

# INTRODUCTION

## BACKGROUND

The BreastScreen Australia Program commenced in 1991, as a joint program of the Australian and state and territory governments. The main objective of the BreastScreen Australia Program is to reduce mortality and morbidity from breast cancer. The program targets women aged 50–69 years, but also screens women aged 40–49 years and 70 years and over, and is regularly monitored against agreed performance indicators. An annual monitoring report is produced by the Australian Institute of Health and Welfare (AIHW) with the Australian Department of Health and Ageing (DoHA).

While the program is monitored annually there has not been a comprehensive evaluation of the performance of the program since its inception. With this in mind, the Australian Health Ministers' Advisory Council (AHMAC) set up the BreastScreen Australia Evaluation Advisory Committee (EAC) to develop an Evaluation plan to undertake an extensive evaluation of the program.

Ten projects analysing different aspects of the program were commissioned to identify key findings and make recommendations for the BreastScreen Australia Program. EAC members acted as sponsors to projects, providing expert advice to consultants and reviewing project findings.

The evaluation addressed the following objectives endorsed by AHMAC in June 2006:

1. assess the outcomes delivered by the BreastScreen Australia Program
2. assess the extent to which the program has achieved its aims and objectives
3. assess the appropriateness, efficiency and effectiveness of the program
4. assess and address the ongoing and unresolved issues impacting on the program
5. identify opportunities to improve the program overall.

This analysis is one of the 10 commissioned projects used to develop the final report on the evaluation of the BreastScreen Australia Program in accordance with the Evaluation plan. This analysis, undertaken by staff from the Cancer and Screening Unit at the AIHW, was guided by the designated sponsors from the EAC. This project was an analysis of the BreastScreen Australia Program performance data to establish if differences exist in participation and performance across population subgroups and jurisdictions, and identify trends in participation and performance over time.

The analysis uses data from the state and territory BreastScreen programs to assess trends in participation and performance in the program over the 10-year period 1996–2005. As data were analysed sponsors were provided with preliminary results which they used to further direct the analysis.

## PURPOSE

The objectives of this project were:

- Determine the trends in the program's performance against the agreed performance indicators over time (participation, detection of invasive cancers, interval cancer rate, program sensitivity, detection of ductal carcinoma in situ, recall to assessment, rescreening, incidence of breast cancer, incidence of ductal carcinoma in situ, and mortality).
- In relation to performance indicators, determine whether differences exist across eligible age groups and population subgroups, and identify where these are most pronounced. Population subgroups include: geographic region (ASGC); socioeconomic status (SEIFA); Aboriginal and Torres Strait Islander women; women who reported that they speak a language other than English at home; and women at high risk (women with a family history of breast cancer, women with a previous history of breast cancer or DCIS and women with symptoms who present for screening).
- Review participation rates by age group and population subgroups.
- Review participation rates by screening round and age group for different intervals (0–15, 16–27, 28–36, 37–48 and >48 months).
- Examine participation and rescreening data to determine level of service provided across population subgroups.
- Identify any trends in morbidity associated with participation in the program as reflected by: technical repeats; time between screening and result; time between screening and assessment; invasive assessment procedures and results; preoperative diagnosis rate; and false negative and false positive results as defined for fine needle aspiration and core biopsy.

## SCOPE

The performance indicators against which the program is monitored reflect the key aims and objectives of the BreastScreen Australia Program. They assess progress towards achieving the overall aim of reducing mortality and morbidity from breast cancer. Broadly, these relate to maximising participation, rescreening and the detection of cancers, while ensuring services are acceptable and appropriate (NQMC 2004).

This report is presented in two main parts. The first part describes trends using the BreastScreen Australia performance indicators that measure program activity, performance and outcomes over the 10-year period 1996–2005. Performance indicators are described using a variety of screening rounds, time periods and population subgroups. These indicators are presented primarily in 5-year epochs, 1996–2000 and 2001–2005, to smooth yearly variation and allow for easy comparison. Incidence and mortality are reported briefly to provide context for other indicators.

The second part of the report describes morbidity trends (both positive and negative) over the 10-year period 1996–2005. This section reviews recall to screening for technical reasons, time between screening and provision of results, as well as between screening and assessment, and invasive assessment procedures. Preoperative diagnosis rate and the performance of the program against the National Accreditation Standards (NAS) (NQMC 2004) related to fine needle aspirations and core biopsies are also included.

A variety of data sources was used to prepare this report. State and territory BreastScreen Australia programs provided de-identified unit record data for the purpose of analysing participation and performance trends for the BreastScreen Australia Program for the years 1996–2005 as a specific request for this project. Limitations with the dataset developed from the request are detailed in Appendix C. Data supplied for the BreastScreen Australia monitoring report 2004–2005 and previous monitoring reports were also used. Other data sources included the Australian Cancer Database (formerly the National Cancer Statistics Clearing House), and the National Mortality Database, held at the Australian Institute of Health and Welfare (AIHW).

National Accreditation Standards (NQMC 2004), although developed for individual screening services rather than for the national program as a whole, provide an indication of the national program's performance. Therefore, in addition to their calculation for fine needle aspirations and core biopsies, where NAS performance objectives exist that relate to any of the data in this report, they have been included.

The report was prepared by the Cancer and Screening Unit of the AIHW under the guidance of the project sponsorship team of Professor David Roder as lead sponsor, and supporting sponsors Professor Dallas English, Dr Frida Cheok and Ms Valerie Lang, as well as the BreastScreen Australia Evaluation Taskforce of DoHA. State and territory BreastScreen Australia programs have contributed the program data underpinning the report, as well as providing valuable feedback on the report.

## STATISTICAL SIGNIFICANCE

Statistical analyses are useful tools that aid in the interpretation of data. In this report, 95% confidence intervals have been used to determine if a statistically significant difference exists between compared values. While the approximate comparisons presented might understate the statistical significance of some differences, they are sufficiently accurate for the purposes of this report. For more information on 95% confidence intervals, please see Appendix C.

### Interpretation

The confidence intervals presented in this report can be used as a guide to whether differences in a particular rate are consistent with chance variation. Where the confidence intervals do not overlap, the difference between rates is greater than that which could be explained by chance and is regarded as statistically significant.

It is important to note that overlapping confidence intervals do not imply that the difference between two rates is definitely due to chance. Instead, an overlapping confidence interval represents a difference in rates which is too small to allow differentiation between a real difference and one which is due to chance variation. It can therefore only be stated that no statistically significant differences were found, and not that no differences exist.

As with all statistical comparisons, care should be exercised in interpreting the results of the comparison. If two rates are statistically significantly different from each other, this means that the difference is unlikely to have arisen by chance. Judgment should, however, be exercised in deciding whether or not the difference is of any clinical significance.

### Terminology

Whenever statistical significance is reported, the term 'significant' is used in lieu of the term 'statistically significant'. Importantly, this is the only context in which the term significant or any of its derivatives are used; any use of the terms significant, significantly or significance should therefore be interpreted as a statistically significant result, as determined by the presence of non-overlapping confidence intervals, as described above.

## KEY FINDINGS

### PARTICIPATION AND RESCREENING

The BreastScreen Australia Program aims to maximise the proportion of women aged 50–69 years who are screened every 2 years, and to ensure equitable access for women in this age group.

#### Participation

Participation of women aged 50–69 years in the BreastScreen Australia Program was 51.4% in 1996–1997 when reporting began, increasing to a peak of 57.1% in 2001–2002. Participation has remained steady at around 56% since this peak, being 56.2% in 2002–2003, 55.7% in 2003–2004, and 56.2% in 2004–2005.

While the participation rate has remained stable, there has been an overall increase in the number of women aged 50–69 years participating in the program, from 844,626 in 1996–1997 to 1,188,720 in 2004–2005.

The target age group for the BreastScreen Australia Program is women aged 50–69 years; however, women aged 40–49 years and 70 years and over are also eligible to attend. The impact of these additional women on the program is substantial, with 1,614,871 women aged 40 years and over screened by the program in 2004–2005.

Queensland had the highest proportion of women aged 40–49 years and women aged 70 years and over screened within the program for most reporting periods (31.5% and 23.2% in 2004–2005, respectively). New South Wales and the Australian Capital Territory both experienced a sudden drop in the number of women aged 40–49 years screened within the program, which may reflect a move towards maintenance of participation by women in the target age group. In New South Wales, this decrease was from 22.7% in 2002–2003 to 12.7% in 2004–2005. In the Australian Capital Territory, the decrease was from 21.0% in 2000–2001 to 11.3% in 2002–2003 and 6.2% in 2004–2005.

Comparison of the jurisdictions is not straightforward because there are substantial differences between the states and territories in terms of population, area, geographic structure, program structure, and other factors. Without taking these contributing factors into consideration, participation of women aged 50–69 years was highest in South Australia (61.9% in 2004–2005) and lowest in the Northern Territory (41.1% in 2004–2005) for all reporting periods between 1996–1997 and 2004–2005.

Participation for women aged 50–69 years was highest in Inner regional and Outer regional areas (58.3% and 59.7% respectively, in 2004–2005), followed by Remote areas (57.8% in 2004–2005), and Major cities (54.8% in 2004–2005). Participation in Very remote areas was relatively lower (45.8% in 2004–2005).

Participation for Aboriginal and Torres Strait Islander women aged 50–69 years was low when compared to the national rate (25.2% in 1996–1997 and 35.3% in 2004–2005), as was participation for women aged 50–69 years who reported speaking a language other than English at home (39.4% in 1996–1997 and 43.2% in 2004–2005).

The proportion of women screened who reported a family history of breast cancer, a previous history of breast cancer or ductal carcinoma in situ (DCIS), or breast symptoms was also assessed. Of these, women who reported a family history of breast cancer comprised the highest proportion of women screened in the program (13.1% in 2004–2005 for women aged 50–69 years), followed by women with breast symptoms (3.3% in 2004–2005 for women aged 50–69 years). Women with a previous history of breast cancer or DCIS comprised the lowest proportion of women screened (1.0% in 2004–2005 for women aged 50–69 years). Notably, women who reported breast symptoms were more likely to be in the 40–49 years age group (7.2% of women screened in 2004–2005).

### Rescreening

Rescreening rates of women aged 50–67 years in the BreastScreen Australia Program increased with each screening round. In 2003 (the latest year for which data were available) 60.5% of women who attended their first screen were rescreened within 27 months, 69.5% of women who attended their second screen were rescreened within 27 months, and 80.1% of women who attended their third or subsequent screen were rescreened within 27 months.

Rescreening rates within the program decreased significantly between the years 2000 and 2003, from 66.3% to 60.5% in the first screening round, from 75.7% to 69.5% in the second screening round, and from 84.2% to 80.1% in subsequent screening rounds.

The Australian Capital Territory had a significant increase in its rescreening rate between 2002 (at which time its rescreening rates were the lowest in Australia) and 2003. This increase was from 47.5% to 74.4% after the first screening round, from 53.7% to 82.4% after the second screening round, and from 67.4% to 90.0% after third and subsequent screening rounds). The reduction in screening of women aged 40–49 years noted earlier in the 2002–2003 reporting period may have allowed this jurisdiction to focus on rescreening women in the target age group.

The proportion of women rescreened within 27 months decreased between 1996 and 2002 (the latest year with complete data for this screening interval) for all age groups and all screening rounds. For women aged 50–69 years, this decrease was from 72.2% to 61.6% between the first and second screening round. Conversely, the proportion of women aged 50–69 years rescreened within 28–36 months increased between 1996 and 2002 for all screening rounds. For women aged 50–69 years, this was from 5.7% to 8.3% between the first and second screening round. These trends indicate that a greater proportion of women were being rescreened within 28–36 months instead of 27 months.

## CANCER DETECTION

The BreastScreen Australia Program aims to maximise the number of cancers and small cancers detected, while minimising the number of unnecessary recalls and investigations.

### Detection of invasive cancers

Detection of invasive cancers within the BreastScreen Australia Program increased with increasing participation between 1996 and 2001. Despite participation remaining steady since this time, the rate of cancer detection has continued to rise.

Detection of all-size invasive cancers for women aged 50–69 years at their first screen increased from 60.1 per 10,000 women screened in 1996–2000 to 73.4 per 10,000 women screened in 2001–2005. For women aged 40 years and over, the detection rate increased from 60.8 to 74.3 per 10,000 women screened. For subsequent screens, detection of all-size invasive cancers in women aged 50–69 years increased from 38.5 per 10,000 women screened in 1996–2000 to 42.5 per 10,000 women screened in 2001–2005. For women aged 40 years and over an increase also occurred, from 36.6 to 40.4 per 10,000 women screened.

Early in the program (1996–2000) there were apparent differences in the detection of invasive cancer, with cancer detection higher in Major cities than in other regions (60.4 per 10,000 women screened for first screens, and 43.4 for subsequent screens). There was also a lower detection rate in Aboriginal and Torres Strait Islander women (29.8 compared with the national rate of 56.3 per 10,000 women screened for all-size cancers detected in first screens) for women aged 50–69 years in 1996–2000. These apparent differences were no longer present in 2001–2005 for women aged 50–69 years, with no significant differences found between regions in the detection rate of all-size invasive cancers, and no significant differences found in the detection rate of all-size invasive cancers in Aboriginal and Torres Strait Islander women compared with the national rate in first or subsequent screening rounds.

Women who reported a family history of breast cancer, women with a previous history of breast cancer or DCIS, and women who reported breast symptoms, experienced notably higher cancer detection rates in comparison to the national rate.

The proportion of invasive cancers detected by the program that were small ( $\leq 15$  mm) cancers has changed little between 1996 and 2005, remaining above 60% for all years, with only a slight decline evident over this period.

### **Sensitivity**

An interval cancer is an invasive breast cancer that is diagnosed after a screening episode that detected no cancer and before the next scheduled screening episode.

The interval cancer rate remained relatively stable between 1996 and 2003 (the latest year for which data were available). For women aged 50–69 years, for 0–12 months after a negative screening episode, this was 6.9 per 10,000 women screened in 1996–1999 and 6.7 per 10,000 women screened in 2000–2003 for first screens, and 7.6 per 10,000 women screened in 1996–1999 and 7.4 per 10,000 women screened in 2000–2003 for subsequent screens. These rates compare favourably with the National Accreditation Standard of  $<7.5$  per 10,000 women screened. There is no similar standard for the 13–24 months after a negative screening episode, but interval cancer rates in this period for women aged 50–69 years also remained relatively stable between 1996 and 2003, ranging between around 12 and 14 per 10,000 women screened for first and subsequent screens. It should be noted that the occurrence of interval cancers does not necessarily represent any failure in detection, since most interval cancers on review are found to have grown between screening intervals, or were in dense breast tissue and therefore not visible with screening mammography.

## Ductal carcinoma in situ (DCIS)

Although the natural history of DCIS is not well understood, there is evidence that women with DCIS are at increased risk of developing invasive breast cancer, and, accordingly, the BreastScreen Australia Program aims to maximise detection of DCIS. Similar to detection of invasive cancer, DCIS detection rates were higher in first screens than in subsequent screens, and increased between 1996 and 2005. For women aged 50–69 years, this was from 12.9 per 10,000 women screened in 1996–2000 to 18.5 per 10,000 women screened for first screens, and from 8.7 to 10.3 per 10,000 women screened for subsequent screens.

## Recall to assessment

Women with a suspicious mammography results are recalled for further assessment.

Between 1996–2000 and 2001–2005 the recall to assessment rate for women aged 50–69 years increased significantly for first screens, from 6.9% to 9.2%, and for subsequent screens, from 3.8% to 4.0%. Although the program aims to minimise unnecessary investigations, it is likely that the noted increase in recall to assessment rates contributed to favourable trends in cancer detection rates.

## MORBIDITY

This section looks at several markers of potential morbidity within the BreastScreen Australia Program. Where differences exist between population subgroups, it should be stressed that no causality has been intended or attributed to the population subgroups themselves.

## Technical repeat status

Technical repeat status indicates whether or not additional films were taken due to the technically unsatisfactory nature of a woman's films at the screening visit. These additional films are called technical repeats. The program aims to minimise recall rates and retaking of films.

The rate of technical repeats performed decreased significantly between 1996–2000 and 2001–2005 for all age groups, from 4.1% in 1996–2000 to 3.7% of women screened in 2001–2005.

## Time between screen and assessment

The BreastScreen Australia Program aims to minimise the time between screen and assessment.

For those women recalled for assessment, the median time between screening and assessment remained fairly constant between 1996 and 2002 at around 15 days, but increased in 2003, 2004 and 2005 to 17, 18 and 20 days, respectively. This trend was also reflected in the proportion of women with a time between screening and assessment of 28 days or less, which was 85.7% in 1996–2000, only slightly lower than the National Accreditation Standard of  $\geq 90\%$ , but decreased significantly to 79.2% in 2001–2005. The increase in the number of women screened, coupled with the increase in recall to assessment rates, would have contributed to the increase in time between screening and assessment between 2002 and 2005.

### Technical quality of biopsies

Fine needle aspirations and core biopsies can be used as part of an assessment to aid in diagnosis of benign or malignant lesions and play an important role in minimising the number of women who require further procedures, including a more invasive diagnostic open biopsy. Within the BreastScreen Australia Program, there was a clear trend of a decreasing rate of fine needle aspirations and an increasing rate of core biopsies. Fine needle aspiration rate decreased from 13.9% of assessments in 1996–2000 to 9.9% in 2001–2005, while core biopsy rate increased from 10.4% of assessments in 1996–2005 to 15.8% in 2000–2005.

Core biopsies have a greater ability to give a definitive (benign or malignant) result than fine needle aspirations (90.3% of core biopsy results were definitive compared with 72.6% of fine needle aspiration results in 2005). As a result, an increase in their use is associated with a decreased need for women to undergo further procedures to secure a benign or malignant diagnosis.

National Accreditation Standards (NAS) for fine needle aspirations and core biopsies indicated high quality within the program for the period 1996–2005. Inadequate and false negative rates of fine needle aspirations were well within the NAS at 11.5% and 4.9% in 2001–2005, respectively. The false positive rates of fine needle aspirations and core biopsies were slightly above the NAS at 1.5% and 1.3% in 2001–2005, respectively. This should be interpreted with caution, since it is possible some of these cases would have turned out not to be true false positives. Absolute and complete sensitivity of fine needle aspirations and core biopsies all met or exceeded the NAS, especially absolute and complete sensitivity of core biopsies which, at 89.6% and 95.2% in 2001–2005, respectively, were well above the NAS. Positive predictive values of fine needle aspirations and core biopsies were 97.6% and 98.6% in 2001–2005, respectively.

### Preoperative diagnosis rate

The preoperative diagnosis rate is the proportion of women diagnosed with invasive cancer who received a definitive diagnosis of cancer prior to surgery. A definitive diagnosis of cancer before surgery means women only undergo a one-stage surgical procedure.

The preoperative diagnosis rate in the BreastScreen Australia Program (data restricted to Victoria, Queensland, Western Australia and the Australian Capital Territory) increased from 64.2% of women diagnosed with invasive cancer in 1996 to 94.3% in 2005 (with a significant increase from 73.0% in 1996–2000 to 90.0% in 2001–2005). A major factor contributing to this increase in preoperative diagnosis rate is likely to be the increased improvement in diagnostic techniques used at assessment, and primarily the increase in core biopsy use in favour of fine needle aspirations, with core biopsies more likely to give a definitive result.

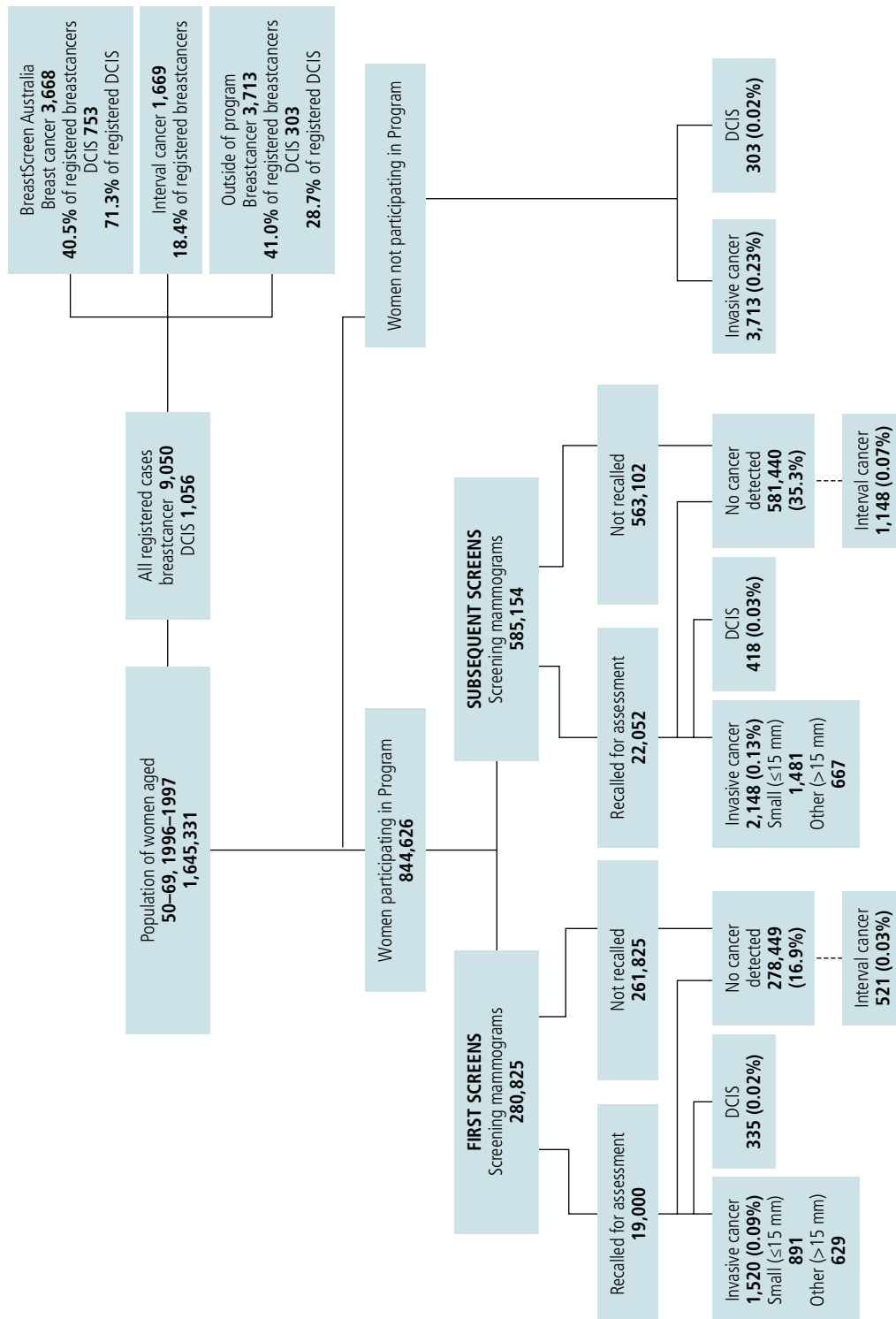
## SCREENING PATHWAY FLOWCHARTS

Flowcharts of the screening pathway are provided on the following pages as a preface to detailed analysis of the steps along the pathway. These flowcharts provide a schematic view of participation, assessments, cancers and DCIS. Numbers are presented for 1996–1997 and 2002–2003, these being the first and last reporting periods for which complete data are available. The flowcharts illustrate the outcomes of the program in terms of the women who participated, the number recalled for assessment and the number of breast cancers detected. The cancers detected are classified as small (<15mm), other and DCIS. The flowchart also shows interval cancers and cancers detected in women aged 50–69 outside the BreastScreen Australia Program. The final outcomes of invasive cancer, DCIS and interval cancer for women within and outside the BreastScreen Australia Program are presented along the base of the flowchart as the total number of cases, as well as being represented as the proportion of the total number of eligible women aged 50–69 in the Australian population.

In 1996–1997, there were 9,050 cases of breast cancer identified in Australian women aged 50–69 years. Of these 3,668 (40.5%) were detected in women in the BreastScreen Australia Program, 1,669 (18.4%) were interval cancers, and 3,713 (41.0%) were detected in women outside the program. In 1996–1997, there were also 1,056 cases of DCIS identified in Australian women aged 50–69 years. Of these, 753 (71.3%) were detected in women in the BreastScreen Australia Program, and 303 (28.7%) were detected in women outside the program.

In 2002–2003, there were 11,762 cases of breast cancer identified in Australian women aged 50–69 years. Of these 5,380 (45.7%) were detected in women participating in the BreastScreen Australia Program, 2,013 (17.1%) were interval cancers, and 4,369 (37.1%) were detected in women outside the program. In 2002–2003, there were also 1,716 cases of DCIS identified in Australian women aged 50–69 years. Of these, 1,258 (73.3%) were detected in women in the BreastScreen Australia Program, and 457 (26.6%) were detected in women outside the program.

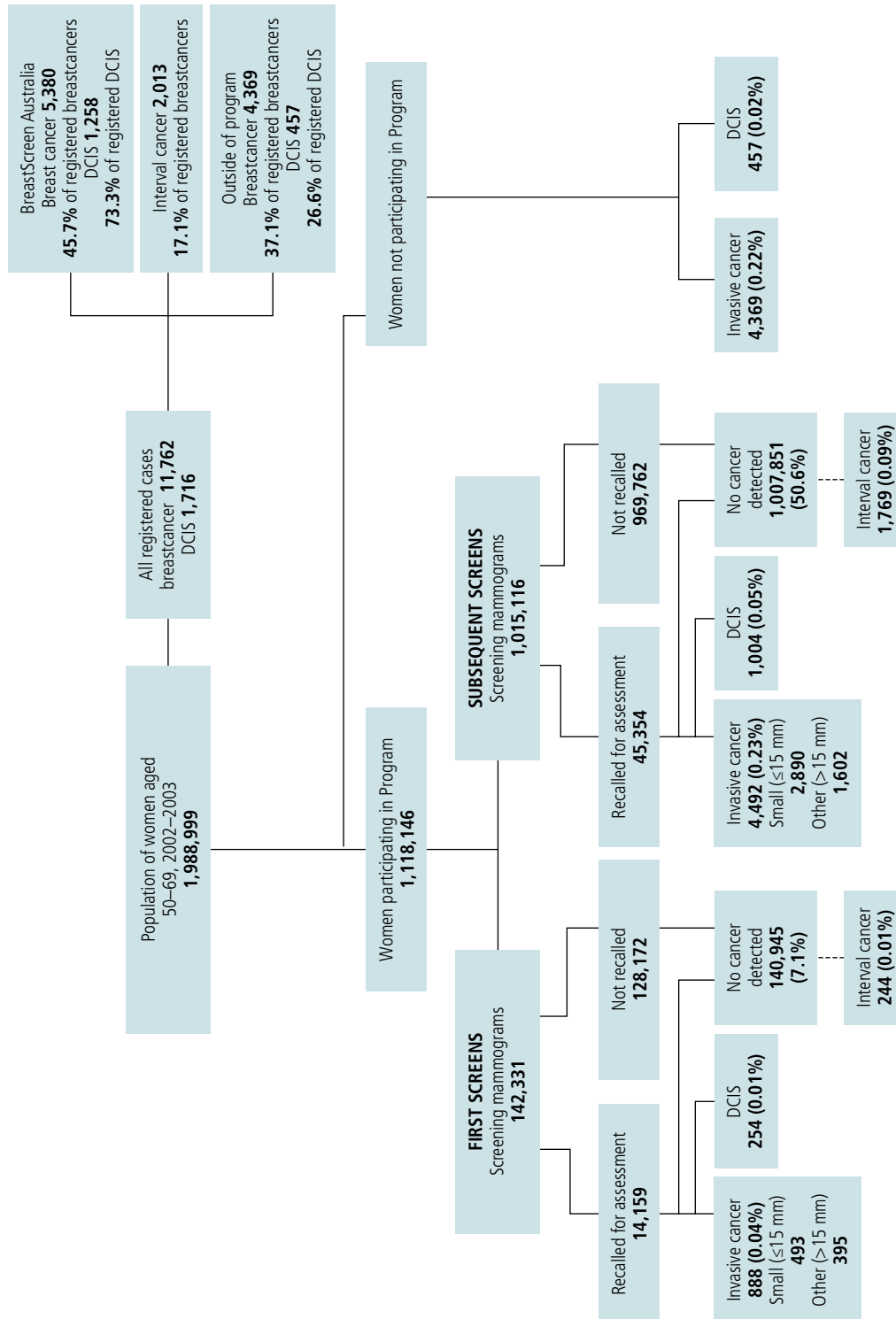
**Flowchart 1: Screening Pathway 1996–1997**



Notes:

1. The final outcomes of invasive cancer, DCIS and interval cancer for women are presented along the base of the flowchart as the proportion of the total number of eligible women aged 50–69 in the Australia population.
2. The discrepancy between the number of women participating in the Program and the number of women screened is due to a difference in the way these are calculated.

**Flowchart 2:** Screening Pathway 2002–2003



Notes:

1. The final outcomes of invasive cancer, DCIS and interval cancer for women are presented along the base of the flowchart as the proportion of the total number of eligible women aged 50–69 in the Australia population.
2. The discrepancy between the number of women participating in the Program and the number of women screened is due to a difference in the way these are calculated.