Inquiry into improving New Zealand's environment to support innovation through clinical trials

Report of the Health Committee

Forty-ninth Parliament
(Dr Paul Hutchison, Chairperson)
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Contents

Inquiry into improving New Zealand's environment to support innovation through clinical trials

We instigated this inquiry because of concerns that New Zealand has lost its advantage as a good place to carry out clinical trials. Most submissions we received backed up this view and called for improvement. The main elements of the system can be put right at almost no cost, and we believe the returns for New Zealand patients, the health service, and the economy will be significant.

Recommendation

1 We recommend to the Government that it implement the recommendations of this report in order to achieve internationally competitive ethical review processes, holding patients' safety paramount; a simple process for the ethical and scientific review of single and multi-centre trials; and internationally cost-competitive services. This should be led by the Ministry of Health, and completed within six to 12 months of this report being presented.

Our key recommendations should be acted on urgently (within 12 months of this report's presentation) and aim to

- simplify and streamline ethical review processes
- promote collaboration between Government departments to coordinate the system
- develop a national health research action plan to foster innovation and commercialisation
- develop a framework for clinical trial research throughout district health boards, to be facilitated by a hub.

Summary of recommendations

The Health Committee makes the following recommendations to the Government:

Key recommendations

Simplify and streamline ethical review processes

- That it implement the recommendations of this report in order to achieve internationally competitive ethical review processes, holding patients' safety paramount; a simple process for the ethical and scientific review of single and multi-centre trials, and internationally cost-competitive services. This should be led by the Ministry of Health, and completed within six to 12 months of this report being presented. (p. 5)

Collaboration between the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise

- That it establish a strong collaborative framework between the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise to coordinate and promote as efficiently as possible clinical trial activity in New Zealand, through both the public and private systems, to assist personal health as well as economic growth. There should be a progress report to the Government within nine months of this report being presented and the framework should be achieved within 12 months of this report being presented. (p. 25)

National health research action plan that fosters innovation and commercialisation where appropriate

- That it ensure that a culture that values research is embedded in the New Zealand public health system, by forming a national health research action plan to foster innovation and commercialisation where appropriate. The national health research action plan should be developed by the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise. The national health research action plan should be implemented by a single agency, for example the National Health Board or another agency, to ensure cross-sector collaboration. This recommendation should be achieved within nine months. (p. 26)

National framework for clinical trial research through district health boards

- That it establish a national framework for clinical trial research at district health boards. (p. 43)

Build constructive and transparent relationships with the international biotechnology and pharmaceutical industries

- That it work with the pharmaceutical industry to establish, within 18 months, a body to facilitate liaison between the Government and the pharmaceutical industry. (p. 40)
- That it make efforts to build constructive, professional, and transparent relationships with the international biotechnology and pharmaceutical industry through innovative mechanisms that do not undermine Pharmac's role of purchasing pharmaceuticals at the best possible value. (p. 40)

Ensure excellent scientific infrastructure to run clinical trials

- That it ensure that scientific infrastructure is regarded as a core part of New Zealand's basic infrastructure. (p. 26)

Establish a long-term objective in research and development investment

- That it establish a long-term objective of bringing New Zealand's public and private investment in research and development up to international benchmarks (including research and development relating to clinical trials when benchmarks are available). (p. 26)

New Zealand to urgently assess Australian and United Kingdom clinical trials reports

- That it assess the Australian Government's Clinical Trials Action Group's report *Clinically competitive: boosting the business of clinical trials in Australia* urgently, with a view to ensuring that the New Zealand systems are at least as efficient and effective as the Australian systems, if not more so, by the end of 2011. (p. 27)
- That it formally review the United Kingdom Academy of Medical Science's report *A new pathway for the regulation and governance of health research.* (p. 27)

Ethics committees

- That it ensure that the current robustness of the clinical trials ethics evaluation is preserved with respect to patient safety, and where necessary is strengthened. (p. 29)

Timeliness of approvals and setting expectations

- That it remove duplication in the processes carried out by the Health and Disability Ethics Committees, the Standing Committee on Therapeutic Trials, and district health boards, and in consulting with Māori. (p. 32)
- That it monitor as a performance measure the time taken by Health and Disability Ethics Committees to process applications. The Health and Disability Ethics Committees should process expedited reviews within 30 calendar days, and other applications within 45 calendar days. (p. 30)
- That it require the Health and Disability Ethics Committees to widen the access to expedited review so that intervention studies, including clinical trials, are eligible for such review. (p. 31)
- That it require ethics committees to meet as frequently as needed to achieve best-practice timeliness. (p. 31)
- That it require the Standing Committee on Therapeutic Trials to carry out all scientific reviews within 30 calendar days. (p. 30)
- That it set up a central clearing house for the Health and Disability Ethics Committees. The clearing house should distribute applications to the appropriate committees in a timely fashion. (p. 34)
- That it permit researchers to make minor changes (as guided by best practice) to the application form, with notification to the Health and Disability Ethics Committee. The changes should be at the discretion of the Chairperson of the ethics committee. (p. 33)

Process of application, format, and forms

- That it implement a system of electronic submissions of clinical trial applications to make the application process more efficient, within 12 months of this report being presented. (p. 33)
- That it require that the Health and Disability Ethics Committees update and review application forms to remove any text that is repetitive or ambiguous. (p. 33)

- That it establish comprehensive standardised operating procedures for Health and Disability Ethics Committees, to ensure consistency in decision-making within and between ethics committees. (p. 32)
- That it instruct the National Ethics Advisory Committee or the Ministry of Health to make clear guidelines for ethnic and Māori consultation within nine months of this report being presented. The guidelines should be clearly aimed at maximising protection, expertise, and efficiency, and should clarify the purpose of Māori consultation. (p. 32)
- That it introduce a facility for preview of all applications to Health and Disability Ethics Committees, the Standing Committee on Therapeutic Trials, and the Gene Technology Advisory Committee. (p. 33)
- That it ensure that any fees charged by ethics committees in the processing of applications for the approval of clinical trials represent good value for services rendered, that unnecessary compliance costs are not imposed, and that fees are internationally competitive. (p. 35)
- That it assess the options for charging fees for ethics committee review. (p. 35)

Nature and configuration of committees

- That it consider restructuring the Health and Disability Ethics Committees and revising their member categories on the basis of study type, differentiating between clinical trials and other sorts of studies. (p. 34)
- That it reduce the membership of the ethics committees from the current 12 to eight, allowing the Chairperson to co-opt for expert advice. (p. 34)
- That it require that all members of the ethics committees have the appropriate technical or clinical training to understand the matters they are dealing with by instituting a training programme for new members. (p. 34)
- That it ensure the Health and Disability Ethics Committees are resourced appropriately. (p. 35)
- That it consider establishing a new dedicated ethics committee for sponsored clinical research with an application fee charged, on a cost-recovery basis. This new committee should come under the existing Health and Disability Ethics Committee umbrella, and should be highly efficient in processing applications. (p. 35)

Australian Clinical Trials Notification and Clinical Trials Exemption system

- That it review international approaches to the regulatory review systems, in particular the Australian Clinical Trials Notification and Clinical Trials Exemption system, with a view to adopting the most efficient and robust system that would align with other countries' regulatory systems. Following this review it should establish a streamlined regulatory approval process for applications that have already been approved by the United States of America Food and Drug Administration, the European Medicines Agency, or have gone through the Australian regulatory process. (p. 36)
- That it carry out the necessary work towards greater alignment with the Australian system where it is appropriate. (p. 36)

The role of Pharmac

- That it require Pharmac to consider, within 18 months, developing a pharmaco-economic analysis expertise on clinical trials which could be used by pharmaceutical companies on a fee-for-service basis to evaluate the prospective value of medicines being trialled (similar to the service provided by the National Institute of Clinical Excellence in the United Kingdom). (p. 39)
- That it require the Ministry of Health, the Ministry of Science and Innovation, and the Ministry of Economic Development to develop, within 18 months, a model to establish an innovation fund for co-sponsoring with pharmaceutical companies, specific clinical trials involved in research aimed at health issues specific to New Zealand's population. Pharmac should not be involved in the funding or management of the funding but could have representation on a research allocation body. (p. 39)
- That it work with the pharmaceutical industry to establish, within 18 months, a body to facilitate liaison between the Government and the pharmaceutical industry. (p. 40)
- That it make efforts to build constructive, professional, and transparent relationships with the international biotechnology and pharmaceutical industry through innovative mechanisms that would not undermine Pharmac's role of purchasing pharmaceuticals at the best possible value. (p. 40)

District health boards

- That it establish a national framework for clinical trial research at district health boards. (p. 43)
- That it work with key clinical leaders to develop a well-coordinated national strategy for clinical trials and research at district health boards. The strategy should be endorsed by the Ministry of Health, and establish that research is a core activity undertaken by district health boards. There should be formal coordination with private clinical research service providers. (p. 43)
- That it require both public and private sector clinical trial sponsors to have secure indemnity agreements, representing international best practice. (p. 41)
- That it encourage district health boards to conduct clinical trials by introducing key performance indicators relating to timeliness and the cost and efficiency of carrying out clinical trials. (p. 44)
- That it require district health boards to remove duplication in the ethical review process. (p. 41)
- That it require district health boards to adopt an aligned approach when implementing nationalised agreements with sponsors engaged in multi-site clinical trials. (p. 44)
- That it establish the appropriate and sustainable infrastructure to support clinical trials. (p. 44)
- That it encourage clinicians to undertake clinical research through incentives or funding, and make provision for them to receive incentives similar to those available to university researchers. (p. 44)

- That it fund district health boards to undertake clinical research as a front-line activity. (p. 44)
- That it allocate funding to district health boards for the purchase of technology needed to conduct clinical trials. (p. 45)
- That it implement a simplified, optional standard clinical trial agreement for all applications within 12 months. (p. 41)
- That it standardise the processes and documentation required by district health boards. (p. 42)

Improve the coordination of the clinical trials sector

- That it require clinical trials conducted solely in New Zealand, clinical trials that are New Zealand-led, and international studies that are partially conducted in New Zealand to be registered with the Australian New Zealand Clinical Trials Registry. (p. 47)
- That it work with key clinical leaders to develop a well coordinated national strategy for clinical trials and research at district health boards. The strategy should be endorsed by the Ministry of Health, and establish that research is a core activity undertaken by district health boards. There should be formal coordination with private clinical research service providers. (p. 43)

Public funding of clinical research

- That it ensure the Health Research Council of New Zealand has enough flexibility in its functions to promote innovative scientific health projects that are likely to have economic benefits for New Zealand. (p. 51)
- That it set a medium-term objective of bringing New Zealand's public and private investment in research and development up to international benchmarks. (p. 51)
- That it give priority to achieving optimal clinical trial frameworks, infrastructure, and coordination in New Zealand within 12 months of this report being presented, and make funding available for this purpose. (p. 52)
- That it consider purchasing research infrastructure relevant to supporting clinical trials, and make every effort to ensure that it is used on a coordinated national basis so that as many institutions as possible can benefit from the investment. (p. 52)

Promote New Zealand as an environment in which to conduct clinical trials

- That it continue to establish innovative incentive schemes to support public and private research and development through clinical trials where a clear benefit to New Zealand can be demonstrated. (p. 54)
- That it promote New Zealand Trade and Enterprise's action plan to establish New Zealand as an intelligent global niche player in the clinical trials industry. (p. 54)

1 Introduction

Clinical trials of medicines, medical devices, and other therapies are aimed primarily at benefiting those suffering ill health. This inquiry has shown clearly that clinical trials are beneficial to patients, clinicians, medical scientists, innovators, and workforce recruitment as well as to the health standards in the countries in which they are carried out.

In 2009 the National Ethics Advisory Committee's annual report included the following summary statement of the importance of clinical trials:

> Evidence from clinical trials is a fundamental driver of innovation, patient safety and improved care. In general, it is at least as safe and beneficial for patients to receive care in a clinical trial as it is outside a clinical trial, because care in such trials is more systematically planned, delivered, monitored and followed up. Clinical trials can bring treatments to clinics before they would otherwise be introduced. Additionally, healthcare organisations that are active in clinical research generally practise excellent patient care and have high retention of key clinical staff. (p. iii)

Over the past few decades bioactive and functional foods have become increasingly prominent and are likely to be subject to more demand for proof of their efficacy and safety from clinical trials. This sector is of particular importance to New Zealand. The clinical trial industry also provides pivotal support to other New Zealand industry sectors. All the major markets in the world where products are sold with therapeutic claims require clinical data to attest to their safety and efficacy. Food exports are New Zealand's largest industry. Clinical trials could be used to demonstrate the functional value of specific foods and bioactives, which would serve to increase the production and export of value-added food products rather than primary food exports.

We heard various estimates of the amount generated by the clinical trials industry in New Zealand over the last few decades. There appear to be no accurate records. We were told by our specialist adviser Cranleigh Health that 10 years ago pharmaceutical trials in New Zealand were generating in excess of $100 million. The Health Strategic Initiatives Review Committee told us that the industry's annual review indicates that New Zealand's aggregate annual clinical trial revenue is now less than $30 million. The Researched Medicines Industry Association, however, told us that the figure would be higher than $30 million, as it has determined that more than $30 million was spent on research and development in 2009 by only six of its member companies. We understand that Merck Sharp & Dohme (New Zealand) Limited estimate that total industry expenditure could be more than $45 million annually. By contrast with the most optimistic estimate of New Zealand's income from trials, Australia has a clinical trial industry with an annual value of AU$450 million from clinical trials of pharmaceuticals alone. The significant reduction in the value of the New Zealand clinical trial industry is indicative of a weakening competitive advantage.

There has been strong criticism of the environment for conducting clinical trials in New Zealand. Professor Shaun Holt argues, "Our ethics system has become so unwieldy it is unethical…the process has grown into a hugely complicated bureaucracy, that has lost touch with its original aims".[1] Others have pointed out a lack of coordination between New Zealand's DHBs, friction between Pharmac and pharmaceutical companies, a lack of investment in science, research, and development in general, and a lack of modern technical infrastructure.

We believe that New Zealand's current clinical trial environment already has many of the key requirements for successful development in this area. They include patients who have not been exposed to medicines previously, diverse patient groups, ethnic sub-population groups, and an English-speaking health sector with high ethics and well-respected physicians. We were told that many New Zealanders wish to participate in research for its benefits to themselves or to others in their situation. However, New Zealand is not maximising the clinical trial opportunity and the benefits it can deliver.

Benefits derived from clinical trial activity flow on to deliver broad health, workforce, educational, and financial benefits to the health sector. They also have significant "spillover" effects for similar industries, and can be a key to the growth of the medical device, biotechnology, and functional food or food for health industries. In fact, without such a clinical trial infrastructure these industries will struggle to build momentum. In addition, low investment in clinical trials can have an adverse effect on health service delivery and patients' outcomes.

Other countries have developed a competitive, organised clinical trial industry by investing in the activities that broadly provide an optimal trial environment. Competition for clinical research studies in the Asia Pacific region is increasing, as South Korea, Hong Kong, Singapore, and Taiwan provide favourable conditions for such research.

In 2010 the Australian Government appointed an action group to cement Australia's position as a good place to conduct clinical trials. We consider it vital that New Zealand's environment for clinical trials should be as good as, if not better than, Australia's.

We believe New Zealand should fulfil its potential for clinical trials. Cranleigh Health has estimated that by 2020 New Zealand could generate revenue of $250 million annually from clinical trials for basic medical research, and attract $50 million from other sources. We understand that the medical device and functional foods industries could each generate billions of dollars a year in export revenue. We agree unequivocally and unanimously, however, that that the rigor of the ethics approval process must remain paramount. The National Ethics Advisory Committee was clear that while ethics committee standards are high, their process could be improved. We are extremely conscious of the lessons learnt from the Cartwright, Gisborne, and Greenlane inquiries. There is wide agreement that the current robustness of the clinical trials ethics evaluation process must be retained, if not strengthened.

[1] "Our ethics system is now so unwieldy, it's unethical", *New Zealand Herald,* 2 March 2009, p. 11.

Terms of reference

Our inquiry considered how to bring about

- coordinated nationwide approaches to clinical trials and performance measures
- streamlined ethics approvals systems
- national patient referral networks, and better ways to approve, establish, and conduct clinical trials
- the removal of unnecessary barriers
- benefit to New Zealand patients, as well as the New Zealand innovation system, health system, and economy through clinical trials.

Our report summarises our findings. We also heard from Professor Peter Gluckman on how to improve New Zealand's environment for clinical trials to support knowledge-based innovation, to improve both healthcare and economic growth.

We consider New Zealand has a significant opportunity that should be acted on now to make it a much better place to carry out clinical trials, not only for pharmaceuticals, but also medical devices, functional foods, and bioactives. It is important that the Government take note of the details of this report.

Terminology used in this report

Clinical trial	Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to medicines, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, and others (World Health Organisation 2011).[2]
Clinical trial phases	In general, clinical trials are required for pharmaceuticals, biotechnology and medical devices to test them in human populations for safety (phase 1), efficacy (phase 2), and comparison with existing interventions (phase 3). • Phase 1 trials look at whether a trial treatment is safe or has any harmful effects. The research team will also find out the best dose to use. • Phase 2 trials look at how well a treatment works. Only a treatment that has got through these two phases goes into phase 3 testing.

[2] World Health Organization, 2011, Health Topics–Clinical trials, http://www.who.int/topics/clinical_trials/en/, last accessed 2 March 2011.

	• Phase 3 trials test a new treatment against the existing standard treatment. If it gives better results, it may become the new standard treatment. Phase 4 trials may be carried out post-approval or licensing of the drug or medical device to record the long-term term risks and benefits of the drug or device, collect information about any new side-effects, or to identify other possible uses of the drug or medical device. Each phase progresses to larger populations. Phase 3 and 4 studies can involve tens of thousands or hundreds of thousands of patients in multiple countries.
Functional food	Similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions (Health Canada 1998).[3]
Bioactives	Compounds that confer, or have the potential to confer, physiological or health benefits to people, animals, and plants (Foundation for Research Science and Technology 2007). [4]
Biologics or biological products	A wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available (United States of America Food and Drug Administration, 2011). [5]

[3] Health Canada, 1998, *Policy paper–Nutraceuticals/functional foods and health claims on foods,* http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/nutra-funct_foods-nutra-fonct_aliment-eng.php, last accessed 20 May 2011.

[4] Foundation for Research, Science, and Technology, 2007, *Bioactives domain review,* http://www.frst.govt.nz/files/Bioactives_Jul2007.pdf, last accessed 20 May 2011.

[5] United States of America Food and Drug Administration, 2011, *What are "biologics" questions and answers,* http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm133077.html, last accessed 2 March 2011.

Nutraceutical	A product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease (Health Canada 1998).[6]

[6] Health Canada, 1998, *Policy paper–Nutraceuticals/functional foods and health claims on foods,* http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/nutra-funct_foods-nutra-fonct_aliment-eng.php, last accessed 20 May 2011.

2 The benefits of clinical trials to New Zealand

We understand that the principal objective of undertaking clinical trials is to find safe and effective health interventions that can be used to improve the health of individuals and populations. This objective must be achieved in a way that ensures that participants in clinical trials are fully informed and safe.

Research on the benefits of clinical trials

We were interested in the research carried out by Lyn Murphy and William Maguire, and their subsequent paper *Quantifying the benefits and costs of conducting sponsored clinical trials: some preliminary results.*[7] The paper identifies the benefits and costs of sponsored clinical trials in a publicly-funded New Zealand hospital from the viewpoints of the Centre for Clinical Research and Effective Practice, the Counties Manukau District Health Board, and society in general. The study examined two clinical trials over an eight-year period, which included the pre-trial, trial, and post-trial stages. The clinical trials were long-term phase 3 randomised, controlled clinical trials designed to assess preventative medicine for patients at risk of serious cardiovascular events. The control group (those not on a clinical trial) were matched, and met the entry criteria for the clinical trials.

Research results

For the centre, undertaking clinical trials is financially worthwhile, and it has a net present value to the organisation of $201,363 between 2001 and 2009. The Counties Manukau DHB received benefits from undertaking clinical trials, including cost avoidance (in the form of pharmaceuticals, laboratory testing, and chronic care management). Although the DHB also had some indirect costs from undertaking the trials, its involvement was still marginally worthwhile, with a net present value of $10,019. New Zealand society received considerable benefit as a result of the two clinical trials. The decreased mortality rate for the participants in the clinical trials, as opposed to those not on the clinical trials, resulted in a saving of over $5 million. Overall, the results of the research demonstrate definite benefits from the two clinical trials. The authors of the research caution, however, that the results may not be generally true for other clinical trials or clinical research organisations.

Benefits for patients

Patients who participate in clinical trials may receive

- new medicines and treatments
- better or more intensive medical care than they would otherwise
- education about their conditions to help them to manage their health better.

[7] http://w3.manukau.ac.nz/aaac/ARA_2010_papers/Murphy_Maguire.pdf, last accessed 6 May 2011.

Benefits for the health system

We heard about the benefits a clinical trials industry could provide for clinicians, and for the health sector in general. We were told that clinical research helps to attract and retain many able and creative doctors. Although New Zealand cannot provide medical salaries that are competitive internationally, it might be able to attract staff by offering the New Zealand lifestyle combined with the professional satisfaction of working on cutting-edge, high-quality clinical research. Working on clinical research keeps clinicians abreast of international best practice. We consider that one of the most important benefits of conducting clinical trials is its contribution to establishing an evidence base to secure affordable and effective healthcare. Manufacturers of products undergoing clinical trials may also reduce costs for DHBs by providing patients with free supplies of the medicines, and by contributing to their overhead costs.

Educational benefits

We were told that clinical trials bring various educational and professional development benefits for those involved:

- Specialist clinicians further their professional development and participate on the world stage when involved in clinical trials.
- Junior doctors who are involved in clinical trials often go on to be leaders in their fields.
- Recognising clinical trial activity would help retain New Zealand clinical researchers and scientists.
- A culture of cutting-edge medicine and innovative practice would allow New Zealand to retain the most able and creative doctors.
- Clinical trials are important for the retention and recruitment of senior clinicians.

Benefits to the economy

As outlined in the introduction to this report, we are confident that if the environment in New Zealand is made ideal for carrying out clinical trials, the amount of money generated for the economy could grow to hundreds of millions of dollars. A report prepared for New Zealand Trade and Enterprise found that

- for each $1 million spent on the biotechnology industry a further $1.03 million is created in the economy, resulting in a total output of $2.03 million
- for each $1 million of direct gross domestic product from the clinical trials industry, a further $950,000 is generated, resulting in a GDP multiplier for the industry of 1.95
- for every full-time equivalent job in biotechnology, a further 2.41 jobs are created in the broader economy, representing an employment multiplier for the industry of 3.41. [8]

[8] Norman, David, and Nana, Dr Ganesh, *2009 Multipliers for the Biotech and Biotech-active Industry in New Zealand*, BERL, Wellington, 2009.

There are no studies of the economic multiplier effects of clinical trials but it is reasonable to expect that they would be at least the same as the biotechnology sector in general.

Many participants in clinical trials receive positive health benefits. The value that clinical trials in New Zealand can contribute to quality-adjusted life years per capita has not been quantified.[9] It would be informative to quantify the clinical trial impact. Murphy and Maguire assess the benefits of health outcomes for the case group and control group in two clinical trials in their report *Quantifying the benefits and costs of conducting sponsored clinical trials: some prelimary results.*[10] They calculate the value of statistical life years saved over the period of the trials to be over $5 million. At a high level, the financial benefits of clinical trials include the following:

- Clinical trial research can contribute to reducing costs in the health system.
- Clinical trials could add significant value to New Zealand-generated intellectual property. The demonstration of a clinical application will almost certainly increase its economic value and consequently lead to more attractive technology licensing and trade sale options.
- Clinical trials can make large cost savings where there are distinct populations (such as Māori and Pacific Island communities) who respond differently to certain treatments.
- Pharmaceutical companies engaged in clinical trials have a history of supporting specialist teams of researchers (for example, Pfizer supporting cancer research at the University of Auckland).
- Two tranches of money can be retained by DHBs—a percentage of the trial cost charged as an overhead, and the trial surplus. This could represent more than 25 percent of the trial cost. These retained earnings provide funding for specific internally run trials led by the DHB's clinicians (who may be incentivised by the rewards of participation).

Study: A study was undertaken in the USA to derive an indication of the financial benefits of clinical trials. The study reviewed all phase 3 randomised trials funded by the US National Institute of Neurological Disorders and Stroke before 1 January 2000. The analysis indicated that for every dollar spent on clinical trials and associated costs, there was at least a four-fold net economic benefit to society. After 10 years, the programme of trials resulted in an estimated additional 470,000 quality-adjusted life years at a total cost of US$3.6 billion. Valuing a quality-adjusted life year per-head gross domestic product, the projected net benefit to society after 10 years was US$15.2 billion.[11]

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[9] Quality-adjusted life years is a health index; a year in perfect health is equal to a one QALY, while death is zero QALY, and the value of a year of ill health is discounted. For example, a year with gastric cancer might have a value equal to 0.5 QALY.

[10] http://w3.manukau.ac.nz/aaac/ARA_2010_papers/Murphy_Maguire.pdf, last accessed 6 May 2011.

[11] Johnstone, Dr S Claiborne, Rootenberg, Dr John D, Katrak, Shereen, Smith, Wayne S, Elkins, Jacob S, "Effect of a US National Institutes of Health programme of clinical trials on public health and costs", The Lancet, Vol. 367, Issue 9519, 22 April 2006, p. 1319.

Table 1 Summary of the benefits of clinical trials

Benefits	Summary
Health benefits	Patients have access to new medicines. Patients receive a higher standard of care. DHB staff involved in clinical trials gain additional knowledge which can be applied to benefit other patients.
Financial benefits	A USA study projects for every dollar spent on clinical trials at least a four-fold projected net economic benefit to society.[12] Positive clinical trial data adds significant value to intellectual property generated in the biotechnology, pharmaceutical, medical device, bioactive and functional health food sectors. Phase 4 studies can lead to cost-savings by determining which sub-populations (for example ethnic groups) respond to specific medicines. Pharmaceutical companies engaged in clinical trials may also support academic research. DHBs can derive income by taking a fee as a percentage of the clinical trial cost, or retaining any surplus. Clinical trials can add significant value to bioactive and functional health foods by supporting health label claims, attracting premiums in overseas markets.
Educational benefits	Specialist clinicians involved in clinical trials benefit by learning and the opportunity to develop a global presence in their fields. Top clinicians seek to engage in clinical research and are likely to stay in New Zealand if offered the opportunity to conduct clinical research as an integral part of their employment.

Value of clinical trials to devices, food, and bioactive sectors

The clinical trial industry also provides pivotal support to other New Zealand industry sectors. All major markets in the world where products are sold with therapeutic claims require clinical data to support their safety and efficacy. New Zealand needs an efficient clinical trial environment to allow the growth of emerging industries in the medical devices, health IT, functional foods, and nutraceuticals sectors. Clinical trials will be required to

[12] Ibid, p. 1319.

validate new products in these sectors as a prerequisite to capital support for growth and export.

New Zealand has an increasingly large functional health food/bioactive industry. Health ingredients and functional health foods are the fastest-growing sectors of the New Zealand food industry. Clinical trials can be used to support label claims to the extent allowed by various jurisdictions.

The ethical review process for trials involving functional foods is the same process as for a therapeutic clinical trial. The trial process for functional foods should be rationalised, with the removal of irrelevant requirements such as toxicology studies on food with a long history of safe consumption.

Food exports are New Zealand's largest industry. Clinical trials can be used to demonstrate the functional value of specific foods and bioactives, which can increase value-added food exports rather than primary food exports. Investment in infrastructure including database development and high-tech equipment to measure the chemical composition of food can complement the data generated from clinical trials.

Medical devices

Clinical data is sought throughout the product development cycle of medical devices. The depth of ethical review of medical device trial applications varies depending on the class (1, 2, or 3) of the medical device, as defined by the United States' Federal Drug Administration. For example, a class 1 device might be an arm sling and a class 3 device could be an inflatable cardiac stent. During the clinical trial of a medical device a minor change may be made by the manufacturer. An expedited ethics review should be possible when there are very minor changes to a device that has already received ethics approval.

Consumer rights in clinical trials

Participants in clinical trials enjoy all the protections of New Zealand law and policy. This includes all the protections established by the Code of Health and Disability Services Consumers' Rights 1996. The National Ethics Advisory Committee has observed that participants in clinical trials benefit at least as much as similarly placed people who do not participate in clinical trials, and are as well protected. Sponsors and investigators in clinical trials must ensure that injuries to participants attract at least ACC-equivalent compensation where participants do not have access to ACC itself (as is the case in many clinical trials).

The Women's Health Action Trust told us that the New Zealand systems regulating clinical trials were designed to protect patients' rights and safety, following cases in which these principles were disregarded. The 1988 Report of the Cervical Cancer Inquiry (also known as the Cartwright Inquiry Report) asserted that new knowledge could be sought in a system in which the protection of research participants was paramount. The report recommended that "A system focused on the protection of patients and independent of the hospital should be set in place."

The Women's Health Action Trust is concerned that the emphasis in the ethics review system and culture has shifted so that the benefits and opportunities of research are given more weight than the risks to the participants. It also observed that there is an emerging

belief that, because research is used for the common good, individuals are obliged to contribute by participating in it. We are aware that New Zealand already adopts international technical requirements that ensure the balance of safety is in the patient's favour.[13]

Potential conflicts of interest

We were interested to hear the Women's Health Action Trust's concerns about the ethics review system. The organisation told us that although the independence of the Health and Disability Ethics Committees has been strengthened, it does not approve of their administration by the Ministry of Health. It considers that this position leaves the ethical review process vulnerable to political pressures, especially because the Ministry of Health also facilitates research.

The Women's Health Action Trust also foresees risks if commercial principles are introduced in the fiscally constrained health system. It pointed out that if health organisations and health professionals are paid to recruit participants for clinical trials, this might result in their persuading people to take part, rather than informing them fully and leaving them free to make a decision. If participants are paid, the Women's Health Action Trust is concerned that people on lower incomes might be vulnerable to pressure. Submitters told us that in New Zealand it was generally easy to recruit people to participate in clinical trials because they felt they were helping others.

Transparency of ethics committee decisions

The Women's Health Action Trust told us that it is difficult for members of the public to scrutinise the actions of the ethics committees, as finding details of the committees' agendas and minutes is a complex and frustrating task. We heard that the Women's Health Action Trust supports the regional focus of the ethics committees, but is concerned that some applications that involve issues of national importance have been considered regionally, diminishing the opportunity for public discussion and debate. We also heard views that any new operational standard for the ethics committees should follow a process of public consultation. Some ethics committees may lack understanding of medical devices and the way they are developed, and of their relative risk compared with medicines.

Risks for participants

Although clinical trials can offer the hope of being first to use a new therapy, there are potential disadvantages for participants. A patient may be in the control group, which is treated with a placebo, or the new therapy may damage their health. Patients need to go into a trial with their eyes wide open, and with clear, informed consent. Medicines New Zealand told us that if there was any risk of harm arising from a person not being treated, subjects would be given current standard treatment in addition to a placebo. Safeguards are built into clinical protocols routinely where the absence of active treatment might harm a patient.

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[13] New Zealand is an active observer of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for clinical research.

We understand that trials are normally testing the new intervention against the current standard of care; therefore the patient is rarely in a situation of receiving a placebo unless there is no current standard of care.

The Women's Health Action Trust told us of its concerns about the potential abuse of power by clinicians during clinical trials, but we consider that this risk is best managed through effective systems for regulatory and ethical review, as well as review and monitoring by the institutions hosting the trials. After a trial has achieved ethical approval, the potential for abuse of power would be no different to that risk within the rest of the health system.

3 Creating an effective clinical trials environment

We recognise that the market for clinical trials is competitive. The clinical trials industry is global, and easily transferable. Developing countries are seen as attractive places to conduct clinical trials because of their improving educational and healthcare infrastructures, and relatively low costs. We heard that emerging countries like India and China have problems with safety and quality, and that New Zealand could promote itself as more similar to the European Union and the United States of America in these respects while still offering a relatively cost-effective environment. New Zealand needs to improve its scientific infrastructure to help drive economic growth.

We understand that the following are the key requirements for an effective clinical trials environment:

- trained and motivated medical staff
- internationally compliant ethical review processes, with patients' safety paramount
- accessible anonymised electronic medical records which can be searched for data
- a simple process for the ethical and scientific review of a multi-centre trial
- the capacity for a trial to undergo the processes for ethical approval, scientific review, and any other necessary scrutiny simultaneously, for example by the Gene Technology Advisory Committee
- new patient populations who had not previously been treated for a number of conditions being researched
- internationally cost-competitive service
- a national publicly funded healthcare system, to allow the establishment of a national network for access to patients
- the ability to recruit and retain patients
- Government support.

New Zealand's strengths and weaknesses

We believe that the investment that New Zealand makes in research and development, including the clinical trial industry, is low relative to the OECD average. Countries such as Singapore and South Korea implemented a strategy of investing in their medical-technology industries 15 years ago. Today both have strong revenue-generating medical-technology business sectors.[14] New Zealand has strong capabilities for conducting phase 1 and phase 2 trials and can clearly also run larger later-stage trials.

[14] Submission from Roche Products New Zealand Limited April 2010.

A compelling statistic is the low level of private and Government investment in research and development in New Zealand as a percentage of GDP (see table 2 below).

Table 2 Comparison of New Zealand, Australia, and OECD investment into research and development

Geographic region	Government-financed research and development as a percentage of GDP	Business-funded research and development as a percentage of GDP
New Zealand	0.5%	0.47%
Australia	0.77%	1.36%
OECD average	0.65%	1.46%

Compared with other OECD countries against which New Zealand benchmarks itself the New Zealand public investment in the medical research sector is low. The New Zealand clinical trial sector suffers as a result of this low investment. According to OECD biotechnology statistics New Zealand did not have any biotherapies or experimental biotherapies in clinical trials in December 2007. This can be compared with 393 in the United States, 70 in the United Kingdom, 25 in Denmark, 15 in South Korea, and 14 in Australia. Biotherapies include large molecule recombinant proteins such as enzymes, hormones, and monoclonal antibodies. Biotherapies are one type of human therapeutic. NZBio's SIGHT report indicates that New Zealand had 12 human therapeutic products in clinical trials in 2008.[15]

We were told that New Zealand's public funding in biomedical research and development contributes 70 percent of the biomedical research and development budget. This can be compared with a public funding contribution of 30 percent in the United States and 40 percent in Australia. We believe New Zealand needs to create the environment to increase private investment in biomedical research and development. To achieve this New Zealand needs an excellent tertiary education sector with a ready supply of graduates and an up-to-date scientific infrastructure. New Zealand should regard scientific infrastructure as a key part of its national infrastructure programme. Because most of New Zealand's international competitors use incentive schemes to attract private research and development it is important that the Government use the most cost-effective and efficient schemes possible to address New Zealand's low research and development investment.

An environment more conducive to clinical trials could foster private-sector investment in research and clinical trial activity, and allow value to be extracted from New Zealand's health assets.

New Zealand needs to be attractive to overseas sponsors of multinational research projects. An environment conducive to pharmaceutical companies funding these trials in New Zealand is required if the clinical trial industry is to grow. We were told that two factors are important for a productive clinical trial environment for pharmaceuticals:

- The efficiency with which the New Zealand health system can interface with the pharmaceutical companies to deliver an efficient clinical trial outcome.

[15] http://www.nzbio.org.nz/portals/3/files/NZBIO_2009_SIGHT_Report_finalweb.pdf, last accessed 20 May 2011.

- Pharmaceutical companies having sufficient business in New Zealand to warrant their financial investment into clinical trials.

A number of submitters said that New Zealand is a suitable site for the early phases of drug trials—Professor Gluckman told us, for example, that New Zealand is a good place for the early phases of trials in clinical physiology—but that the small size of its market is a disadvantage for the later phases. We also heard suggestions that New Zealand's clinical trials industry could concentrate on medical devices, health IT, and bioactives. Professor Gluckman told us that New Zealand's strengths are its competencies in medical science and bio-engineering, its high-quality health care system, its strong adherence to the rule of law, and its patent protection regulations. Other submitters told us that New Zealand is a good place to be part of international phase 3 and phase 4 trials. New Zealand needs to ensure that there is excellent scientific infrastructure in New Zealand to run internationally competitive trials on a coordinated basis. (Any investment must be associated with clear performance indicators that demonstrate value for money).

We heard from Professor Gluckman that New Zealand's hospital system fails to exploit its potential for innovation. New Zealand hospitals do not have access to the equipment or infrastructure that are increasingly necessary in early-phase studies. In contrast, the UK's National Health System has established NHS Innovations London Ltd, a highly successful agency created specifically to support innovation.

We understand that New Zealand's unique ethnic mix provides particular advantages for trials. Professor Gluckman said that there is an increasing need for clinical trials to be conducted upon specific ethnicities because of growing pharmaceutical markets in Asia. New Zealand's demographics allow researchers to compare people of European, Pacific, and Asian origins in the same clinical trials.

Many submitters also suggested ways to improve New Zealand's regulatory system to support clinical trials. These suggestions are explored in chapter 4.

We are concerned that Government departments in New Zealand have not worked together in the past. There is increasing realisation that close collaboration and coordination is needed in order to go from a clinical trial to a product, available to a patient.

Recommendations

2 We recommend to the Government that it establish a strong collaborative framework between the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise to coordinate and promote as efficiently as possible clinical trial activity in New Zealand, through both the public and private systems, to assist personal health as well as economic growth. There should be a progress report to the Government within nine months of this report being presented and the framework should be achieved within 12 months of this report being presented.

3 We recommend to the Government that it ensure that a culture that values research is embedded in the New Zealand public health system, by forming a national health research action plan to foster innovation and commercialisation where appropriate. The national health research action plan should be developed by the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise. The national health research action plan should be implemented by a single agency, for example the National Health Board or another agency, to ensure cross-sector collaboration. This recommendation should be achieved within nine months.

4 We recommend to the Government that it ensure that scientific infrastructure is regarded as a core part of New Zealand's basic infrastructure.

5 We recommend to the Government that it establish a long-term objective of bringing New Zealand's public and private investment in research and development up to international benchmarks (including research and development relating to clinical trials when benchmarks are available).

International examples

The United Kingdom

In January 2011 the United Kingdom Academy of Medical Science published a report *A new pathway for the regulation and governance of health research,* which proposes key principles to underpin health research in the United Kingdom. It makes recommendations to

- create a new health research agency to rationalise the regulation and governance of all health research
- create within the health research agency a new national research governance service to facilitate timely approval of research studies by national health service trusts
- improve the United Kingdom environment for clinical trials
- provide access to patient data that protects individual interests while allowing approved research to proceed effectively
- embed a culture that values research in the National Health Service.

The Australian Government's Clinical Trials Action Group

The Australian Government's Clinical Trials Action Group released its report *Clinically competitive: boosting the business of clinical trials in Australia* on 2 March 2011. The report addresses key issues including

- the timelines of clinical trial approvals
- the benefits of e-health for clinical trials
- how to improve patient recruitment systems and the level of support for clinical trials networks.

The report focuses on how to improve the timeliness of ethics and research governance review, including

- acceptance of a single ethical review for multi-centre human health and medical research
- adoption of common policies, procedures, and forms
- efficiency through national consistency of processes
- adequate support structure for conducting clinical trials.

The report proposes that policy on clinical trials be introduced that

- provides an incentive to reach a 30-day timeframe for both ethics and governance review, for which sponsors would pay a defined additional amount to support increased efficiency
- supports a 60-day calendar timeframe mechanism for governance review
- allows concurrent review of the ethics and governance components of a clinical trial
- includes clinical trial activity and timelines of approvals for clinical trials as a key performance indicator when jurisdictions negotiate new agreements with public hospital chief executive officers.

Recommendations

6 We recommend to the Government that it formally review the United Kingdom Academy of Medical Science's report *A new pathway for the regulation and governance of health research.*

7 We recommend to the Government that it assess the Australian Government's Clinical Trials Action Group's report *Clinically competitive: boosting the business of clinical trials in Australia* urgently, with a view to ensuring that the New Zealand systems are at least as efficient and effective as the Australian systems, if not more so, by the end of 2011.

4 The regulatory framework

Health and Disability Ethics Committees

There are seven Health and Disability Ethics Committees in New Zealand: Northern X, Northern Y, Central, Upper South A, Upper South B, Lower South, and the Multi-Region Ethics Committee. The Health and Disability Ethics Committees (termed "ethics committees in this report) are established under section 11 of the New Zealand Public Health and Disability Act 2000. There are also seven accredited University Institutional Ethics Committees.

The Multi-Region Ethics Committee (MREC) has primary responsibility for the review of national and multi-region health and disability research and innovative practice in New Zealand. Submissions from clinicians and the industry sector commented that the ethics committees are correctly placed within a sound legislative framework. We wish to acknowledge the hard work and dedication put in by members of the ethics committees, the Health Research Council of New Zealand, the Standing Committee on Therapeutic Trials, the Gene Technology Advisory Committee, and Medsafe.

The Health Research Council of New Zealand, the Standing Committee on Therapeutic Trials, the Gene Technology Advisory Committee, and Medsafe

Health Research Council of New Zealand and the clinical trial approval procedure

Section 30 of the Medicines Act 1981 specifies that the Director-General of Health may approve a clinical trial of new medicines only on the recommendation of the Health Research Council of New Zealand (HRC). The HRC maintains two standing committees to consider clinical trial applications. These committees make recommendations to the Director-General. The Standing Committee on Therapeutic Trials (SCOTT) considers applications for new unregistered pharmaceutical-type medicines, and the Gene Technology Advisory Committee (GTAC) considers applications for trials involving gene and other biotechnology therapies. A summary of the differences between the New Zealand and Australian systems for the clinical trial approval process for medicines is attached to this report as Appendix B.

Role of Medsafe in the clinical trial approval procedure

Medsafe administers the application and approval process for clinical trials under the delegation from the Director-General of Health. Medsafe receives and processes applications, liaises with SCOTT or GTAC and the applicant, and issues approval letters. All communication regarding applications for approval of clinical trials must be addressed through Medsafe.

National Ethics Advisory Committee

The National Ethics Advisory Committee (NEAC) is an independent advisor to the Minister of Health. The NEAC's statutory functions under section 16 of the New Zealand Public Health and Disability Act 2000 are to

- advise the Minister of Health on ethical issues of national significance in respect of health and disability matters
- determine nationally consistent ethical standards across the health sector
- provide scrutiny of national health research and health services.

We are aware that the NEAC carried out a comprehensive review of ethics committees in 2003. We consider the Government should re-examine this review with the object of implementing any remaining pertinent recommendations.

The ethics application process

The two essential aspects of the ethics review process are robustness and timeliness. There is a consensus amongst submitters that the ethics review and approval process is robust but slow. Inefficiencies in the ethics review process were highlighted by submitters. We consider that these limitations are not indicative of a weak ethics approval system, but of inefficient process, with administrative issues and a heavy workload. We consider that the rigor of ethical assessment must be maintained or strengthened. This position is strongly supported by the Woman's Health Action Trust submission. However, we believe significant gains can be made in the efficiency of the process.

Recommendation

8 We recommend to the Government that it ensure that the current robustness of the clinical trials ethics evaluation is preserved with respect to patient safety, and where necessary is strengthened.

Comparisons with the ethics application process in other countries

We were told that the ethics application process in the United States of America usually takes fewer than 30 days. We are aware that competition in the Asia Pacific region for clinical research studies is increasing, with South Korea, Hong Kong, Singapore, and Taiwan providing favourable conditions for research. We understand that to be in the top 25 percent of possible locations, the average time to obtain ethics approval should be fewer than 40 days. Industry feedback indicates that ideally the approval time should be decreased to fewer than 30 days. New Zealand will have to achieve this in order to keep up with the international community. The mean time taken for clinical trial approvals by New Zealand ethics committees is now considerably longer than those in many overseas jurisdictions. As enrolment in many multinational commercial studies is competitive, long approval times reduce New Zealand's involvement in these trials.

Improving timeliness

The Covance submission suggested that for multi-centre research the average time from submission to an ethics committee's approval is more than 80 days. The Merck Sharp & Dohme (New Zealand) Limited submission said that from its experience the ethics review

process typically takes about 115 days. There are no standard national timelines for ethics committees' responses and subsequent review. We consider that key performance indicators relating to timeliness in processing applications to ethics committees should be set and monitored. For example, the timeliness of meeting responses, subsequent reviews, and correspondence about reports and requests might be monitored.

Recommendation

9 We recommend to the Government that it monitor as a performance measure the time taken by Health and Disability Ethics Committees to process applications. The Health and Disability Ethics Committees should process expedited reviews within 30 calendar days, and other applications within 45 calendar days.

We understand from several submitters that the scientific review process carried out through SCOTT is efficient, with an average time of 14 days to make a decision. We are impressed by this, and would like to ensure that this efficiency is maintained. We were told that SCOTT is required to carry out the scientific evaluation within 45 days. Consequently, the current efficiency is extremely good, and we would like to ensure that this efficiency is maintained. Submitters suggested reducing the evaluation time to 30 days with exemptions for highly complex applications on a stop-clock basis.

Recommendation

10 We recommend to the Government that it require the Standing Committee on Therapeutic Trials to carry out all scientific reviews within 30 calendar days.

We recently learned of a New Zealand company with a long history of clinical trials involving bioequivalent replications of patented medicines. We understand that in the past, while ethics committee approval was obtained, the process was otherwise timely and low cost. We are aware that, acting on Crown Law advice, Medsafe now requires a bioequivalent (which has overseas jurisdiction approval) to be treated as a new medicine under section 30 of the Medicines Act. In addition to ethics committee approval applicants are now required to obtain SCOTT approval and pay a considerably larger fee. This may reduce the number of trials undertaken at a time when New Zealand aspires to increase trial volume. We are aware that the Ministry of Health is considering measures to reduce the time and cost to approval of bioequivalent replications, and want to encourage those measures.

The expedited review process

The MREC makes regular use of the expedited review process. We understand that of the 224 applications reviewed by the MREC in 2009, 98 were expedited review applications. We understand that a shortened application form is used in this process, and one or more members are delegated by the full ethics committee to carry out the review, allowing an expedited review to be carried out independently of the usual meeting schedule. The median approval time for a full review is 55 to 80 days, while for the expedited review process it is seven to 25 days. We were told that research that poses higher risks is subjected to full review, while that which is considered lower-risk undergoes the expedited review process. The ethics committees use the expedited review process for observational

studies; whereas intervention studies in which researchers intentionally alter people's care, including clinical trials of medicines or medical devices, always undergo full ethical review.

To improve the timeliness of ethical reviews, the single-region ethics committees should make better use of the existing scope for expedited review and of the chairperson's discretion. In addition, ethics committees should increase awareness of these processes amongst their members and in the industry.

Recommendation

11 We recommend to the Government that it require the Health and Disability Ethics Committees to widen the access to expedited review so that intervention studies, including clinical trials, are eligible for such review.

Meeting frequency

The frequency of the MREC's meetings should be increased. This committee, which provides ethical review of all clinical trials performed in more than one centre, meets only once a month. Most phase 3 trials sponsored by pharmaceutical companies are multi-country. Consequently, delays can make New Zealand less attractive as a site for clinical trials. Ethics committees in other countries meet twice weekly, weekly, or fortnightly.

Recommendation

12 We recommend to the Government that it require ethics committees to meet as frequently as needed to achieve best-practice timeliness.

Standardising and improving the ethics review process

We heard from some submitters that they thought that different ethics committees treat applications in different ways. For example, we heard anecdotally that some ethics committees insist on any payment to subjects being included in the written information provided to subjects. However, at least one ethics committee insists on excluding this information. Some ethics committees will allow the mention of payments in advertising, others will not. We consider that process standardisation is required.

While a standard operating manual for ethics committees is available, the process for evaluation is different in different regions. National standards should be established for the following purposes:

- for ethics committees to ensure consistency in decision-making between and within committees
- for a training programme for new ethics committee members
- for a clinical trial agreement to cover components such as consent and safety evaluation.

Recommendation

13 We recommend to the Government that it establish comprehensive standardised operating procedures for Health and Disability Ethics Committees, to ensure consistency in decision-making within and between ethics committees.

Preventing duplication

In the current ethics review process there is duplication between the evaluation of clinical trials by the ethics committees and by DHBs in locality assessments. Evaluation by the ethics committees should not be duplicated by the DHBs. If applied as intended, the DHB locality assessment process should not overlap with the ethics committee's responsibilities. The purpose of the locality assessment should not include a scientific and ethical evaluation of the clinical trial, but rather focus on the impact of the trial on DHB resources and facilities.

Submitters also reported some procedural duplication between ethics committees, SCOTT, DHBs, and Māori consultation. The role of each committee needs to be clearly defined and the terms of reference for each party involved in the regulatory process (including the ethics committees, SCOTT, and DHBs) need to be clarified.

Recommendation

14 We recommend to the Government that it remove duplication in the processes carried out by the Health and Disability Ethics Committees, the Standing Committee on Therapeutic Trials, and district health boards, and in consulting with Māori.

Māori and ethnic consultation requirements

The current ethics committee consultation process involves input from ethnic groups. Significant delays can occur because of consultation with specific ethnic groups such as Māori. It is recommended that a standardised national approach to consultation with Māori and other ethnic groups be introduced into the ethics review process. Where a trial is targeted at an ethnic group, such as a clinical trial investigating treatments specific to Māori, then appropriate consultation is required.

Recommendation

15 We recommend to the Government that it instruct the National Ethics Advisory Committee or the Ministry of Health to make clear guidelines for ethnic and Māori consultation within nine months of this report being presented. The guidelines should be clearly aimed at maximising protection, expertise, and efficiency, and should clarify the purpose of Māori consultation.

Electronic submissions

In New Zealand, clinical trial submissions to ethics committees are not made electronically. Ethics committees request one original and 12 double-sided copies for each clinical trial application. This regularly results in an application of approximately 500 to 1,000 pages. The application is reviewed for completeness and then copies are mailed to individual committee members. Electronic submissions and an online application process should be implemented immediately. Electronic submissions are standard in most jurisdictions,

including the European Union, Japan, the United States of America, Australia, Canada, and the Nordic countries. The Food and Drug Administration in the United States of America has been accepting electronic submissions for more than 10 years. The ethics committees should develop an electronic submission process, and should also take the opportunity to update and review their forms, as we were told that some of the text is repetitive or ambiguous.

Recommendations

16 We recommend to the Government that it implement a system of electronic submissions of clinical trial applications to make the application process more efficient, within 12 months of this report being presented.

17 We recommend to the Government that it require that the Health and Disability Ethics Committees update and review application forms to remove any text that is repetitive or ambiguous.

Communication

Concern was raised that the information requirements for ethics applications are not specific. Consequently, requests for additional information by the ethics committee have led to delays in the application's approval. Submitters suggested that it would be helpful for trial sponsors to be able to communicate with Medsafe, SCOTT, or GTAC before lodging an application, so that any technical matters or misunderstandings could be resolved in advance, avoiding delays. We heard that in the United States of America the Food and Drug Administration holds "pre-investigative new drug meetings" to sort out minor issues before the application process. We were told that it would be helpful to permit submitters to make minor changes that have no ethical implications to the application form, in order to avoid unnecessary duplication of process.

Recommendations

18 We recommend to the Government that it introduce a facility for preview of all applications to Health and Disability Ethics Committees, the Standing Committee on Therapeutic Trials, and the Gene Technology Advisory Committee.

19 We recommend to the Government that it permit researchers to make minor changes (as guided by best practice) to the application form, with notification to the Health and Disability Ethics Committee. The changes should be at the discretion of the Chairperson of the ethics committee.

Coordinating the ethics committees

Central clearing house

We consider that regional ethics committees should be retained, as they allow researchers to attend ethics committee meetings in their provincial area. In order to improve the application assessment process, a central clearing house should be established to allow researchers to choose whether to have their applications considered by their regional ethics committee or have them fast-tracked and considered by another regional ethics committee at the next meeting.

Recommendation

20 We recommend to the Government that it set up a central clearing house for the Health and Disability Ethics Committees. The clearing house should distribute applications to the appropriate committees in a timely fashion.

Committee membership

The central clearing house system should also allocate research to the ethics committees whose members have the most pertinent knowledge, and for large projects a pool of overseas experts could comment on request. An alternative would be to restructure the ethics committees and revise their member categories on the basis of study type (for example clinical trials, and other sorts of study). This would make review more expert, attracting and retaining members who have expertise in oncology, cardiology, medical devices, functional foods, bioactives, and so on.

Recommendation

21 We recommend to the Government that it consider restructuring the Health and Disability Ethics Committees and revising their member categories on the basis of study type, differentiating between clinical trials and other sorts of studies.

Size of ethics committees

Currently ethics committees consist of 12 people, six with technical backgrounds and six lay people. The Regional Ethics Committee submission suggested reducing the number to 10, keeping an equal number of technical and lay people. Information about the membership of ethics committees is attached to this report as Appendix C.

We consider that it is important, where major trials are to be considered, that a minimum number of members be set. Smaller overall numbers or a different balance of lay and expert representation might be perceived as insufficiently robust, or might not cover the necessary areas of expertise. However, there might be sense in having a flexible arrangement whereby less complex applications could be considered by fewer members. It is of paramount importance that the ethics process be robust, and that there be a certain number of lay people as well as technical experts available to consider an application. This might mean that for certain applications as few as six people might suffice, whereas in other instances the ethics committee might wish to bring in extra expert advisers.

Recommendations

22 We recommend to the Government that it appoint to individual Health and Disability Ethics Committees members with specific expertise in areas including paediatrics, oncology, medical devices, genetics, functional foods, and bioactives.

23 We recommend to the Government that it reduce the membership of the ethics committees from the current 12 to eight, allowing the Chairperson to co-opt for expert advice.

24 We recommend to the Government that it require that all members of the ethics committees have the appropriate technical or clinical training to understand the matters they are dealing with by instituting a training programme for new members.

Ethics committee resources

Several submitters commented on the capacity of the ethics committees and we were told that the issue of workload pressures on ethics committees needs to be addressed. More resources are required to process the ethics applications efficiently and promptly, as some ethics committees have a heavy workload. For example, 224 applications were reviewed by the MREC in the 2009/10 financial year. Some regional ethics committees appear to be under-resourced, as meeting agendas are reported to be consistently full, so that some applications, even if submitted on time, may be deferred until the following meeting.

A user-pays system could provide additional resources. This is accepted practice in several jurisdictions including the European Union, the United States of America, and Australia. To address the shortfall in resources, it was suggested that the ethics committees consider charging fees for applications from sponsored clinical research trials. All sponsored clinical trial applications could be considered by a new ethics committee. There is already a provision for the ethics committees to set up such a committee, as noted in the oral submission made by the chairs and members of ethics committees. Investment, funded by a fee mechanism, is needed to increase the available capability and capacity for ethical review and monitoring of clinical trials by the regional ethics committees.

Recommendations

25 We recommend to the Government that it ensure the Health and Disability Ethics Committees are resourced appropriately.

26 We recommend to the Government that it consider establishing a new dedicated ethics committee for sponsored clinical research with an application fee charged, on a cost-recovery basis. This new committee should come under the existing Health and Disability Ethics Committee umbrella, and should be highly efficient in processing applications.

27 We recommend to the Government that it ensure that any fees charged by ethics committees in the processing of applications for the approval of clinical trials represent good value for services rendered, that unnecessary compliance costs are not imposed, and that fees are internationally competitive.

28 We recommend to the Government that it assess the options for charging fees for ethics committee review.

Australian and international examples

International benchmarking and the Australian Clinical Trials Notification and Clinical Trials Exemption system

Benefit could be gained from reviewing international approaches to the ethics review process. We were told that the Australian system is efficient; however it is in the process of making significant changes. New Zealand must adapt its system to be better than other countries' systems by benchmarking patient safety and timeliness of process. Set out in Appendix B is a summary of the Australian clinical trials review process.

Regulatory harmonisation with Australia

We were told by New Zealand Biotech 2003 Incorporated (NZBIO), the national association for the biology-based industries, that it advocates "more regulatory harmonisation with Australia." NZBIO notes that the Australian regulation is harmonised very closely with its European counterpart. Primorus Clinical Trials Ltd, a clinical trials provider, said that it would welcome revisiting the concept of a trans-Tasman joint agency to regulate therapeutic products, noting this would mean both New Zealand and Australia could be viewed externally as a single market with a single regulatory process. It argued that "the need to expand the consultative pool of expertise available to New Zealand regulation and ethical committees lends itself to a formalised alignment with overseas organisations such as the TGA (Therapeutic Goods Administration) in Australia."

Recommendations

29 We recommend to the Government that it review international approaches to the regulatory review systems, in particular the Australian Clinical Trials Notification and Clinical Trials Exemption system, with a view to adopting the most efficient and robust system that would align with other countries' regulatory systems. Following this review it should establish a streamlined regulatory approval process for applications that have already been approved by the United States of America Food and Drug Administration, the European Medicines Agency, or have gone through the Australian regulatory process.

30 We recommend to the Government that it carry out the necessary work towards greater alignment with the Australian system where it is appropriate.

5 The role of Pharmac

We acknowledge that Pharmac has achieved a successful model for purchasing medicines at the best value for New Zealand. Some submitters considered that the policies of Pharmac have resulted in significant diminished investment by pharmaceutical companies in clinical trials. Rather than shy away from this controversial subject, we felt that it was worthwhile to look for innovative ways to build a more transparent, constructive, and professional relationship between the pharmaceutical industry and Pharmac that would lead to net benefits for New Zealand.

To achieve this we describe possible examples, but leave room for others. We consider that Pharmac should consider developing

- a pharmaco-economic analysis expertise that could be used by drug companies on a fee-for-service basis to evaluate the prospective value of medicines being trialled.
- an innovation fund, to fund public good New Zealand trials to give a clear signal to the pharmaceutical industry that New Zealand wishes to engage with it constructively.
- an industry liaison body similar to the Australian Pharmaceutical Industry Strategy Group that would work to build a transparent, constructive, professional relationship.

Pharmac is the New Zealand Government body responsible for managing the Pharmaceutical Schedule, which lists Government-subsidised medicines. The agency's purpose is to assist in the delivery of a world-class medicines system for New Zealanders in the most cost-effective way possible. Pharmac has a mandate to secure, within a fixed budget, the best health outcomes for eligible New Zealanders that can reasonably be achieved from pharmaceutical treatment within the funding provided.

Pharmac's latest Statement of Intent reflects significant savings: "A conservative estimate is that since 2000, Pharmac has secured savings to the New Zealand Government, which in the current year are worth in excess of $700 million. At the same time, the number of new medicines and patients receiving them have both increased."

Pharmac uses research to inform its pharmaceutical funding decisions. Pharmac has previously provided funding for one clinical trial for a biological treatment. Pharmac's primary research interest is in the comparative effectiveness of medicines. Pharmac is considering how, and under what circumstances, it could assist the industry to generate data that is relevant to pharmaceutical funding decisions.

Pharmac and pharmaceutical companies

The Pharmac policy of sourcing generic medicines provides excellent value for the New Zealand health system, achieving yearly savings of more than $700 million relative to the cost of the equivalent branded medicines. This policy is naturally not popular with the

pharmaceutical companies, which have said it is a disincentive for pharmaceutical companies to invest in clinical trial research in New Zealand. However, they generally accept that the relationship between pharmaceutical companies and Pharmac has improved.

The submissions we received reflected multiple views on the effect of Pharmac's mandate on clinical trials, some of which are contradictory. Nine submitters considered that Pharmac's policies had either led to a withdrawal of trial investment activity (as in the case of Pfizer withdrawing $60 million worth of funding from the University of Auckland in 2004) or influenced whether pharmaceutical companies would sponsor clinical trials in New Zealand.[16]

In its oral submission, Pfizer informed us that, while it continues to have concerns about the transparency of Pharmac's decision-making process, it would consider doing trials in New Zealand regardless of whether Pharmac would fund a medicine. Merck Sharp & Dohme (New Zealand) Limited told us its research arm is entirely separate from sales and marketing and is externally funded, and that it does not decide whether to fund a trial in New Zealand on the basis of Pharmac's policies.

While Pharmac should not be deterred from its focus on purchasing pharmaceuticals for New Zealanders at the best possible value, we feel it is important that Pharmac have a transparent, professional, and constructive relationship with pharmaceutical companies and the biotech industry in general. The area of clinical trials can provide common ground.

Pharmac's role in research and development

The objectives and functions of Pharmac are set out in sections 47 and 48 of the New Zealand Public Health and Disability Act 2000. Pharmac's primary objective (section 47(a)) is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achieved from pharmaceutical treatment and from within the amount of funding provided." One of its functions (section 48(c)) is to "engage as it sees fit, but within its operational budget, in research to meet the objectives set out in section 47(a)". Pharmac's functions are to be carried out "within the amount of funding provided to it" (section 48).

To our knowledge, Pharmac has pursued its clinical research mandate to only a limited extent. For example, as mentioned above, Pharmac contributed toward the costs of a clinical trial on Herceptin and has a working relationship with the investigator.

Pharmac's expertise in pharmaco-economic analysis is critical to its success. We consider there is a case for Pharmac to use its existing expertise in understanding the economic costs and benefits of clinical trials to also provide advice to companies.

The National Institute of Clinical Excellence in the United Kingdom provides services to clinical trial sponsors that could be adopted by Pharmac. We understand that the institute will make pharmaco-economic evaluations of the value of patient outcomes of a drug trial.

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16 Subsequent to Pfizer's withdrawal, however, Roche stepped in to fill the breach.

This is carried out on a fee-for-service basis, and "without prejudice" that the drug might be purchased in the future if the drug is successful.

Recommendation

31 We recommend to the Government that it require Pharmac to consider, within 18 months, developing a pharmaco-economic analysis expertise on clinical trials which could be used by pharmaceutical companies on a fee-for-service basis to evaluate the prospective value of medicines being trialled (similar to the service provided by the National Institute of Clinical Excellence in the United Kingdom).

Innovation fund

We consider that the Ministry of Health, the Ministry of Science and Innovation, and the Ministry of Economic Development should establish an innovation fund, for co-sponsoring with pharmaceutical companies, specific clinical trials that are aimed at health issues specific to New Zealand's population (for example, disease that has a high impact on Māori health). The fund should not erode Pharmac's budget to purchase medicines for New Zealanders. The funding might come from the Ministry of Health, the Ministry of Science and Innovation, or the Ministry of Economic Development. Our expectation is that the funding would be matched by the private sector. This arrangement should be aligned with Pharmac's Pacific Responsiveness Strategy, which has the aim of ensuring that Pharmac is well attuned to the health needs of the Pacific Island and Māori communities. Pharmac would not be involved in the funding but could have representation on a research allocation body.

Such an initiative would send a clear signal to pharmaceutical companies that while Pharmac must continue its role in providing cost-effective medicines, New Zealand is willing to engage with the industry to bring new medicines to the New Zealand market. It would also signal to the global pharmaceutical industry that the New Zealand clinical trial industry was "open for business", and would be likely to attract more clinical trials to New Zealand. The size and nature of such an innovation fund should be determined after discussion with key stakeholders.

Recommendation

32 We recommend to the Government that it require the Ministry of Health, the Ministry of Science and Innovation, and the Ministry of Economic Development to develop, within 18 months, a model to establish an innovation fund for co-sponsoring with pharmaceutical companies, specific clinical trials involved in research aimed at health issues specific to New Zealand's population. Pharmac should not be involved in the funding or management of the funding but could have representation on a research allocation body.

Patent life extension

New Zealand, unlike Australia and the USA, does not offer a patent life extension for pharmaceuticals in recognition of the typically long time between patent filing and the product reaching the market. The time between registration and expiry of a patent is 20 years. We were told that it now takes upwards of 15 years from early development to registration approval for a drug. We were told that the economic effect of this policy for New Zealand is that Pharmac can source cheaper generic versions of many new medicines

a relatively short time after they come to market. A new drug may be on the market fewer than five years before its patent expires in New Zealand. If the patent life policy were changed to align it with Australia and the United States of America, it would be received well by pharmaceutical companies, but would increase the cost of delivering medicines to New Zealanders. We note that the issue of intellectual property was discussed at the Transpacific Partnership talks in December 2010. This issue was under discussion by the Commerce Committee when recently reviewing the Patents Bill.

Partnership with the pharmaceutical industry

We recognise that the pharmaceutical industry is one of many sectors and stakeholders that could contribute to bringing clinical trials to New Zealand. The pharmaceutical industry has been interested in forming a closer relationship with the Government since at least 2003. This would necessitate consultation with pharmaceutical companies, and engagement with them by the Government on strategic initiatives.

We note that the pharmaceutical industry's main role in New Zealand is simply that of supplying pharmaceutical products. Pharmaceuticals are important for the nation's health, and the Government funds about three quarters of New Zealand's expenditure on them. The industry also invests in research and development in New Zealand, however, including clinical trials.

The Australian Pharmaceuticals Industry Strategy Group may be a useful model for a relationship between the industry and government. This high-level taskforce was established by the Australian Minister of Innovation, Industry, Science and Research in 2008. It was commissioned to develop a plan to increase investment in pharmaceutical research and development, clinical trials, and manufacturing in Australia over the next decade.

We believe such a group should be established in New Zealand to help build and maintain a transparent, professional, and constructive relationship between the industry and the Government.

Recommendations

33 We recommend to the Government that it work with the pharmaceutical industry to establish, within 18 months, a body to facilitate liaison between the Government and the pharmaceutical industry.

34 We recommend to the Government that it make efforts to build constructive, professional, and transparent relationships with the international biotechnology and pharmaceutical industry through innovative mechanisms that would not undermine Pharmac's role of purchasing pharmaceuticals at the best possible value.

6 The role of district heath boards

In order to achieve an efficient, robust ethics assessment process, national and regional coordination are needed.

Locality assessment

One of the functions of DHBs is to carry out a "locality assessment" of a proposed trial to ensure that arrangements are suitable and the investigator has appropriate resources for conducting the research or clinical trials. The locality assessment contributes to the ethical review process.

The research governance process of a number of DHBs includes a research review; but many smaller DHBs have no such process and these responsibilities reside with the Chief Medical Officer. Some DHB governance processes can take as long as the ethics review approval process, and many submitters asserted the need to remove duplication from this process and shorten approval times.

Recommendation

35 We recommend to the Government that it require district health boards to remove duplication in the ethical review process.

DHB clinical trial processes

Injuries sustained by participants in some clinical trials are not covered by New Zealand's no-fault accident compensation scheme. When a DHB takes part in such a trial, it is important that it is indemnified by the trial sponsor in case of injury to participants. A standard indemnity and compensation agreement has been created to harmonise the treatment of these matters by all DHBs, but there is inconsistency in the DHBs' implementation of the agreement. Both the public and private sectors must have secure indemnity agreements.

We believe that when a multi-centre clinical trial is conducted, DHBs should have a procedure for agreeing to requested variations in standard clinical trial agreements. Failure by DHBs to adopt an aligned approach negates the benefits of nationalised agreements. When one DHB adopts a contractual position at variance with other DHBs without discussing it with them, this creates an impediment for the contracting company.

Recommendations

36 We recommend to the Government that it require both public and private sector clinical trial sponsors to have secure indemnity agreements, representing international best practice.

37 We recommend to the Government that it implement a simplified, optional standard clinical trial agreement for all applications within 12 months.

38 We recommend to the Government that it standardise the processes and documentation required by district health boards.

DHB income from clinical trials

DHBs derive income from running clinical trials in two ways: by charging an overhead as a percentage of the clinical trial revenue; and by retaining a clinical trial cash surplus. DHBs may also obtain revenue as a result of the commercialisation of research, such as income from royalties from patents, intellectual property licensing and so on.

We were told that there is no consistency amongst DHBs as to whether an overhead is charged and at what rate. Some DHBs charge pharmaceutical companies to review clinical trial documentation before a trial starts. Clinical principal investigators are not directly remunerated for implementing a clinical trial, and the value of this unpaid principal investigator contributes to any surplus.

Recommendation

39 We recommend that all district health boards should have an agreed methodology for determining the costs of clinical trials.

Establishing clinical trials research as an essential part of DHB activity

We believe that if New Zealand is to have an internationally competitive clinical trials industry, a nationally integrated system must be established to increase its competitiveness with overseas trial services.

New Zealand does not have a national strategy for conducting clinical research or trials at DHBs. There is no requirement for DHBs to take a proactive stance towards contracted clinical research, and their priorities are focused on delivering core clinical services. Such a strategy could be aligned to a national health research action plan to foster innovation and commercialisation.

Many submitters said that they would like to see clinical research recognised as an essential part of DHB activity, as such a culture already exists in the DHBs. Professor Gluckman told us that he considered that "the hospital system's latent potential for innovation should be encouraged and it is not generally recognised as a valuable source of innovation for new knowledge for both health benefits and economic drivers."

The Crown Funding Agreements between the Minister of Health and DHBs include an Operational Policy Framework, which sets out the business rules and the reporting requirements for DHBs, including requirements when conducting research and implementing innovative procedures or treatments. These requirements include policies and procedures for seeking ethical review and advice from an approved ethics committee, in accordance with the current Operational Standard for Ethics Committees, and for consulting Māori.

An option would be to have an explicit requirement or expectation that most DHBs be involved in clinical trials. Any such requirement would need to be included in the Operational Policy Framework. The resource and funding implications of setting such an expectation for clinical trial activity would need to be assessed and addressed.

If reporting on such a requirement were considered necessary, it would have to be stipulated in the reporting requirements along with a valid measure. DHBs are currently required to report against 30 to 40 measures. The planning principle is that there should be no growth (and preferably a reduction) in the reporting burden. There is an annual review of reporting measures, and a new measure, clinical leadership, has been introduced recently.

We would like to see

- a national strategy to recognise research and knowledge-based innovation as core activities for most DHBs
- agreed clinical trial documentation to support clinical trial activity
- a unified clinical research strategy, endorsed by the Ministry of Health, and developed in conjunction with key New Zealand clinical opinion leaders.

The New Zealand Association for Clinical Research is working on a template agreement for clinical trials in New Zealand. Provided DHBs support this initiative (as has been done with the indemnity template) this will be implemented this year. Equally important will be the recommendation that DHBs harmonise their budget negotiation processes so that multi-centre trials do not have to go through multiple budget negotiations. The clinical trial agreement involves costings for nurses, laboratory space, clinical research, and so on.

We are aware of the possible formation of a research, innovation, and commercialisation hub to service the North and South Islands. This might provide coordination for DHBs' clinical trials and other research, as well as for Crown research institutes, universities, and the business sector.

Denmark and Singapore have highly successful economic development agencies, which operate as a single coordinating body for the whole country and are not fragmented. We regard it as vital that such hubs in New Zealand should not crowd out the private sector nor should they become bureaucratic silos in themselves.

Provided such a hub is aligned appropriately with DHBs throughout the country, and that overseas researchers or investors can access it easily through a single highly efficient, accountable agency, we believe the concept should be pursued actively. This would mean full collaboration between the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise.

Recommendations

40 We recommend to the Government that it establish a national framework for clinical trial research at district health boards.

41 We recommend to the Government that it work with key clinical leaders to develop a well coordinated national strategy for clinical trials and research at district health boards. The strategy should be endorsed by the Ministry of Health, and establish that research is a core activity undertaken by district health boards. There should be formal coordination with private clinical research service providers.

42 We recommend to the Government that it encourage district health boards to conduct clinical trials by introducing key performance indicators relating to timeliness and the cost and efficiency of carrying out clinical trials.

43 We recommend to the Government that it require district health boards to adopt an aligned approach when implementing nationalised agreements with sponsors engaged in multi-site clinical trials.

DHB resources and infrastructure

All public clinical trials require DHB infrastructure to support them. An appropriate infrastructure provides the environment to deliver quality clinical research. We believe that consideration should be given to replacing individual DHB research offices with clinical research networks involving multiple DHBs, possibly coordinated through a hub that services the North and South Islands. A shared service policy would facilitate the management of clinical trials, which are often undertaken in multiple sites and multiple DHBs. A structure and funding would need to be agreed amongst the DHBs. This structure should have the flexibility to accommodate the differences between DHBs.

The dedicated time that clinicians spend on research should be recognised in DHBs as front-line activity and resourced accordingly. The Medical Technology Association of New Zealand told us that 85 percent of medical technology innovation arises from hospitals. To capture the value of this innovation and commercialise medical technology, clinicians will need to participate in clinical trials, and DHBs will need to support this process by championing emerging technology.

Several submitters said that DHBs should be funded to develop and retain clinical trial staff, and supported with the appropriate infrastructure. This infrastructure should include high-technology equipment to provide analytical data for early-phase studies. Professor Gluckman said that New Zealand's hospitals do not have access to high-tech equipment such as magnetic resonance spectroscopy, PET scanning, and other equipment increasingly used in clinical physiology and phase 1 and 2 studies. Singapore has invested in such equipment and this has attracted clinical trial activity.

We were told that bio-imaging and biomarker analysis are increasingly providing valuable data for many clinical trials. Many New Zealand hospitals do not have these technologies. We believe that investment should be made in establishing this capability as part of the implementation of a national clinical trials strategy.

Recommendations

44 We recommend to the Government that it establish the appropriate and sustainable infrastructure to support clinical trials.

45 We recommend to the Government that it encourage clinicians to undertake clinical research through incentives or funding, and make provision for them to receive incentives similar to those available to university researchers.

46 We recommend to the Government that it fund district health boards to undertake clinical research as a front-line activity.

47 We recommend to the Government that it allocate funding to district health boards for the purchase of technology needed to conduct clinical trials.

7 Improving the coordination of the clinical trials sector

National clinical trials register

We consider that improvements are needed in the system for collecting national data on clinical trial activity. More comprehensive national data should be collected and made easily accessible to researchers, the industry, and the community. The United States of America National Institute of Health, in collaboration with the United States of America Food and Drug Administration, maintains a public database of clinical trials on the website ClinicalTrials.gov. New Zealand has a similar database, the Australian New Zealand Clinical Trials Registry (ANZCTR). Data from this database could provide the basis for evaluating clinical trials' performance over time. Additional resources would be required to capture and analyse the data to allow the efficiency and effectiveness of New Zealand's clinical trials to be monitored effectively.

We consider that all trials should be recorded in a publicly accessible register, either in New Zealand or overseas. Registration provides clinicians and trial participants and other interested parties with access to trial information. It may help researchers find gaps in their own research and prevent trial duplication. The ANZCTR is a voluntary online register of clinical trials being undertaken in Australia and New Zealand. The ANZCTR meets international requirements for clinical trials registers, and is recognised by the World Health Organization clinical trials portal, which allows international registers to be searched world-wide.

Currently, some studies may be registered on the ANZCTR, and others on other clinical trials registers, such as ClinicalTrials.gov. run by the United States of America National Institute of Health and the United States of America Food and Drug Administration. In theory some trials recruiting patients in New Zealand may not be registered at all, but such trials could not be published in credible journals, so in practice this is unlikely.

Mandatory registration of all clinical trials recruiting patients in New Zealand would be valuable**.** There are several ways this might be done. One option is mandatory registration on the ANZCTR, which would be a convenient way to collect data on all the trials happening in New Zealand. A drawback of this approach would be that it might result in trials being registered on multiple international registers, and thus increase compliance costs. Whether the larger compliance costs would be warranted would need further consideration.

Another option is mandatory registration on any reputable international clinical trials register. This would allow the trial sponsor to choose the most appropriate register for their particular trial. However, it has the drawback that the data and information on New Zealand clinical trials would remain fragmented. We therefore believe that mandatory registration on the ANZCTR is the better option.

Recommendation

48 We recommend to the Government that it require clinical trials conducted solely in New Zealand, clinical trials that are New Zealand-led, and international studies that are partially conducted in New Zealand to be registered with the Australian New Zealand Clinical Trials Registry.

National patient referral networks

Electronic patient record systems in DHBs

Significant improvements will be made to the public health system's electronic patient records by the implementation of the National Health IT Board's National Health IT Plan. The plan has two phases. The first focuses on regionalising IT systems, so they are linked and integrated with regional services planning. Currently the system is fragmented, with multiple databases which cannot "talk" to each other. Phase 1 (July 2010–June 2012) will create the capability to transfer health information and patient records electronically between healthcare organisations (for example, between primary and secondary care for the purposes of referral); and the systems used in secondary and tertiary facilities will be consolidated into regional and national platforms.

The second phase, targeted for completion by 2014, involves developing the capability for a shared electronic care record (linked with the National Health Index) for every patient. This record will be accessible by linking to existing systems run by healthcare organisations, and will include a regional clinical results repository. Gateways and authorising processes will be needed to access patient data for research purposes, to preserve the privacy of patient records.

These IT developments will improve the state of base clinical data significantly, and thus the quality of clinical information and the safety of services. They will also provide a better foundation for clinical trials work.

Links to national databases

The National Health Board IT Plan proposes improvements for researchers and others wishing to use health data. The plan would establish four regional clinical database repositories. These regional repositories could then be linked with national repositories of health data. It is intended that everyone needing access (including researchers) will be able to access the appropriate level of data in this national repository directly by 2014. Ethics committee and Ministry of Health approval will continue to be required to access data that raises privacy issues, or if researchers intend to contact the people whose data is held.

The Ministry of Health will continue to make data from its national collections databases available through publications and by providing a service whereby ministry analysts extract and collate a confidential dataset tailored to the researcher's needs, and provide the context for the data. Often requests are made for datasets that have not previously been collated. The ministry is well-placed to provide this added-value service, as it can meet its obligations as a custodian of personal health information, and save infrequent users of data the expense of specialist self-service software and health network connections. There are no current plans to change the way this data is made available to the research community.

Roche told us there is a great deal of information and competence that exists within the Ministry of Health that can be accessed for research purposes. Thought could be given to establishing well advertised "fee-based" services by which researchers, industry bodies, and biotechnology companies could use the ministry expertise to provide specialist service.

The National Cancer Programme (a collaboration between the ministry, the DHBs, and the regional cancer networks) is an example of a clinical area where those involved are working to improve the patient data and information support structure.

Access to population data for clinical research purposes

The Ministry of Health collects population survey data including information about the prevalence of particular medical conditions, especially chronic conditions. This data can be accessed from survey reports; from data tables of survey results on the ministry's website; by asking the ministry to carry out small pieces of research; or by applying for access to the micro-data files. Confidentiality issues need to be dealt with prior to release. Applications are considered and processed every two months.

The Population Health Survey's micro-data files are being transferred to the Official Statistics data archive, which is managed by Statistics New Zealand. This will not affect researchers' ability to access population survey data.

National data collection on and performance measures for clinical trials

A set of national metrics would help with monitoring clinical trial activity, and allow the production of data for export promotion purposes. To be efficient and comprehensive, more data than is currently available electronically would be needed. This proposal would require sector leadership and coordination to implement, and possibly funding. It is not a Ministry of Health priority, but could be developed by the industry, or be included in a national strategic approach to health research.

We note that the Australian Government's Clinical Trials Action Group's report *Clinically competitive: boosting the business of clinical trials in Australia* was released in February 2011 (see page 27). This paper contains recommendations that might facilitate improvement in the New Zealand clinical trials environment.

Strategies and plans

We understand that the Health Research Council of New Zealand has statutory functions that relate to national health research policy. We consider that there would be value in a well-coordinated national strategic approach to health research, including clinical trials, in New Zealand but this should involve collaboration between the Ministry of Health, the Ministry of Science and Innovation, the Ministry of Economic Development, and New Zealand Trade and Enterprise.

National strategy for cancer research or oncology clinical studies

We consider that there is a need to develop strategies for cancer-related research. Significant changes are taking place in the research, science, and technology sector, and the Cancer Control Strategy and the Cancer Control Strategy Action Plan 2005–2010 both highlighted the need for a strategic approach to cancer control research.

Any strategies developed for cancer research should be aligned with an overarching national strategy for all clinical trials in New Zealand. There should be national coordination between the objectives of the national clinical trials strategy and the national health research action plan, while optimising access to the medicines approved for specific clinical conditions.

8 Public funding of clinical research

Economic assessment of the potential benefits of public investment in clinical research

New Zealand Trade and Enterprise is conducting a broad study of the economic benefits of the clinical trials industry to New Zealand. One of the aims of this project is to estimate the future economic value of the clinical trials industry. The project (covered in more detail in chapter nine) is likely to be completed in six to eight months. We consider that this study will provide important information about the costs and benefits of clinical trials and health care delivery.

Health Research Council of New Zealand

We were advised that the statutory functions of the Health Research Council of New Zealand and its funding priorities focus on research that is relevant to human health, including biomedical research and public health research. Arguably this definition of health research does not prevent the council from also considering the economic outcomes of research with a health focus. We understand that a change of legislation would therefore not be needed for the council to take economic outcomes into account in setting its funding priorities.

Most of the HRC's investment funding is received from Vote Research, Science and Technology, and is allocated under its funding agreement for the purpose of obtaining scientific research and development that improves the health status of New Zealanders. Both the Estimates of Appropriations for Vote Research, Science and Technology and the Output Agreement between the Minister of Science and Innovation and the HRC include wording to this effect. The Minister of Health's annual letter of expectations to the HRC indicates that the HRC should contribute to improving health outcomes, improve health delivery, and produce economic gain. Therefore, although some HRC-funded research may generate economic benefits from the subsequent development of products and services, this is not the primary motivation for its investments. Nonetheless, health research funded by the HRC can create economic benefits by reducing sickness and the cost of health service delivery.

Investments in health-related research specifically intended to produce economic outcomes were made through the Foundation for Research, Science and Technology, and are now made through the new Ministry of Science and Innovation.[17] The rationale was that effective commercially-driven investments require a specific set of skills, knowledge, and stakeholder relationships. It has also been considered desirable to avoid duplicating the functions of the Health Research Council of New Zealand and the foundation.

[17] The third reading of the legislation to create the new Ministry of Science and Innovation was completed in December 2010.

The Ministry of Science and Innovation has recently reviewed research, science, and technology priorities and its vote structure. The resulting changes were described in a document *Igniting Potential* that was released early in 2010. They have been reflected in the 2010/11 funding agreements between the Minister and funding and investment agents.

While we understand that extending the role of the HRC to include investing specifically for economic outcomes would be a significant policy change, we see it as an important function that could bring new opportunities to benefit New Zealanders.

Recommendation

49 We recommend to the Government that it ensure the Health Research Council of New Zealand has enough flexibility in its functions to promote innovative scientific health projects that are likely to have economic benefits for New Zealand.

University funding to recognise commercial research

Guidelines released by the Tertiary Education Commission in July 2010 for assessing the quality of research carried out by tertiary education organisations help determine how much funding each organisation receives from the Performance-Based Research Fund. These new guidelines emphasise commercial research and the entrepreneurial application of research. They will apply from the next quality evaluation round in 2012. This was one of a number of recommendations made by the Performance-Based Research Fund Reference Group which have been endorsed by the Minister for Tertiary Education, and the Minister of Science and Innovation.

Funding for clinical research

The Government has stated that in the current fiscal environment any extra Government spending will have to be of the highest quality. New Zealand is very dependent on tourism and primary products for export earnings. To attract more sustainable income it makes sense to develop innovative high-value products.

An optimal clinical trials environment and framework in New Zealand would assist the exploitation of the country's huge potential in the bio-pharmaceutical, medical device, functional food, and bioactive fields. Both public and private investment in science research and development in New Zealand are below OECD levels. Many countries with high research and development investments (such as Singapore, Finland, Denmark, and Taiwan) also have high growth.

Recommendation

50 We recommend to the Government that it set a medium-term objective of bringing New Zealand's public and private investment in research and development up to international benchmarks.

Funding for clinical trials infrastructure and support

We received submissions about the lack of funding dedicated to clinical trials infrastructure, particularly infrastructure involving cooperative multi-centre groups. We considered a suggestion that additional funding be used to support national clinical trials

coordinators. The benefits of any additional Government funding for such infrastructure would have to be assessed carefully against other priorities. We accept that additional information would be required to assess the merits of such funding, but understand that obtaining it would not be expensive.

Recommendation

51 We recommend to the Government that it give priority to achieving optimal clinical trial frameworks, infrastructure, and coordination in New Zealand within 12 months of this report being presented, and make funding available for this purpose.

The Government provides some dedicated funding for research infrastructure. For example, the Ministry of Science and Innovation funds large-scale research infrastructure, which would otherwise have been prohibitively expensive. It can be wasteful if expensive equipment purchased from public funds is used by only one institution.

Recommendation

52 We recommend to the Government that it consider purchasing research infrastructure relevant to supporting clinical trials, and make every effort to ensure that it is used on a coordinated national basis so that as many institutions as possible can benefit from the investment.

Funding of research overheads

One submitter suggested that institutions undertaking or commissioning research should cover research overheads. Under New Zealand's system of full-cost funding for research, the overhead rate for each university is calculated according to a formula. This system has been used since 2003. Research overheads represent, on average, about 40 percent of research grants paid out by the Health Research Council of New Zealand.

A review of health research overheads has recently been completed by the Ministry of Science and Innovation. It was undertaken at the request of the Ministers of Health, Tertiary Education, and Science and Innovation, in response to concerns about the transparency of costing of research overheads charged by universities. The HRC has recently notified the Ministry of Science and Innovation that it will change its research proposal application forms to make the value of overhead charges more transparent.

9 Promoting New Zealand as an environment in which to conduct clinical trials

Industry collaboration and promoting New Zealand as a destination for clinical trials

We consider that the proposal of more collaboration between Government and industry has merit and generally would be better instigated by the industry itself, rather than by the Government. The New Zealand Association of Clinical Research is the professional association for clinical researchers in New Zealand. It aims to foster and promote clinical research, and its members come from a broad range of organisations involved in clinical research. The association made a submission indicating its support for the intent of our inquiry. An organisation such as the association may be well placed to lead an increase in industry collaboration with other relevant bodies.

New Zealand Trade and Enterprise's clinical validation project

Promoting New Zealand as a destination for clinical trials may create value for the economy. New Zealand Trade and Enterprise is the Government agency responsible for improving the international competitiveness of New Zealand's businesses. NZTE is conducting a clinical validation project, to develop a "five-year vision for the broader clinical validation industry".

We understand that the first phase of the project involves completing initial due diligence, after which NZTE will compile and evaluate realistic strategic options for New Zealand in pharmaceuticals, medical technologies, bioactives, and health IT. Initially health IT will be investigated mostly as an enabler to the other three industries.

We were told that after completing this phase, NZTE will choose which, if any, of the strategic options it will pursue. NZTE envisages that it will reach this phase by mid-2011, and it will then present an "action plan" setting out critical success factors for achieving the five-year vision, and "what needs to be done, by whom, and when". The action plan will aim to establish New Zealand as an intelligent global niche-player in the clinical validation industry, and enable New Zealand companies in the health industry to develop high-value products.

NZTE told us that its goals are for New Zealand companies to undertake more clinical validation work both domestically and internationally, and for overseas organisations to conduct more clinical validation work in New Zealand. The achievement of these goals would increase revenue, and thus produce a direct economic benefit.

Financial incentives

The previous Government introduced a 15 percent tax credit for eligible expenditure on research and development activity in 2007, with effect from the 2008/09 income year. The

tax credit was repealed following the 2008 general election but remained in place for the 2008/09 income year.

The Government supports clinical trials through the Health Research Council of New Zealand and the new Ministry of Science and Innovation. To be eligible for funding through the Ministry of Science and Innovation, proposals must be seeking to create wealth for New Zealand. The Ministry of Science and Innovation can support up to 25 percent of the cost of up to phase 2 clinical trials based primarily in New Zealand, but not phase 3 or beyond. Consideration could be given to making industry grants available to joint ventures between New Zealand and international companies.

Recommendations

53 We recommend to the Government that it continue to establish innovative incentive schemes to support public and private research and development through clinical trials where a clear benefit to New Zealand can be demonstrated.

54 We recommend to the Government that it promote New Zealand Trade and Enterprise's action plan to establish New Zealand as an intelligent global niche player in the clinical trials industry.

Appendix A

Committee procedure

We called for public submissions on the inquiry. The closing date for submissions was 16 April 2010. We received 58 submissions, and heard 32 of the submissions. We heard evidence at Auckland and Wellington.

We received advice from the Ministry of Health, the Ministry of Science and Innovation and specialist advice from David Clarke.

Committee members

Dr Paul Hutchison (Chairperson)
Dr Jackie Blue
Hon Ruth Dyson (until 9 February 2011)
Kris Faafoi (from 9 February 2011)
Kevin Hague
Hon Luamanuvao Winnie Laban (until 13 October 2010)
Iain Lees-Galloway
Hon Damien O'Connor (from 13 October 2010 until 9 February 2011)
Grant Robertson (from 9 February 2011)
Eric Roy
Nicky Wagner
Michael Woodhouse

We wish to thank our advisers and all submitters for their extremely helpful views on this subject. In particular we wish to thank the Ministry of Health, the Ministry of Science and Innovation, David Clarke and Dr Neil Domigan from Cranleigh Health, and Professor Sir Peter Gluckman.

Appendix B

Comparison of the regulatory review process in New Zealand and Australia

Note: This discussion is limited to medicines that are not post-registration. Post-registration medicines do not need the approval of Standing Committee On Therapeutic Trials (SCOTT) but still need to undergo the ethical review process.

Summarised in tables 3 and 4 are the key aspects of the Australian and New Zealand review processes.

The Australian system allows electronic submission and only one scientific review is required. While New Zealand has two review processes, these can run in parallel. Ethics committees can defer a decision until hearing from SCOTT. All submissions must be in paper form.

The Australian system is of comparable price when one site is used but will be more expensive with multiple sites. New Zealand has a one-off cost independent of the number of sites used.

Currently there are separate application forms for SCOTT and the regional ethics committees. There is duplication of review processes between ethics committees and SCOTT, which is reflected in the application forms. Australia has adopted a streamlined two option notification system—Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX).

The Australian Clinical Trial Notification and Clinical Trial Exemption System

In Australia, clinical trials of unapproved therapeutic goods (including new medicines, medical devices, and blood products) can be lawfully conducted under one of two schemes.

On one hand, approval may be gained through the Clinical Trial Exemption scheme (CTX), administered by the regulator, the Therapeutic Goods Administration (TGA). This scheme involves the TGA itself reviewing the safety and efficacy data for the product in question. This scheme resembles the New Zealand regulatory environment, in which approvals for trials involving new medicines are administered by Medsafe.

Alternatively, the trial may progress under the Clinical Trial Notification scheme. This involves an ethics committee assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device, the ethical acceptability of the trial process, and approving the trial protocol.

Approvals from four parties (the investigator, sponsor, institution, and ethics committee) are required for a trial to progress under this scheme. Once these approvals are obtained, the sponsor notifies the TGA, pays the required fee, and the trial can then commence.

Nearly all clinical trials of unapproved therapeutic goods in Australia go through the CTN scheme. In 2010, just two of 297 trials went through CTX.

A sponsor can conduct any number of trials under the CTX application without any further TGA assessment as long as the product in the study continues under the approvals usage guidelines. Each new trial must be notified to the TGA, but there is no fee for this additional notification under the CTX scheme.

Table 3 Regulatory approval

	New Zealand	**Australia**	**Comment**
A clinical trial requires approval by (or notification to) a regulatory body if it involves…	…a "new medicine" [NB: all clinical trials in New Zealand, whether they involve a new medicine or not, must also be approved by a health and disability ethics committee, as well as by the institution[s] in which they are to be conducted.	…an "unapproved therapeutic good", including: an unapproved medicine, an unapproved medical device, an unapproved complementary medicine, an unapproved blood product, a new indication or route of administration of an approved product.	A broader range of clinical trials require regulatory approval in Australia than in New Zealand. In New Zealand, trials of new indications or uses of an approved medicine do not require approval by the regulator.
The regulatory body that gives this approval (or receives this notification) is…	-de jure: the Director-General of Health, on the recommendation of the HRC -de facto: Medsafe, on the recommendation of SCOTT	…the Therapeutic Goods Administration (TGA).	None.
The regulatory body reviews…	- the safety and efficacy of the medicine - the suitability of the researchers to conduct the trial, and - the scientific validity of the trial design.	- CTX: the safety and efficacy of the medicine. - CTN: nothing; review of safety and efficacy is done by ethics committees, not by the TGA.	SCOTT review looks at more aspects of clinical trials than that conducted by the TGA under the CTX scheme.

	New Zealand	Australia	Comment
An approval (or notification) applies to…	…the clinical trial itself. On submission of new information the approval can be amended at no cost to include additional study sites and changes to the study protocol.	- CTX: the use of the unapproved therapeutic good for any number of clinical trials within the approved "Proposed Usage Guidelines." - CTN: the clinical trial itself at a named site. A separate CTN must be submitted as additional study sites are approved and where the study protocol is changed.	Whereas approval in New Zealand and CTN notification in Australia apply to the clinical trial itself, approval under the Australian CTX scheme applies to certain uses of the unapproved therapeutic good.
Responsibility for determining whether a trial should be (a) approved by or (b) notified to the regulator lies with…	In NZ the sponsor cannot choose between seeking approval from, or notifying, the regulator. All trials within scope must be approved by the regulator. The study sponsor or ethics committee must determine if the trial utilises a new medicine and therefore requires an exemption from the Medicines Act.	….the sponsor, principal investigator, ethics committee, and institution ("Approving Authority").	In Australia, the TGA cannot require that a given clinical trial within scope should be approved (CTX) rather than notified (CTN). In Australia, where the HRECs lack expertise, CTN applications would be referred to the regulator (TGA).
Approval by (or notification to) the regulator costs…	…NZ$6,525	CTX: either AU$1,390 or AU$17,300 CTN: AU$280 per study per site.	In both Australia and New Zealand, the costs of regulatory approval or notification are very low compared to the total cost of running a clinical trial.

	New Zealand	Australia	Comment
Approval is given within…	- de jure: 45 days - de facto: 12.6 days (in 2009/10 year by SCOTT).	- CTX: either 30 days or 50 days, depending on the information submitted with the application - CTN: approval is not given	In New Zealand, regulatory approval is a very efficient process.
The number of applications received for approval (and notifications) per year is…	…97 (in 2009/10 year to SCOTT).	- CTX: 2 (in 2009) - CTN: 3,201 notifications, for 684 trials (in 2009).	Fewer applications for regulatory approval are received in New Zealand than applications for approval (or notifications) in Australia. NB: the effect of the CTN scheme requiring a separate notification for each study site cannot be ascertained.

If a CTN is submitted legally the sponsor does not have to wait for the TGA's acknowledgment letter before starting the study, although it is advisable to wait for acknowledgement in case there is anything that invalidates the notification.

Under the CTN scheme, trials can begin once the approvals above are obtained, and the sponsor has notified the TGA. Approvals are obtained quickly. This change has been instrumental in Australia building its clinical trial industry rapidly.

Under the CTX scheme, a sponsor submits an application to conduct clinical trials to the TGA for evaluation and comment. A sponsor cannot commence a CTX trial until:

- written advice has been received from the TGA regarding the application
- approval is obtained from an Ethics Committee and the institution at which the trial will be conducted.

The applications to the TGA and the Ethics Committee can be lodged simultaneously; however, the sponsor must convey comments made by the TGA and ethics committees.

There is a proposal to establish an Australia New Zealand Therapeutic Products Authority. The aim is to establish a joint agency to regulate therapeutic products replacing the current agencies of the Therapeutic Goods Administration in Australia and Medsafe in New Zealand. This project is currently on hold.

Table 4 Ethics approval

	New Zealand	Australia	Comment
The ethics committee is responsible for…	reviewing all ethical aspects of the trial, including its scientific validity. reviewing study documentation, including informed consent documents. ensuring appropriate Māori consultation has been carried out. approving each locality in the trial, and each investigator at those localities.	CTX: reviewing all ethical aspects of the trial, except the safety and efficacy of the unapproved therapeutic good. CTN: The TGA does not review any data relating to the clinical trial and the HREC is responsible for ensuring that there is an assessment of the scientific validity of the trial design, and the safety and efficacy of the medicine or device, as well as the ethical acceptability of the trial process.	None.
Approval from an ethics committee is given within… and costs….	no time limit within which approval must be given. no cost to the applicant.	- no time limit within which approval must be given (2009: range in practice was 14-297 days, according to the Australian Government's recently released Clinical Trials Action Group report). - e.g. AU$3,000 excl GST (for industry-sponsored clinical trials in the Queensland public health system).	While many Australian ethics committees charge substantial fees for review, particularly for industry-sponsored studies, ethics committee review does not attract a fee in New Zealand.

Appendix C

Membership of Health and Disability Ethics Committees

The seven Health and Disability Ethics Committees are ministerial committees established under section 11 of the New Zealand Public Health and Disability Act 2000. Each member is appointed by the Minister of Health, and the guiding principle behind the appointments is to ensure that the ethics committees have the appropriate expertise, skills, knowledge, and perspectives to conduct ethical reviews of the best quality.

The six regional ethics committees each have 12 members, while the Multi-Regional Ethics Committee consists of no more than 16 members. One half of the total membership of the regional ethics committees is lay members, including a lay Chairperson and a non-lay Deputy Chairperson. The Multi-Regional Ethics Committee has six lay members and at least six (though no more than 10) non-lay members including a lay Chairperson and a non-lay Deputy Chairperson. A lay person is a person who is not

- currently, nor has recently been, a registered health practitioner (for example, a doctor, nurse, midwife, dentist or pharmacist)
- involved in conducting health or disability research or who is employed by a health agency and who is in a sector of that agency which undertakes health research
- construed by virtue of employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.

The lay membership of the ethics committees is required to include an ethicist, a lawyer, representatives of consumer perspectives, and representatives of community perspectives. The regional ethics committees' expert membership is required to include

- two health researchers
- a pharmacist or pharmacologist
- a biostatistician
- and two health practitioners.

The Multi-Regional Ethics Committee's expert membership is required to include

- at least two health researchers
- at least one pharmacist or pharmacologist
- at least one biostatistician
- at least two health practitioners.

Any meeting of the Multi-Regional Ethics Committee requires at least seven but no more than 12 members to attend in total, with a balanced number of lay and non-lay members in attendance. Health researchers and health practitioners may rotate (on a regular basis) their attendance of meetings.

At any time each Health and Disability Ethics Committee must have at least two Māori members. Māori members should have a recognised awareness of te reo Māori, and an understanding of tikanga Māori. All members of ethics committees are expected to have an understanding of how the health sector responds to Māori issues and their application to ethical review.

The membership of the ethics committees should include expertise in the main kinds of health and disability research which include interventional, observational, kaupapa Māori, and social research, and in both quantitative and qualitative research methods.

Each member should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important for committees to be comprised of people from a range of backgrounds and ethnicities.

Despite the membership of the ethics committees having been drawn from groups identified with particular interests or responsibilities in connection with health and community issues, the members are not in any way the representatives of those groups. They are each appointed in their own right, to participate in the work of the ethics committees as equal individuals of sound judgement, relevant experience, and adequate training in ethical review.