

Introduction

Cancer

Cancer is a group of several hundred diseases in which abnormal cells are not destroyed by normal cell processes but instead proliferate and spread out of control. Cancers are distinguished from each other by the specific type of cell involved and the place in the body in which the disease begins.

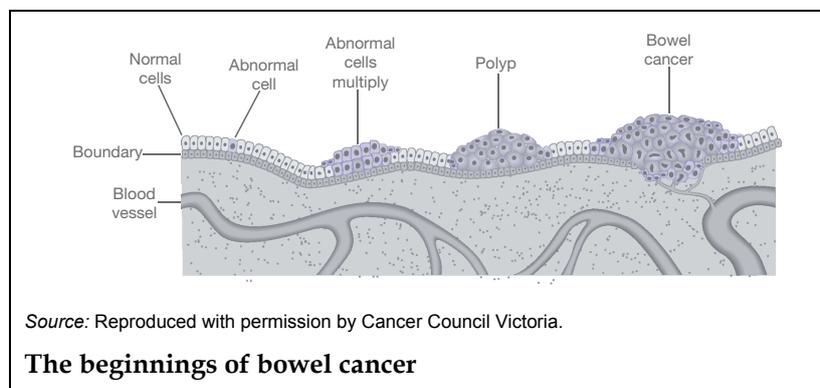
Normally, cells grow and multiply in an orderly way to form tissues and organs that have a specific function in the body. Occasionally, however, cells multiply in an uncontrolled way, after developing from a random genetic mutation, or after being affected by a carcinogen, and form a mass which is called a tumour or neoplasm. Tumours can be benign (not a cancer) or malignant (a cancer). Benign tumours do not invade other tissues or spread to other parts of the body, although they can expand to interfere with surrounding healthy structures. The main features of a malignant tumour are its ability to grow in an uncontrolled way, and to invade and spread to other parts of the body (metastasise).

Although various risk factors for cancer have been identified, for most cancers the causes are not fully known. While some of the causes are modifiable through lifestyle changes, some others are inherited and cannot be avoided through personal action. However, the risk of death due to particular cancers may be reduced through intensive monitoring of individuals at high risk, reducing external risk factors, detecting and treating cancers early in their development, and treating them in accordance with the best available evidence.

Many cancers can be serious and even fatal. However, medical treatment is often successful if the cancer is detected early, which is the aim of cancer screening programs. The goal of treatment is to destroy the cancer cells and stop them from returning. This can be done by surgery to remove the growth or by other methods such as chemotherapy (cancer-destroying drugs) or radiation therapy.

Bowel cancer

Bowel cancer refers specifically to cancer of the large intestine (that is, the colon or rectum). It is also known as colorectal cancer. Generally all bowel cancers involve a multistage process in which a series of cellular mutations occur in epithelial cells of the large intestine over time.



Early stages of these mutations result in benign polyps that are relatively common in old age. However, a cell may then undergo additional changes and become a benign adenoma, and ultimately, with further mutations, a malignant cancer. These mutations occur relatively slowly making early detection and removal of small cancers, and polyps that may become cancerous, effective in preventing morbidity or mortality from bowel cancer.

Exact causes of these cellular mutations are largely unknown. While a proportion of bowel cancers are thought to be due to a hereditary component, most cases are sporadic (Weitz et al. 2005), with many attributed to environmental factors. Australian males have higher rates of bowel cancer incidence than females (AIHW 2009), and this may be in some part due to differences in environmental risk factors between males and females, some of which may be modified by lifestyle changes.

Diet has been implicated as a risk factor for bowel cancer, with high fat and meat, low fibre diets showing a greater risk in observational studies (Bingham et al. 2005; Norat et al. 2005). However, in a recent study, vegetarian diets were also shown to increase bowel cancer risk (Key et al. 2009). Other environmental influences such as lower physical activity, higher alcohol consumption and excess body weight may also be linked to the higher incidence rates of bowel cancer.

The incidence of bowel cancer is known to increase with age – about 93% of people diagnosed in Australia in 2006 were aged 50 or older (AIHW 2009). Comorbidity with other gastrointestinal conditions (such as Crohn disease, ulcerative colitis and familial adenomatous polyposis) is also seen. Several other hereditary traits also increase the risk of bowel cancer.

Bowel cancer may be present for many years before showing symptoms (such as rectal bleeding, change in bowel habit or anaemia) as they are not generally exhibited until the cancer has reached a relatively advanced stage. However, death can be prevented and survival rates can be significantly improved in cases where the disease is detected and treated early. Evidence from clinical trials has shown that regular (biennial) screening using faecal occult blood testing, which can detect evidence of rectal bleeding not visible to the naked eye, can reduce mortality from bowel cancer by 15%–33% (DoHA 2005).

Bowel cancer treatment

Treatment for bowel cancer always involves surgery to excise the cancer, with or without adjuvant chemotherapy or radiation therapy. Prognosis depends mainly on the stage of development of cancer. It has been recommended that colorectal cancer diagnoses in Australia use the Australian clinopathological stage (ACPS) classification system (ACN 2005):

- A. Submucosa or into but not through muscularis propria** – Cancers diagnosed at this stage showed a 93% 5-year survival rate in a 2004 American study.
- B. Through muscularis propria** – Cancers diagnosed at this stage showed an 82% 5-year survival rate.
- C. Spread of cancer to lymph nodes** – Cancers diagnosed at this stage showed a 59% 5-year survival rate.
- D. Metastatic disease** – Cancers diagnosed at this stage showed an 8% 5-year survival rate (O'Connell, Maggard & Ko 2004). Palliative care is commonly used at this stage.

Similar rates have been shown in Australia (Morris, Lacopetta & Platell 2007).

Further, removal of non-benign polyps and adenomas during colonoscopy (for example, as the diagnostic tool following a positive faecal occult blood test) may also reduce the risk of these developing into bowel cancer. It should be highlighted that improved treatment outcomes are expected with an earlier diagnosis.

Bowel cancer incidence and mortality

In Australia in 2006, the risk of being diagnosed with bowel cancer by the age of 85 years was 1 in 10 for males and 1 in 14 for females, with the risk increasing sharply from the age of 45 years (AIHW 2009). Since 1982, incidence of bowel cancer has been increasing slightly each year, with 13,591 new cases diagnosed in 2006. Around 93% of these were in people aged over 50 years, the age at which bowel cancer screening is recommended to start in asymptomatic people.

Bowel cancer accounts for 10% of all deaths from invasive cancers, with 3,801 deaths in 2006, making bowel cancer the second most common cause of cancer-related death after lung cancer (AIHW 2008).

It has been estimated that worldwide in 2002, around 1 million new cases of bowel cancer were diagnosed (9.4% of worldwide cancer diagnoses), and 530,000 deaths from bowel cancer (7.9% of all worldwide cancer deaths) (Parkin et al. 2005).

Screening

Population-based screening involves the systematic use of a test to identify individuals who have a previously unrecognised disease in an asymptomatic target population (that is, in people not showing any symptoms of the disease). The aim of population-based screening is to reduce the burden of disease, which may include a reduction in the incidence, morbidity and mortality of the disease, through detection at an early stage in individuals who would not otherwise know they were affected (Wald 2001; Strong 2005; APHDPCSS 2008).

The screening test used in a population-based screening program is not intended to be diagnostic; rather it aims to distinguish between individuals who test positive (and so may have or may develop the disease) and need further specific testing to determine whether they have the disease, and those who test negative (show no early indications of the disease) and need no further testing (Strong 2005; APHDPCSS 2008). The screening test should both minimise false-positives (a positive screening result that further diagnostic testing showed was actually negative) and maximise true-positives. False-positives place extra load on diagnostic resources, and cause unnecessary stress to those screened. So balanced information as to the benefits and potential harms of the screening should be made available to the target population to ensure they can make an informed decision about their participation (APHDPCSS 2008).

In 1968, the World Health Organization endorsed 10 principles to be used when determining if a new population-based screening program should be introduced for a disease or condition (Wilson & Jungner 1968). These principles were designed to ensure that the disease in question was well-understood and the correct test, treatment and resources were in place to allow screening to be of benefit to the target population. Currently in Australia there are eight National Health Priority Area cancers: lung cancer, bowel cancer, melanoma, non-melanocytic skin cancer, prostate cancer, breast cancer, cervical cancer and non-Hodgkin lymphoma (NHPAC 2006). Of these, bowel, breast and cervical cancer have

met the criteria for approved population-based screening programs. This report focuses on the National Bowel Cancer Screening Program.

Bowel cancer screening

Background

In 1996, the Australian Health Technology Advisory Committee systematically reviewed the literature on screening for bowel cancer against the World Health Organization principles for the assessment of a screening program. They concluded that, if further pilot testing was encouraging, Australia should develop a bowel cancer screening program for the at risk population – the ‘well population aged over 50’ (AHTAC 1997).

The Bowel Cancer Screening Pilot Program was conducted between November 2002 and June 2004 to test the feasibility, acceptability and cost-effectiveness of bowel cancer screening in the Australian community. Following the success of this Pilot, the Australian Government implemented the first phase of the National Bowel Cancer Screening Program (NBCSP) in late 2006. In July 2008, the Australian Government allocated a further \$87.4 million over 3 years for the second phase of the Program.

The National Bowel Cancer Screening Program

The goals of the NBCSP are to reduce the incidence of, and mortality due to, bowel cancer, through screening to detect abnormalities of the colon and rectum at a pre-cancerous stage; and, where bowel cancer has developed, to detect cancers at an early stage to maximise the effectiveness of treatment.

Population-based bowel cancer screening involves testing for signs of bowel cancer in people who do not have any obvious symptoms of the disease. People with symptoms or a significant family history are encouraged to discuss these with their primary health care practitioner. In accordance with the National Health and Medical Research Council guidelines for the prevention, early detection and management of colorectal cancer (ACN 2005), these people should be referred directly to diagnostic assessment (generally colonoscopy). However, it is recognised that some people at increased risk may not seek the assistance of a medical professional (for example, those who are symptomatic but reluctant to act on their symptoms). As a result, all people of the target ages are invited to screen regardless of evidence of previous symptoms or a significant family history.

Population-based screening programs require an accurate, reliable, safe and simple test that can detect the presence of disease before the onset of clinical symptoms. A faecal occult blood test (FOBT) is a non-invasive test which detects microscopic amounts of blood in the bowel motion. The NBCSP uses the Fujirebio Inc. immunochemical FOBT, as opposed to the traditional guaiac FOBT used in some other countries, as it has shown higher sensitivity and specificity, does not require dietary restrictions and can be easily used at home (ACN 2005).

The NBCSP has been phased in gradually to help ensure that health services, such as colonoscopy and treatment services, are able to meet any increased demand. This is consistent with the introduction of other screening programs, such as the National Cervical Screening Program, which was also phased in over several years. Start dates and target ages for each phase are outlined in the following table.

NBCSP phases and target populations

Phase	Start date	End date	Target ages	Target age birthdays included
1	7 August 2006	30 June 2008	55 and 65 years	1 May 2006–30 June 2008
2	1 July 2008	30 June 2011	50, 55 and 65 years	1 January 2008–31 December 2010

Note: Data for invitees aged 55 or 65 years is available for the entire reporting period. Data for invitees aged 50 years is only available from 1 July 2008.

Phase 1 of the NBCSP began in Queensland in August 2006, and was progressively rolled out to the remaining states and territories by April 2007. Invitation packs, including a FOBT, were sent directly to participants by the National Bowel Cancer Screening Register (the Register). The method of distributing invitations and FOBT kits varied between jurisdictions, as shown in the following table.

National Bowel Cancer Screening Program phase 1 rollout schedule, states and territories

State	Distribution	Start date
Queensland	Geographic	7 August 2006
New South Wales	Birth date	14 August 2006
Australian Capital Territory	Birth date	11 September 2006
South Australia	Geographic	22 January 2007
Victoria	Birth date	29 January 2007
Western Australia	Geographic	29 January 2007
Northern Territory	Geographic	5 March 2007
Tasmania	Birth date	2 April 2007
Australia	..	7 August 2006

Notes

1. Birth date distribution: involves eligible participants being identified and invited to participate generally within 4 weeks of their 50th, 55th or 65th birthday, with an initial catch-up period for delayed start of the Program.
2. Geographic distribution: involves the full cohort of eligible people being issued invitations across the period of screening according to their postcode, so invitations are sent to people in the eligible age groups at the same time as others living in their area.

All jurisdictions switched to the birth date rollout method for phase 2, with the addition of people aged 50 years being invited to screen. Phase 2 invitations also included a pre-invitation letter (Figure B.2) in an effort to improve participation rates (Cole et al. 2007).

Once completed, participants are requested to post their completed FOBT to a central pathology laboratory for analysis. Results of this analysis are sent to the participant, the participant's nominated primary health care practitioner and the Register. Participants with a positive result, indicating blood in their bowel motion, are advised to consult their primary health care practitioner to discuss further diagnostic testing – in most cases, this will be a colonoscopy.

Responses to invitations, and the outcomes for those who complete the screening test, are monitored to the point of definite diagnosis for those who are found to have bowel cancer (DoHA 2008). Refer to Appendix B for a complete representation of the screening pathway from invitation to diagnosis.

National Bowel Cancer Screening Program monitoring reports

The Australian Institute of Health and Welfare (AIHW) produces annual monitoring reports for the Australian Government Department of Health and Ageing (DoHA) to help manage the NBCSP. These reports analyse data extracted from the Register (maintained by Medicare Australia) and provide an overview of screening participation and outcomes.

Each NBCSP annual monitoring report presents statistics for the previous calendar year on the progression of eligible participants through the screening pathway, and covers participation, FOBT results, follow-up investigations and outcomes. Analyses are presented by age, sex, state and territory, geographic region, socioeconomic status, Aboriginal and Torres Strait Islander status, language spoken at home, and disability status.

As a participant's progression through the screening pathway may span more than a single calendar year, the report also presents trend data from the Program's inception in 2006.

Finally, the most recent incidence and mortality data for bowel cancer are presented as an indication of current status of bowel cancer in Australia. As the NBCSP only began in late 2006, and the relatively small population currently focused on for screening, any influence screening has on incidence and mortality rates may not be shown for several years.

Analytical methods

Invitees who were outside the target ages or did not live in Australia at the time of the invitation were excluded from the eligible population. Those people correctly invited, but who had either opted off or suspended participation in the NBCSP (due to reasons such as a recent colonoscopy or previous diagnosis of bowel cancer) as at 31 January 2009 were also excluded from the NBCSP population eligible for analysis. There were 21,894 invitees excluded from this report for these reasons.

The term 'participation' is used in this report to refer to participation in the screening test. Hence, the participation rate is the proportion of the eligible people invited to participate in the NBCSP who agreed to participate by returning a completed FOBT. The FOBT positivity rate refers to the proportion of positive FOBT results out of all valid FOBT kits returned; kits that were inconclusive were excluded from this rate, and participants were requested to complete another FOBT kit. The proportion of people with a positive FOBT result and who subsequently visited a primary health care practitioner is referred to as the primary health care practitioner follow-up rate. The proportion of people with a positive FOBT who subsequently had a colonoscopy is referred to as the colonoscopy follow-up rate.

Due to the lag time between invitation and completion of an FOBT, calculation of a crude participation rate will result in an underestimate of the true participation rate. For current participation, modelled rates based on the time it takes each individual invited for screening to respond by returning a completed FOBT are calculated by following each invited person, and recording the time it takes him or her to respond. This allows a response rate over time from the date of invitation. The modelled response rates were calculated using the Kaplan-Meier methods. A description of the Kaplan-Meier method appears in Appendix D. A similar approach was used to determine current primary health care practitioner and colonoscopy follow-up rates. As the time taken to progress through the pathway can span calendar years, trend data using crude rates are also provided where applicable to gain a more comprehensive picture of true program performance.

Identification of participants as Aboriginal and Torres Strait Islander peoples, having a disability, or speaking a language other than English is by self-identification to Medicare

Australia through this or other programs. The denominator for initial participation rates stratified by these characteristics is calculated from Australian Bureau of Statistics population estimates from the 2006 Census of Population and Housing. See Appendix D for statistical methods.

Data issues

Data are collected about participants and their screening outcomes from a variety of sources throughout the screening pathway, and stored in the Register. The data are collected on forms completed by participants, primary health care practitioners, colonoscopists, pathologists, nurses and other specialists or administrative staff on behalf of health professionals.

Completion of NBCSP forms by practitioners is not mandatory, and there is the possibility of inconsistent reporting. For example, Assessment, Colonoscopy and Histopathology Report forms are received from different sources and may be entered in any sequence; however, each must have a positive FOBT result to be included. This means that there may be data for colonoscopies without an associated Assessment form, and data for histopathology results without a completed Colonoscopy Report form. When inconsistencies occur, these are noted in monitoring reports to provide an indication of the reliability of the data.

The analyses presented in this report are based on data recorded in the Register for people invited between 1 January 2008 and 31 December 2008, and includes all activity up until 31 January 2009. Data for the whole year were available for people aged 55 and 65 years due to their inclusion in phase 1 of the NBCSP, which ran until 30 June 2008. Data for people aged 50 years is only available for the period 1 July 2008 to 31 December 2008 due to their recent inclusion in phase 2 of the NBCSP only.

Because of time lags in reporting and under-reporting by clinicians, data on primary health care practitioner consultations, colonoscopies and colonoscopy outcomes in this report understate the true performance of the NBCSP in this period and should be interpreted with caution.

The NBCSP has used differing rollout methods across states and territories, and care should be taken in making comparisons between states and territories or geographic locations. Where numbers of responses to invitations are small, caution should also be applied drawing inferences between groups.

As identification of Aboriginal and Torres Strait Islander status, disability status or language spoken other than English is through self-identification through the NBCSP, care should be taken in interpreting data for these groups.

The introduction of a new FOBT kit in December 2008, which was found to be unreliable, may have had a lowering effect on the 2008 positivity rate; however, this effect would have been minimal, as less than 5% of FOBT kits were affected. Those people invited in December 2008 affected by this issue were given the opportunity to retest in 2009.