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Briefing on Breast Cancer Issues in New Zealand

For: **Hon. Dr Jonathan Coleman, Minister of Health**

CC: **Hon. Peseta Sam Lotu-liga, Associate Minister of Health**
Hon. Peter Dunne, Associate Minister of Health
Hon. Annette King, Labour Health Spokesperson
Hon. Kevin Hague, Greens Health Spokesperson

From: **Breast Cancer Aotearoa Coalition (BCAC)**

Date: **17th March 2015**

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1. Introduction

BCAC is grateful for the opportunity to meet with the Minister of Health, Dr Jonathan Coleman and other Members of Parliament to discuss key issues affecting the breast cancer sector in New Zealand.

These issues are of national importance given the significant impact breast cancer has on the New Zealand community.

Breast cancer:

- is the most common form of cancer to affect women, with more than 3000 women diagnosed each year
- accounts for more than 28 per cent of all new female cancers
- kills over 600 women every year and is the second most common cause of death from cancer for women
- disproportionately affects Māori women who are 45 per cent more likely to get the disease and more likely to die from it than non-Māori women
- affects more than 150 women under the age of 40 each year
- has a significantly higher mortality rate in New Zealand than Australia.

[Figures taken from: Cancer: New Registrations and Deaths 2011, Ministry of Health; Campbell et al., Breast cancer survival in New Zealand women, ANZ J Surg 2014; Alafeishat et al., Cancer mortality and incidence trends comparing New Zealand and Australia for the period 2000-2007, NZMJ 2014; Waldon et al. 2014, A comparison of cancer statistics in New Zealand and Australia: 1996 – 2007, NZMJ 2014]

These statistics clearly show that there is work to be done to improve health outcomes for New Zealanders with breast cancer. In our briefing document we aim to highlight the areas where a real difference can be made for those diagnosed with this disease.

We outline:

- recent Government initiatives on breast cancer care
- actions needed to improve outcomes for breast cancer patients.

2. Government Initiatives on Breast Cancer Care

Since BCAC met with the former Minister of Health last year, the Government and Ministry have taken positive steps to improve the breast cancer treatment pathway. These include:

- Continuing to measure and monitor Faster Cancer Treatment wait time indicators, including the 62-day cancer target introduced in October 2014.
- Supporting and facilitating the Breast Cancer Tumour Stream Working Group in finalising elements of the *Standards of Service Provision for Breast Cancer Patients in New Zealand* (BC Standards).
- Intervening when the three northern DHBs were found to be acting outside their legal requirements in refusing to provide funded medicines for cancer patients who were accessing additional treatments in the private sector.
- Increasing funding in the 2014 Budget for psychosocial care for cancer patients.

BCAC applauds all of these actions. Each of them will contribute to improved, more efficient and effective treatment and care for the growing number of New Zealanders diagnosed with breast cancer. But while the BC Standards contain key elements needed for timely, high quality detection, treatment and care, many of the requirements are not yet being met by DHBs. Timely implementation and monitoring is essential in bringing New Zealand closer to achieving best practice breast cancer care.

Excess breast cancer deaths in New Zealand compared to Australia have been calculated at up to 19% (120 excess deaths per year, *Alafeishat et al. 2014*), while 5 year survival rates of 90% in New Zealand compared to 93% in Australia represent a 40% higher mortality rate for breast cancer cases here (*Campbell 2014*). One of the factors contributing to these shocking statistics is thought to be our reduced and slower access to medicines (*Campbell et al 2014*; *Waldon et al 2014*). In this document we highlight the medicines of greatest priority for funding to help reduce this difference and we encourage the Minister to ensure innovative, effective cancer medicines are made available to patients in a more timely manner.

3. Priority Issues

BCAC consulted our member groups as well as cancer clinicians around New Zealand to reveal priority issues for those affected by the disease. Action in the following areas is needed to improve the wellbeing and health outcomes for breast cancer patients in our country.

3.1 Medicines access

BCAC is fully aware that PHARMAC has the role of evaluating medicines and determining priorities for funding. The Minister has overall responsibility for ensuring New Zealanders have

fair and reasonable access to effective medicines that will ensure best possible health outcomes for individuals and the community. Thus in representing our members BCAC wishes to make the case to the Minister for improved funded access to breast cancer medicines. This will require the allocation of additional budgetary funding for medicines as PHARMAC is constrained in its decisions by the total pharmaceutical budget. Medicines recommended by PHARMAC's PTAC for funding wait on average 2.6 years before being listed on the pharmaceutical schedule, with those given high priority for funding taking up to 5 years (Medicines NZ, 2013). New Zealand's access to effective medicines remains low and slow compared to that of Australia, the UK and Canada and for breast cancer patients this costs lives and has a devastating impact on families and communities. Important new medicines funded for breast cancer in Australia and not New Zealand, include pertuzumab (Perjeta, from July 2015), nab-paclitaxel (Abraxane, from 2009), eribulin (Halaven, from 2013) and everolimus (Afinitor, from 2014).

BCAC's member group Metavivors NZ provides a voice for those with advanced breast cancer in New Zealand. This dynamic group of New Zealanders represents a cross section of our society. These people, mostly women, are some of our most engaged and passionate members. Many have young families and are desperate to be alive to support their children as they grow up. Metavivors include professionals in education, medicine, law, social services and many other areas. These are fine New Zealand citizens who need and deserve the support of our public health system. They are well aware of recent research advances that have identified medicines able to provide greater longevity and quality of life and they want and need access to these. They are also aware of the better access to medicines provided in other similar countries and have asked BCAC to raise this matter with the Minister.

Improving quality of life and extending life for New Zealanders with advanced breast cancer should not be seen simply as a charitable act towards an individual who is "going to die anyway". Every person in this situation is surrounded by a network of family members, employers, care givers, and other groups and members of society. Their quality and length of life affects a community: their parents, spouses and children, their friends and workmates, their ability to work, to care for themselves and others, and their demands on their healthcare providers. Although unmeasured as far as we are aware, there are significant social and economic costs associated with providing less-than-optimal medicines for those living with advanced breast cancer.

Below we discuss two medicines that would provide additional months and years of life for those with advanced breast cancer. Clinical trials are under way to determine their benefits in early breast cancer, but results are not yet available. We believe these proven breakthrough medicines should be funded in New Zealand now to give those with advanced breast cancer their best shot at life.

We also discuss a medicine that would free up significant resources in chemotherapy infusion units, resulting in system-wide faster cancer treatment and another medicine that would

improve the quality of life of many breast cancer patients and has been funded in Australia since 2009. We mention two other innovative medicines that are funded in Australia but can only be accessed in the private sector in New Zealand.

3.1.1 Pertuzumab (Perjeta)

HER2-positive breast cancer is present in around 1 in 5 women diagnosed. It is an aggressive form of the disease likely to progress more quickly than other forms of breast cancer. Results from the CLEOPATRA trial (*Swain et al. 2015*) clearly show that adding pertuzumab to trastuzumab and docetaxel as a first line treatment in women with metastatic HER2-positive breast cancer results in an extraordinary additional overall survival benefit of 15.7 months, taking median overall survival to 56.5 months. Following these breakthrough results, Australia announced in December 2014 that pertuzumab would be funded from July 2015 in the public health system. Any lag in funding of pertuzumab here will increase trans-Tasman differences in breast cancer mortality.

Funding this medicine would provide a significantly extended lifespan for many New Zealand patients.

Swain et al. 2015, Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. N Engl J Med 372: 724-734

3.1.2 Trastuzumab emtansine (Kadcyla)

Kadcyla is a new generation of cancer drug, called an anti-body drug conjugate (ADC), which recognises and targets a powerful chemotherapy agent to HER2-positive cancer cells with minimal side-effects.

The large international clinical study, EMILIA, demonstrated its effectiveness as a "second line" strategy in patients with metastatic HER2-positive breast cancer whose cancer had eventually advanced after treatment with Herceptin and a taxane. Kadcyla extended the life of these women by 5.8 months (*Verma et al. 2012*). Kadcyla was approved by the US FDA in February 2013. It is currently under consideration for funding in Australia.

Verma et al. 2012, Trastuzumab Emtansine for HER2-Positive Advanced Breast Cancer N Engl J Med 367: 1783-91

3.1.3 Trastuzumab - subcutaneous injection (Herceptin SC)

Results from the HANNAH study in women with HER2-positive early breast cancer showed that giving Herceptin (trastuzumab) by subcutaneous injection led to comparable efficacy, as well as increased convenience for both patients and clinicians due to a faster administration time than the traditional intravenous method (5 minutes vs 30-90 mins). The NOAH study also showed Herceptin SC to be effective in patients with metastatic breast cancer until the cancer progresses *(http://www.medsafe.govt.nz/profs/Datasheet/h/herceptinscinj.pdf)*.

Use of subcutaneous injection significantly reduced the time patients spent at the treatment centre as well as time spent by clinicians administering the medicine, thereby saving valuable resources. Patients preferred the subcutaneous method as they felt less pain and irritation than with the IV form. There is no need for insertion of a port-a-cath, thus reducing the problems with infection and blockage that patients may encounter.

The key advantage of Herceptin SC is the amount of clinic time that would be saved, thus freeing up infusion capacity for other patients. This resource is a critically limiting step in achieving the Minister's Faster Cancer Treatment targets and Herceptin SC offers a system-wide advancement in treatment speed for patients with other cancers requiring chemotherapy.

BCAC understands the SC product will cost no more that the current infusible form. We also understand that PHARMAC is hesitant to fund Herceptin SC as they are anticipating that an infusable biosimilar trastuzumab may become available over the next few years and there could be resistance from clinicians and patients to returning to a slower, less convenient method of administration.

3.1.4 Nab-paclitaxel (Abraxane)

Taxanes (paclitaxel and docetaxel) are important treatment options in early and metastatic breast cancer. However their use is often compromised by significant toxicity as they are delivered in a solvent that requires slow infusion (compromising faster cancer treatment), causes a hypersensitive reaction in some patients and can lead to chronic irreversible neuropathy (nerve damage that can cause severe pain and cramps, muscle loss, bone degeneration, and changes in the skin, hair, and nails). Nab-paclitaxel is a newer formulation of paclitaxel, delivered as a colloid bound to albumin rather than in a solvent, that has been shown to have a low toxicity profile and to offer significant advantages (*Cucinotto et al. 2013*) such as:

- No hypersensitivity reactions
- Avoidance of high dose steroids as premedication, enabling its use in diabetics
- Neuropathy occurs, but unlike with other taxanes can be reversed
- Infusion times of 30 mins with no premedication vs 90 mins for weekly paclitaxel (when premedications are included)
- Evidence of activity in taxane-pretreated disease.

In addition to the reduced toxicity, nab-paclitaxel also allows a more efficient use of outpatient oncology facilities. While all patients requiring a taxane would benefit, those who have already shown an allergic reaction or have contraindications to a standard taxane are in urgent need of nab-paclitaxel.

Nab-paclitaxel was funded in Australia in 2009 and has since become the preferred taxane, with 71% of Australian patients who use a taxane being treated with nab-paclitaxel by September 2011.

Recent results have shown nab-paclitaxel to be more effective than conventional paclitaxel in eliminating breast cancer tumours prior to surgery (pathological complete response in chemotherapy in a neo-adjuvant setting) in women with aggressive early breast cancer (*Untch et al 2014*), providing a further strong reason to fund this medicine.

Cucinotto et al 2013, Nanoparticle Albumin Bound Paclitaxel in the Treatment of Human Cancer: Nanodelivery Reaches Prime-Time? J Drug Deliv. 2013; 2013: 905091.

Untch et al. 2014, A randomized phase III trial comparing neoadjuvant chemotherapy with weekly nanoparticle-based paclitaxel with solvent-based paclitaxel followed by anthracyline/cyclophosphamide for patients with early breast cancer (GeparSepto); GBG 69. Paper presented at the 2014 San Antonio Breast Cancer Symposium; December 9-13, 2014; San Antonio, TX. Abstract S2-07.

3.1.5 Everolimus (Afinitor) and eribulin (Halaven)

These are two additional innovative medicines funded in Australia for advanced breast cancer that are only accessible in New Zealand for those who can afford to pay for them in a private clinic. Afinitor is used in post-menopausal women with advanced hormone-receptor positive, HER2-negative breast cancer, in conjunction with exemestane. Halaven is used in patients who have received at least two prior chemotherapy regimens for late-stage disease, including both anthracycline and taxane-based chemotherapies.

ACTION POINTS

1.) We ask the Minister:
- to increase the allocation to the pharmaceuticals budget as a vital means of reducing breast cancer mortality, improving patient quality of life and reducing cancer treatment times.

2.) We ask the Minister to consider and discuss with PHARMAC:
- the outstanding benefits of funding Perjeta as a “first line” strategy and Kadcyla as a “second line” strategy in the treatment of metastatic HER2-amplified breast cancer;
- the faster cancer treatment times and greater patient convenience that would be achieved by funding Herceptin SC for subcutaneous injection
- the faster treatment times, reduced hypersensitivity and chronic ongoing neuropathy for patients, and greater effectiveness that would result from funding Abraxane
- the benefits of providing additional targeted treatment options through funding Afinitor and Halaven.

3.2 Access to clinical trials

Access to clinical trials for New Zealand patients is extremely limited. Clinical trials offer breast cancer patients the opportunity to gain early access to innovative life-saving or life-extending treatments. Many patients are frustrated to learn of innovative medicines available in overseas trials that they cannot participate in. Some patients, particularly those with advanced disease, have recently chosen to move to Australia to participate in trials that offer access to promising new medicines. Relocating is difficult and disruptive for these patients and their families, and can mean separation from loved ones at a time when every day together is precious.

The lack of a robust clinical trial environment in New Zealand is outlined in the 2011 Report of the Health Committee chaired by Paul Hutchinson, entitled *Inquiry into improving New Zealand's environment to support innovation through clinical trials* (the Hutchinson Report). Four years later, patient access to clinical trials has not improved, suggesting little progress has been made in implementing the recommendations of the report.

The Hutchinson Report outlines the many benefits of clinical trials to patients, clinicians, the health system and the wider economy.

For patients some benefits of clinical trial participation include:

- Receiving new medicines and treatments
- Better or more intensive medical care than they would otherwise receive
- Education about their conditions to enable them to manage their health better.

NZ's public health system and its clinicians would also benefit from having a stronger clinical trial environment. Some of these benefits include:

- 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
- DHB staff involved in clinical trials gain additional knowledge which can be applied to benefit other patients.

Significant financial benefits to the economy were also documented in the Hutchinson Report including:

- A USA study projects that for every dollar spent on clinical trials at least a four-fold projected net economic benefit to society

- Positive clinical trial data adds significant value to intellectual property generated in the biotechnology, pharmaceutical, medical device, bioactive and functional health food sectors.

The Hutchinson Report notes that New Zealand already has many of the key requirements for a successful clinical trial environment to operate in. These 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. (*Hutchinson, P12*) The Report indicates that alongside the many benefits of clinical trials that low investment in clinical trials can have an adverse effect on health service outcomes and patients' outcomes.

ACTION POINTS

We ask the Minister to:

- initiate a Ministry of Health project involving relevant stakeholders in order to identify and undertake or facilitate key actions to achieve effective implementation of the recommendations of the Hutchinson Report, including ensuring the Government:
  - gives priority to achieving optimal clinical trial frameworks, infrastructure, and coordination in New Zealand and making funding available for this purpose *(Hutchinson Report, p52)*
  - works to improve industry collaboration and promote New Zealand as a destination for clinical trials. *(Hutchinson Report, p53)*

3.3 Ability to review the safety and ethical status of clinical trials in New Zealand

BCAC is very supportive of well designed, ethical clinical trials as the mechanism by which medical knowledge is advanced, treatments improved and quality and length of life increased for breast cancer patients. However, we are deeply concerned that New Zealand's current ethical framework includes no mechanism or body with the role of reviewing the safety and ethical status of clinical trials that have gained past approval and are currently under way in New Zealand. We discovered this critical gap following our approach to the Health and Disability Ethics Committees (HDECS) to raise concerns regarding a trial that was under way and recruiting patients.

New research findings highly relevant to the trial in question were released in 2012 and published in 2013. A large French trial (PHARE) had demonstrated that six months of Herceptin treatment was not as effective as 12 months in preventing cancer recurrence and subsequent death (*European Society of Medical Oncology 2012; the San Antonio Breast Cancer Symposium 2012; Pivot et al., 2013*). A trial under way in New Zealand (Synergy or Long Duration, SOLD) was testing the effectiveness of only two months of treatment. The PHARE results gave a strong

indication that the shortened duration of treatment offered in one of two arms in the SOLD trial would endanger the lives of New Zealand women participating in and being recruited to the trial. We submitted to the Northern B Ethics Committee that this evidence rendered SOLD unable to meet several requirements of New Zealand's Ethical Guidelines for Intervention Studies (2012).

Having received multiple written and verbal submissions from BCAC, supported by submissions from an expert biomedical statistician, and responses from the trial's principal investigator, the Committee concluded that it was outside their scope to consider the status of a trial that had previously been approved. BCAC was faced with a "dead end" and there was no right of appeal to a body that could review or overturn the decision of the Committee. We had raised genuine serious concerns about a trial that we believed to be endangering the lives of many New Zealand women, and we submit that the current ethics system failed us and, more importantly, failed the women in the trial.

We believe it essential that New Zealand's ethics structures be modified to include a mechanism to enable review of the scientific merit, safety and ethical status of a trial that is under way. Such review could be undertaken by a body with appropriate expertise such as the Standing Committee on Therapeutic Trials (SCOTT), the group that reviews trials when they are first proposed.

The National Ethics Advisory Committee (NEAC) is currently undertaking a cross-sectoral review of ethics arrangement including a consultation phase. BCAC has provided a submission to the consultation outlining our concerns and suggesting extension of the SCOTT Terms of Reference to include review of the safety and ethical status of clinical trials that are under way (*see Appendix 1*).

Pivot et al. 2013. 6 months versus 12 months of adjuvant trastuzumab for patients with HER2-positive early breast cancer (PHARE): a randomised phase 3 trial. Lancet Oncol. Jul;14(8):741-8. doi: 10.1016/S1470-2045(13)70225-0.

ACTION POINTS

We ask the Minister to:

- extend the SCOTT Terms of Reference to include review of the safety and ethical status of clinical trials that are under way, or alternatively
- establish an additional independent body able to effectively review the safety and ethical status of clinical trials under way in New Zealand.

3.4 Implementation and monitoring of breast cancer standards

It has been reassuring to see the establishment of the *Standards of Service Provision for Breast Cancer Patients in New Zealand.* However, many of the standards have not yet been

implemented and this continues to impact directly on the health and wellbeing of cancer patients.

Our members across the country have identified several elements of the standards that should be implemented as a priority:

- Access to delayed breast reconstruction
- Lymphoedema treatment
- Fertility preservation

3.4.1 Access to delayed breast reconstruction

In recent months BCAC has become aware of women in the Waikato, Counties Manukau and Dunedin regions who are being dropped from surgical waiting lists and referred back to their GPs without receiving breast reconstruction surgery. Most recently, it was discovered that no women in Dunedin had received reconstructive surgery for the whole of 2014, due to a lack of funding and available theatre time [NZ Herald, 29 Jan 2015, *Dunedin woman forced to wait years for breast reconstruction*].

The issue was raised in late 2014 with the Ministry of Health's National Clinical Director Cancer and BCAC was informed that following discussions between the Elective Surgery group and DHBs, the Ministry had introduced three categories for delayed reconstruction. These are:

1) "Immediate" reconstruction - done at the time of mastectomy, often by the mastectomy surgeon or another (often plastic) surgeon
2) "Delayed primary" reconstruction - done after chemotherapy or radiotherapy is finished
3) "Secondary reconstruction" - elective delayed reconstruction (usually more than one year after original mastectomy).

BCAC is concerned that women who do not make a decision at the outset of their treatment plan will be placed in the "Secondary Reconstruction" category resulting in their surgery becoming a low priority. Having to wait many months or years, being considered a low priority, being dropped from surgical waiting lists and not even being sure whether you will receive breast reconstruction is deeply upsetting to women who have already been through breast cancer.

Being in this situation can impact deeply on emotional wellbeing and quality of life. Pressure to make a decision on breast reconstruction while simultaneously dealing with a diagnosis of breast cancer can add to patient stress and may lead to decisions that are not the best option either medically or psychologically.

BCAC notes the Breast Cancer Standard on Breast Reconstruction:

Standard 8.6 Breast Reconstruction

Clinicians discuss delayed or immediate breast reconstruction with all women who are due to undergo mastectomy, and offer it except where significant comorbidity precludes it. All appropriate reconstruction options are offered and discussed with women, irrespective of whether they are all available locally.

ACTION POINT

We ask the Minister:

- to ensure adequate surgical resources are in place to provide timely post-mastectomy breast reconstruction for all women who need it, including those who do not make a decision to reconstruct at the outset of their treatment.

3.4.2 Lymphoedema treatment

Lymphoedema is a painful and debilitating swelling condition that follows lymph node removal in breast cancer surgery (*see Appendix 2*). When consulting our members in preparation for this briefing, we received multiple submissions from patients, breast care nurses and physical therapists requesting that we ask the Minister to act with urgency to implement this standard. Currently lymphoedema services are being provided by very few DHBs and women are suffering needlessly from this condition. BCAC is pleased that management of lymphoedema is included in the Breast Cancer Standards, and we ask that this Standard be implemented and monitored.

Standard 9.3 - Management of Lymphoedema

Women who develop lymphoedema have access to lymphoedema assessment and therapy services, including complex physical therapy and fitting, provision and replacement of compression garments where indicated.

Good Practice Point 9.16

Lymphoedema assessment and therapy services are available to all women within a reasonable timeframe. Women are advised about lymphoedema prevention and support services available locally and nationally.

ACTION POINT

We ask the Minister to:

- to ensure that comprehensive lymphoedema services are provided by every DHB to ensure that women have equitable access to this important treatment wherever they live in New Zealand, likely involving:
    - a training budget to upskill breast care nurses in lymphoedema massage and kinesio taping
    - establishing a mobile lymphoedema service so that women in rural areas can access this treatment.

3.4.3 Fertility preservation

As noted in earlier Ministerial Briefings (*see Appendix 3*), young women diagnosed with breast cancer generally have aggressive forms of the disease requiring chemotherapy that is likely to compromise future fertility. Good options exist for fertility preservation (*Fertility Preservation for People with Cancer: A New Zealand Guideline. Ministry of Health, 2014*) and New Zealand specialists are willing and able to provide these. Approximately 150 young women are diagnosed with breast cancer each year in New Zealand and we estimate around half of these would want to make use of the service at a total cost of around $550,000. This small investment would have a huge positive benefit for young women diagnosed with breast cancer who are hoping to have future families.

Good Practice Point 8.31

Fertility issues and options for fertility preservation need to be discussed with premenopausal women prior to commencing chemotherapy, preferably well in advance, so that chemotherapy is not unduly delayed if women wish to undergo fertility preservation treatment. Consultation with a fertility specialist is arranged for those women who wish to preserve fertility. Women must receive timely access to fertility assessment and treatment.

Good Practice Point 10.11

Effects on fertility need to be discussed and consultation with a fertility specialist must be arranged for young women who wish to preserve fertility.

ACTION POINT

We ask the Minister to:

- set aside funding to allow timely access to specialist fertility advice and treatment for women under the age of 40 diagnosed with breast cancer, involving
    - initial assessment with a fertility specialist to discuss treatment options
    - oocyte, ovarian tissue and embryo cryopreservation treatment.

3.5 Intrabeam intra-operative radiotherapy

Intrabeam intra-operative radiotherapy (IORT) involves provision of a single treatment of radiotherapy during breast cancer surgery to remove the tumour in patients with low risk early breast cancer. This provides an extremely convenient, efficient and effective option for patients as well as for radiation treatment clinics, in contrast to current standard courses of treatment with whole breast external beam radiation therapy (EBRT) which is given each weekday for three to five weeks. The extended treatment period required for EBRT is often stressful and

disruptive to the lives of patients, and can cause financial hardship, especially for those living at significant distance from radiation oncology treatment facilities. This drives women to make treatment choices that are less than optimal, e.g. women living in Northland are more likely to choose mastectomy ahead of wide local excision or to refuse radiation therapy altogether because of the disruption involved in attending treatment sessions in Auckland. Rates of breast cancer recurrence and mortality did not differ following IORT vs EBRT with 5 years follow-up, but IORT was associated with fewer non-breast cancer-related (cardiovascular and other cancer) deaths and reduced skin and cosmetic damage (*Vaidya et al. 2013*).

The introduction of Intrabeam into our public health system would reduce the level of time and resource needed to treat qualifying patients and has the potential to reduce waiting times for the treatment of other patients with the standard linear accelerator machines. In 2013 BCAC requested that the National Health Committee consider introducing IORT as a funded option in New Zealand's public health system (*see Appendix 4*), and we are pleased that this is now under active consideration.

Vaidya, J., Wenz , F., Bulsara, M. et al. 2013. Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial. Lancet: Nov online.

Action Point

We ask the Minister:

- To facilitate the introduction of intraoperative radiotherapy (IORT) using Intrabeam as a radiation therapy option for selected breast cancer patients within the public health system.

4. Information on BCAC

The Breast Cancer Aotearoa Coalition (BCAC) is an incorporated charitable society established in 2004 to provide a unified, evidence-based voice for the New Zealand breast cancer sector. Our membership comprises more than 30 breast cancer-related groups from around New Zealand, as well as many individual members.

BCAC is run by a committee of women who have experienced breast cancer. We work as volunteers to make world class detection, treatment and care accessible to all those affected by breast cancer in New Zealand. By virtue of our experience and knowledge of this disease, as well as our networks across breast cancer patients, groups and clinicians around the country we are able to provide unique insights into improvements that can be made in the provision of breast cancer services.

BCAC provides direct support to those diagnosed with breast cancer through provision of our *Step by Step* resource pack, our informative website www.breastcancer.org.nz and our web videos at http://www.breastcancer.org.nz/share-your-story/web-videos

4.1 BCAC member groups

- Age Concern
- Alleviate
- Ascot Radiology Pink Dragons
- Boobops Dragon Boat Team
- Breast Cancer Action Trust
- Breast Cancer Network
- Breast Cancer Research Trust
- Breast Cancer Support Inc
- Breast Cancer Support Northland Trust
- Breast Cancer Support Tauranga Trust
- Breast Health NZ
- Busting With Life
- HER2 Heroes
- Inflammatory Breast Cancer Australasia
- Kenzie's Gift
- Look Good Feel Better
- Lymphoedema Support Network
- Metavivors NZ
- PINC & STEEL
- Rotorua Breast Cancer Trust
- Shocking Pink
- Sweet Louise
- Taranaki Dragons
- Te Ha o te Oranga o Ngati Whatua
- Terrier Race Against Time
- The Gift of Knowledge
- The Mamazon Club
- The New Zealand Breast Cancer Foundation
- Waikato Breast Cancer Trust
- Waikato Treasure Chests
- Well Women and Family Trust (formerly WONS)
- YWCA Encore

4.2 BCAC representatives who will visit the Minister of Health

Chairperson: Elisabeth (Libby) Burgess (MNZM)
Libby is a scientist based in Auckland and was a member of the Guideline Advisory Team that developed *Evidence-based Best Practice Guidelines for the Management of Early Breast Cancer* in New Zealand. She is a consumer representative of the Breast Cancer Special Interest Group and the National Breast Cancer Tumour Stream Working Group that developed the *Standards of Service Provision for Breast Cancer Patients in New Zealand*. Libby has actively campaigned on a range of breast cancer issues including the need for fully funded access to Herceptin and other breast cancer medicines, provision of breast reconstruction and timely access to treatment and care. Libby had breast cancer in 1998. She became a Member of the New Zealand Order of Merit in the 2011 New Year's Honours List for her breast cancer work.

Deputy Chair: Dr Chris Walsh (MNZM). Chris was diagnosed with HER2 + breast cancer in March 2006 and joined the campaign to fund Herceptin for 12 months. She has a nursing background and completed her PhD 18 months after her diagnosis. 'I believe that we would have a better health system if consumers had meaningful engagement with those who provide health services. I hope to contribute to BCAC and help make the experience of a breast cancer diagnosis less traumatic for women in New Zealand through undertaking research and representing BCAC in various forums.' Chris works at the Health Quality Safety Commission as Director of a 'Partners in Care' programme which is designed to address improved consumer engagement across the health and disability sector. She is also Chair of the National Cancer Consumer Advisory Group and is on various other national cancer groups as a consumer representative. Chris is also a Director of a consultancy business. Chris was made a Member of the New Zealand Order of Merit (MNZM) in the 2010 New Year's Honours list for services to women's health.

Secretary: Rowena Mortimer

Ms Mortimer is a lawyer who was diagnosed with breast cancer in 2005. She lives in Auckland, is married and has two children. She believes that consumers can play an important role in the planning and delivery of health services. She is a former member of the National Cancer Consumer Regional Advisory Group and has represented consumers on the Northern Cancer Network Collaborative and chaired their Consumer Reference Group. Rowena was also a member of the Northern Cancer Network Breast Cancer Tumour Stream Steering Group.

Committee Member: Moana Papa

Moana is of Māori (Te Arawa, Ngati Kahungunu, Te Whanau-a-Apanui) and Samoan heritage and lives with her husband and two children in Otara, South Auckland. For the last 15 years Moana has worked in community development in Manukau City and Auckland. Moana was responsible for forming Wahine Toa, a group for Māori and Pasifika women with breast cancer and has also liaised with Māori and Pasifika women affected by breast cancer and with related advisory groups. Moana is a member of Metavivors NZ, a group for those with advanced breast cancer.

Appendix 1

National Ethics Advisory Committee
Kāhui Matatika o te Motu

Submission form

Discussion document on the cross-sectoral ethics arrangements for health and disability research

Introduction

The National Ethics Advisory Committee (NEAC) is seeking your feedback on the current health and disability research ethics arrangements, issues with these arrangements and ideas for enhancing them.

This work covers the responsibility for ethical health and disability research and the standards, processes and structures that support this responsibility.

Your feedback will help to inform advice and recommendations to the Associate Minister of Health on how to address the current issues. Your feedback will also inform NEAC's 2015 review of *Ethical Guidelines for Observational Studies* and *Ethical Guidelines for Intervention Studies*.

You can access an electronic version of the discussion document on NEAC's website http://neac.health.govt.nz/consultations

How to have your say

We are seeking feedback by **Friday 27 February 2015**.

To take part, please complete this submission form. You can complete the submission form electronically and send by email to neac@moh.govt.nz or post a printed copy to us to:

National Ethics Advisory Committee Secretariat
PO Box 5013
Wellington 6145

If you have any questions, please contact us by email at neac@moh.govt.nz.

Official Information Act 1982
Your submission may be requested under the Official Information Act 1982. If this happens, it will normally be released to the person who requested it. However, if you are submitting as an individual (rather than representing an organisation), your personal details will be removed from the submission if you check the following boxes:

☐ I do not give permission for my personal details to be released under the Official Information Act 1982.

☐ I do not give permission for my name to be listed in the summary of submissions.

After you've taken part

Your feedback will be analysed and summarised by secretariat staff. The analysis of submissions will be considered by NEAC and assist the committee to provide advice to the Associate Minister of Health.

A summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details under the Official Information Act 1982, the name of the organisation will be given if supplied.

☒ I do want to receive a copy of the summary of submissions.

Submitter's details

Name:	Libby Burgess
If this submission is made on behalf of an organisation, please name that organisation here:	Breast Cancer Aotearoa Coalition
Address/email:	bcac@breastcancer.org.nz
Telephone:	021 990 244

Your feedback

The discussion document outlines issues across six areas, discusses current and other possible responses to these issues, and asks questions for feedback. The final section gives you an opportunity to tell us about anything else that has not been covered by the six areas.

1. Complex research ethics landscape
2. Māori and health research
3. Alternative ethical review structures
4. Peer review for scientific validity
5. Audit and audit-related activity
6. Innovative practice
7. Other issues

The questions in the discussion document are replicated below. We have included a space for you to write your response to these questions.

By way of background, the Breast Cancer Aotearoa Coalition (BCAC) raised concern about the safety and ethical status of the Synergy or Long Duration (SOLD) clinical trial with the Northern B Ethics Committee and asked that the committee review their approval for the trial in light of emerging relevant data from the global clinical trial sphere. In particular, results from the PHARE clinical trial (presented at the European Society of Medical Oncology 2012 and the San Antonio Breast Cancer Symposium 2012 and then published in the Lancet Oncology in 2013) gave a strong indication that the shortened duration of treatment offered in one of two arms in the SOLD trial would endanger the lives of New Zealand women participating in and being recruited to the trial. We submitted that this evidence rendered SOLD unable to meet several requirements of the Ethical Guidelines for Intervention Studies.[1] Having received multiple written and verbal submissions from BCAC, supported by submissions from an expert biomedical statistician, and responses from the trial's principal investigator, the Committee concluded that it was outside their scope to consider the status of a trial that had previously been approved. We believe it essential that New Zealand's ethics structures be modified to include a mechanism to enable review the scientific merit, safety and ethical status of a trial that is under way. Such review could be undertaken by body such as SCOTT. This experience is the basis of the following submissions.

[1] See Appendix One: BCAC Submissions on PHARE trial to HDEC

As a Coalition of over 30 breast cancer groups as well as individual members throughout New Zealand, BCAC has an important role in representing the interests of New Zealand breast cancer patients. We work collaboratively across the health sector to ensure those diagnosed have access to evidence based best practice detection, treatment and care so that all patients experience the best possible outcomes. We also aim to ensure that patients receive high quality information to enable them to make well informed decisions about their treatment and care. Our position regarding clinical trials generally is a very supportive one; however, we consider that it is important that clinical trials in New Zealand are safe for all participants, current and future, and vital that there are the appropriate mechanisms in place to enforce this.

Please feel free to contact us on any of the following points raised.

1. Complex research ethics landscape

a. What could be done to achieve more cohesion across the ethical review system?

b. How useful is NEAC's statement of *Goals, objectives and desired outcomes of an ethical review system* (GODO)?

c. Are the GODO goals adequately covered by the objectives?

d. How could the GODO statement be improved?

e. Is the plurality of functions that various public agencies (eg, Ministry of Health, NEAC, HRC) have to set standards for researchers and for ethics committees sufficiently clear and coherent overall?

f. What would help parties involved in research navigate through the current system?

g. What mechanism(s) could be used to direct or facilitate access to ethical review where a researcher is otherwise unable to access it?

h. What would an opt-in review option for HDECs mean for HDEC workloads, and how would it fit with the recent changes? Does this have the potential to create inefficiencies?

i. Who could provide informal advice for borderline cases for HDEC review or minimal risk applications excluded from HDEC review?

j. How might monitoring and accountability mechanisms for researchers (eg, to ensure good design and conduct of research and communication of results) be improved?

The Standard Operating Procedures for the Health and Disability Ethics Committees (SOPs) outline that an annual safety report must be submitted by the trial researchers. Clause 206.1. states that the annual safety report must include "*a brief description and analysis of new and relevant findings that may have a significant impact on the safety of participants".*

BCAC considers that if there is evidence within the clinical trials arena that has relevance for a trial that is under way, it is the responsibility of the principal investigator to raise this and distinguish this from their own trial. For transparency, this information should also be reported to patients participating and being recruited for the trial to allow them to make a fully informed decision about continuing with or commencing the trial.

New evidence from the trial in question or from another relevant clinical trial may bring into question the safety and ethical status of the trial, and where this occurs recruitment should be suspended and a full SCOTT review instigated.

We note that the SOLD trial has been under way since 2007 and no results have yet been released. BCAC requested that the Ethics Committee seek provision of an interim analysis by the investigators or the Data Monitoring Committee to allow some scrutiny of participant outcomes but this was not undertaken.

While the responsibility for providing meaningful trial updates lies initially with the principal investigator, this researcher has a high level of investment in the trial and may not be the first to recognise evidence that participants may be in danger. There is currently no mechanism for other informed parties to submit relevant data and have this considered through independent medical and ethical review. For example, BCAC submitted data from the PHARE trial to the Northern B Ethics Committee as we deemed this highly relevant to the ethical and safety status of the ongoing SOLD clinical trial. The Committee received multiple written and verbal submissions but concluded that review of the status of a trial that was already approved was outside their scope.

In the case of the SOLD trial, the outcome of the PHARE trial[2] was not reported within an annual safety report to the Northern B Ethics Committee. It is important that the annual reporting mechanism functions as a genuine review rather than a "rubber stamping" exercise.

k. How might monitoring and accountability mechanisms for ethics committees be improved?

As per the SOPs, when the issues regarding the SOLD trial were raised by BCAC, the Northern B Ethics Committee (the Committee) undertook an investigation and accepted further submissions from BCAC and submissions from the Principal Investigator of the trial. The outcome of this investigation delivered the following response from the Committee:

The Committee has considered its role in relation to the ethical review of studies. The 2012 Standard Operating Procedures for Ethics Committees make it clear that, whilst committees are responsible for checking that appropriate peer review of the scientific merits of the study has been carried out prior to the study being approved, it is not the role of the ethics committee to conduct peer review. If the SOLD trial were a new application, the Committee would require evidence of independent peer review of the scientific basis and methodology of the study as well as SCOTT review. The Committee does not have scope to review the scientific merits of the SOLD study. Ethics committees do not proactively monitor approved studies. The Committee is satisfied that there is a Data Safety Monitoring Committee in place to monitor the SOLD trial. The Committee notes that the SOLD study is continuing world-wide and that it has not received notification from the Data Safety Monitoring Committee that there are safety concerns in relation to the trial. The Committee has decided that there are insufficientgrounds to justify withdrawing ethical approval for the SOLD trial.[3]

The comments of the Committee that they were not able to peer review the scientific validity are accepted by BCAC. However, we consider that

[2] See Appendix Two: PHARE Pivot, Romieu et al. 2013

[3] See Appendix Three: Northern B Ethics Committee Letter, dated 14 August 2013

there needs to be a mechanism in place for HDECs to defer to an expert body, such as the Standing Committee on Therapeutic Trials (SCOTT), to review trials under way to ensure that, when issues are raised, the trial still reaches the standards set out in the *Ethical Guidelines for Intervention Studies (NEAC,2012)*.

In light of the the inability of the Commitee to scientifically peer review the merits of the SOLD trial, we consider that the Committee were unable to meet the powers vested in them by the SOPS, particularly clause 219.5 which states that an HDEC may reconsider the approval that is in place for any study on the basis of *any other information received by the HDEC in writing from any party which the chair considers, on reasonable grounds, may give grounds for suspending or cancelling approval*. The powers vested in the committee by the SOPS are redundant if the committee does not have the ability to competently review scientific merits of studies.

This confirms that the ethics review system should be strengthened by allowing a mechanism for scientific peer review of trials already under way.

SCOTT, being the body that approves intervention studies in the first instance, is well equipped to then review the studies should information be brought to their attention that the merits of a study have been compromised or that a study may no longer be scientifically or ethically valid.

Furthermore, the Northern B Ethics Committee stated its willingness to defer to an overseas body that is inaccessible to the New Zealand doctors, researchers, patients, patient advocates and other citizens who may have an interest or concern or are invested in the trial. Clinical trials undertaken in New Zealand must be held to a New Zealand standard, irrespective of their being overseen by an overseas body. There must be an avenue for HDECs, or another appropriate body as suggested above, to examine all relevant evidence and, where deemed necessary, to withdraw approval for a trial on the basis of that evidence. Such review processes should be available where evidence comes to light, either from trial researchers or submitted by other parties, that raises serious valid concerns about the safety of trial participants. This is essential in ensuring the safety and protection of current and future trial participants.

We consider that it is fundamental to the intergrity of the ethics system in New Zealand that clinical trials, which are already underway and have had ethics approval, must continue to meet the ethical standards set out in the *Ethical Guidelines for Intervention Studies (NEAC,2012)*. In order to reassure the public that our ethics system is robust there must be avenues to examine all aspects of a clincical trial that is under way. This must

include the ability to conduct scientific peer review as well as review of safety and ethical status.

2. Māori and health research

a. What additional support or guidance on Māori research ethics would be helpful?

b. How could Māori ethical ideas and frameworks be placed at the centre of research guidelines?

c. Would integrating Māori ethical ideas and frameworks into the core principles of New Zealand's general research guidelines be one way of contributing to or supporting placing Māori ethical ideas and frameworks at the centre of research guidelines?

d. What are the barriers for researchers in undertaking an appropriate consultation process with Māori?

e. What mechanisms could be available for HDECs to obtain further advice, if required, on Māori consultation and research design?

f. What more could be done to ensure research outcomes are relevant to Māori interests, aspirations and wellbeing?

3. Alternative ethical review structures

a. What mix of HDECs and institutional ethics committees (both public and private sector) should be allowed or encouraged?

We have no particular suggestions on the mix of committees but we do note that it is vital that ethical approval and review processes are conducted by fully independent panels. It would be extremely difficult for committee members to make unbiased judgement on clinical research proposed by colleagues or workmates. Working and personal relationships are very likely to colour the views of colleagues with decision-making powers. It would, for instance, be difficult for internal committees to criticise or refuse approval for work proposed by an influential Head of Department who is in a position to affect staff career development. In the interests of natural justice, as stated in clause 54 of the SOPS, HDECs must ensure that their decision making is impartial and transparent. As noted, this is inherently difficult when facing colleagues with whom one has a close working relationship; allowing independent experts to be brought in from outside region provides a possible means of reducing this difficulty.

b. Should the emergence of ethics committees that are established by standalone businesses or trusts be allowed, or even encouraged?

c. Should alternative ethical review structures be monitored, and if so, who could do this?

d. What would an accreditation process for alternative review structures need to include to be credible?

e. Are there any other suggestions (apart from accreditation) for ensuring good

governance frameworks and quality of review for ethical review structures?

f. What is the indemnity status of alternative ethical review structures?

g. Is the indemnity status a barrier to seeking ethical review from alternative structures?

4. Peer review for scientific validity

a. What are the barriers to accessing scientific peer review?

When a trial is first proposed, the SCOTT review mechanism is in place for scientific peer review. However, once a trial is under way there is no further access to an independent body able to conduct scientific peer review. This is the case even when new evidence comes to light suggesting a trial may be unsafe for participants. BCAC notes that a trial's Data Monitoring Committee has a role in reviewing participant safety during a trial but that the integrity of New Zealand's ethics system requires a further ability to conduct an independent medical and ethical review where concerns have been raised. Often trial Data Monitoring Committees are based outside New Zealand and the identity of committee members is unknown so they cannot be approached. There is currently no mechanism by which concerned parties can provoke review of a clinical trial that is under way in New Zealand. We suggest that the clinical trial system be modified to include a mechanism for further SCOTT review where required.

Furthermore, in Part Two, Clause 11 of the SOPs outlines that an HDEC may suggest or require that additional peer review be carried out if they do not consider that that scientific peer review is "sufficiently robust". This, too, should be extended to include the ability to suggest or require additional peer review of a trial already underway when evidence is submitted to the HDEC that clearly raises valid questions of the scienfitic

validity of the trial.

b. What other options could be provided for researchers seeking scientific peer review?

c. What additional guidance on scientific peer review would be helpful?

d. What mechanisms could be available for HDECs to obtain advice on the scientific peer review of a proposed study?

We consider that the SCOTT review mechanism currently in place is an appropriate means for HDECs to obtain advice on the scientific and ethical merits of a newly proposed trial. However, we submit that a further mechanism should be available for HDECs to obtain advice on the scientific and ethical status of a study that is already under way. See our comments in relation to this throughout our submissions.

5. Audit and audit-related activity

a. Does the current classification of studies into observational research and audit or related activity act as a barrier to audit and related activity?

b. Do you think the definition of audit could be improved, and if so, how?

c. How useful is it to classify studies into observational research and audit for

the purposes of knowing whether or not ethical review is required?

d. Are there other international approaches for distinguishing between research and audit that have worked well?

e. Could a risk assessment approach be applied to observational studies when thinking about whether or not ethical review is required?

6. Innovative practice

a. Should further guidance be developed on innovative practice?

b. What guidance on innovative practice would be helpful for health professionals?

c. What are your views on current processes for reviewing innovative practice?

7. Other issues

a. What other issues are associated with the cross-sectoral ethics arrangements for health and disability research?

As noted, in BCAC's experience, the Northern B Ethics Committee was unable to effectively review and ascertain whether a clinical trial that was under way continued to meet the requirements set under the Ethics Guidelines. In order for the integrity of clinical trials to be upheld in New Zealand, an ongoing review mechanism must be established for cases where concerns are raised about the validity, safety or ethical status of a trial.

BCAC was faced with a "dead end" and there was no right of appeal to a body that could review or overturn the decision of the Committee. We had raised genuine serious concerns about a trial that we believed to be endangering the lives of many women, and we submit that the current ethics system failed us and, more importantly, failed the women in the trial.

Furthermore, Clause 9 of the SOPs refers to Right 4 (2) of the Code of Health and Disability Services Consumer Rights 1996 which is the right to appropriate standards and states, in particular, that "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards" but disclaims, essentially, that the researchers are themselves responsible for ensuring that their research meets these standards at all times not HDECs. We submit that in order for researchers/investigators to be transparent, and meet this standard, there must be the ability for third parties to hold these researchers/investigators to account. A system that states that a researcher/investigator must uphold certain ethical standards but does not allow the ethics system to hold them accountable is fundamentally flawed.

b. How might these issues be addressed?

As submitted above, BCAC considers that it is appropriate for clinical intervention trials that are under way to be subject to review by an independent New Zealand body capable of undertaking scientific and ethical consideration as occurs when a trial hypothesis is initially proposed. As noted, a suitable body already in existence is the SCOTT committee.

We suggest, as a possible remedy for this flaw, that the SCOTT Committee's terms of reference should be extended to allow for HDECS that have received information questioning the scientific merits, safety or

ethical status of an ongoing clinical trial, to refer to SCOTT for review and guidance as they currently do for proposed trials.

Additionally, the SCOTT terms of reference should be extended to include a provison such as clause 219.5. of the HDECS SOPs which would allow SCOTT to reconsider approval on the basis of information received from any party.

Appendix 2

Lymphoedema prevention, treatment and aids - information from *Briefing on Breast Cancer Issues in New Zealand* by BCAC, 2012

Lymphoedema treatment

Lymphoedema is a common side effect of breast cancer surgery, particularly when women have lymph nodes removed as part of their treatment. Around 13 per cent per cent of those who have axillary node dissection during breast cancer surgery will develop significant lymphoedema that requires treatment (*Asim et al,. 2013*). Lymphoedema often occurs in the arm or hand on the side of breast surgery, but it can also occur in the breast, underarm, torso, or back. The condition results in an excessive build-up of fluid in one or more of these areas and requires specialist and on-going care. If women do not receive treatment, swelling can worsen and result in permanent changes to the tissue.

Lymphoedema can be a debilitating condition that can severely impact on quality of life. Currently, the Ministry of Health does not require DHBs to provide a lymphoedema service for breast cancer patients so many women are not getting the care they need. The service levels provided throughout the country are patchy. In some areas women receiving breast cancer treatment through a public hospital have no access to lymphoedema services and women in many rural areas have poor access to lymphoedema practitioners.

Lymphoedema is a common side-effect of breast cancer surgery and treatment should be provided within any comprehensive breast cancer treatment programme. We'd like to see the Ministry of Health direct DHBs to include this as part of breast cancer service coverage.

A cost-effective way to address this issue would be to offer training to breast care nurses to provide some of the lymphoedema treatment required by women. To address service inequalities in rural areas we suggest the establishment of a mobile lymphoedema service in which a trained breast care nurse or lymphoedema practitioner could travel to rural areas to provide treatment on a regular basis for women who need it.

Action points

- Ministry of Health to include lymphoedema treatment as part of breast cancer service provision by District Health Boards.
- Provide a training budget to upskill breast care nurses in lymphoedema massage and kinesio taping so that they can provide treatment for women with lymphoedema.
- Establish a mobile lymphoedema service so that women in rural areas can access this treatment if they need it.

3. Muhammad Asim, Alvin Cham, Sharmana Banerjee, Rachael Nancekivell, Gaelle Dutu, Catherine McBride, Shelley Cavanagh, Ross Lawrenson, Ian Campbell, 2012. Difficulties with defining lymphoedema after axillary dissection for breast cancer. *NZ Medical Journal* 125 No 1351, pgs. 29-39.

Appendix 3

Fertility - information from *Briefing on Breast Cancer Issues in New Zealand* by BCAC, 2012

Fertility Preservation

Around 150 New Zealand women under the age of 40 will be diagnosed with breast cancer every year. Many of these women will either have not started their families or have not completed them. Younger women are frequently diagnosed with a more aggressive form of breast cancer and this is more likely to require chemotherapy treatment. The chemotherapy agents used to treat breast cancer can have a detrimental effect on the ovaries, with 20 to 70 per cent of women becoming menopausal as a result of treatment. Women are also usually advised to delay conception for a number of years after a breast cancer diagnosis which can further impact on fertility.

In order to preserve their fertility options, younger women who are about to undergo chemotherapy need to consider either oocyte (egg) or embryo cryopreservation, in which eggs or embryos are frozen for potential future use. For some, ovarian tissue cryopreservation may be an option. When these women are ready to become pregnant the frozen egg or ovarian tissue is thawed, fertilised and transferred to the uterus as an embryo.

However, cryopreservation of oocytes, ovarian tissue and embryos is not currently publicly funded for women who become menopausal as a result of chemotherapy treatment.

We believe women should have choices about their future fertility options and that women who have been treated for breast cancer should have access to publicly funded fertility treatment, just as other women who have been identified as infertile do.

We would like to see New Zealand women affected by breast cancer receive a funded first assessment with a fertility specialist to discuss their options. Where the woman is medically fit, has sufficient time and is informed of the potential risks of hormonal treatment, she should be offered a publicly funded cycle of oocyte or embryo cryopreservation.

We estimate that around half of the 150 women aged 40 or less diagnosed with breast cancer each year would wish to access a specialist assessment and approximately half of these women may wish to undergo either oocyte or embryo cryopreservation. The cost of subsidising this service for around 75 women a year at a cost of $7,500 per treatment would be approximately $550,000. We believe this spending would be well received by the general public and would make a dramatic difference for young women with breast cancer for whom the prospect of losing their fertility can be extremely distressing.

We are aware that the current providers of fertility treatments in New Zealand have the capacity and the willingness to provide a comprehensive fertility preservation service. The National Child Cancer Network has recently established a Fertility Preservation Working Group.

This group is currently working on nationally agreed guidelines for fertility preservation that will include recommendations for adult cancer patients.

Action Points

- Provide funding for women with breast cancer under the age of 40 to have an initial assessment with a fertility specialist to discuss treatment options.
- Publicly fund oocyte, ovarian tissue and embryo cryopreservation treatment for women under the age of 40 with breast cancer.

Appendix 4

Intrabeam – BCAC letter to National Health Committee November 2013

Associate Professor Anne Kolbe
Chair
National Health Committee
Ministry of Health
PO Box 5013
Wellington

19th November 2013

Dear Associate Professor Kolbe,

Re: Request to consider introducing intraoperative radiotherapy using Intrabeam for selected patients with breast cancer

I write on behalf of the Breast Cancer Aotearoa Coalition (BCAC), an incorporated society with charitable status representing more than 30 New Zealand breast cancer-related organisations as well as individual members throughout the country.

BCAC requests that the National Health Committee consider introducing intraoperative radiotherapy (IORT) using Intrabeam as a radiation therapy option for selected breast cancer patients within the public health system.

The provision of a single treatment of radiotherapy intra-operatively using Intrabeam provides an extremely convenient and efficient option for patients as well as for radiation treatment clinics. This is in contrast to current standard courses of treatment with whole breast external beam radiation therapy (EBRT) given each weekday for three to five weeks. The extended treatment period required for EBRT is often stressful and disruptive to the lives of patients, and we are hopeful that this may be avoided for appropriately selected patients. The introduction of Intrabeam into our public health system would reduce the level of time and resource needed to treat qualifying patients and has the potential to reduce waiting times for the treatment of other patients with the standard linear accelerator machines.

The Intrabeam technique delivers radiation directly to the tumour bed, the most common site of breast cancer recurrence. The TARGIT-A (Targeted Intra-operative Radiotherapy) clinical trial randomised patients to receive either whole breast EBRT or IORT using Intrabeam, with updated results recently published in The Lancet (Vaidya et al. 2010; 2012; 2013). The trial began recruiting patients in 2000 and closed after the enrollment of 3451 women. The 3451 patients have had a median follow-up of 2 years and 5 months, while four-year follow-up is available for 2020 patients and five-year follow-up for 1222 patients.

Some patients received IORT to the tumour bed at the time of initial surgery to remove the tumour (pre-pathology group, n=2298), and some had it during a second surgical procedure (post-pathology group, n=1153). The local recurrence rate for the pre-pathology IORT group of 2.1% (1.1 – 4.2) was not significantly different from that in the standard EBRT treatment arm of 1.1% (0.5 – 2.5) (p= 0.31)). The recurrence rate was somewhat higher in the post-pathology group.

Breast cancer mortality did not differ between the combined pre- and post-pathology IORT group at 2.6% (1.5 – 4.3) and the EBRT group at 1.9% (1.1 – 3.2) (p=0.56). However, there were significantly fewer non-breast cancer deaths with IORT at 1.4% (0.8 – 2.5) compared to 3.5% (2.3 – 5.2) for EBRT (p=0.0086). This was due to fewer cardiovascular deaths (2 vs 10) and fewer deaths from cancers other than breast (8 vs. 16). In the pre-pathology group, at 5 years (n=2298), there were 29 deaths in those receiving IORT and 42 in those receiving EBRT. Overall 5 year mortality was 3.9% (2.7 – 5.8) (37 deaths) for the combined IORT group vs 5.3 (3.9 – 7.3) (52 deaths) for EBRT (p=0.099) (n = 3451).

We suggest that patient selection criteria for the use of Intrabeam IORT in New Zealand be set to be the same as those used for the TARGIT trial. We further suggest that every effort be made to use the therapy at the time of initial surgery, as this appears to achieve the best result in disease-free survival.

Thirty-three centres in 10 countries recruited patients to the TARGIT-A trial and we note that IORT using Intrabeam is now gaining rapid and wide uptake around the world. More than 5000 women with breast cancer have been treated worldwide with this form of IORT. We are pleased to see the introduction of IORT with Intrabeam into New Zealand at a private Auckland clinic and hope to see this adopted for appropriately selected patients in the public health system in the near future.

BCAC therefore asks that the National Health Committee look into the Intrabeam IORT technology with a view to introducing this option into our public hospitals for appropriately selected women with early, low-risk breast cancer.

Yours sincerely,

Libby Burgess, MNZM
Chairperson
Breast Cancer Aotearoa Coalition
www.breastcancer.org.nz

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