kConFab

August 2024

Kathleen Cuningham Foundation Consortium for research into Familial Breast cancer

NEWSLETTER

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Dear kConFab families

Since our last edition, we are pleased to report that there has been much progress. It is truly inspiring to see the advances being made by our researchers and clinicians that are only possible because of your willingness to share personal medical information and donate biological samples.

Updates in this edition include:

- **BRCA-P clinical trial:** Professor Geoff Lindeman is recruiting for a trial testing Denosumab to prevent breast cancer in women who carry a *BRCA1* mutation (page 3)
- **Biomarker Study:** kConFab is requesting an annual blood collection for early detection of breast and ovarian cancer (page 4)
- **Lifestyle questionnaire:** We have updated the kConFab questionnaires to capture new contemporary data on birth control, hormone therapy, pregnancy, chemical exposure(s), and more (page 5)
- **New Telehealth Service:** Professor Kelly-Anne Phillips now offers a telehealth service for breast cancer prevention medications (page 6)
- **Reconstruction types and complications after mastectomy:** Four breast surgeons have been working with kConFab to analyse data related to immediate breast reconstruction types and complications after mastectomy in *BRCA1* and *BRCA2* mutation carriers. This world-first study wouldn't be possible with-out our participants who generously shared their personal information. The outcome of this study can be found on page 5.
- **Professor Martha Hickey** is recruiting for the TUBA WISP study. This study aims to determine whether risk-reducing salpingectomy (RRSO) with delayed oophorectomy can prevent ovarian cancer as effectively as the standard risk-reducing salpingo-oophorectomy RRSO) in women who carry a *BRCA1* or *BRCA2* mutation. More details about this study can be found on page 4.
- **Dr Jessica Logan** and her team in Adelaide are making strides in the diagnosis and prognosis in prostate cancer patients. Their work is partly based on the tissue samples and data provided by recruited kConFab participants. You can find an update about their work on page 7.

To make your contact with us easier, we have updated the kConFab home page over the past 18 months *(www.kconfab.org)*. New features on the home page include a summary of recent kConFab research publications that you may find to be of interest. Under the section "For the Families", we have added a general summary about our work, explaining why and how our research work is advancing our understanding of familial cancer, leading to improved cancer prevention and treatment. We have added a dedicated section where you can update your address details or add changes to your cancer treatment.

In closing, because of the generosity and co-operation of our families, kConFab has become one of the world's best resources for research into familial aspects of breast, ovarian and, in recent times, prostate cancer. Your communications to us about new family members who become eligible to join kConFab, new diagnoses of cancer in your family and about impending surgery for the removal of either normal or cancer (breast, ovarian and prostate) tissue have enabled us to continue to support cutting-edge world-wide research.

On behalf of the entire kConFab team, I want to thank you most sincerely for your ongoing support. We hope that you find this newsletter informative, and we always look forward to your feedback.

Professor Sherene Loi,
Chairperson, kConFab Executive Committee.

National Breast Cancer Foundation

NBCF-FUNDED RESEARCH INTO GENETIC AND FAMILIAL ASPECTS OF BREAST CANCER

The largest not-for-profit funder of breast cancer research in Australia the National Breast Cancer Foundation (NBCF) is celebrating its 30th anniversary this year.

Since its inception in 1994, NBCF has invested over $200 million into more than 600 projects across the continuum of breast research from fundamental biology research to treatment and survivorship research and supported over 1,800 researchers from 120 institutions.

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This year alone, NBCF has awarded 19 new research projects with a combined investment of $13.5 million to help progress towards its vision of Zero Deaths from breast cancer. This year's research grants include projects focused on understanding genetic drivers of breast cancer in young women, how technology can be used to improve breast cancer screening, and how breast cancer cells survive and spread informing better treatment options for some aggressive forms of breast cancer.

Of the most recent 19 research projects funded by NBCF, three studies are exploring genetic and familial aspects of breast cancer:

Working towards a prevention strategy for individuals with a faulty BRCA2 gene

Professor Jane Visvader from Walter and Eliza Hall Institute of Medical Research will use samples from people with a faulty BRCA2 gene and new technologies to unravel the behaviour of single cells (both breast ductal and surrounding immune cells) within precancerous tissue and emerging tumours.

Findings have the potential to reveal new precision prevention strategies in addition to novel biomarkers and therapeutic targets for BRCA2 faulty gene carriers.

A study of twins and sisters for predicting breast cancer risk from mammograms.

Twins Research Australia Director, Professor John Hopper from the University of Melbourne and his team will collect data detected from mammograms by artificial intelligence such as breast density and texture, blood samples and personal information including family history and lifestyle from 1,000 twins and sisters who we have previously studied; 1,000 twins without breast cancer and an additional 100 pairs of twins affected by breast cancer. Using this information, they will calculate their personal risk score automatically at the time of their mammogram.

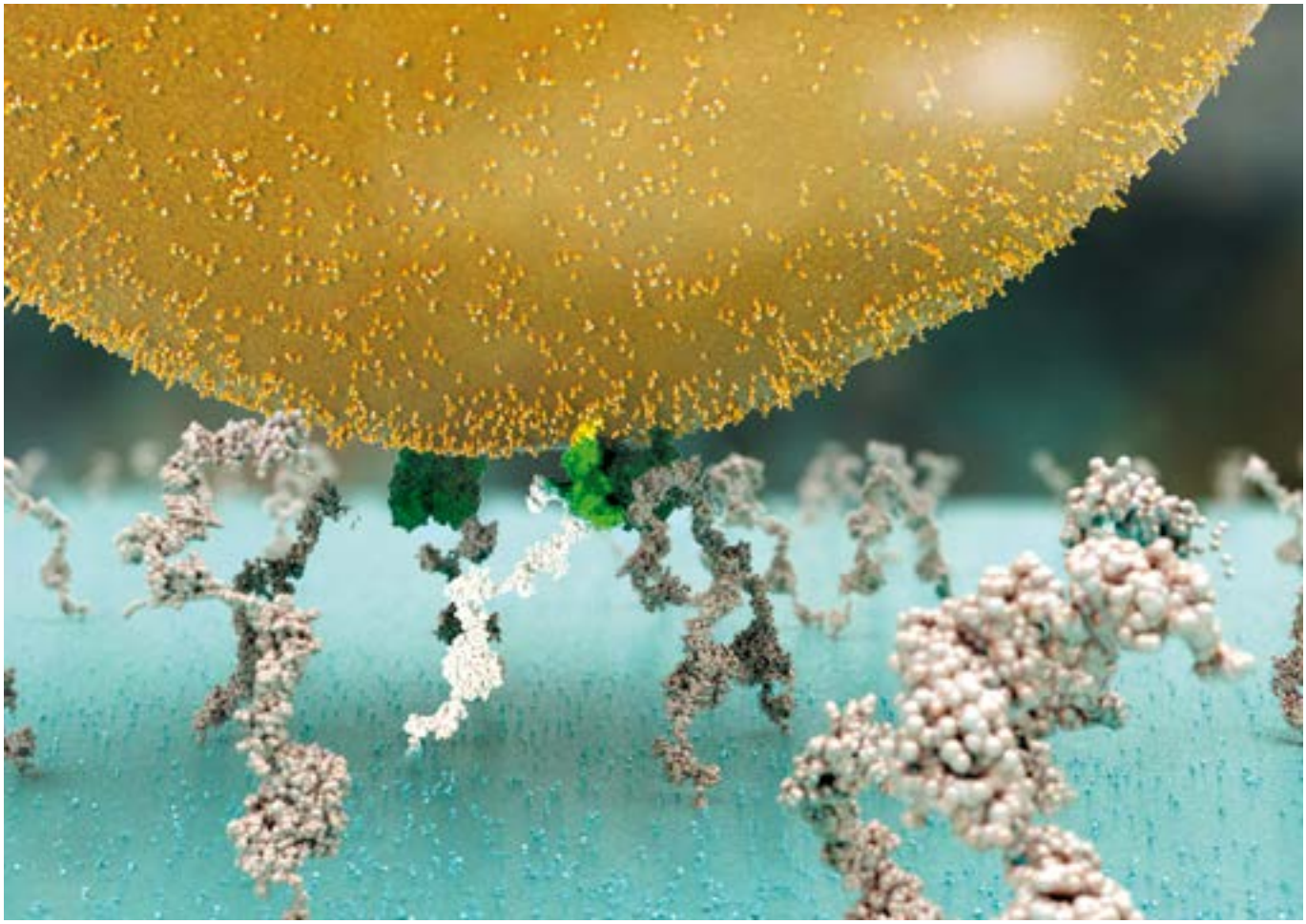
Findings could potentially lead to new ways to reduce risk of breast cancer and identify women and their families at high risk.

Understanding the collective influence of genetic variants on breast cancer risk.

Women with a high polygenic risk score have over three times the risk of developing breast cancer. Professor Paul James from University of Melbourne aims to define the biological mechanisms by which a high polygenic risk score promotes cancer development, and a low polygenic risk score provides protection.

Findings will help accelerate translation of the polygenic risk score as a major tool for effective risk assessment, reveal the basis for some individual's intrinsic risk of breast cancer and pave the way for innovative therapeutic interventions.

NBCF is proud to support these and other world-class cancer research projects towards our vision of Zero Deaths from breast cancer. To find out more about the research NBCF is funding or to make a donation to NBCF please visit *nbcf.org.au*.



BRCA-P clinical trial – an international breast cancer prevention study for *BRCA1* mutation carriers.

By Professor Geoffrey Lindeman
Joint Head, Stem Cells and Cancer Division at the Walter and Eliza Hall Institute and Medical Oncologist, The Peter MacCallum Cancer Centre and Royal Melbourne Hospital, Melbourne.

The international BRCA-P clinical trial has been running since 2020 and is likely to close recruitment soon. We are seeking female *BRCA1* gene mutation carriers who are not currently considering surgical mastectomy to participate. The aim of the study is to understand if a drug called denosumab can decrease or prevent the risk of developing breast cancer in women with a *BRCA1* gene mutation.

Approximately 1 in 400 women in Australia carry a BRCA1 gene mutation. These women have a 70% risk of developing breast cancer and 40% risk of developing ovarian cancer over the course of their lifetime. Currently, mastectomy (surgical removal of the breasts) is the recommended method for reducing the risk of breast cancer, but many women would prefer to delay this intervention and instead choose to have regular screening with mammography and/or MRI scans instead. These are very helpful to detect early, more manageable cancers but do not prevent breast cancer. The BRCA-P clinical trial hopes to offer women a non-surgical treatment option that could delay or even prevent the need for mastectomy.

BRCA-P is testing the effectiveness of a drug called denosumab as a breast cancer prevention agent. In the laboratory denosumab has been shown to switch off the culprit cell that gives rise to breast cancer in women with a faulty *BRCA1* gene. Denosumab is already used in the clinic to reduce the risk of bone fracture in patients who have thin bones ('osteoporosis') and to keep bones strong for patients who have cancer that has spread to bone. Its safety profile is therefore well understood. The BRCA-P trial will determine if denosumab can be 'repurposed' as a breast cancer prevention drug.

Women who participate in the BRCA-P trial will continue to receive close monitoring and scans through their own specialist(s) and will receive additional follow-up in partnership with the BRCA-P study team. Participants will be randomly assigned to receive either denosumab or placebo as a small injection (under the skin) every 6 months for up to 5 years. The study is 'double blinded' which means that participants (and the study team) will not know whether they are being treated with denosumab or placebo. This is very important, as it is the only way to properly determine whether denosumab has breast cancer prevention properties and to identify if there are any unwanted side effects or benefits (such as strengthened bones).

The trial is being led in Australia by Breast Cancer Trials (BCT) – Australia's largest clinical trials research group, which has been conducting clinical trials research for more than 40 years.

To be eligible for the BRCA-P study, participants must:

- Be women with a *BRCA1* gene mutation
- Be aged 25-55 years
- Never had breast or ovarian cancer
- Not be pregnant or trying to conceive right now. Eligibility can be discussed with the BRCA-P team if a future pregnancy is planned
- Not have had a mastectomy to prevent breast cancer
- Not be taking any breast cancer prevention drug such as Tamoxifen.

More information about the BRCA-P trial can be found online at the Breast Cancer Trials ***breastolution*** website, or by calling 1800 777 253 or 0403 663 165 or emailing ***brcap@wehi.edu.au***

https://breastolution.breastcancertrials.org.au/

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The collection of an annual blood samples for future use in biomarker studies for breast and ovarian cancer risk prediction and early detection assays.

Professor Christobel Saunders,
Department of Surgery Royal Melbourne Hospital, Melbourne Medical School and
Professor Sherene Loi,
Peter MacCallum Melbourne.

This kConFab initiative, supported by the National Breast Cancer Foundation, is conducting a pivotal study involving participants between 25-50 years of age who are either mutation carriers or non-carriers.

These individuals will not have undergone a risk-reducing mastectomy, or they may have had cancer in one breast while retaining the other healthy breast. The study, managed by Lody Mokdsi, involves collecting annual blood samples over three years during participants' regular mammogram/MRI imaging appointments for early cancer detection. This research is crucial for improving clinical classification and expanding biological knowledge for the early detection of breast cancer and particularly for ovarian cancer detection, where effective screening methods are currently lacking.

Since January 2023, 520 participants have contributed to this research by providing blood samples, with a second round of collections now underway. Early detection of 32 cancers, 29 breast and 3 ovarian, underscores the project's importance. The team values the participants' willingness to contribute despite the inconvenience, as these efforts are vital for advancements in cancer prevention and monitoring. Even if a participant decides to have a risk-reducing mastectomy during the three-year period, their previously collected blood sample(s) remain crucial for this research project.

We are still looking to recruit participants to this important project so if you are a *BRCA1* or *BRCA2* mutation carrier, between 25-50 years of age and retain one or both breasts please email Lody *(lody.mokdsi@petermac.org)* or Heather *(Heather.thorne@petermac.org)* for further information.

TUBA-WISP II study

Are you at high risk of ovarian cancer and considering options to reduce your risk?

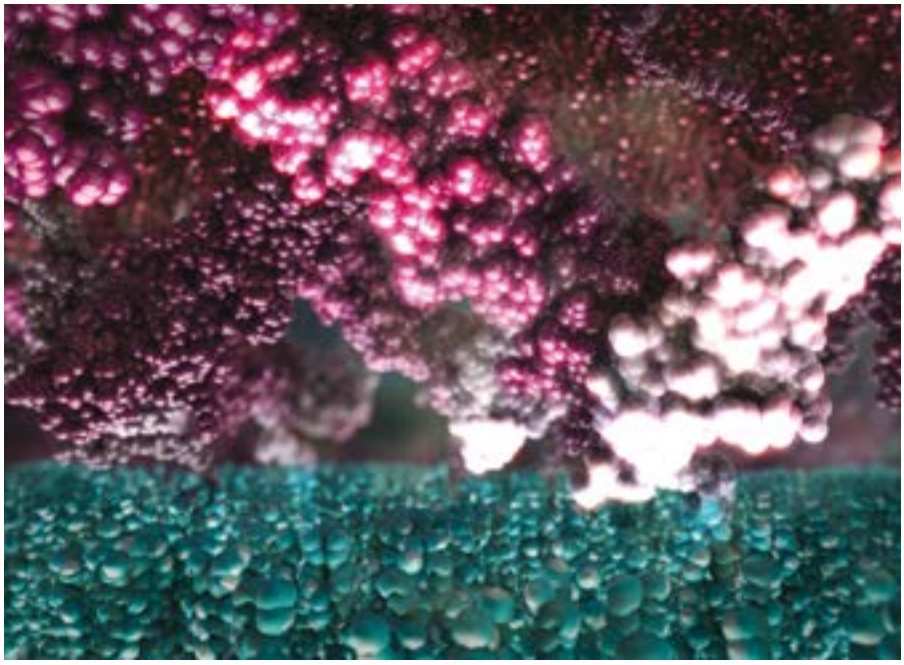
By Professor Martha Hickey,
Department of Obstetrics, Gynaecology & Newborn Health MDHS Research Precinct, The Royal Women's Hospital, The University of Melbourne.

The TUBA WISP study is indeed a significant research initiative that aims to address the critical question of whether removal of the fallopian tubes (risk-reducing salpingectomy (RRS) with delayed oophorectomy (removal of the ovaries) can prevent ovarian cancer as effectively as the standard risk-reducing salpingo-oophorectomy (removal of the ovaries and fallopian tubes (RRSO) in women with *BRCA1* and *BRCA2* mutations (pathogenic variants).

The study is designed to investigate if RRS, which preserves ovarian function and potentially reduces the adverse effects associated with RRSO, offers a non-inferior alternative in terms of ovarian cancer risk reduction.

The TUBA WISP II study is an international prospective multicenter preference trial, where participants can choose between the standard RRSO or the experimental strategy of RRS with delayed oophorectomy. This approach allows for the comparison of cancer risk between the two methods.

The study's hypothesis is that postponing oophorectomy after salpingectomy, to the age of 40–45 for *BRCA1* or 45–50 for *BRCA2* years, compared with the current standard salpingo-oophorectomy at age 35–40 for *BRCA1* or 40–45 for *BRCA2*, is



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non-inferior regarding tubo-ovarian cancer risk.

The results of this study could potentially change global practices for ovarian cancer prevention and provide valuable insights into the mechanisms of ovarian cancer development.

For more detailed information or to participate in the study, interested individuals can visit the official TUBA WISP study website

You can help us answer this critical question.

Please Scan the QR Code below to find out more or email us at:

TUBA-WISPIIAustralia@unimelb.edu.au

Factors Influencing Immediate Reconstruction Types and Complications after Mastectomy in kConFab participants.

Chenyi (Amber) Mao, Jasmina Kevric, Christobel Saunders, Anita Skandarajah
The University of Melbourne, The Peter MacCallum Cancer Centre, The Royal Melbourne Hospital, Melbourne.

Immediate breast reconstruction in the same operation as mastectomy is a safe and commonly performed procedure for breast cancer treatment or prevention in *BRCA1* and *BRCA2* gene mutation carriers, offering improved quality of life.

Although there is existing medical literature that acknowledges the expected rate of complications from different types of reconstruction, there are no studies looking at women's experience and reporting of complications.

The gap between what doctors say and patients feel is crucial to grasp. We wanted to understand what factors predict immediate reconstruction, what type of reconstructions are used, and understand the patient's perspective on complications.

We used the kConFab database and found 476 Australian women who carry a *BRCA1* or *BRCA2* gene mutation who underwent breast reconstruction between 2002 to 2023. Our study was predominantly of Victorian women, primarily of European ethnicity. 450 (94.5%) women opted for immediate breast reconstruction. We found that immediate reconstruction was more likely in women under 50 and slightly more likely in the private than public sector. When compared to reconstruction with implant, using the patient's own tissue was the preferred choice amongst women above 50, those with a higher body mass index and unsurprisingly, when a plastic surgeon was involved in the reconstruction. Unfortunately, the factors that influenced the rate of reported complications were living in regional and rural area and having surgery for cancer rather than as a preventative procedure. Overall, nipple/tissue necrosis was reported by 4.16% of women, while implant loss was reported by 3.75%. 2.5% were dissatisfied with the outcome. Women who used their own tissue for reconstruction reported more complications (68%) compared to using implants (21%), where 41% needed additional surgery after their immediate breast reconstruction.

Our patient's opinion is crucial and should always be a part of the pre-op discussion and how we handle complications. One downside (but also a good thing) of this study is that the complications are based on what patients tell us, not by someone else. This study helps doctors understand how a complication feels from each patient's perspective. It's important for all women to fully understand the types of reconstruction available and have a say in the decision-making for mastectomy and reconstruction. From a clinical viewpoint, it is important that we audit our complication rates across the country and benchmark with international cancer centres. We can potentially avoid complications by carefully selecting the operation for each patient, performing surgeries in specialised centres with high patient volume, and promptly detecting problems and reviewing patients.

A/Professor Anita Skandarajah (left) and Dr Chenyi (Amber) Mao (right)

A new, second kConFab questionnaire collecting information about chemical exposure at home and in the workplace.

As mentioned in the editorial, we have gained approval from our ethics committee to ask new questions on the themes of occupational history, residential history within age groups, hair product and personal care product use, due to the demand from our researchers who have projects associated with environmental

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modifiers that may be associated with breast and ovarian cancer in our young participants.

This is a new and expanding research area due to emerging biospecimen technologies that link laboratory findings to the environmental data. The difference with this new, second questionnaire will be that new participants will be invited to log into Redcap at the time of recruitment to complete the questionnaire, i.e., a kConFab staff member will not directly administer the questionnaire. Our contact details will be included so we are available to answer any questions that participants may have. The questionnaire will only take 10 mins to complete, and we plan to approach you every 2 years to update the information.

Changes to the kConFab Clinical Follow-Up Project.

As of 2024, the kConFab Clinical Follow-Up Project is changing the way it follows up participants.

We will no longer be sending out three-yearly questionnaires. Instead, we will continue collecting information on participants using data that is routinely collected by cancer registries and government agencies and is suitable for our project requirements. So, while you will no longer be reminded of your contribution through the arrival of a questionnaire every three years, be assured that you are still very much contributing to advances in how we can treat and reduce the risk of cancer. We are so grateful for the time that you have given to completing questionnaires in the past. Our website will remain active, with information about publications that have used the kConFab Clinical Follow-Up Project data. If you need to notify us of any updates, please contact 1800 221 894 or email *heather.thorne@petermac.org*

A New Way To Help Prevent Breast Cancer

By Professor Kelly-Anne Phillips
Principal Investigator kConFab Follow-Up Study. The Peter MacCallum Cancer Centre, Melbourne.

We now have effective tablet medications that halve the risk of developing breast cancer for women who are at increased risk.

Unfortunately, many women who would benefit are not currently getting access to these medications. Our kConFab research found that most GPs feel they do not have enough knowledge to prescribe these medications*. To respond to this problem a new telehealth Service has commenced at the Peter MacCallum Cancer Centre.

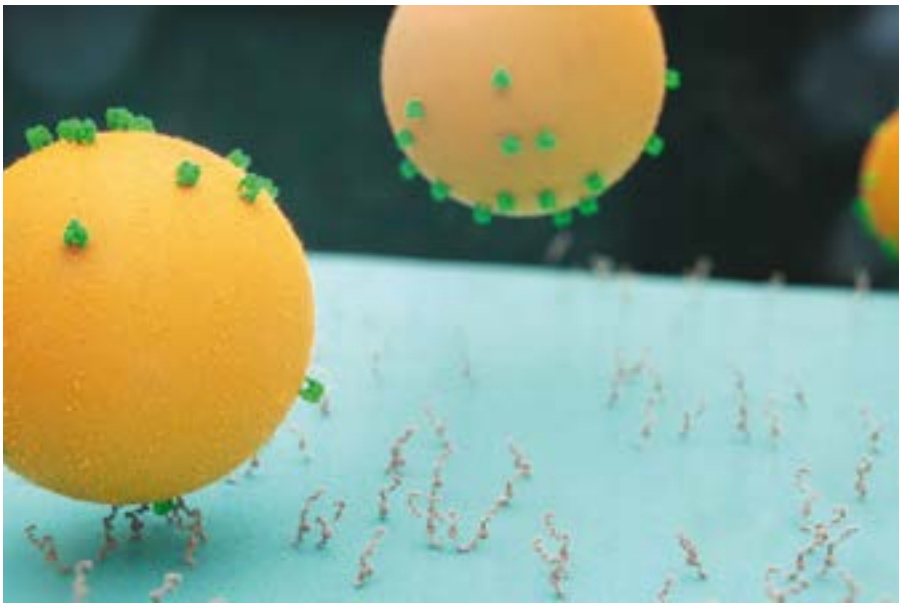
The new "Preventing Cancer with Medications (PCMed) Service" is delivered via telehealth. You can access this service online, anywhere in Australia, with a referral from your doctor. The Service provides personalised information about medications that reduce breast cancer risk and supports women to make a decision that is right for them. For women who do choose to use medications, the Service provides access to support for the woman and their GP over the 3-to-5year treatment course. The PCMed Service may be suitable for you if you meet these criteria:

- Female
- Interested in considering taking medications to help prevent breast cancer.
- Aged 20-70 years old.
- Increased risk of breast cancer according to the iPrevent online tool**
- No history of invasive breast cancer or ductal carcinoma in-situ (DCIS), but women with (lobular carcinoma in-situ (LCIS) are encouraged to attend.
- No prior or current use of breast cancer prevention medications

If you are unsure of your breast cancer risk, you can visit iPrevent *(www.iprevent.net.au)* and complete your risk assessment. Referral information for PCMed is included in "My Options" if you are eligible. If you would like any further information including how to obtain a referral to this Service, please email us at: *PCMedService@petermac.org*

* Macdonald et al Breast Cancer Chemoprevention: Use and Views of Australian Women and their Clinicians. Cancer Prev Res (Phila). 2021;14(1):131-144. doi: 10.1158/1940-6207.CAPR-20-0369

** *www.petermac.org/iprevent*



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Development of Technology to Optimise Prostate Cancer Treatment Selection in Australia

By Dr Jessica Logan
Postdoctoral Researcher in Medical Science, Priority Impact Research Award – Future Leader funded by Prostate Cancer Foundation of Australia & Professor Doug Brooks, Lead, Mechanisms in Cell Biology and Disease Research Concentration, Clinical and Health Sciences, University of South Australia.

Prostate cancer is the second most common cancer in Australian men, and the fourth most common cause of cancer-related deaths.

In 2022, the expenditure for prostate cancer by the Australian health care system hit a staggering $1.35 billion annually, making this cancer the nation's single most costly disease to manage and treat. These figures also signify the increasing disease burden of prostate cancer on Australian men, their families, and our community.

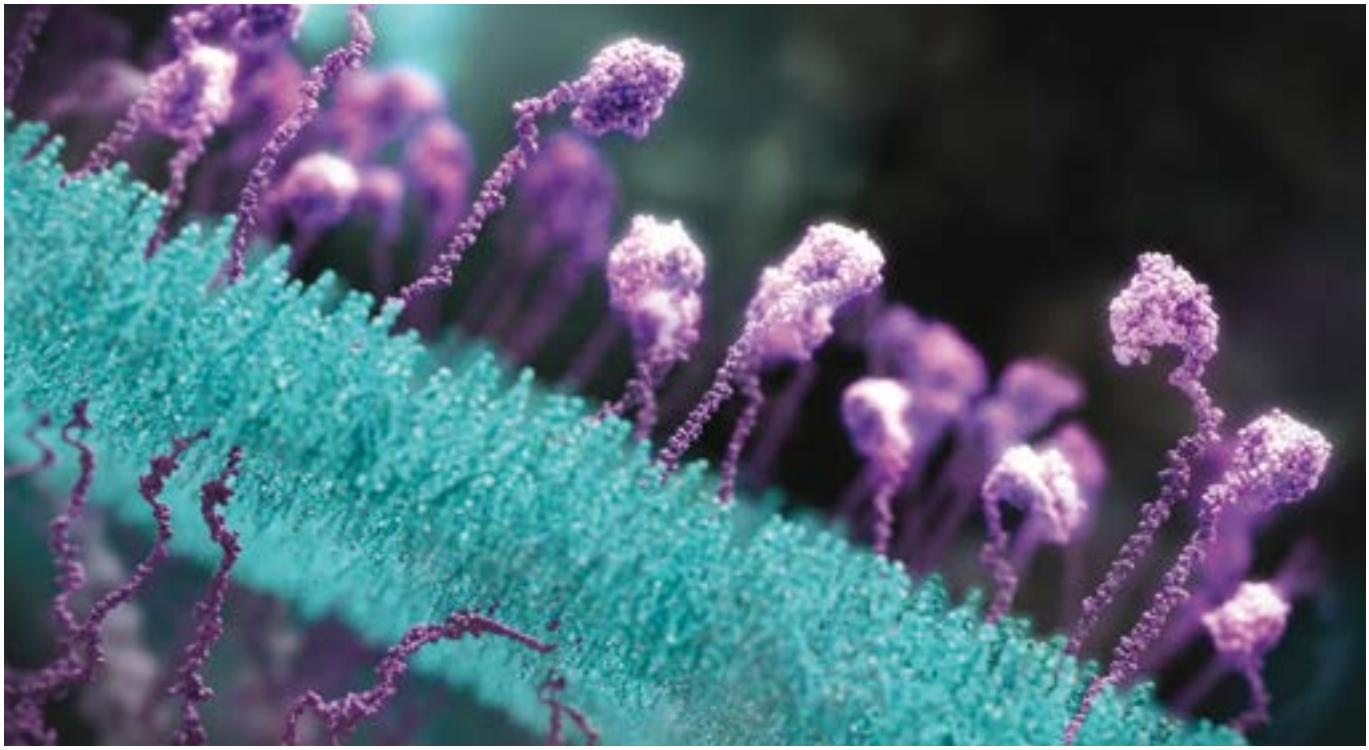
Alarmingly, the incidence of prostate cancer is predicted to double by 2030.

Over the last 10 years, our international collaborative team focused on the vision to produce an innovative product that meets the defined need to improve prostate cancer tissue pathology assessment and grading. This new technology needed to be based upon the molecular changes underpinning prostate cancer cell biology and designed to be adaptable within current practice frameworks and accessible across multiple demographics. Ultimately, this innovative solution needed to be accurate and reliable, to provide a paradigm shift in prostate cancer diagnosis and prognosis.

The team made the seminal discovery of altered endosomal* biology in prostate cancer, which identified fundamental changes in the cell biology of this cancer, enabling for the first time the identification of biomarkers, known as Appl1, Sortilin and Syndecan-1, that precisely define the primary pathogenesis in prostate cancer tissue. We have validated this panel of biomarkers in cohort studies, to demonstrate more reliable pathology assessment and accurate stratification of prostate cancer patients. The team has successfully developed this innovative technology and with the Australian company Envision Sciences, have partnered with Quest Diagnostics, who have produced and implemented a lab developed test of prostate cancer tissue in the USA.

These biomarkers have been screened and tested on the kConFab patient cohort, evaluating their ability to aid in the diagnosis and prognosis of prostate cancer patients. We are also evaluating how the patterns of biomarker expression correlate with different patient mutations that impact on the cell biology of the cancer. To optimise treatment selection for Australian men, a prospective multi-centre cohort study is required to further validate the biomarker technology and to provide an evidence base for Therapeutic Goods Administration (TGA) approval to implement this new prostate cancer tissue test in this country.

*Endosomes play crucial roles in various physiological processes, such as nutrient uptake, sorting and delivery of macromolecules, and regulation of cell surface receptors and transporter expressions.



Research into FAmilial Breast Cancer
Kathleen Cuningham Foundation
CONsortium for research into FAmilial Breast Cancer

Collaborating Family Cancer Centres

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The Royal Melbourne Hospital
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Victorian Regional Family Cancer Clinics:

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Austin Health Family Cancer Clinic
Tel: 03 9496 3027

Bendigo/ Mildura
Peter MacCallum Cancer Centre
Family Cancer Clinic
Tel: 03 8559 5322

Geelong/Warrnambool
Royal Melbourne Hospital Family
Cancer Clinic
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Monash Medical Centre Family
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St Vincent's Cancer Genetics Clinic
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