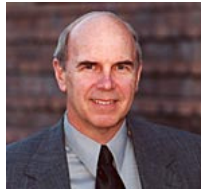


The Herceptin debate: what price a woman's life?**By Professor Don Iverson**

Professor Iverson is Dean of the Faculty of Health and Behavioural Sciences at the University of Wollongong. He has a special interest in breast cancer research, serving on the Board of Directors for the National Breast Cancer Centre and the NSW Cancer Council Research Committee. He has also written a report for the National Breast Cancer Foundation on breast cancer research priorities.



Professor Don Iverson

What price do we as a nation put on a woman's life?

Breast cancer is the number one cancer-related killer of Australian women, yet the Therapeutic Goods Administration (TGA) has not yet given approval for the use of a drug that is recognised as the biggest breakthrough in breast cancer treatment in two decades.

The drug - Herceptin - is a therapeutic antibody treatment that has previously been shown to increase survival time among women whose breast cancer has spread. Three recent studies have demonstrated that Herceptin dramatically reduces the mortality rate in women who have HER-2 positive early breast cancer. Herceptin has been approved by the TGA for use in women whose breast cancer has spread, but use of the drug among women with early breast cancer has not been approved by the TGA.

Herceptin is one of the new family of so-called "targeted" drugs that are designed to follow genetic pathways in the body. Unlike chemotherapy, which typically results in damage to healthy organs and tissue, this extraordinary new drug is designed to specifically target the cancer and the HER-2 protein while having very few damaging side-effects.

HER-2 occurs in one in four women with breast cancer, but those who have it are at an especially high risk of developing aggressive breast cancer. Their survival rate after treatment is considerably lower than women who have other forms of breast cancer.

The recent trials on Herceptin found that women with early breast cancer who took the new drug after surgery (mastectomy or lumpectomy) and chemotherapy reduced their likelihood of having a recurrence of breast cancer by 52% and reduced their likelihood of dying from breast cancer by 33%.

These are stunning results, and should be great news for Australian women, especially those who are HER-2 positive. But without TGA approval for use in the treatment of early breast cancer, patients must pay for the drug. And this is the problem.

Herceptin currently costs around \$60,000 - enough to put it out of reach of most Australian women. It is clearly an expensive new drug. However, the nation should accept that treating eligible women with Herceptin is an investment that is entirely justified given its demonstrated ability to reduce breast cancer recurrence and improve survival rates.

Obviously the loss of a life has a tragic impact on the victim and her family, so it should be our priority to explore all reasonable avenues to save that life.

But if legislators and the TGA need more convincing of the worth of this \$60,000 investment, they can simply be pragmatic and count the cost to the nation of the loss of a life. Consider the example of a 45-year-old mother of two. If she dies of breast cancer, then the nation loses 20 or more years of her productive life, not to mention the childcare and other costs of caring for her family, and the psychological impact that the loss of their mother will have on her children.

As a nation we seem prepared to meet the hundreds of thousands of dollars that major transplant surgery costs, the thousands of dollars spent each year on patients requiring associated haemodialysis, and the ever escalating costs associated with high-tech medical procedures.

On that basis, we shouldn't quibble about spending \$60,000 for Herceptin. It really is a small price to pay when its capacity to save many women's lives has been proven beyond doubt.

Having said that, a recent study published in the British Medical Journal examined the increase in the cost of pharmaceuticals over a 14 year period in the province of British Columbia. The study found that 80% of the increases in government expenditure on pharmaceuticals were due to the introduction of 'me-too' drugs - drugs that replaced existing drugs but without any significant clinical benefit. Less than 20% of the increase was related to 'breakthrough' drugs - drugs that had a significant clinical benefit over existing drugs or drugs that are effective in treating conditions for which no viable treatment previously existed.

Herceptin for the treatment of HER-2 positive early breast cancer is one such drug. It is entirely feasible that the cost of Herceptin and other 'breakthrough' drugs could be paid for if the TGA did not allow the ever increasing number of 'me-too' drugs to be

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approved. This is an important issue as it is reasonable to expect a number of 'breakthrough' drugs will be released in the near future as the basic research conducted over the past decade begins to pay significant benefits. The Commonwealth needs to address this situation immediately.

Prostate cancer is the most common cancer in men.

Like breast cancer, prostate cancer is an insidious and deadly disease. Over 11,000 cases of prostate cancer are diagnosed annually in Australia, and treatment of prostate cancer all too frequently results in severe complications, notably incontinence and impotence. Next to lung cancer more men die from prostate cancer than any other cancer. To date, there is no conclusive clinical trial data to demonstrate that treatment of prostate cancer prolongs life.

Given this scenario and the fact that the political decision-making process is dominated by males, one has to wonder if a drug was released tomorrow that had as dramatic an impact on prostate cancer recurrence and survival rates as Herceptin has on early breast cancer whether that drug would be 'fast tracked' for approval by the TGA

When any 'breakthrough' drug has been demonstrated through internationally accepted clinical trials to have a significant benefit on cancer recurrence and/or survival rates, the drug should be 'fast tracked' for approval by the TGA. The only benefit from delaying the decision to approve such drugs is cost-savings--but this occurs at the cost of lives that could be saved. The Federal government should resolve this and future similar situations by requiring the TGA to immediately 'fast track' approval of Herceptin for the treatment of early breast cancer.

Key facts about breast cancer in Australia

- One in 11 women will be diagnosed with breast cancer before the age of 75.
- Breast cancer is the second most common cancer among Australian women, after non-melanoma skin cancer.
- In Australia in 2001 a total of 11,791 women and 95 men were diagnosed with breast cancer.
- The risk of breast cancer increases with age. Almost 24 per cent of new breast cancer cases diagnosed in 2001 were in women aged 20-49; 49 per cent in women aged 50-69; and 27 per cent in women aged 70 and over.
- The incidence of breast cancer in women rose from 100.5 cases per 100,000 population in 1991 to 117.2 cases per 100,000 population in 2001; an average increase of 1.4% per annum.
- The increase in incidence in the 50-69 year old age group in 1993 and 1994 was most likely the result of the introduction of the national breast cancer screening program, given that this has been the main target age group.
- The five-year relative survival rate for Australian women with breast cancer during 1992-97 was 84 per cent, compared with 72.3 per cent in 1982-86. The five-year relative survival rate represents the proportion of people who would survive five years after diagnosis with cancer if all other causes of death were excluded.
- Breast cancer is the most common cause of cancer-related death in women in Australia.
- A total of 2594 women died from breast cancer in Australia in 2001 (last available national figures).
- From 1991 to 2001, the breast cancer mortality rate declined by an average of 2.2 per cent per annum.

As there is currently no means of preventing breast cancer, the focus in reducing deaths has been on finding breast cancer as early as possible and ensuring women receive the best available treatment. To identify breast cancer in its earliest stages the National Breast Cancer Centre recommends that all women from the age of 50 have a regular mammogram, be aware of the normal look and feel of their breasts and see their doctor immediately should any unusual signs or symptoms occur. The government and the TGA are responsible for ensuring that women with breast cancer have access to the best available treatments. This will not be the case until Herceptin receives TGA approval for use in the treatment of early breast cancer among women who are HER2 positive.

Reference:

Statistics from Cancer in Australia 2001 (864kb pdf external link) ([Australian Institute of Health and Welfare \(AIHW\)](#)) and Australasian Association of Cancer Registries, 2004).

Last reviewed: 24 May, 2007