Australia & New Zealand Breast Cancer Trials Group

Submission to the

Strategic Review of Health and Medical Research in Australia

Summary

The Australia and New Zealand Breast Cancer Trials Group is the largest independent, oncology clinical trials research group in Australia and New Zealand. It conducts clinical trials for the treatment, prevention and cure of breast cancer.

The purpose of this submission is to highlight the contribution made by our group and other cooperative groups to improve the health of Australians and to stress the importance of continuing this work.

A national and integrated model of support is needed to facilitate clinical research in Australia. The ability to translate research into targeted treatments for patients requires collaboration between laboratory and clinical researchers, industry partners and government.

Australian research has contributed to many of the global advances in medical treatment, such as survival improvements in cardiovascular disease. Much of the improved outcome for cardiovascular disease has resulted from the use of biomarkers to reduce risk. By contrast, although there have been significant improvements in breast cancer mortality there is no reliable measurable biomarker for breast cancer risk.

The highest priority for Australia is the development of a well-funded genomics discovery facility to (i) assist the discovery of bio markers for mechanisms and targets across all health disciplines; (ii) promote linkage of bio discovery initiatives to controlled outcomes to confirm new treatment targets; (iii) retain and develop new Australian scientific talent. This must also include adequate staffing and funding of such research.

Priority areas for breast cancer research include the conduct of neoadjuvant studies with tissue collection and biomarker research.

There is substantial potential to improve breast cancer outcomes through clinical trials. In addition to the funding provided by NHMRC and other granting bodies there is a need to ensure that clinical trials units receive appropriate government support. The provision of expertise and funding to make this possible should be mandatory for all hospital oncology departments.

Breast cancer research conducted in Australia, predominantly by the ANZBCTG, has contributed to the significant improvement in breast cancer related mortality that has occurred over the last thirty years.

Introduction

The ANZBCTG strongly supports the joint submission made to the McKeon Review by COSA and the Cancer Council representing the fourteen cancer cooperative clinical trials groups (CCTG), however as the longest established cancer clinical trials group in Australia we believe a separate distinct submission is warranted. The purpose of this submission is to highlight the contribution made by such cooperative groups, and to stress the importance of their continuing work.

Background

The ANZBCTG research program involves multicentre national and international clinical trials and brings together over 500 researchers in 80 institutions throughout Australia and New Zealand. This collaboration facilitates the conduct of clinical research in many centres with a wide national geographical spread and ensures the efficient sharing of knowledge, expertise and resources. As a result of such teamwork the translation of research into improved patient outcomes is expedited. Cooperative group clinical research, led by academic clinicians is unique in its focus on answering the clinically important questions that translate into such improved outcomes for patients.

The ANZBCTG has promoted the value and importance of consumer involvement in the planning and conduct of clinical trials research by establishing the Consumer Advisory Panel (CAP) in 1998. This innovation has been recognised globally.

Significant funding is required to support the activities of cooperative groups. Whilst the support from Australian funding bodies such as Cancer Australia and the NHMRC has been and is vital, and much appreciated, it was acknowledged by the ANZBCTG Board of Directors nearly 20 years ago that this was insufficient. As a result, in 1994 the fundraising and education department, Breast Cancer Institute of Australia (BCIA) was established, to ensure additional ongoing funding and increased public awareness of the ANZBCTG research program.

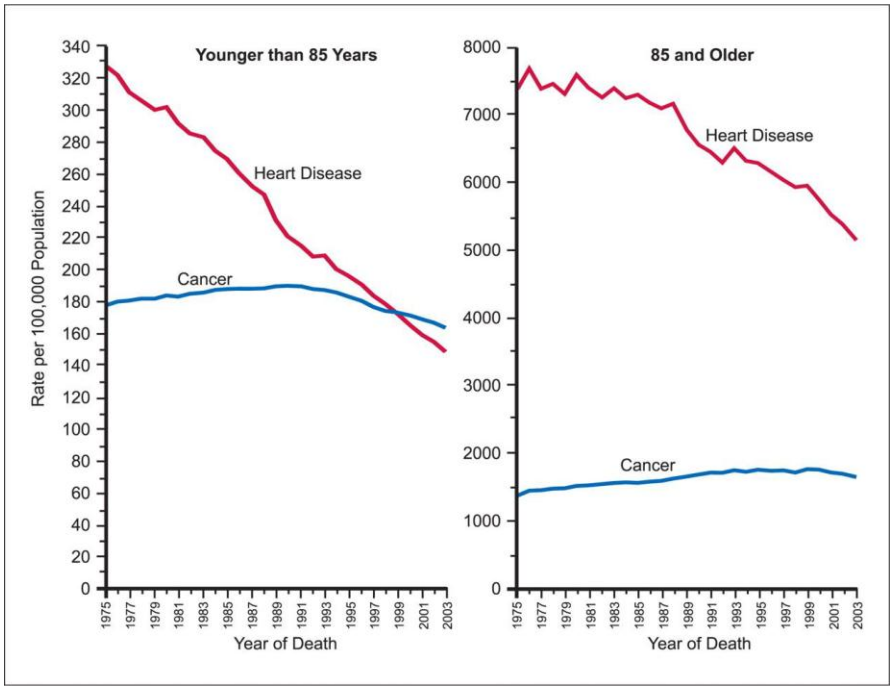
Despite the success of these funding mechanisms, there remain considerable barriers to conducting clinical research, both in financial and logistical dimensions. The ANZBCTG is grateful for the opportunity afforded by the McKeon Review to address these issues, whilst also examining the 'big picture' view of Australia's global position in medical research. We consider our extensive experience in clinical trials research places us in an excellent position to stress the importance of continuing to conduct such research in Australia, and also to provide insight into the ways in which barriers may be reduced or removed.

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

Australian breast cancer research has always 'punched above its weight' in terms of contribution to clinical trials and the advancement of patient outcomes. The clinicians and scientists involved in these endeavours also facilitate the highest quality patient care.

1. Contribution to advances in medical treatment

Australian research has significantly contributed to many global advances in medical treatment, such as survival improvements in cardiovascular disease.



From Jemal, A. et al. CA Cancer J Clin 2007;57:43-66.

Figure 1: Falling Cardiac Mortality

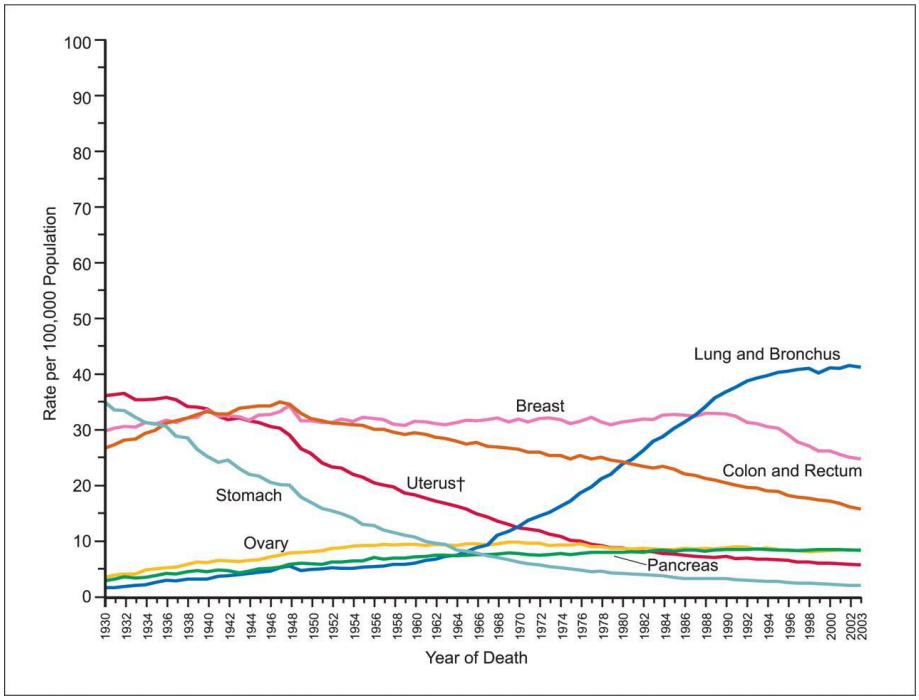
Much of the improved outcome for cardiovascular disease has resulted from the use of biomarkers such as cholesterol and blood pressure to identify individuals at increased cardiovascular risk for whom prescription of risk reduction strategies improves survival. These findings are of global significance and Australian researchers have contributed through clinical trials.

By contrast, although there have been very significant improvements in breast cancer mortality (Figure 2) there is no reliable measurable biomarker for breast cancer risk. Adjuvant systemic treatment is given after surgery and thousands of women and their doctors do not know if the treatment was effective or not until failure occurs with a reoccurrence of breast cancer. Virtually no community follow up is conducted, yet after treatment many women have high risk of reoccurrence of breast cancer more than 15 years after diagnosis and treatment. Clearly discovery of biomarkers for risk, such as in the management of cardiovascular health could provide effective personalised treatment and prevention targets and such research must be a high priority.

Similarly, breast cancer research conducted in Australia, predominantly by the ANZBCTG, has also contributed to the significant improvement in breast cancer related mortality that has occurred over the last thirty years.

Table 1: ANZBCTG Clinical Trial Recruitment – **Total 13,833 patients**

	Before 1990	**1990-1999**	**2000-2009**	**2010-current**
Prevention	-	2309	1429	708
Adjuvant	1287	2292	3142	473
Metastatic	1000	701	430	62
TOTAL	**2287**	**5302**	**5001**	**1243**



From Jemal, A. et al. CA Cancer J Clin 2007;57:43-66.

Figure 2: Breast Cancer Mortality

The median age of death from breast cancer is 68 years, substantially less than that for cardiovascular disease (87.3 years), chronic pulmonary disease and lung cancer (73.2 years) and chronic dementias (88.1 years). Hence there is a substantial potential and indeed imperative to improve outcomes from breast cancer through clinical trials. Testing new interventions in populations that are at higher risk of new events, as determined by biomarkers is cost effective and efficient and facilitates earlier results, as demonstrated by cardiovascular health research.

Australia already has the capability in terms of skills and experience to contribute. The ANZBCTG is developing a tissue bank supported by a grant awarded by the Breast Cancer Research Foundation (USA). Further development of expertise and capability by ANZBCTG in studies in the neoadjuvant (preoperative) setting are assets that will further expedite advances.

2. Retention of Australian expertise and influence on patient outcomes

Australia has a wealth of talent in all phases of health research. Many of those involved in research also provide leadership in a diverse range of health related activities including high quality patient care. It is therefore imperative to support medical research in Australia, in order to retain this experience within Australia.

An ASCO report states that 'Medical societies and educational institutions should encourage and train cancer care providers to conduct clinical research as an integral component of patient care" (Accelerating Progress Against Cancer, ASCO's Blueprint for Transforming Clinical and Translational Research, November 2011). The knowledge gained from cooperative group trials has established therapies that are now routinely used to treat patients with breast cancer.

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

In addition to the funding provided by NHMRC and other granting bodies, to support specific projects and individual major research centres, clinical trials units that undertake the fundamental

work of clinical trial patient recruitment and care in hospitals all around the country, must receive appropriate government support. The provision of expertise and funding to make this possible should be mandatory for all hospital oncology departments. Currently there is no funding for such work and most units depend on higher than cost income from pharmaceutical company sponsored trials to subsidise participation in cooperative group studies.

Mechanisms to expedite approval processes for clinical trials at individual sites are also a high priority. The centralised ethics process has not been able to impact approval times as the individual site governance processes have now become the main barrier to trial start up. If this delay can be circumvented, it will positively impact on the competitiveness of Australia in the global arena.

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

A national and integrated model of support is needed to facilitate clinical research in Australia. The ability to translate research into targeted treatments for patients requires collaboration between laboratory and clinical researchers, industry partners and government. The highest priority for Australia is the development of a first class well-funded genomics discovery facility, in order to (i) assist the discovery of biomarkers for mechanisms and targets across all health disciplines; (ii) promote linkage of bio-discovery initiatives to controlled outcomes to confirm new treatment targets; (iii) retain and develop new Australian scientific expertise. Initial priorities must also include adequate staffing and funding of such research. In breast cancer research priority areas for support include the conduct of neoadjuvant studies with tissue collection in conjunction with biomarker research.

Other priorities include education of clinicians regarding the conduct of clinical research and current research results and their interpretation. Cooperative groups are well placed to provide this education, as ANZBCTG has done for the last 30 years.

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

Promotion of collaboration between Australian cooperative groups, individual researchers, pharmaceutical company researchers and their international counterparts is a priority. The ANZBCTG has long fostered such relationships, for example with the Breast International Group (BIG), Cancer Research UK (CR-UK), the International Breast Cancer Studies Group (IBCSG), Translational Research in Oncology (TRIO), National American Breast Cancer Group (NABCG) and the National Surgical Breast and Bowel Project (NSABP). These have resulted in Australia's involvement in many of the most important breast cancer trials in the last twenty years: primary prevention trials, IBIS 1 (tamoxifen, placebo) and IBIS 2 (anastrozole, placebo, including a bone substudy); the first adjuvant aromatase inhibitor trials (ATAC, BIG 1-98, and IES) and one of the major adjuvant Herceptin trials (HERA). Access to these major international clinical trials would not have been possible without the links the Group has established. Patients and clinicians would have been disadvantaged if these trials had not been available. It is therefore a priority that appropriate collaborations are maintained to support ongoing participation.

Continuing to support an Australian contribution to international consensus statements, treatment guidelines, meta-analyses and overviews, including in the breast cancer sphere, the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) or 'Oxford Overview', St Gallen Consensus Statements and Cochrane reviews will optimise translation of health and medical research into better health and wellbeing.