



**Criteria for Cancer Society of New Zealand
Assessment, Endorsement and Identification of
Action Relating to Cancer Screening**

June 2005

EXECUTIVE SUMMARY

During the past twenty years the Cancer Society of New Zealand has undertaken a range of activities relating to cancer screening, drawing upon work undertaken by other bodies in determining its position on a particular form of screening. In December 2004 the National Board of the Society, on advice from the National Health Promotion Committee (NHPC), identified the need for the Society to develop its own criteria for assessing screening.

This policy document, developed to address this need, provides:

- a) Criteria of the Cancer Society of New Zealand for:
 - Assessing and endorsing a particular form of cancer screening
 - Identifying appropriate action to be undertaken by the Cancer Society in relation to a particular form of cancer screening
- b) The process by which such criteria will be applied
- c) The core contents of Cancer Society position statements on screening
- d) The rights and responsibilities of individuals, the Cancer Society and health professionals with regard to cancer screening.

This document is intended to provide transparency, both within and outside the Society, with regard to the process by which the Society develops policy, determines priorities for action and addresses the rights of individuals with regard to cancer screening.

Screening as a method of early detection

Early detection means detecting cancer prior to the development of symptoms or as soon as is practicable after the development of symptoms. Its aim is to detect the cancer when it is localised to the body organ of origin, before it has time to spread to other parts of the body.

Early detection of cancer prior to the development of symptoms occurs through screening. Screening is a process whereby people who have no symptoms are invited (either directly or through publicity) to undergo a test or procedure, usually at regular intervals during certain stages of a person's life. In some instances, the purpose of screening is to detect cancer at an early stage of development. In others, screening identifies precursors of cancer, the treatment for which can reduce the risk of cancer developing. Although a number of cancer screening tests have been developed, only a few have been proven effective and therefore recommended for defined populations (Minister of Health 2003).

Screening differs from services for those who go to their doctors with a problem. It involves apparently well people, a vast majority of whom will not have cancer. Although screening is a process that has the potential to be of benefit, it also has the potential for harm. If screening is to be offered by a doctor, promoted through the media or endorsed by the Cancer Society, there needs to be clear evidence that the benefit will outweigh the harm.

The focus of this document is on cancer screening. Issues relating to the early detection of cancer other than by screening are to be addressed in a separate document.

Cancer Society of New Zealand criteria for assessment, endorsement and identification of action relating to cancer screening

During the past twenty years the Cancer Society of New Zealand has undertaken a range of activities relating to cancer screening, including the development of position statements on particular forms of screening. These statements have been based on international reviews of published evidence and the findings of national multidisciplinary advisory groups on which the Society has been represented.

The criteria below have been developed to enable the Cancer Society to assess a particular form of screening, to determine whether it should be endorsed by the Society and to identify what action should be undertaken by the Cancer Society in relation to that form of screening. These criteria draw upon the criteria of other organisations but have been developed to address the roles and responsibilities of the Cancer Society.

Criteria for Cancer Society Assessment, Endorsement and Identification of Action Relating to Cancer Screening

1. The cancer is an important health problem.
2. The cancer is appropriate for screening (i.e., there is a recognisable early stage).
3. There is a suitable screening test (one which is acceptable and has adequate sensitivity and specificity).
4. There is high quality evidence, ideally from randomised controlled trials, that screening is effective in reducing incidence and/or mortality.
5. There is agreement on the most effective treatment for people who are diagnosed with cancer or a cancer precursor (pre-cancer) as a result of screening.
6. Screening does more good than harm.
7. People with positive screening results will have access to timely and appropriate investigations and treatment.
8. Screening can be provided in a continuous manner in conjunction with necessary quality assurance and evaluation.

1. INTRODUCTION

1.1 *The Cancer Society and Cancer Screening*

During the past twenty years, the Cancer Society of New Zealand has undertaken a range of activities relating to cancer screening and cancer screening policy. These are outlined as follows:

- **Position as independent authority**

As reflected in feedback and correspondence, the Society is perceived as an organisation that can be relied upon to provide appropriate scientific advice, independent of political considerations or the activities of lobby groups.

- **Provision of information to consumers and health professionals**

Consumers and health professionals often approach the Society for information regarding cancer screening. In response to these requests, information on screening and on the Society's position statements is posted on the national website, included in information sheets and published in Cancer Update bulletins for general practitioners. During the mid-90's screening also was the focus of print media-based information programmes on breast and prostate cancer. Frequently the Society is called upon to comment on draft materials produced by other organisations, including the media.

- **Influence on government policy**

Since 1985 the Cancer Society has influenced government policy through its participation in, and in some instances financial contribution to, at least fifteen national multi-disciplinary screening committees on cervical, breast, bowel and prostate screening. The Society has also advised government on the expertise required for membership of these groups.

- **Advocacy for screening policy**

The Cancer Society has undertaken advocacy vis-à-vis its position statements by issuing media statements, responding to media inquiries, making submissions (e.g., the need for legislation for the cervical screening programme and the appropriate age for breast screening) and appearing before the Health Select Committee. The Society also has actively promoted cervical screening for women aged 20-70 years and breast screening for women aged 50-69 years, and it has been a strong advocate for the establishment of organised screening programmes for both.

- **Advocacy for national screening programmes which meet WHO requirements for effectiveness**

Recognising that appropriate, high-quality, organised screening programmes are among the most powerful cancer control strategies available (Screening Working Group 2002), the Cancer Society has undertaken advocacy to ensure that New Zealand's national breast and cervical screening programmes meet requirements for effectiveness. Examples of such advocacy include involvement (by way of party status) in both the National Women's and Gisborne Inquiries, membership of programme advisory groups and issuance of media statements. In the early 1990's the Society also contributed \$300,000 to the evaluation of the pilot mammography screening programmes established by Government in the Waikato and Otago regions.

- **Unique institutional memory**

Within an ever-changing health sector, the Society has been able to serve as an institutional memory and to provide documentation not retained by Government agencies, e.g. for the Gisborne Cervical Screening Inquiry.

1.2 Cancer Society review of cancer screening

In early 2004 the role of the Cancer Society in cancer screening and the process by which its position statements are developed was reviewed by the National Board. In response to the Board's request for feedback, Divisions of the Society unanimously supported:

- the need for the Society to have an ongoing role in cancer screening, including the development and promulgation of position statements
- use of an evidence-based approach to develop position statements
- the process by which position statements are developed, with some enhancements recommended.

In response to this feedback, the National Health Promotion Committee identified the need for criteria for endorsing a particular form of cancer screening and the process by which such criteria will be applied.

1.3 The need for Cancer Society criteria

As identified above, both consumers and health professionals view the Cancer Society as an independent, authoritative source of information on cancer screening. With this role comes a responsibility to ensure that information is correct and up-to-date, and that the Society only endorses or promotes screening for which there is good evidence of benefit. Because screening is often controversial, it is important that the Society has clear criteria upon which to base its position and that these are explicit to those seeking information.

A number of groups have developed criteria for assessing screening, all of which build upon the World Health Organization principles of screening first proposed in 1968 (Wilson and Junger 1968). Examples include the United Kingdom National Screening

Committee (2000), the Canadian Strategy for Cancer Control: Screening Working Group (2002) and the National Health Committee (2003). While drawing upon these examples, the criteria developed by the National Health Promotion Committee are specific to the role and responsibilities of the Cancer Society, e.g. addressing consumer needs, responding to media requests for organisational views and participation in government policy working groups.

1.4 *Policies, guidelines and protocols*

The criteria will be used as a basis for developing the Society's position statement on a particular form of screening. A position statement, which represents the stance agreed upon by the Society, differs from clinical guidelines and protocols. Guidelines are advice for clinicians to be tailored for the needs of individual patients depending on all the information available to them. Protocols are defined programmes for treatment or care.

2. CANCER SCREENING

2.1 *What screening is*

Screening is a process whereby people who have no symptoms are invited (either directly or through publicity) to undergo a test or procedure, usually at regular intervals at certain times in a person's life. In some instances the purpose of screening is to detect cancer at an early stage of development, for example screening for breast cancer. In other cases, such as cervical screening, screening identifies precursors of cancer, the treatment for which can reduce the risk of cancer developing.

Screening tests sort those who probably have disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred for further tests for a definitive diagnosis.

Screening differs from the diagnosis of people seeking help for symptoms in that the process is offered to apparently well individuals. In some instances the same test can be used for both purposes; for example, mammograms (x-rays of the breast) used for those without symptoms are described as screening mammograms; when used to diagnose symptoms they are known as diagnostic mammograms.

The vast majority of those who are screened will not have cancer. For example, within the first screening round of BreastScreen Aotearoa, in every 1000 women screened, 6 were diagnosed with breast cancer. The other 994 were not.

2.2 *The screening pathway*

Screening is not just the initial test but also a series of events that comprise the screening pathway. From a consumer perspective these include:

- publicity and/or an invitation to be screened
- information about screening (e.g., its purpose, the likely benefits and risks, the accuracy of the test, follow-up procedures if the test is positive, the availability and cost of diagnostic services, etc.)
- being offered the test (or discussions relating to a request for the test)
- having the test
- receiving the test results
- assessment and diagnosis if the test is positive (i.e., suggests the presence of disease)
- discussion with and support for those who are screened, as and if needed (includes information and clarification of test results and counselling/support for those with a cancer diagnosis)
- possible treatment

The acceptability and effectiveness of cancer screening requires attention to quality assurance at each step of the screening pathway.

2.3 The ethics of screening

When an ill person consults a health professional, apart from the usual commitment of health professionals to do their best for an individual patient, no prediction of a good outcome can be given in advance. In contrast, those who take part in screening are apparently well, and usually participate because they have been invited to, or because screening has been promoted to them on the understanding that it can benefit them. Clearly, if a reputable organisation such as the Cancer Society endorses or promotes screening, people will assume that screening must be beneficial. The Society therefore has an ethical obligation to promote screening only if there is good evidence of benefit (Cochrane and Holland 1971).

There are potential risks associated with *screening* for cancer, and these differ from the risks associated with *treatment* of cancer. When a patient is unwell, and approaches the health system for help, any risks and/or benefits of treatment accrue to that individual. An ill person may decide to take a risk (e.g., take a drug that may produce side effects) in order to get better. In screening, however, people are apparently well and may be less inclined to accept risks. Also, with screening, risks and benefits can accrue to different individuals (for instance individuals with true positive tests may benefit from screening while individuals with false positive or false negative tests are harmed).¹ Thus, when screening is promoted, people must be informed of the potential risks, and screening must be organised and monitored to ensure the risks are kept as low as possible.

2.4 Ways that screening is undertaken

Cancer screening occurs in two ways: through organised screening programmes and in an opportunistic fashion (i.e., outside organised programmes).

In a screening programme, screening is offered or promoted to defined, often large groups of people; hence they are described as *population* screening programmes. In screening programmes all activities along the screening pathway are planned, co-ordinated, monitored and evaluated. *Opportunistic screening* of individuals occurs in the absence of formal co-ordination, monitoring and evaluation, often when a person presents to the health system for another reason (National Health Committee 2003). Opportunistic screening occurs either because it is actively offered by a health professional or because it is requested by an individual.

Because the ethical implications are the same for population screening programmes and opportunistic screening offered by a health professional, the Cancer Society criteria apply to both.

¹ No screening test is 100% accurate. A false positive test is one where, after further investigations, the person does not have the disease. A false negative test is one where, after a negative result, the person is found to have disease (i.e. the disease was missed).

2.5 Screening and surveillance

In the context of this document, screening refers to the testing of asymptomatic individuals who are at average risk of developing a particular form of cancer. Surveillance refers to ongoing assessment of those known to have had a cancer or to be at increased risk of a particular cancer, for example, due to a personal or family history of cancer.

Because the prevalence of a cancer is likely to be higher in those at increased risk, a greater proportion of this group could potentially benefit from surveillance testing. Because surveillance recommendations require different criteria and also additional and/or different tests, they are not addressed in this document.

3. CRITERIA FOR ASSESSMENT, ENDORSEMENT AND IDENTIFICATION OF ACTION RELATING TO CANCER SCREENING

3.1 Screening which meets criteria

The Cancer Society will endorse screening for both individuals and populations which meet the following criteria:

1. The cancer is an important health problem.

In this context, the *importance* of a cancer as a health problem is a combination of its incidence and the potential for screening to benefit people with that cancer. For example, although the incidence of cervical cancer is considerably lower than the incidence of breast cancer in New Zealand, screening for cervical cancer has the potential to prevent invasive cervical cancer, thus reducing the incidence as well as mortality from invasive cervical cancer, whereas screening for breast cancer primarily aims to reduce breast cancer mortality but not incidence of the disease.

2. The cancer is appropriate for screening.

For a cancer to be appropriate for screening there needs to be a recognisable early stage, where treatment can provide a better outcome than treatment offered at a later stage.

3. There is a suitable screening test.

The screening test must be acceptable, and must have adequate sensitivity and specificity (see glossary) so that a high proportion of those with the cancer will be correctly identified, and so that false negative and false positive tests (see glossary) can be kept to a minimum.

4. There is high quality evidence, ideally from randomised controlled trials, that screening is effective in reducing incidence and/or mortality.

Using methods such as survival comparisons, observational studies, or ecological studies to assess screening is misleading. These studies are vulnerable to lead-time, length, selection, and overdiagnosis biases, which can cause any benefit of screening to be overestimated, and at worst, can make screening appear beneficial even when it is not (see glossary). Only an appropriately designed and analysed randomised controlled trial can avoid these biases, and determine whether screening for cancer really is beneficial (Gray 1997, Black 2000, Auvinen *et al* 2002).

Unfortunately we cannot assume that screening is always beneficial. Randomised controlled trials have revealed that some screening procedures (such as screening for lung cancer using chest x-rays and sputum cytology in high-risk individuals, and

screening for breast cancer with breast self-examination), which were previously assumed to be beneficial, are not (Black 2000, Marcus *et al* 2000, Thomas *et al* 2002).

5. There is agreement on the most effective treatment for people who are diagnosed with cancer or a cancer precursor (pre-cancer) as a result of screening.

There should be evidence that treatment is effective, and treatment should be offered by appropriately qualified and experienced health professionals according to established guidelines.

6. Screening does more good than harm.

Ethically, the Society should not endorse or promote screening if the benefits do not outweigh the risks. Although most people focus on the benefits of screening, unfortunately there are also risks associated with screening. The benefits and risks of screening are shown below:

Benefits and risks of screening

<i>Benefits</i>	<i>Risks</i>
Improved prognosis for some people diagnosed by screening	Longer morbidity for people whose prognosis is unaltered
Less radical treatment which cures some people with early cancer	Over-treatment of questionable abnormalities
Reassurance for those with negative test results	False reassurance for those with false negative results
	Anxiety and sometimes morbidity for people with false positive results
	Hazard of screening test (e.g., radiation)

Adapted from Chamberlain JM. Which prescriptive screening programmes are worthwhile? *J Epid Com Hlth* 1984; 38: 270-7.

7. People with positive screening results will have access to timely and appropriate investigations and treatment.

Screening aims to detect cancer early, at a stage where treatment will be more effective than later treatment. If investigations are delayed, treatment may not be early enough to achieve this aim. Also, a delay between receiving a positive test and receiving further investigations can cause considerable anxiety to those with positive tests. At worst, delays could cause the harms associated with screening to outweigh the benefits.

8. Screening can be provided in a continuous manner in conjunction with necessary quality assurance and evaluation.

The best way to minimise the risks associated with screening is to deliver screening in an organised programme with appropriate quality assurance and evaluation (WHO 1988, Gray 1997, Vainio & Bianchini 2002). The programme must ensure that all activities along the screening pathway (See Section 2.2) can be provided, and that these are planned and co-ordinated. As demonstrated in Gisborne, however, where cervical smears were misread over a period of years, there is potential for harm, even within a programme, if that programme is not appropriately monitored. Examples of lack of quality outside a screening programme also exist in New Zealand.²

Thus, to ensure that potential benefits outweigh the potential risks, there is a need for quality assurance and evaluation of all aspects of the screening pathway.

3.2 Screening that does not meet criteria

For screening that fails to meet the Cancer Society criteria, the Cancer Society will not endorse or promote screening, nor will it support screening being actively offered to individuals by health professionals. As with all screening, however, the Cancer Society recommends that those who request screening should be provided with information to enable them to make an informed choice.

Utilising the flow chart on page 14, the Society also will identify what action it should undertake in relation to a particular cancer to which the criteria have been applied. In some cases such action will involve advocacy by the Society, for example, for appropriate services to be developed; in others, action to reduce the incidence or impact of a particular form of cancer other than through screening will need to be identified.

² A 'look-back' programme in Gisborne discovered that PSA tests had been incorrect over a period of time. As a result, 117 patients were notified of the error and advised to consult their GP for retesting. As identified by Tairāwhiti Healthcare Limited, "this was distressing for them and their families and whānau, but thankfully no one suffered any physical harm".

3.3 Self-requested or doctor-initiated opportunistic screening

The Cancer Society recognises that individuals will request screening and doctors will offer screening on an opportunistic basis. The Cancer Society recommends that such screening should be undertaken on the basis of informed choice. As outlined in 3.4 and in section 7, individuals should be informed about the potential benefits and risks of a particular form of screening and the likely implications of a positive or negative result.

3.4 Screening as an informed choice

As identified by the United Kingdom National Screening Committee (UKNSC), all those who choose to be screened (on an opportunistic basis or as part of an organised programme) should do so on the basis of informed choice, and they should appreciate that in being screened, there is a risk of an adverse outcome (National Screening Committee 2000). They should also be aware that they are not just consenting to a screening test but to the full screening pathway (National Health Committee 2003).

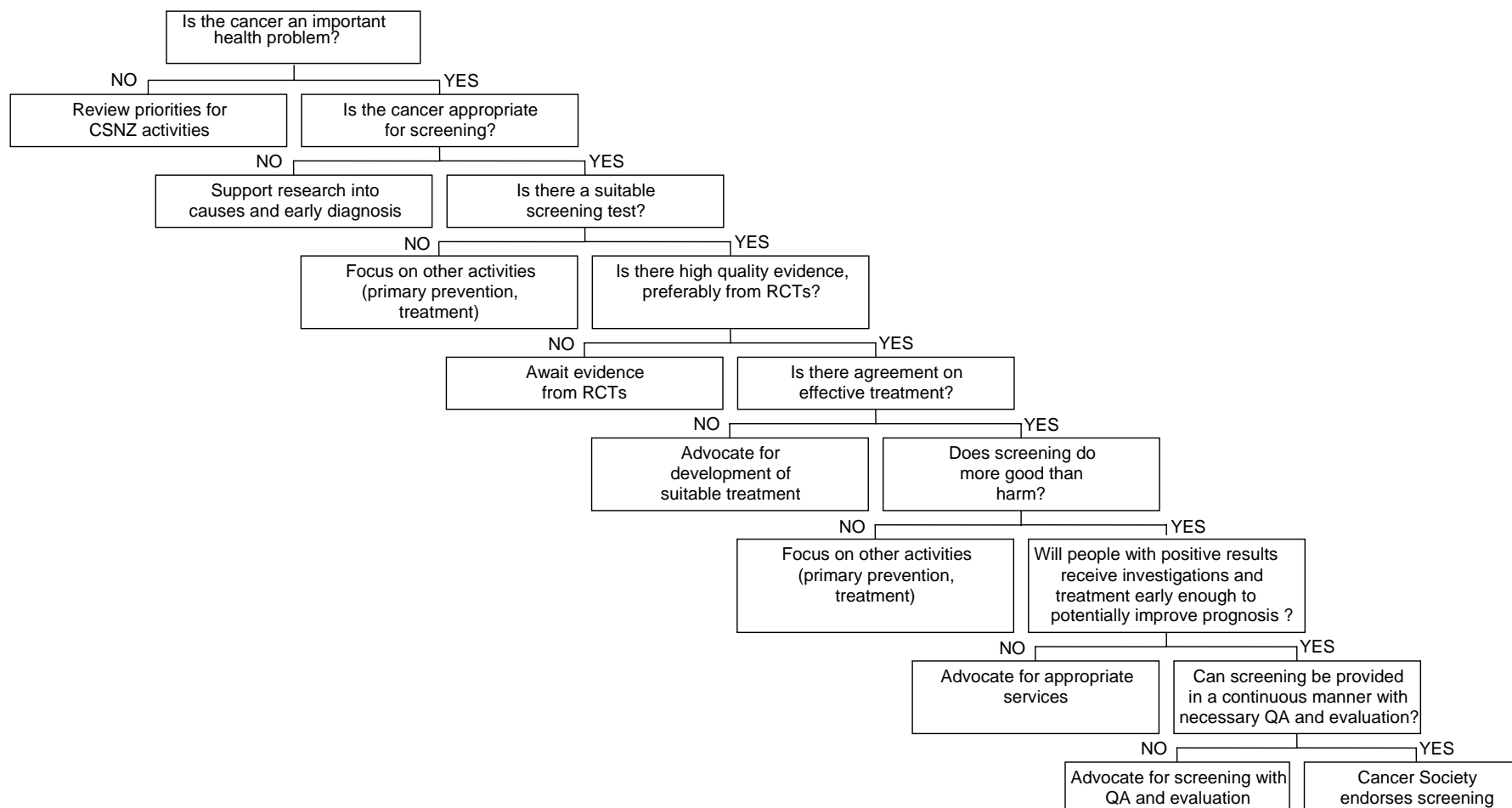
3.5 Economic issues

Economic issues are only relevant if a decision has been made that screening is beneficial and acceptable. If these criteria were met, then economic efficiency would have to be addressed. Economic efficiency has not been included in the Cancer Society criteria because the Society does not directly fund screening. Instead, the Society's role is to endorse effective and acceptable screening programmes.

It is sometimes assumed that a decision not to proceed with population screening is based on cost. In fact, the cost of screening only becomes relevant if screening meets all of the criteria. In such cases, the Cancer Society may wish to lobby for government funding.

The Cancer Society recognises that there are economic implications of screening. Where benefit has been demonstrated, warranting the introduction of an organised programme, it is important that sufficient funding is available for the programme to commit adequate resources to ensure that the expected benefits are achieved.

IDENTIFICATION OF CANCER SOCIETY ACTION RELATING TO CANCER SCREENING



5. PROCESS BY WHICH SCREENING CRITERIA ARE APPLIED

The process by which the criteria outlined above will be applied to forms of cancer screening as a basis for the development and regular review of position statements and identification of appropriate action by the Cancer Society of New Zealand is as follows:

- a) The screening sub-committee of the National Health Promotion Committee considers available evidence and applies criteria accordingly.

The sub-committee comprises members of the NHPC who have expertise in cancer screening, along with invited expertise, the Medical Director and a representative of the National Support and Volunteer Services Committee.

- b) The National Health Promotion Committee approves a draft position statement and refers this to the Chief Executives Advisory Committee for divisional consultation and feedback, and to others outside the Society for peer review.
- c) The screening sub-committee and National Health Promotion Committee consider feedback and finalise the position statement, which is referred to the Board for approval.
- d) The NHPC normally reviews each position statement every two years or sooner if new evidence becomes available.

However, occasionally a review may be delayed if it is dependent upon the outcome of other current reviews or if new evidence is soon to be published.

- e) Position statements will remain valid until such time that they are reviewed and revised according to the process outlined above.

6. CANCER SOCIETY POSITION STATEMENTS ON CANCER SCREENING: PURPOSE AND CONTENT

6.1 *Purpose of a position statement*

The purpose of a Cancer Society position statement on cancer screening is to document the Society's assessment of a particular form of screening based on its agreed criteria. A position statement also will provide the basis for Cancer Society action in relation to those forms of cancer to which the criteria have been applied.

6.2 **Content of position statements**

All position statements should:

- a) Address each of the criteria for that particular form of screening
- b) Provide appropriate references
- c) Summarise recommendations of other agencies/organisations
- d) Be based on the best available evidence (e.g., from published international consensus statements and/or reports of multidisciplinary groups in New Zealand)
- e) Include information about the potential benefits and risks of a particular form of screening and the likely implications of a positive or negative result
- f) Acknowledge that all screening should be undertaken on the basis of informed choice
- g) Include a summary statement that the type of screening does or does not meet the CSNZ criteria for endorsement
- h) Where screening does not meet the CSNZ criteria, the position statement will include the following:

Because screening for ... cancer does not meet the CSNZ criteria, the Cancer Society does not recommend screening for ...cancer nor does it endorse screening being promoted or actively offered by health professionals. The Society recommends that those considering or requesting screening should be given information about the potential benefits and risks to enable them to make an informed choice.
- i) Identify the key actions arising from position statements (e.g., advocacy for change in government policy, etc.).

7. RIGHTS AND RESPONSIBILITIES

In its role in relation to cancer screening, the Cancer Society of New Zealand acknowledges the following rights and responsibilities:

- a) The individual has the right to request a screening test and to be well informed about the test and the implications of the test result³.
- b) The Cancer Society has a responsibility to be an authoritative source of information on screening.
- c) The Cancer Society has a responsibility to ensure that staff responsible for responding to requests for information are well informed and equipped to undertake this role.
- d) The Cancer Society has a responsibility to apply its screening criteria in a consistent and transparent fashion for the protection of the individual.
- e) According to the Medical Council of New Zealand, doctors have a “special duty of care” to make asymptomatic persons “aware of the limitations of screening and the uncertainties, in particular the chance of false positive and false negative results. Before obtaining consent the doctor should explain, or give information to the patient that explains:
 - the purpose of the screening,
 - the uncertainties,
 - any significant medical, social or financial implications of the condition for which the screening is done and,
 - follow up plans, including availability of counselling and support services.” (Medical Council of New Zealand 2002).

³ Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996. Two rights of the Code of importance when considering screening – Right 6 (the right to be fully informed) and Right 7 (the right to make an informed choice and give informed consent).

GLOSSARY

Early detection

The detection of cancer prior to the development of symptoms, or as soon as practicable after the development of symptoms.

True positive

The screening test correctly identifies a person with disease

False positive

After a positive test, further investigations show that the person does not have the disease

True negative

The screening test correctly identifies a person without disease

False negative

After a negative test, the person develops clinically recognisable disease

Lead time bias

Screening advances the date of diagnosis and thereby extends the interval between diagnosis and death even if the time of death is unchanged. People whose disease was detected by screening will appear to have longer survival than people diagnosed in the normal way.

Length bias

Fast growing tumours will progress rapidly through the preclinical phase and will therefore be less likely to be detected by screening. Screening at infrequent intervals will therefore detect a disproportionate number of slow growing tumours with a good prognosis.

Precursor

A condition preceding onset of disease. A cancer precursor is sometimes described as a pre-cancer.

Selection bias

People who take up the offer of screening may differ in their underlying risk of disease and/or mortality so that their prognosis would have differed from non-participants even in the absence of screening.

Overdiagnosis bias

Screening may detect abnormalities that are of questionable malignancy and would not have been diagnosed in the absence of screening.

Sensitivity

The ability of the screening test to correctly identify those *with* the disease

Specificity

The ability of the screening test to correctly identify those *without* the disease

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