Evaluating Cancer Therapies and Developing a Cancer Program

Extracts from a presentation by

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The medical profession has a good track record in trauma intervention.

It does not have such a good record in the treatment of degenerative diseases such as cancer, coronary heart disease and arthritis.

In this presentation I will cover:

- The evidence for efficacy of orthodox and alternative therapies
- What this means in terms of paradigms for cancer
- What is the *alternative* paradigm?
- What therapies fit into this approach?
- What is the role of orthodox therapies?
- How to put together a cancer control program

Lack of evidence for medical intervention:

"Only about 15% of medical interventions are supported by solid evidence... This is partly because only 1% of the articles in medical journals are scientifically sound."

Richard Smith, Editorial "Where is the wisdom...? The poverty of medical evidence." BMJ (October 5) 1991; 303: 198-99.

Recently the peer-review system (that decides what to publish) has also come into disrepute:

"If peer review were a new medicine it would never get a licence...We had great difficulty in finding any real hard evidence of the system's effectiveness, which is disappointing, as peer review is the cornerstone of editorial policies worldwide"

Tom Jefferson, from the Cochrane Collaboration Methods Group interviewed by The Guardian (London) Sydney Morning Herald Jan 18-19, 2003.

What has led to this situation?

First let us look at what the consensus of opinion was up to 200 years ago before the development of what is now known as modern Western medicine.

In ~400 BC Hippocrates, the founder of Western Medicine believed that cancer was caused by an accumulation of toxins arising in the body in the form of "black bile".

In ~150 AD Galen, the founder of experimental physiology and pathology continued Hippocrates' ideas on cancer causation (black bile toxins) and treated the condition with medicines, diet and some surgery.

In 1520 AD Paracelsus believed that "it is not the physician who heals, but nature". Identify the cause. Treatment should then be designed to strengthen the body's own defences.

Paracelsus also said: "It should be forbidden and severely punished to remove cancer by cutting, burning, cautery, and other fiendish tortures. It is from nature that the disease arises and from nature comes the cure, not the physician."

His system of treatment included not only remedies but also a form of psychotherapy, because the causes of every disease are "to be found in the soul and spirit as well as in the body". He was thus the founder of the psychosomatic approach.

Josef Issels, Cancer: A Second Opinion. Hodder and Stoughton, London, 1975.

From about 1800, with the development of the achromatic microscope, individual cancer cells could be seen.

All of the past thousands of years of knowledge and experience in the treatment of cancer was thrown out and it became the accepted dogma that the tumour was the disease, not a local symptom of a disease of the whole body. So its removal was assumed to be a cure.

Surgery and anaesthetics became more sophisticated and became the only mode of treatment until radiotherapy was developed in the early part of the 20th century and chemotherapy was added from the 1950s.

What I am arguing is therefore that in throwing out this old accepted paradigm of cancer being a systemic disease 200 years ago Western medicine has been travelling along a dead end street. As a result fewer than 6% of medical interventions for cancer have been shown to be effective in terms of extending life.

What is basis of my claim? What constitutes reliable evidence?

The following summarises reliability of claims for efficacy in decreasing order of reliability:

• Properly run randomised controlled trials supported by epidemiological evidence -	BEST
• Properly run randomised controlled trials -	GOOD
• Comparison of incidence and mortality over time -	FAIR
• Epidemiological evidence -	FAIR
• Increasing percentage 5-year survival supported by epidemiological evidence -	FAIR
 Increasing percentage 5-year survival - 	POOR
• Anecdotal/Clinical evidence -	POOR

Epidemiological evidence looks at how a particular intervention, such as a new treatment, change in treatment or new screening technique affects mortality after its intervention.

For example the introduction of the Pap test for cervical cancer in the 1950s had no subsequent impact on the rate of change of uterine cancer mortality. This had already been falling for many years as can be seen from the next slide.

Insert slide Pap Test.jpg (available from author on request)

So what I am saying is that for cancer fewer than 6% of interventions are supported by reliable evidence such as at least properly run randomised trials, the top two levels of reliability.

The types of cancer with some evidence for efficacy are:

- Short-term increase in survival from cutting out or shrinking tumours obstructing or pressing on vital organs using surgery, radiotherapy or chemotherapy (anecdotal evidence)
- Chemotherapy for acute childhood lymphocytic leukemia (ALL) (increasing survival rates)
- Chemotherapy for some sub-groups of women with breast (poorly run randomised trials)
- Tamoxifen for breast cancer (properly run randomised trials)

In none of these cases is there any evidence for Cure. What is Cure?

Cure means that a group of people treated for a particular type of cancer have the same mortality rate as a comparable group of healthy people in the community.

As no such group of people exists among treated cancer patients it is misleading to use the word cure. Instead I use *control* or *eliminate*.

What is the meaning of the terms control and eliminate?

Control means the ability to live a long and good quality life, ultimately not dying of the cancer but with it.

For example many people die of natural causes but still have breast, prostate or other cancer present in their body.

Eliminate means that all traces or symptoms of the cancer have gone.

This does not necessarily mean that the person will not die of cancer later if the causes of the cancer have not been removed.

Most treatments for cancer are apparently based on an invalid paradigm, explaining why they have little proven effect on survival. The term *cure* has been modified by the medical profession to: *survival for 5 years without evidence of the disease*. This covers up the lack of cure for any type of cancer.

In addition those who survive 5 years are incorrectly claimed to have survived this long only as a result of medical intervention, whereas there is no evidence for this claim.

The Inefficacy of Orthodox Cancer Treatments

The following information refers mainly to scientific evidence based on results from clinical trials.

It is not meant to imply that particular treatments don't provide survival benefits to some people.

If results show no overall benefits, this could mean that some people benefit and live longer, but there must also be a comparable number who are harmed and live for a shorter time.

Today's audience represents a special group, many of whom are using alternative therapies.

Some orthodox therapies when used alone provide no proven benefit – yet when used with an alternative therapy can provide significant benefits.

Similarly, early detection of cancer is of little use unless a therapy based on a valid paradigm is then

used.

What led me to conclude that medical science in the cancer field was seriously flawed?

I will illustrate this in reference to cancer surgery but the same conclusion applies generally to radiotherapy and chemotherapy.

I will then look at an alternative paradigm about what cancer is and how to choose an alternative cancer therapy based on that paradigm.

Evaluating Surgery for cancer

In 1993 I published a paper in which I presented evidence that showed that surgery had not been proven in any randomised trial to be an effective treatment for any type of cancer, ie had not been shown to extend life or reduce mortality by comparing a treated group with an untreated group.

I therefore had to use other methods of evaluating the efficacy of surgery.

Benjamin, D. The Efficacy of Surgical Treatment of Cancer. Medical Hypotheses 1993; 40: 129-138.

I used six different methods to evaluate surgery:

- □ the graphical method
- comparison of survival over time
- □ the dose response method (extent of intervention)
- comparison of incidence and mortality
- epidemiological method
- □ alternative paradigm method

None of these methods showed that surgery had affected survival or mortality for any type of cancer

All the evidence pointed to cancer being a systemic disease for which surgery would be irrelevant, in other words a disease explained by an alternative paradigm.

In 1996 I presented evidence that, contrary to widespread claims, mammograms don't save any lives and that:

- □ Claims for efficacy of earlier surgical intervention are based on flawed randomised trials that ignored the effects of five other variables including the harm done by radiotherapy. There should be only one variable in a properly run randomised trial.
- □ If any of these variables were used differently in the study group as compared with the control group, the conclusions from the trials were invalid.

The variables in the two arms of all of the six trials:

- use of mammograms
- □ time of surgical intervention (how early)
- extent or degree of surgical intervention (mastectomy vs lumpectomy)
- use of radiotherapy
- use of chemotherapy
- use of hormone therapy

Benjamin, DJ. The Efficacy of Surgical Treatment of Breast Cancer. Medical Hypotheses 1996; 47: 389-397.

All of these other variables were used differently in the study group when compared with the control group

I therefore tried to identify which of these other variables could have affected mortality, and how their different use in the two groups might have produced this apparent reduction in breast cancer mortality

I found that most of the apparent saving of lives could be explained by women who would have died from breast cancer instead dying from other causes, due to the harmful effects of radiotherapy damaging the heart and respiratory systems.

All trials were flawed because their authors had not noticed that the reduced deaths from breast cancer were accompanied by a similar increase in deaths from other causes, giving no significant overall benefit from screening.

My 1996 findings have recently been confirmed by members of the Nordic Cochrane Group in Denmark who concluded that because of flaws in all of the trials, screening for breast cancer with mammography is unjustified. There is no evidence from such trials that mammograms save lives or even extend survival.

Olsen, O and Gøtzsche, P. Cochrane review of screening for breast cancer with mammography Lancet 2001; **358***: 1340-42.*

The actual effect I identified, harm from radiotherapy, has also been confirmed in several papers:

1. A review of 36 randomised trials comparing mortality after surgery and radiotherapy with surgery alone. The observed 6% reduction in deaths from breast cancer was accompanied by a 24% increase in deaths from other causes which the reviewers attributed to damaging effects of radiotherapy on the heart. There was no overall benefit observed from the radiotherapy.

Early Breast Cancer Trialists' Collaborative Group. Effects of Radiotherapy and Surgery on Early Breast Cancer – An Overview of the Randomised Trials. NEJM 1995; **333** (22): 1444-1455.

- 2. An analysis in Sweden of this effect found that patients who received the highest dose of radiotherapy had a
 - □ 30% increase in heart failure
 - □ 100% increase in deaths due to cardiovascular disease
 - □ 150% increase in death due to ischemic heart disease

The difference became clear after 4-5 years and continued to increase up to 10-12 years.

Geynes G et al. Long-term cardiac morbidity and mortality in a randomized trial of pre- and postoperative radiation therapy versus surgery alone in primary breast cancer. Radiother Oncol (Aug) 1998; **48** (2): 185-190.

The actual mechanism of the damage to the heart has been established.

The excess observed in another analysis was confined to the sub-set of patients treated with tangential cobalt-60 fields for left-sided tumours, where the dose to the myocardium was greatest.

They observed that for left-sided tumours the dose to the left anterior descending coronary artery remained high even with newer techniques with lower doses.

Cuzick J et al. Cause–Specific Mortality in Long-Term Survivors of Breast Cancer Who Participated in Trials of Radiotherapy. J Clin Oncol (March) 1994; **12** (3) 447-453.

Another form of screening for breast cancer, breast self-examination (BSE) has also recently been found to produce no benefits in survival.

So early detection of breast cancer has no benefit if only orthodox treatments are then used.

Baxter, N. Preventive health care, 2001 update: Should women be routinely taught breast self-examination to screen for breast cancer? CMAJ (June 26) 2001; **164** (13): 1837-46.

Thomas DB et al. Randomized trial of breast self-examination in Shanghai: final results. J Natl Cancer Inst 2002; 94 (19): 1445-57.

What I have said in relation to breast cancer also applies in relation to surgery for other forms of cancer. For example:

A recent paper reported on the result of a randomised trial comparing Radical Prostatectomy with Watchful Waiting for prostate cancer. This is probably the first randomised trial to evaluate the effects of surgery by comparing survival or mortality with an *untreated* group.

It also contained serious flaws. For example

- it used an ambiguous definition of "*death from prostate cancer*" and claimed a 50% reduction in mortality using surgery as compared with watchful waiting.
- An analysis of the deaths from other causes showed that most of the apparent reduction in deaths
- from prostate cancer could be explained by
 - wrong attribution of deaths from prostate cancer to deaths from other causes in the treated group; or
 - deaths from other causes attributed to prostate cancer deaths in the watchful waiting group.

The reduction in overall mortality was not significant.

Holmberg L et al. A randomized trial comparing radical prostatectomy with watchful waiting in early prostate cancer. N Engl J Med (Sep 12) 2002; **347** (11): 781-9.

Comment by Scott D Stern in NEJM of (January 9) 2003; 348 (2): 171.

Similarly a paper reporting on results of a randomised trial comparing mortality after PSA screening with an unscreened control group also contained serious flaws.

- Although its authors claimed a 69% reduction of deaths as a result of screening they arrived at this figure by
 - comparing only 23% of those invited for screening in the Invited group (who were actually screened) with 93.5% of those in the Uninvited group (who were actually unscreened), a meaningless comparison in randomised trials because they were unmatched groups; or, in a second analysis by
 - combining part of the Invited group with part of the Uninvited group (those actually screened in each group) and compared their mortality with that of a different group made up from combining part of the Invited group with a part of the Uninvited group (those actually unscreened in each group), another meaningless comparison because they were unmatched.

An even more serious flaw was that

• the authors completely ignored the deaths from other causes in their calculations

When the whole Invited group was compared with the whole Uninvited group the difference in mortality was not significant – the only meaningful comparison.

Labrie F et al. Screening decreases prostate cancer death: first analysis of the 1988 Quebec Prospective Randomized Controlled Trial. Prostate 1999; **38**: 83-91.

Comment by Rob Boer and F Schröder. Quebec Randomized Controlled Trial on Prostate Cancer Screening Shows No Evidence for Mortality Reduction. The Prostate 1999; **40**: 130-131; and Freda Alexander and Robin Prescott. Reply to Labrie et al. The Prostate 1999; **40**: 135-136.

Surgery can of course extend a life by removing an obstruction to a vital organ such as the bowel, but this does not affect the cancer process, as the tumour appears to be only a symptom of that process.

Similarly there is no proven significant benefit from radiotherapy or chemotherapy – except for the same life-threatening situations.

Rather, post-operative radiotherapy and chemotherapy have been found to **increase** mortality in all forms of cancer where these therapies have been evaluated.

For example a trial comparing radiotherapy added to surgery with surgery alone for Post-operative radiotherapy (PORT) for non-small cell lung cancer showed that

PORT Meta-analysis Trialists Group. Post-operative radiotherapy in non-small-cell lung cancer: systematic review and meta-analysis of individual patient data from nine randomised controlled trials. Lancet 1998; **352**: 257-263.

An analysis of records from 1.2 million cancer patients showed that non-cancer deaths constituted 21% of all deaths and were 37% higher than expected, and most occurred shortly after diagnosis. So the authors attributed it to treatment.

This excess in deaths from other causes ranged from 9% for breast and colon cancer to 173% for lung cancer. Major causes of these excess deaths were heart and respiratory failure, the types of death expected from radiotherapy and chemotherapy.

Brown, Barry W et al. Non-cancer deaths in White Adult Cancer Patients. JNCI 1993; 85 (12): 979-987.

Surely early detection resulting from screening must save lives as is claimed. It is used for many other types of cancer: cervix (Pap smear), colon (fecal occult blood test) and lung (X-rays)

A recent review of randomised trials evaluating screening for cancer has also cast doubt on the benefits of these forms of screening for the same reason that I discovered that the mammogram and PSA screening trials were all flawed: Authors had looked only at reduced deaths from the cancer and ignored comparable increases in deaths from other causes resulting from harm caused by the screening or subsequent treatment.

Let us have a look at this evidence.

The first slide describes the evidence necessary to show that a particular type of cancer screening is effective in reducing the cancer mortality rate using a properly randomised controlled trial.



- In the two columns their height represents the total number of deaths from all causes in the two arms of the trial: the screened group and the unscreened (control) group.
- In the top section of each column is a black area representing how many of these overall deaths were due to the particular type of cancer.
- For the screening to be effective in saving lives the black section at the top of the left column must be smaller than the black section in the right column; AND, IN ADDITION
- The height of the white section in each column must remain the same.
- If the black section in the left column decreases and the white section increases by about the same amount, there is no proven benefit from screening.

The second slide shows in Figure A the results of 7 randomised trials evaluating breast cancer screening using mammography.

Most of the trials were found to have serious flaws. The one with the fewest flaws Malmo showed no reduction in deaths from breast cancer and a reduction in deaths from other causes.

The Health Insurance Plan of New York (HIP) Trial was found to be flawed for several reasons. The Gothenburg Trial showed a small benefit that was not significant. The Edinburgh Trial was flawed due to poor randomisation, which was based on screening centres, not individuals. The Canadian Trial 1 (women aged 40-49) showed slight harm from screening but this was not significant. The Canadian Trial 2 (women 50-59) also showed greater harm but this was also not significant.

Cancer authorities usually quote the results of one of the flawed trials called the Swedish 2 County trial. There was a reduction in deaths from breast cancer (~30%) shown as a fall of 1.2 on the left column, accompanied by a comparable increase in deaths from other causes, shown as an increase of 1.3. The net result was no overall benefit. This result suggests that treatment harmed many of the

women and they died as a result of the treatment, thus reducing the apparent deaths from breast cancer.

Death resulting from treatment should be included among deaths from the cancer for which they were being treated. This did not happen, mainly because many of the women who died had several problems: the breast cancer had produced some symptoms but these were accompanied by heart problems caused by damage from the radiotherapy, and respiratory problems caused by chemotherapy.

Unless the determination of cause of death is "blinded" the real cause of death can be missed.

The third slide shows in Figure B the results of three trials evaluating colon cancer screening using the Fecal Occult Blood Test (FOBT).

Insert slide colon screen3.jpg ((available from author on request)

In the first two trials (Minnesota and Nottingham) there was a fall in deaths from colorectal cancer but in each case this was accompanied by a similar increase in deaths from other causes, showing the effect of harm from the treatment.

In the third (Funen) trial, although there was an apparent fall in deaths from colorectal cancer, the accompanying larger fall in deaths from other causes throws some doubt on the validity of the trial. In any case the fall in overall deaths was not significant.

When a result is *not significant* this means the confidence interval in the result is wide enough to include zero, ie no benefit. This suggests the result is likely to be due to chance, not treatment.

The fourth slide shows in Figure C the results of two trials evaluating X-ray screening for lung cancer.

Insert slide lung screen3.jpg ((available from author on request)

Both trials showed an apparent increase in deaths from lung cancer after screening.

In the Czechoslovakian Trial the difference in all-cause mortality between the two groups was much greater than the lung cancer mortality in the control group despite the fact that the two groups were

well matched after randomisation. This suggests an under-reporting of deaths from other causes (and therefore also from all causes) in the control group biasing the results against screening.

Black W, Haggerstrom D and Welch HG. All-cause Mortality in Randomized Trials of Cancer Screening. J Natl Cancer Inst, 6 Feb 2002; **94**(3):167-73; Author's response to discussion:5 June 2002; 94(11):865-6.

So like prostate cancer screening, none of the other screening trials showed any benefit from earlier intervention following screening. Despite this clear evidence, cancer authorities are arguing for retaining breast cancer screening, extending it down to women aged 40-49 and introducing colon cancer screening.

It would therefore appear that "expert" opinion is based not on evidence but faith and vested interests.

There has been much recent debate about the benefits of early detection, particularly with prostate cancer. It shows a serious misunderstanding of the nature of evidence by some "experts".

The following are some quotes from the two sides of the debate:

Alan Coates, CEO State Cancer Council -

"In the absence of symptoms there is no point in having a PSA test. The test turns healthy old men into cancer patients or cancer suspects without any proof that it helps stop them dying from the disease".

Australian Financial Review, 13 February 2003.

Phillip Stricker, Director of urological oncology, St Vincents Hospital -

"We have treatment that can cure prostate cancer. And you can't find cancer of the prostate if you don't look for it".

Sydney Morning Herald, 18 April 2003.

Michael Schildberger, former Executive Producer and host of Channel Nine's "A Current Affair" -

If I'd listened to Professor Coates' advice I'd probably be dead by now.

Anthony Costello, professor and director of urology at Royal Melbourne Hospital -

Coates is preaching a very old dogma and the debate has moved on...Coates is relying on epidemiology, which isn't an exact science and there is now enough clinical evidence to show that diagnosing prostate cancer early through PSA testing does save lives.

Ralph Hunt, former federal Health Minister also believes he is alive today only because of testing and early treatment.

Alan Coates replies:

Their position is based on an untested assertion and as such is a matter of faith, not science. While it would be nice to think we had moved on, it would be even nicer to have evidence rather than dogma to support this assertion.

Australian Financial Review, 10 and 13 February 2003

What is the evidence behind these opposing assertions? Their relative reliability in relation to prostate cancer is as follows:

• Properly run randomised controlled trials supported by epidemiological evidence -

	BEST	No g	good trials done
• Properly run randomised controlled trials –	GOOD	No g	good trials done
• Comparison of incidence and mortality over time –		FAIR	No evidence
• Epidemiological evidence		FAIR	Some evidence
• Increasing %-age 5-year survival supported by epidemiological evidence evidence evidence by epidemiological evidence e	ence –	FAIR	No evidence
 Increasing %-age 5-year survival – 		POOR	No evidence
 Anecdotal/Clinical evidence – 		POOR	Some evidence

So it would appear that Alan Coates is right: Those claiming benefits from intervention following early detection are making an untested assertion that is a matter of faith, not science.

The same can be said for all other types of cancer that have been evaluated using randomised trials.

Other scientists who have questioned the efficacy of orthodox therapies for cancer include:

Hardin B Jones, Professor of Medical Physics at the University of California at Berkeley:
"... no studies have established the much talked about relationship between early detection and favourable survival after treatment"... "The apparent life expectancy of untreated cases of cancer ... seems to be greater than that of treated cases"..."Neither the timing nor the extent of treatment of the true malignancies has appreciably altered the average course of the disease."

Delivering a "Report on Cancer" at the American Cancer Society's Science Writers' Conference in New Orleans, 7 March 1969.

In 1980 Australian medical doctor **Richard Taylor** (now Associate Professor at Sydney University) had published a damning critique of his profession attacking the excessive use of unproven and unsafe tests, treatment and technologies. He concluded that

"... 'medical science' would be better labelled 'science-fiction medicine'.. This... is particularly apt for a supposedly scientific discipline which pays more attention to promoting its technology than evaluating it, and spends more time stridently announcing victories than carefully analysing failures"

Taylor, Richard. Medicine Out of Control, Sun Books, Melbourne 1979

John Bailar: "The US death rate from all cancers other than lung, stomach and cervix (sites which have shown marked changes in incidence in recent decades) has not altered appreciably since 1950, when chemotherapy was virtually non-existent and other forms of treatment were primitive by modern standards".

He concluded that

"...35 years of intensive effort focussed largely on improving treatment must be judged a qualified failure".

Progress against cancer, New England Journal of Medicine (May 8) 1986; 314 (19): 1226-1232.

Thomas L Dao: Professor of Surgery at Roswell Park Park Memorial Institute's Department of Breast Surgery.

"Despite improved surgical techniques, advanced methods on radiotherapies, and widespread use of chemotherapies, breast cancer mortality has not changed in the last 70 years."

Quoted by Greenberg, DS, in "Progress" in Cancer Research Don't Say It Isn't So. N. Engl. J. Med. 292 (13), 1975, 707-708.

Miles Little: Emeritus Professor of Surgery, University of Sydney

"Despite refinements in surgical technique and management, and increasingly radical surgery, there is considerable doubt about the impact of surgery on the natural history of most malignancies. The apparently logical hypothesis that earlier diagnosis and more radical excision would lead to more cures, has not been borne out in practice. Surgery brings a mechanical approach to a biological problem".

Quoted by Jacka J. in Statistics relating to cancer, p.1 in Cancer - A Physical and psychic profile. Currency, Melbourne, 1977. (addressing a cancer conference at Sydney University in 1974).

James E. Devitt, MD PhD, FRCSC

"...Have we missed the forest by focusing on the tree? Perhaps the **breast lesion is not the cause of the disease but merely the local expression** resulting from a combination of changes in both local organ-tissue and systemic growth-restraining factors."

Breast Cancer: have we missed the forest because of the tree? Lancet 1994; 344: 734-5.

Ulrich Abel, PhD, Biostatistician, Institute for Epidemiology and Biometry, University of Heidelberg, Germany

"Success of most chemotherapies is no less than appalling"... "There is no scientific evidence for its ability to extend in any appreciable way the lives of patients suffering from the most common organic cancers"... "Chemotherapy for malignancies too advanced for surgery, which accounts for 80% of all cancers, is a scientific wasteland".

Chemotherapy of Advanced Epithelial Cancer, Hippocrates Verlag GmbH, Stuttgart, 1990. Biomed & Pharmacother 1992; 46: 439-52.

Despite this information the cancer situation is not at all as bleak as it appears.

There is good evidence for effective treatment based on an alternative paradigm

What is this alternative paradigm?

But before looking at alternatives what is this evidence based medicine that has found flaws in most orthodox therapies?

What is Evidence-Based Medicine?

Practising EBM involves five distinct steps:

- Converting the need for information into an answerable question. The question can be a "background" question involving general knowledge about a particular disease or disorder (such as "what host resistance factors protect asbestos-exposed workers from contracting mesothelioma?") and a "foreground" question involving information about managing patients with this specific disorder (such as "in older patients with pulmonary mesothelioma from crocidolite exposure does adding radiotherapy yield enough reduction in morbidity to be worth its adverse effects?");
- 2. Tracking down the best evidence with which to answer that question;
- 3. Critically appraising the evidence for its validity, size of effect and usefulness in clinical practice;
- 4. Integrating the clinical appraisal with clinical expertise and the patient's unique biology, values

and circumstances;

5. Evaluating one's effectiveness and efficiency in carrying out steps 1-4 and seeking ways to improve them both for next time.

In other words it involves evaluating the latest evidence and seeing how it can best be applied to the patient's particular needs and values.

The Cochrane Collaboration is an international group of medical scientists devoted to increasing the proportion of medical interventions that are based on good evidence rather than on the "opinion of experts"

If one were to look at the Cochrane Library you wouldn't find much in there supporting current interventions for cancer.

The Alternative Paradigm

I have said that there is good evidence for effective treatment based on an alternative paradigm

What is this alternative paradigm?

Let's look at the evidence first, then explore the paradigm, so we can develop a cancer control program based on that paradigm

The Role of the Mind and Emotions in Degenerative Disease

Behaviour therapy is the only method proven in several randomised trials to prevent cancer (and coronary heart disease) and produce a significant reduction in mortality in those with these degenerative diseases. What is behaviour therapy?

According to this evidence, because of their learnt behaviour/temperament, people either

- are susceptible to getting cancer (cancer prone) sometimes called a Type C personality, or
- are susceptible to getting CHD (CHD prone) sometimes called a Type A personality, or
- have emotional problems but don't get cancer or CHD, or
- are **emotionally healthy** and don't get cancer or CHD

Let us look at this evidence

3235 people diagnosed with stress were given questionnaires to determine their personality profiles

901 were categorised as *cancer prone*

818 as coronary heart disease (CHD) prone
570 as a mixture of psychological tendencies but not likely to develop either cancer of CHD
946 as the *healthy autonomous* type

After 13 years follow-up

Of the 901 cancer prone, 39% had died of cancer (7% of CHD)	61% were still alive
Of the 818 CHD prone, 25% had died of CHD (4% of cancer)	75% were still alive
Of the 570 not likely to develop cancer or CHD	81% were still alive
Of the 946 healthy autonomous type	95% were still alive

This strongly supports the hypothesis that degenerative diseases such as cancer and CHD have an emotional basis. How can this knowledge be used for prevention and treatment?

(a) Prevention

When this type of person was treated with a particular type of individual behaviour therapy results were dramatic. For example

Cancer **incidence** treated dropped from **42%** to **26%** Cancer **mortality** dropped from **32%** to **0%**

Using group therapy results were still good but not as dramatic (incidence down from 56% to 32%, mortality down from 47% to 7.5%.

Eysenck, HJ & Grossarth-Maticek, R. Creative Novation Behaviour Therapy as a Prophylactic Treatment for Cancer and Coronary Heart Disease - Results. Behav Research and Therapy 1991; 29 (1): 17-31.

It is therefore clear that behaviour therapy can be used to affect a person's learnt behaviour and thereby significantly reduce their risk of getting cancer and other degenerative disease. But what is its effect on people who have already got cancer? Let us look at the results of five well-run randomised trials:

(b) Treatment

1. Effect of Behaviour Therapy on Terminal Cancer Patients

This study involved 24 pairs of cancer patients with six different types of inoperable cancer, including scrotal (1), stomach (2), bronchiolar (7), corpus uteri (4), cervical (5) and colorectal (5).

Survival times of the treated group averaged **5.07 years** (ranging from 1.7 yrs for bronchiolar to 9.5 yrs for colorectal). For the control group survival averaged **3.09 years** (ranging from 1.0 yrs for bronchiolar to 4.9 yrs for colorectal). This is an increase in survival of **64%**.

2. Effect of adding Behaviour Therapy to chemotherapy for metastasised breast cancer

50 women with metastasised breast cancer for whom chemotherapy had been proposed were divided into pairs matched for age, social background, extent of cancer and medical treatment. One of each pair was then randomised to receive psychotherapy in addition to chemotherapy. 30 hrs of psychotherapy was given to one group of 25 women. The other group of 25 received only chemotherapy.

Mean survival times for the 25 patients who received chemotherapy plus psychotherapy was **22.4 months** compared with **14.08 months** for the 25 who received chemotherapy alone, an increase of **59%**.

3. Effect of adding psychotherapy to no treatment for women with metastasised breast cancer

50 of those who refused chemotherapy in the trial above were matched, then one of each pair was randomised to receive psychotherapy.

Mean survival for the 25 patients who received psychotherapy was **14.9 months** compared with **11.28 months** for the 25 who received no treatment, an increase in **32%**.

It was also observed that the lymphocyte count of those receiving psychotherapy continued to rise over time whereas those not receiving psychotherapy fell, suggesting that the psychotherapeutic intervention may have had its effect through the involvement of the immune system.

Eysenck, HJ & Grossarth-Maticek, R. Creative Novation Behaviour Therapy as a Prophylactic Treatment for Cancer and Coronary Heart Disease - Results. Behav Research and Therapy 1991; 29 (1): 17-31.

4. Effect of structured psychotherapy on women with metastasised breast cancer

A randomised trials measured survival after structured psychotherapy for late stage breast cancer patients:

86 patients with metastatic breast cancer were randomised into two groups, a study group of 50 and a control group of 36. Both groups had routine oncological care, but the study group was offered a $1\frac{1}{2}$ hr weekly supportive group therapy and self-hypnosis for pain for 1 year.

Average survival for the study group was **36.6 months** compared with **18.9 months** for the control group, a **94%** increase in survival.

Spiegel, D. et al. Effect of psychosocial treatment on survival of patients with metastatic breast cancer, The Lancet, October 14, 1989..

5. Effect of structured psychotherapy on people with malignant melanoma

28 men and 33 women with melanoma were randomised into two groups, a study group of 35 and a control group of 26. The study group was given a structured psychotherapy group intervention which lasted about 1¹/₂ hours per week for 6 weeks.

After 6 years there were only 3 deaths out of 34 (9%) in the treated group compared with 10 out of 34 (29%) in the control group (corrected for smaller size) - a **69%** reduction in mortality.

Fawzy FI et al. Malignant melanoma. Effects of an early structured psychiatric intervention, coping, and affective state on recurrence and survival 6 years later. Arch gen Psychiatry Sep 1993; 50 (9): 681-9.

So clearly particular forms of structured psychotherapy such as behaviour therapy have a dramatic effect on survival or mortality, far greater than that observed with any orthodox therapy.

The mechanism of this connection between the mind/emotions and the body is now becoming more widely understood, eg

- unexpressed or inappropriately expressed emotions give rise to circulating protein peptides
- cell receptors on the brain or other organs respond to these peptides and they enter the cells of the organ
- □ cell metabolism is disrupted
- $\hfill\square$ the immune system becomes weakened
- □ health deteriorates

Candace Pert, PhD. Molecules of Emotion, Touchstone, NY, 1999.

Eight factors have identified that lead to disease in general:

- D physiological factors such as poor nutrition, lack of exercise, environmental pollutants
- □ unresolved emotional stress factors
- □ lack of control, power or dominion over one's life
- □ loss of sense of humour, inability to differentiate between the serious and the trivial
- \Box the effect of one's negative belief system
- □ loss of the ability to give and receive love
- □ being in a spiritual vacuum lack of awareness of one's self identity; despair
- □ denial of one's problems inability to accept one's situation, blocking change

Caroline Myss, C Norman Shealy. The Creation of Health, Bantam, Sydney 1999.

So what is this cancer profile that is claimed to lead to cancer?

According to Eysenck the essence of this type of temperament is the absence of autonomy, ie

emotional dependence, which prevents such people from making independent decisions in the light of their own best interests

So what is this behaviour therapy and how does it change a cancer prone person's behaviour profile? The aim of behaviour therapy is to

- increase the person's autonomy, ie his/her independence and ability to make rational decisions that lead to long-term positive consequences, even though this might involve some short-term negative consequences;
- teach the person to avoid behaviours that lead to long-term negative consequences, even where these may be associated with short-term positive consequences.

Evidence therefore supports the alternative paradigm that attributes most disease to emotional factors.

Treatment should therefore be based on either

- behaviour therapy or
- □ systemic therapies capable of reversing the metabolic changes brought about by the emotional factors, ie **healing** therapies

Other Paradigms

While looking for evidence of effective therapies for cancer we have discovered many other therapies based on different theories and paradigms whose efficacy, unlike that of behaviour therapy, have mostly not yet been proven.

Even those that are not yet proven to be effective are relatively safe and cause less harm than most orthodox therapies.

Here are some of the theories with the best scientific basis and the therapies based on them:

Biologically closed electric circuits discovered by Bjorn Nordenström from the Swedish Karolinska Institute. Nordenström subsequently married his approach with that of doctors in China using acupuncture and adapted his therapy to take account of acupuncture points;

Bjorn Nordenström, Biologically Closed Electric Circuits. (self published)

Thus there are additional systems in the body, not recognised by the medical profession, that are involved in healing mechanisms, as Candace Pert has shown.

Gilbert Ling's Association-Induction hypothesis involving structured water (confirmed by NMR) and its implications for cell metabolism as developed by Freeman Cope (many cancer case histories presented by Max Gerson);

According to this hypothesis cells become damaged by mineral imbalances but can be restored if the damage has not lasted too long. The cells' potassium/sodium balance needs to be restored.

The Gerson Diet

□ This diet, high in potassium and low in sodium, can restore energy to the cells

The diet also includes methods of detoxifying the cells using coffee enemas.

Cope, Freeman. A medical application of the Ling association-induction hypothesis: the high potassium low sodium diet of the Gerson cancer therapy. Physiology Chemistry and Physics 1978; 10 (5): 465-468.

Related to all this is the work by Candace Pert already mentioned (who discovered receptors on the

brain for endorphins) and later discovered receptors on other organs for circulating protein peptides caused by emotions. She developed the concept of Molecules of Emotion. These chemicals become stored in cells which then have to be detoxified.

(I have mentioned five randomised trials that have shown dramatic effects of dealing with emotions on the prevention and treatment of cancer and coronary heart disease.)

- □ Virginia Livingstone-Wheeler, Gaston Naessens and Dr Royal Rife claimed that a cancer microbe is involved that, when the conditions are right, it proliferates and overwhelms the body.
 - > Livingstone-Wheeler uses a specially prepared vaccine to kill the microbe and a special diet
 - > Rife used electromagnetic radiation tuned to the microbe's natural frequency to destroy it
 - > Naessens developed 714X to disrupt its growth by flooding it with nitrogen

This evidence suggests that

- **c**ell metabolism is disrupted by injury or emotions
- **cell** energy is then inadequate to maintain cell membrane potential causing further deterioration
- □ pulsating potentials are involved in the healing mechanism so producing suitable fluctuations can stimulate cell repair mechanisms
- □ other fluctuations affect brain frequencies and can stimulate hormone production
- □ cell damage can be repaired if not delayed too long
- □ foreign microbes are susceptible to destruction using particular frequencies or products

What are some of the other therapies based on the alternative paradigms

U Hydrazine sulphate

This is based on interfering with the enzyme that enables the liver to convert lactic acid from tumours into glucose which is then commandeered by the tumour at the expense of the rest of the body – causing cachexia

Responses among 84 terminally ill cancer patients:

> 70% subjective improvement including:

- 86% appetite improvement (hydrazine alone)
- 69% appetite improvement (hydrazine + chemotherapy)

>17% objective improvement, including tumour regression

Gold, J. Use of hydrazine sulphate in terminal and preterminal cancer patients: results of investigational new drug (IND) study in 84 evaluable patients. Oncology 1975; 32: 1-10.

D Phenergan

This is based on weakening the mitochondria – causing cancer cell death – by the use of antihistamines

Jones, GRN. Successful Cancer Therapy with Promethazine: The Rationale. Medical Hypotheses 1996; 46: 25-29.

Therapies designed to boost the natural immune systems such as

Whole Body Therapy of Dr Josef Issels

- 85% 5-year survival with non-metastasised cancer patients
- 16.6% 5-year survival with late-stage cancer patients
- 15% 15-year survival with late-stage cancer patients

These are the best survival figures for late-stage cancer patients ever published.

Issels, J. Immunotherapy in Progressive Metastatic Cancer - A Fifteen-Year Follow-up. Clinical Trials Journal, August 1970: 357-365 - editorial by Phillips S. Dr Joseph Issels and the Ringberg Klinik. Clinical Trials Journal. August 1970: 355-56.

Other therapies designed to boost the natural immune systems such as

Immuno-Augmentative Therapy of Dr Lawrence Burton

Survival among more than 1,000 terminal cancer patients:

- 15-18% 5-year survival with late stage cancer patients
- 50% 5-year survival with mesothelioma patients

Survival among 277 terminally ill patients treated in 1977:

• more than 18% in good health 5 years later

Clement, RJ. Peritoneal Mesothelioma. Quantum Medicine 1988; 1: 68-73.

Iscador based on an extract of mistletoe

Coleys Toxins

Survival among 896 advanced cancer patients, 523 inoperable, 373 operable: 46% 5-year survival with inoperable tumours

50% 5-year survival for operable, including:

•	
• giant cell bone tumours	- 79% (87% operable) 5 year survival
• breast cancer	- 65% (100% operable) 5 year survival
 Hodgkin's disease 	- 67% five year survival
• ovarian cancer	- 67% " " "
• melanoma	- 60% " " "

Nauts H. Bacteria and cancer - antagonisms and benefits. Cancer Surv. 1989; 8: 713-23.

Therapies based on controlling cell growth to enable other therapies to work such as:

Cyto-luminescent therapy

□ Vitamin and enzyme therapy, particularly vitamins A, C, E and selenium

□ Microwave therapy – the Tronado machine

- available in Perth from Dr John Holt
- many anecdotal cases of improvement and increased quality of life with late-stage cancer patients

Therapies based on boosting cell energy using pulsating magnetic fields such as:

using the QRS "mat"

- randomised trials showing benefits with arthritis and rotator cuff tendinitis
- many anecdotal cases of improvement and increased quality of life with late-stage cancer patients
- I have carried out a small randomised crossover trial to measure benefits of this therapy after 8 weeks for cancer patients. Some small positive benefits were found.

Based on the randomised trials that show benefits of the alternative paradigm, the improved percentage 5-year survival and anecdotal evidence of benefits with others, it would appear that

People with cancer should therefore select therapies from all four of the following areas:

Body – Physical therapies to restore the body's systems including Cell metabolism, immune system, detoxification

- □ Mind Therapies to relax the mind and body: meditation, visualisation and imagery
- Emotions Behaviour Therapy or other psychotherapy to eliminate emotional causes of cancer
- □ Spirit Therapies to restore the spirit or psyche: hands-on healing, distance healing, prayer

Counselling should identify where each person is on their healing pathway and what therapies they are open to.

Orthodox therapies, such as minimal surgery, may be useful to complement alternative therapies where this reduces the amount of detoxification needed.