to increase efficiency and ease of application. This could lead to reduction in the costs of grant administration at the level of the institution and the granting agency, as well as freeing time among the research community for more creative pursuits.
- The almost simultaneous deadlines of the ARC and NHMRC act against the generation of high quality proposals. Consideration should be given to moving deadlines for one grant agency into the second half of the year, with funding distributed in line with the financial

year rather than the calendar year. Single annual application for funding bodies is not adequate and leaves holes in funding which are difficult to bridge. This is particularly so for industry related funding and the move to a single ARC linkage round is a retrograde step.

- Although funding for longer or shorter periods than three years is possible in the current system, in practice it proves to be extremely difficult and a very small minority of grants are given for periods other than 3 years in the case of project grants. Consideration should be given to allowing more flexibility in funding duration.
- The increasing focus at NHMRC on panels that are disease specific leads to decreasing support of the fundamental sciences that underpin much of the strength of Australian medical sciences. A dual approach is needed with separate discipline and disease focussed panels. This is not to say that e.g. biochemists or pharmacologists should not have a disease application for many grants – but that the expertise to assess these grants is less likely to be present at a disease focussed panel.
- Consideration should be given as to whether it would be beneficial to separate the basic and applied funding roles of NHMRC, as is the practice in the UK. One suggestion is that applied research should be the direct responsibility of health authorities and the development of a flourishing applied research sector should be made a direct responsibility of Health ministers to encourage more engagement.
- One unfortunate outcome of the situation that grants do not currently cover true research costs is that highly skilled scientists become too expensive to employ on grants. Career paths are truncated; good staff leave, leading to loss of productivity and constant retraining. The Review panel should strongly encourage the Federal government to persist with proposals to increase the level of infrastructure support associated with national competitive grants. This should not be sacrificed in the pursuit of the balanced budget.

#### *CAREERS FOR RESEARCH FELLOWS:*

- Research Fellowships need a better career path and it is particularly difficult to attract and retain the best people especially clinician researchers. It is much easier to enter the Fellowship scheme than to get a renewal as fellowship numbers decrease at senior levels meaning many researchers are pushed out. These issues are not new and were reported in “The Virtuous Cycle-Working together for health and medical research” (1998) [13].
- There needs to be better linkage between industry and academia for Fellows to move between the two. Also introducing a scheme to allow PhD candidates to spend time in industry would lead to a workforce more focussed on applied research and this could lead to better translational outcomes.

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

Identifying general principles to guide the strategic directions and priorities of health and medical research in this country is a complex process. There is general agreement that we need a focus on health problems that are common in this country and a cause of significant morbidity and mortality. Similarly, we need to have a focus on modifying the health system to meet the major demographic challenges of an aging population. There is also general support, we believe, for improvement in system science capacity so that the health system can be modified to run at its optimal capacity. Finally, many health interventions need improved methods at the primary health care level so that improvements in implementation science and behavioural change would also be extremely valuable, particularly in the addressing of diseases of lifestyle. At the same time there is a need to maintain a vibrant basic science environment as the engine room from which improved understanding of disease processes and how these may be modified can continue to be generated. Other factors to take into account are our regional responsibilities in utilising some of HMRS to address health problems of our neighbours who are not in a sufficiently advanced position to address their own needs. Similarly, a strong focus on indigenous health concerns is required. Finally, we need to maintain a strong capacity in infectious diseases such that threats from emerging and re-emerging infections as well as antibiotic resistant organisms can be met. Balancing these competing priorities is difficult and will require coordination with other funding sources, continuing reassessment of how funds are expended and the development of a multi-skilled flexible research workforce who can be redeployed as conditions demand.

- There needs to be more clarity around the National Research Priorities. Within each priority what are the key questions that need to be addressed? We can't do everything and the pool for funding is finite. Many countries have similar national health funding priorities. Australia needs to look where Governments can link together to bring together research teams and gain economies of scale. For example more research could be done on replacing propriety drugs with cost saving generic ones. For example the ASPirin in Reducing Events in the Elderly (ASPREE) trial at Monash University is a longitudinal randomised, double-blind, placebo-controlled trial in healthy elderly 70yrs and above. 20,500 subjects will be followed for 5 years to look at the effect of low-dose aspirin on reducing vascular disease, stroke & cognitive decline, healthy active lifespan. A co-ordinated transnational work plan could provide evidence to provide lower cost but equally efficacious care within our health system. Such studies will not be funded by private enterprise and the costs are probably too large for any single government. However the savings to be gained are substantial.
- Despite the Wills report [13] there are still huge barriers to development of clinician researchers, an important group in translation of discoveries into practice. More attention needs to be paid to research training schemes that have flexible entry and increased emphasis on skills training including clinical trial practice, biostatistics and experimental planning. Practitioner Fellowships have worked well and allow a leveraged funding model where not all salary is paid for by NHMRC as hospital/healthcare network also contribute.
- Since the Wills report [13], we have seen doubling of the NHMRC budget but there has been little change in the size of the HMR-related small businesses/biotech/services sector. Comparatively Denmark is a small country but has biotech and pharmaceutical industries (e.g. Novo Nordisk). Australia has excellent clinical scientists and engineers and yet we do little in the area of medical devices.
- Australia's economic burden associated with health and ageing is projected to increase to unsustainable levels of almost half of the total Federal Government expenditure by 2050 [1].



- Dementia is a significant health problem in Australia, with associated health expenditure projected to outstrip that of any other health condition by the 2060s. Delaying the onset of dementia by 5 years through Australian HMR will result in estimated savings of \$67.5 billion by 2040 [4].
- The pace of data collection throughout the health system has increased at a rapid pace. The ability to develop and analyse large healthcare databases is a specialised skill, which requires development over a long term. Capacity building is needed for undertaking such analyses and need to include teams of epidemiologists, biostatisticians, and data-managers.
- The pace of innovation in healthcare is accelerating, leading to new drugs, new devices and new diagnostic approaches. Unrelenting increases in the cost of healthcare have led to growth in measurement of the cost effectiveness of new treatments and technologies. This has spurred increasing interest in prioritisation of access to care and to comparative efficacy studies designed to establish the superiority (or lack thereof) of new innovations over established approaches. Finding a place for new innovations in clinical practice requires translational research activities. After introduction into practice, the ongoing monitoring of the safety of innovations, their cost-effectiveness and appropriate use will also be required. There is a need for capacity building to ensure researcher teams involve health economists and clinical researchers. There also needs to be improved linkages between basic and applied researchers
- Questions such as how best to target preventive medications and how best to assess their cost effectiveness will require a combination of skills drawn from epidemiology, epidemiological modelling, health economics and actuarial science. These and other skills involving social science, health policy and management, will also be required to measure the cost effectiveness of community based interventions and to compare their effectiveness with individual high risk approaches to treatment
- Improving the safety and quality of healthcare requires measurement using strategies such as clinical quality registries and various indices based on routinely collected administrative data. Epidemiology, biostatistics and clinical and health services research play a key role in the development of improved methods of measuring quality. New legislation and adverse legal findings are leading to increased safety monitoring and risk assessment of new drugs, devices and new clinical procedures. This will require the establishment of registries, cohort studies, data linkage and case-control studies.

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

This is a difficult problem that still awaits solution in Australia. Various governments have made attempts to improve translation. For example, the United Kingdom National Health Service announced a joint funding scheme of £100m with the Wellcome Trust to translate discovery into improvements in health care. Some years later the scheme has yet to make any contribution to health. One area of promise is the Advanced Health Science Centres which bring together universities, research institutes and hospitals to achieve better health outcomes. Although too recent in formation overseas for definitive benefits to yet flow, they have already clearly led to improvements in practitioner training. This scheme is certainly worth trying within Australia and should be appropriately funded. We have mentioned elsewhere the importance of increased numbers of clinician scientists and the importance of innovative schemes to encourage their training and retention in the public hospital system. Finally, improving health and wellbeing presupposes we can measure current levels of health system performance and that appropriate quality assessment is possible. This is not the case currently and greater investment in health registries and methods of assessing current outcomes together with effective means of dissemination of best practice is essential.

- There needs to be better communication of funding agencies supporting translational research. For example more should be done to market and promote the Australian Government initiative – ‘Commercialisation Australia’ and ‘Science and Technology Australia’. Researchers also need to know how source alternative funding sources and engage with regional projects such as the ones found on <http://grantslink.gov.au/>. There also needs to be more development and better communication around jointly funded research opportunities with other countries.
- There is a significant lack of support for translational research through medical research funding. There is NHMRC development funding which is project based and generally of just one or two years duration. Currently there is little support for the building of long-term relationships between industry and academia. Longer-term “linkage-like” schemes that support medical developments would be valuable.
- Improved clinician researcher career paths; promotion of alliances between institutions; integration of academic/research/clinical centres and introduction of more effective science research education to clinicians, and clinical education to scientists would all be valuable initiatives.
- Integration strategies have proven health and economic outcomes and can lead to better translation. For example, integrating prevention and acute health care services through Australian HMR, led to an 87% reduction in hospital readmissions for cardiac-related events, with substantial savings to the health care system [12].
- More should be done to which systematically collect information on treatments and their outcomes from hospitals across Australia and provide an opportunity to monitor and encourage the uptake of guideline via the development of clinical registries. Internationally there are numerous examples where the establishment of clinical registries has improved the uptake of evidence based treatment guidelines by informing clinicians when they are deviating from best practice or from the practice of their peers. Sweden is a country where clinical registries have been widely utilised and now cover approximately 25% of all healthcare encounters. The promotion of best practice by the 90 or so clinical registries in that country are thought to have reduced the growth of healthcare costs by approximately ½ of a per-cent, saving billions of dollars over a 10 year period. At present the Australian

Commission for Safety and Quality in Healthcare is developing a proposal for establishment of a program of key registries in Australia. If developed this scheme will play a key role in promoting this form of translation. The establishment of clinical registries however requires expertise in multiple skills related to 'registry science' which must be developed in this country. These skills include clinical epidemiology, biostatistics, ethics, governance and data-management. Advances in information technology have enabled data management of NHMRC expenditure to be mined for its projected health and economic benefits [9], as well as extrapolating returns on future increased investment [3].

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