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Cohort Profile

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Cohort Profile: Lifepool

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Key Features

- The population cohort Lifepool was established in 2010 and continues to recruit women from the Australian community. The cohort collects baseline health and lifestyle data at recruitment and follow-up is achieved through data linkage and individual survey. Lifepool can facilitate research into breast cancer screening, risk, and treatment as well as other important women's health issues. Resources are available to national and international researchers—send enquiries to lifepool@petermac.org.
- Lifepool recruitment targets women aged ≥40 years who are participating in a population-based mammographic screening programme (BreastScreen Australia). Younger women (≥18 years) are eligible to join and are referred by family and friends.
- Lifepool collects health and lifestyle data by questionnaire and obtains participant consent to allow the collection of data and use of data in future, as-yet unspecified, research. Multiple screening rounds of mammogram images are available for most participants.
- Consent permits access to clinical data and remnant tumour tissue. Over 17 000 DNA samples in total are available, including ∼1200 samples from women with breast cancer.
- Follow-up is facilitated by participants who are under the age of 74 years being invited by BreastScreen Australia for their recommended 2-yearly mammograms. Verification of cancer diagnoses is made by regular linkage to population-based cancer registries.

Why was the cohort set up?

The Lifepool cohort was established as a resource for research into important women's health issues that focuses on improving the screening, prevention, and management of breast cancer, and enables investigation into more personalized mammographic screening using lifestyle factors, genetic markers, and mammographic breast density. It is a prospective study of women that measures outcomes with respect to breast cancer diagnoses against baseline risk factors at enrolment. The recruitment criteria were expanded from women who were unaffected by breast cancer to recruiting prevalent breast cancer diagnoses and women younger than 40 years who had had, or intended to have, a screening mammogram. This expansion in criteria was designed to facilitate and accelerate research into genetic and morphologic differences between screen-detected and interval breast cancers as well as mammographic density and its association with breast cancer risk.

Recruitment commenced in mid-2010 in collaboration with the Victorian BreastScreen service, BreastScreen Victoria (BSV). Operational management and laboratory activities are based at the Peter MacCallum Cancer Centre. Lifepool data are managed by The Ark—an open-source, web-based software system that is designed to manage medical research data [1].

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The resource operates under the leadership of the Chief Investigators, with the support of the Lifepool Access Committee, members of which bring expertise in genomics, genetics, clinical care, population breast cancer screening, epidemiology, qualitative and behavioural research, and consumer advocacy.

Who is in the cohort?

As at July 2024, >55 500 Australian women, recruited principally through the national mammographic screening programme, BreastScreen Australia, were participating in Lifepool. Initial recruitment was based in the state of Victoria (2010–14) and subsequently expanded nationally (2015 onward). Protocols for data linkage with mammographic screening services and key state registries across Australia are established.

Most women were recruited through BSV who operate the BreastScreen Australia Program for the state of Victoria. BSV provides free biennial screening mammograms to Victorian women. Screening is available to women from the age of 40 years. Women aged between 50 and 74 years are actively invited to participate, whereas women aged between 40 and 49 years and >74 years are eligible to screen at their request [2]. Invitation to join Lifepool was sent to all women who were screening at Round 2 or greater and no selection was applied other than an ability to read English, as all project documentation was only available in English. Cohort participants predominantly declared Australian ethnicity. Compared with the general Victorian community [3], there is an under-representation of women who were born in Southeast Asia, Southern and Central Asia, Northeast Asia, and Southern and East Africa. The Lifepool cohort is over-representative compared with the general Victorian population of women born in Australia, New Zealand, South and South-Eastern Europe, and North and Central America (Table 1). To maintain privacy for BSV clients, Lifepool was unable to collect data about women who chose not to join the cohort but speculate that speaking a language other than English is a significant factor in the under-representation of Asian and African ethnicities. Women with a personal history of breast cancer are eligible to participate in the BSV programme when it has been ≥5 years since their most recent diagnosis. Irrespective of the recruitment mechanism, the vast majority of participants (94%) in Lifepool are clients of BSV. Lifepool recruitment targeted women who were attending for second or subsequent round screening to ensure that women who were screening for the first time were not dissuaded from participation by the receipt of additional research-based documents. The average age of participants at recruitment was 60.04 (19.21 to 97.06) years. The current age of participants in the cohort is shown in Figure 1. Figure 1 provides a count of women in the cohort, distributed across 5-year age brackets as a percentage of the total cohort. The majority of women are aged within the target screening population of 50–74 years.

Table 1. Cohort participants' region of birth compared with the Victorian population

Region of birth	Percentage of Lifepool cohort	Percentage in Victorian population
Australia	76.56	70.20
New Zealand	9.17	1.56
UK/Ireland	2.41	3.54
South-Eastern Europe	2.06	1.92
Southern Europe	1.57	1.36
North America	1.33	0.53
Eastern Europe	0.93	0.58
Central America	0.70	0.08
Northeast Asia	0.75	3.58
Northern Europe	0.72	0.09
Southern and Central Asia	0.63	6.37
South America	0.59	0.53
North Africa and Middle East	0.50	2.13
Central and West Africa	0.29	0.10
Other	0.17	0.39
Southern and East Africa	0.11	1.14
Southeast Asia	0.08	4.98
Caribbean Islands	0.05	0.01
Data not available	1.08	

Data are collected through participant questionnaires, mammograms (from which breast density is calculated), and biological specimens (archival tumour tissue and blood or saliva for DNA extraction). For cohort members who reside in the state of Victoria, annual linkage with the Victorian Cancer Registry [4] identifies cancers that are diagnosed within and outside the screening programme.

At recruitment, all participants complete an extensive health and lifestyle questionnaire and provide consent for linkage with cancer registries and the national death index as well as access to screening mammograms and screening programme service data. Participants also permit access to clinical data and archival pathology laboratory tumour samples in the event of a cancer diagnosis. Consent allowing access to data that detail claims under the national health service funder Medicare and medications provided under the Pharmaceutical Benefits Scheme (PBS) is optional. Participants are asked to donate DNA for genetic research under a second-stage consent process and consenting participants provide either blood or saliva. Consent allows the use of all data and biospecimens in future, unspecified research as approved by the Lifepool Access Committee and with appropriate ethical oversight.

This profile report focuses on the data collected in the state of Victoria, where the majority of recruitment occurs and in which all linkage protocols are active.

Important features of the Lifepool resource include:

- linkage with cancer registry data to identify new diagnoses of cancer, including incident breast cancer diagnoses; registry data record breast cancers at the tumour level and so information about multiple tumours that occur over time in an individual woman is captured;
- availability of DNA from women with verified cancer history, updated annually;
- availability of DNA from women with no cancer at time of sample donation, matched for age with cases;
- broad participant consent for use of data in future research into breast cancer and other health issues by researchers, including commercial research groups;
- potential to recontact participants for additional research participation.

Lifepool recruitment remains active across Australia.

In order to recruit interested 'first-time screeners' and younger women, we initiated publicity drives and encouraged existing participants to invite eligible friends and family members to consider joining the Lifepool cohort.

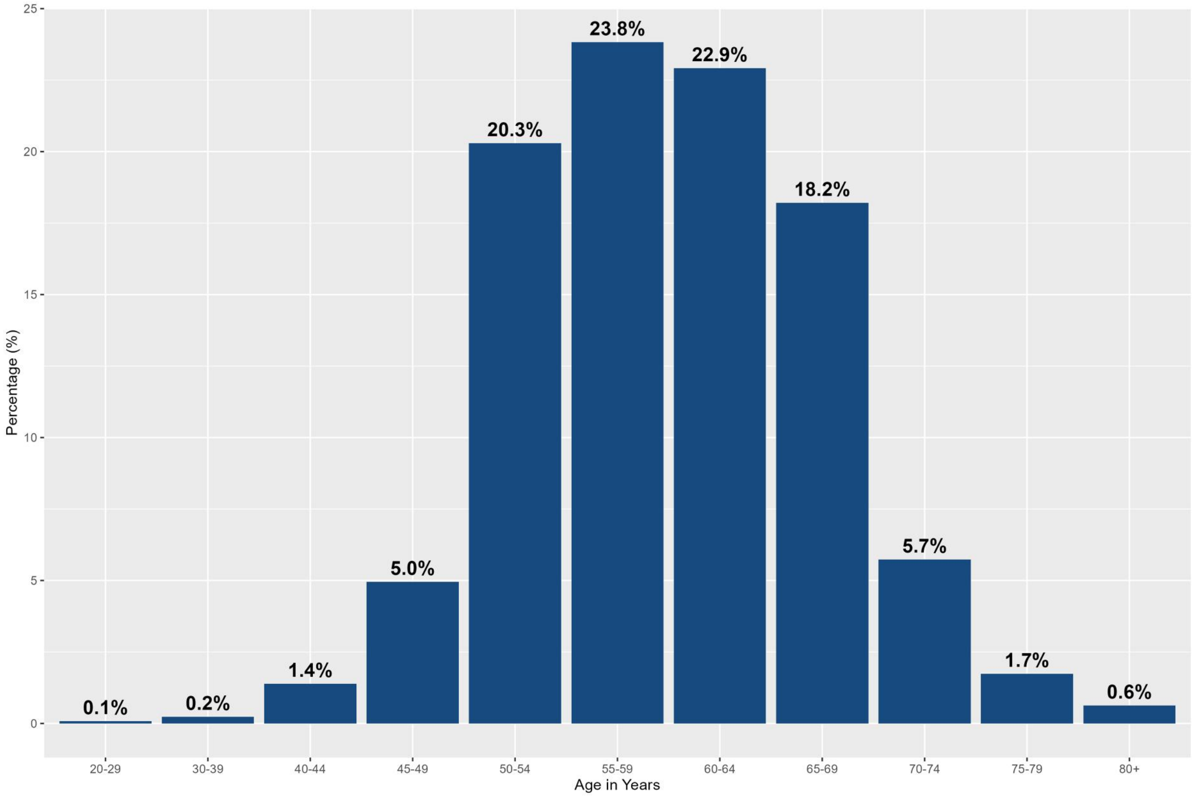

Figure 1. Cohort age range at the end of 2023.

Recruitment protocol

A number of recruitment protocols have been used over the life of the cohort, including two distinct paper-based methods and, more recently, an electronic invitation and recruitment protocol.

Initially, a hard-copy Participant Information and Consent Form and the Baseline Health and Lifestyle Questionnaire were posted to women along with a "Reply Paid" envelope for return of completed documents. The documents were also available for download on the Lifepool website. Document packs were posted to BSV clients on the same day as the mammogram appointment letter. The annual cost for printing and postage for this recruitment protocol was $467 500 AUD ($23 per participant).

BSV performed 365 741 screening mammograms for returning clients in the 24-month period from July 2012 to June 2014 [5]. During this period, 178 168 women (48.7%) were invited to consider participating in Lifepool and 32 963 (18.5% of those invited) agreed to join the cohort.

In order to maintain ongoing recruitment within tight funding constraints, a second method was introduced, which involved only the letter of invitation being posted with the mammogram appointment letter to BSV clients. Women were invited to contact Lifepool by telephone or e-mail to request a document pack. Although the response to the invitation letter was only 12%, ∼71% of the responders became participants. This modified protocol represented a considerable saving in print–post expenditure ($190 000AUD per annum). Notably, the uptake in absolute numbers was lower and the cost per participant was the same ($23 per participant) but, overall, keeping recruitment open, allowing participants to 'self-recruit' friends and family, combined with the development of electronic recruitment capacity (described below) supported this operational change.

National expansion

Beginning in early 2015 in collaboration with Register4 [6], Lifepool commenced recruiting women nationally. Register4, established by the National Breast Cancer Foundation, was a national online database for women and men who were interested in opportunities to participate in cancer research. Register4 is no longer active.

Linkage and data acquisition protocols have been developed with jurisdictions across Australia. The data detailed in Table 2 were available for all Victorian participants as at June 2024.

How often have they been followed up?

Participant follow-up is predominantly passive through linkage with relevant databases. Linkage with the Victorian Cancer Registry is conducted annually, identifying all cancers diagnosed over the calendar year prior to linkage. For all participants who have screened with BSV over the 12 months prior to linkage, a copy of digital mammogram images is obtained along with the screening outcome data.

A newsletter is distributed annually to all participants who have an active e-mail address. In addition, specific subsets of participants who are not contactable by e-mail are selected to receive a hard-copy newsletter by post. These groups may be selected based on age or the length of time since last contact. The newsletter invites women to self-report changes in health and cancer diagnoses are later verified.

Health and lifestyle information

All participants complete a Baseline Health and Lifestyle Questionnaire at enrolment. The questionnaire is provided in the Supplementary File.

Table 2. Lifepool cohort data available (data elements for which consent is 'opt-in' are highlighted in grey)

Cohort data element	Time points	Data held by other data custodians, accessible by Lifepool	Details
Epidemiological questionnaire	At enrolment (baseline)		
Mammogram screening data	At enrolment, access to retrospective and prospective screening data	BreastScreen Victoria	Digital mammogram images Associated screening data, including screening history and cancer outcome data
	Follow-up by BreastScreen bi-annually	BreastScreen Victoria	Digital mammogram images Associated screening data, including screening history and cancer outcome data
Health information	Annual update	Victorian Cancer Registry	All cancers reported Mortality data collected
	Annual update	National Death Index	Date and cause of death
	As required, research-specific requests	Federal data on medical services and prescribed medication use	Medicare billable events and prescribed drugs under PBS
	As required, research-specific requests	Victorian Health Department	Records of emergency hospital admissions and community health interactions
	After breast cancer diagnosis	Medical record and pathology report	Tumour morphology, stage, and grade
Biospecimen collection	After breast cancer diagnosis		Archival tumour blocks retrieved
	After breast cancer diagnosis		DNA extracted from blood or saliva
	Women with no diagnosis of cancer at donation		DNA extracted from blood or saliva

Mammogram data

All participants give permission for access to mammograms and associated results from BreastScreen or other providers. Beginning in February 2006, BSV transitioned from film mammography services to a mix of digital and computed radiography (DR and CR) services, with the transition project completed in June 2013. Analogue mammograms were initially retrieved on a project-specific basis by using the established protocols of the Australian Mammographic Density Research Facility at the University of Melbourne [7].

In 2016, a complete library of all available digital mammograms was provided to Lifepool by BSV. This library is updated annually, with ∼1 100 000 images from >51 000 women held as at June 2024.

Remnant tumour

Incident breast cancer diagnoses are identified through annual linkage with the Victorian Cancer Registry as well as ad hoc direct updates to Lifepool operations staff from affected participants. Registry data enable that collection of histopathology reports and Lifepool collects tumour tissue beyond that required for diagnostic purposes from pathology archives. The formalin-fixed, paraffin-embedded blocks are retrieved and, where possible, quadruplicate 1-mm cores are taken to construct Tissue Microarray blocks together with normal tissue for comparison. DNA from tumours is also extracted after the microdissection of thick sections. These resources are available for use in approved research projects.

DNA from peripheral blood and saliva

A subset of Lifepool participants are asked to donate DNA for genetic research. This Stage 2 consent is opt-in. We approach every participant who has been diagnosed with breast cancer and a subgroup of the cohort with no self-reported or registry-verified cancer diagnosis.

What has been measured?

Linkage data, accurate to the end of 2022, reveal 3017 breast cancers identified in 2764 Lifepool participants recruited in Victoria (2516 invasive and 501 *in situ* cancers, which are 83.4% and 16.6% of the total breast cancers occurring within the cohort, respectively). This distribution (percentage invasive versus ductal carcinoma in situ (DCIS)) of breast cancers diagnosed within Lifepool is consistent with the distribution of DCIS and invasive breast cancers detected within the BSV programme annually since 2012 [5]. There were 10 727 participants with at least one record of cancer diagnosed as at the end of 2022 and a total of 13 196 tumours identified.

The majority of breast cancer cases in Lifepool participants are in women aged between 51 and 74 years, as would be expected in a cohort that was ascertained through a population breast cancer screening programme. Table 3 provides a breakdown of these cancers by age group diagnosed in women before or after recruitment to Lifepool. Multiple cancers in an individual woman are not included.

Mammographic density measurements made by using AutoDensity [8] are available for 48 011 participants.

The distribution of density for age is shown in Fig. 2, which provides a graphical representation of the reduction in percent mammographic density as age increases. Mammographic density has been measured by using the left cranial caudal view.

What has it found?

Genomic DNA donated by Lifepool participants has supported analysis of the clinical benefit and acceptability of population testing for high-risk breast and ovarian cancer genes in the Australian community [15] and enabled a richer understanding of the role of putative breast cancer predisposition genes for risk [9–13, 22, 25, 26]. The extensive library of digital mammogram images coupled with breast cancer screening data and clinical

Table 3. Age of Lifepool participants when diagnosed with breast cancer (incident and prevalent invasive and *in situ* breast cancers)

Age at diagnosis (years)	Incident invasive breast cancers	Prevalent invasive breast cancers	Incident *in situ* breast cancers	Prevalent *in situ* breast cancers
≤40	1	62	0	6
41–50	48	136	14	27
51–60	446	120	98	31
61–70	1013	52	212	9
71–74	360	9	55	1
≥75	176	3	18	0
Total diagnoses	**2044**	**382**	**397**	**76**

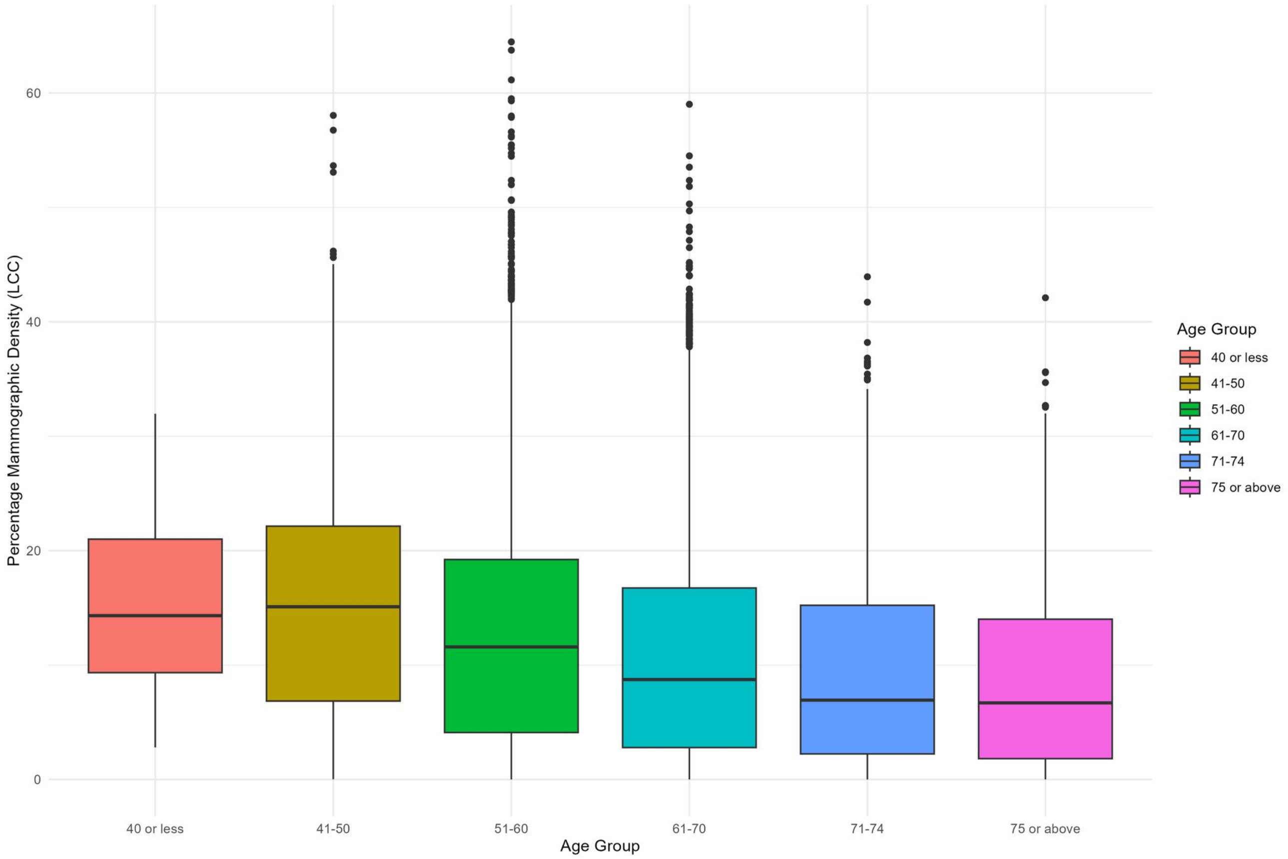

Figure 2. Mammographic density across age groups.

follow-up is supporting analysis of the relationship between mammographic density, breast cancer risk, and more sensitive cancer detection tools [8, 19, 20, 32]. Publications arising from the 36 Lifepool-supported research projects to date have provided insights into the fundamental aspects of the biology of breast cancers and pathologically relevant gene mutations, psychosocial insights into breast cancer risk perception and individual return of mutation results, and the health economics of breast cancer detection and treatment [9–32].

What are the main strengths and weaknesses?

Lifepool presents an important resource for breast cancer researchers as well as other research projects with a particular focus on women's health. The combination of health and lifestyle data, mammographic density data, biospecimens, and clinical information from ≤60 000 women (when recruitment ceases) enables powerful research. Population-control DNA samples in substantial numbers are a key tool for genetic research studies that are seeking to validate new disease-specific mutations.

Follow-up has been passive via linkage with the Victorian Cancer Registry and BSV for cancer outcome updates. Loss to follow-up has been extremely low; up to the end of 2023, 153 women (0.28%) had requested no further contact but agreed to have their data remain available for use and 90 women (0.16%) had withdrawn from the cohort completely. A significant strength of the resource lies in the consent to recontact, which enables follow-up on an individual basis and participants to support additional related research.

Women who do not speak English as a first language may be underrepresented because the questionnaire and consent documents are only available in English. Slightly <20% (45 798) of women screened by BSV in the period from 1 July 2013 to 30 June 2014 reported that they spoke a language other than English at home [5]. This time period represents the most intense period for Lifepool recruitment. It is not possible to ascertain whether language alone was a barrier because Phase 1 recruitment did not capture information about why women declined to participate.

A potential source of bias is the possibility that a more health-motivated group presented for recruitment, as the majority of women who were recruited in Phase 1 (99%) were clients of the BSV programme. In the context of a cohort study, this is only a problem if the relationships of interest (e.g. breast density and breast cancer) are different for respondents and non-respondents. The Lifepool resource provides valuable data and samples for a wide range of potential research projects and is currently enabling studies that incorporate between-group comparisons as well as studies of biological determinants.

Can I get hold of the data? Where can I find out more?

The Lifepool resource is open to application from researchers nationally and internationally. Summary metrics on numbers of participants and biospecimens that are held within the resource are available from the Lifepool Manager, as are the Access Policy and Application Form, via e-mail to lifepool@petermac.org. We encourage researchers to approach Lifepool for access to data and/or samples that support research related to breast cancer screening and prevention, or other significant women's health issues.

Ethics approval

The study has been approved by Peter MacCallum Cancer Centre Human Research Ethics Committee under approval 09–66.

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Supplementary data

Supplementary data are available at *IJE* online.

Author contributions

I.G.C., J.H., P.J., G.M.B., and S.F. applied for original funding, planned the establishment of the cohort, and contribute to the ongoing development of the cohort. C.N. contributes to the ongoing development of the cohort and has oversight of mammographic density measurement. D.A. performed the data management and analyses. L.L.G. contributed to data acquisition and P.P. performed specialist data analysis. V.W., L.C., S.D., and L.N. provide governance oversight. L.D. has operational oversight of the cohort and drafted the manuscript. All authors were involved in the development of this manuscript, including revision and final approval.

Use of artificial intelligence

No AI tools were used.

Conflict of interest: None declared.

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Data availability

See 'Can I get hold of the data?' above.

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