



# THE BRAVO PROJECT

Towards Tailored Breast Screening  
2019 – 2020

*Final report, abridged July 2021*





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## Contents

1. EXECUTIVE SUMMARY.....	3
2. BACKGROUND .....	3
3. PROJECT AIM .....	3
4. METHODOLOGY.....	3
5. RESULTS.....	4
5.1 Data collection.....	4
5.2 Resource requirements - pilot.....	4
5.3 Workflow .....	4
5.4 Qualitative research .....	4
5.5 Resource requirements – protocol implementation.....	5
6. DISCUSSION .....	6
6.1 Consumer engagement .....	6
6.2 Staff engagement .....	6
6.3 New capacity and capability.....	6
7. CONCLUSION .....	7
8. PROJECT TEAM .....	7



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## 1. EXECUTIVE SUMMARY

Over 2019-2020, the BRAVO project (Breast Risk Assessment in Victoria) developed a detailed protocol to pilot routine risk assessment and advice in the BreastScreen Victoria program. This is a critical step towards translation of research evidence on personalised breast cancer risk assessment for the benefit of BreastScreen Victoria clients.

This work was funded by the Victorian Comprehensive Cancer Centre (VCCC) as the 'Toward Tailored Breast Screening' project under the 'Precision Prevention and Tailored Screening' research program, over 2019-2020.

Through close collaboration between VCCC partners and BreastScreen Victoria, the project has:

- designed detailed clinical workflows,
- information systems,
- communication materials,
- generated resource estimates,
- and evaluated a range of potential risk assessment tools.

To inform the protocol design we completed qualitative research with BreastScreen clients and a survey of BreastScreen client-facing staff.

The BRAVO protocol will involve two comparative pilots of an established, detailed risk assessment tool (the IBIS v8 tool) and a simplified approach combining mammographic breast density with information already routinely collected by BreastScreen.

## 2. BACKGROUND

It is widely acknowledged that current research evidence, as well as community expectations, means that the existing approach to population-based breast cancer screening is no longer optimal, and that breast screening services should move towards a more personalised, risk-based screening system. These risks include risk of breast cancer, and risk of reduced screening test sensitivity and specificity due to mammographic breast density.

While there are many active research projects (including within the VCCC alliance members) aiming to identify optimal methods for assessment of such risks and the discriminatory power of risk assessment tools under development, to date there has been relatively little work to translate research-derived evidence on risk assessment into a risk-based screening strategy that could be piloted, trialed or implemented in Victoria's breast screening service.

## 3. PROJECT AIM

To develop a protocol to pilot routine risk assessment and advice in the BreastScreen Victoria program.

## 4. METHODOLOGY

The BRAVO protocol was developed as follows:

- a) Select and design data collection methods for a prototype risk assessment tool (IBIS v8)
- b) Identify resource requirements for a pilot study



- c) Design BreastScreen Victoria workflow for pilot of prototype risk assessment tool
- d) Undertake qualitative research on acceptability and useability of developed communications tools and protocol for follow-up with GPs
- e) Identify resource requirements for a future implementation trial utilising risk assessment and communication tools
- f) Finalise protocol and its related resource requirements for staged implementation

## **5. RESULTS**

### **5.1 Data collection**

To develop a data collection tool for the BRAVO protocol, we adapted the existing data collection form used at each screening episode to include questions to enable IBIS v8 risk assessment, established a process for collecting mammographic density from each screening episode, and designed a database for combining this information and then generating IBIS v8 risk assessment scores. Our general approach is to 'piggyback' on existing risk assessment and advice processes at BreastScreen, currently used to assign some clients to annual screening, based on their personal and/or family history of breast/ovarian cancer. In addition, through our epidemiological analysis of over 45,000 BreastScreen clients included in the lifepool cohort we found that more simplified approaches to risk assessment combining mammographic breast density with information already routinely collected by BreastScreen (e.g. age and family history) are likely to be comparable to more detailed risk assessment tools. This is consistent with emerging international evidence. On this basis, our protocol includes parallel piloting of the IBIS v8 tool and a more simplified approach.

### **5.2 Resource requirements - pilot**

BreastScreen Victoria systems are expected to support routine risk assessment and advice, with appropriate investment in information systems for more widespread implementation. The staff survey indicates a need for additional resources and training to support collection of additional risk factors.

### **5.3 Workflow**

We designed detailed clinical workflows that specify when and how risk information will be collected and then reported back to clients. We aimed to follow the existing process for risk assessment and advice relating to family and personal history of breast cancer (and personal history of ovarian cancer). In summary, clients with a clear screening result would receive their risk assessment and advice with their results letter, while clients referred for assessment of a suspicious screening result would be provided with their risk assessment and advice through a process tailored to their clinical outcomes. Final detail on clinical workflows will need to be co-designed with the involved pilot screening and assessment sites, which will be within the Monash BreastScreen Reading and Assessment Service.

### **5.4 Qualitative research**

Feedback from members of the BreastScreen Victoria Client Representative Group (16 clients via 3 focus groups and 1 interview) indicates that clients value the current standardised approach to screening, and that risk assessment and advice would require careful mitigation of client concerns about the accuracy of their risk factor information and how to best interpret their risk assessment. Some questions in the IBIS v8 tool may generate anxiety or concern from respondents, because the information is difficult to remember and the relationship between the information provided and breast cancer risk, may generate worry. This work highlighted that adding risk questions to routine data collection would confer a



significant impost on some clients, and we expect that additional resources would be required at BreastScreen to address any queries or concerns. On this basis, we formed the view that all risk questions should be well-justified, and the quality and completeness of information provided should be well-monitored during any pilot or evaluation study.

From our survey of client-facing staff we identified potential challenges in implementing more detail risk assessment, in terms of language barriers for a subset of clients, cultural and personal sensitivities around certain topics, and client recall ability. The client facing staff advised that it would be important to communicate clearly to staff about the relevance of collecting specific information that was not collected before, especially if information is generally considered sensitive and private. Staff considered that mode of collection is important, where some information should not be from clients asked via phone, some information requests may lead to follow-up discussions that may require staff to have more (medical) training and additional information at hand to help clients. These requirements will be built into detailed implementation plans for the pilot study.

### **5.5 Resource requirements – protocol implementation**

We have estimated the additional resources that would be required to implement a pilot of routine risk assessment and advice at BreastScreen Victoria. These include the following:

BreastScreen Victoria:

- Coordination of pilot study invitations and responses
- Data management of answers to risk assessment questions, calculation of risk assessment
- Preparing risk advice letter content for clients
- Provision of a trained support person for clients or GPs wanting further clarification of the pilot study
- Proactive information, training and advice for the screening site and engaged stakeholders (e.g. GPs and FCCs)

Pilot screening site:

- Staff time to keep records of pilot study participants attending screening, assist clients to complete the missing risk assessment questions as requested, and keep record of assistance needed.
- Software and hardware to capture breast density measurement on the screening mammography machine.

Research partners:

- Academic leadership
- Research personnel to provide:
  - expert advice risk assessment tools, based on updated evidence reviews
  - qualitative research with pilot study participants at multiple timepoints,
  - qualitative research with BreastScreen personnel including at the pilot screening site
  - provide analysis, report writing and dissemination
  - design of larger-scale studies and applications for funding.

When the pilot study is complete, we will have additional information about the resources required to assess and advise on breast cancer risk at a larger scale, such as for a large-scale evaluation or to enable



a trial of risk-based screening protocols. The resource requirements will depend on findings from the pilot study in terms of the level of assistance required for personnel, clients and external stakeholders, and the preferred approach to risk assessment for larger scale application (i.e. the IBIS v8 tool or a more simplified approach). The pilot study will use an interim data management process to record client responses and calculate risk assessment, to be added to central client records. A larger scale evaluation would require more integrated data management systems, and the costs and timelines will depend on the number of additional fields required; this will be determined after the pilot study is complete.

## **6. DISCUSSION**

### **6.1 Consumer engagement**

A key step in the development of the protocol was to collect qualitative data from client representatives from BreastScreen Victoria about their opinions and views of the notion of risk assessment within BreastScreen broadly, as well as the specific draft protocol instruments to be used. Risk information is intended to be collected through a modified version of the existing BreastScreen questionnaire, to be completed prior to each screen and through the measurement of mammographic density from the screening mammogram. We conducted three focus groups and one interview with 16 BreastScreen client representatives (via Zoom, due to COVID restrictions).

### **6.2 Staff engagement**

We also conducted a survey of key staff from the BreastScreen Contact Centre, Screening Service and the Reading and Assessment Services to gain an understanding of the impact of asking BreastScreen clients for further risk information. The survey focused on clients' answering questions before or during their screening appointments, and focused on the feasibility of this data collection, the expected accuracy of the information required, and the resources that might be required for client-facing personnel.

Of note, the BRAVO pilot studies will include follow-up with participating clients to assess the feasibility, acceptability and clarity of the routine risk assessment and advice, and to monitor and evaluate subsequent behaviour related to the risk information. GPs who receive copies of their patients' risk assessment advice will be able to contact a suitably trained BreastScreen Victoria staff member to raise any questions or concerns, and these will be carefully recorded and assembled as part of the pilot study data.

### **6.3 New capacity and capability**

The Project team consisted of a BRAVO Working Group and an Advisory Group (membership is listed below) which is committed to supporting future projects. The group were able to learn from shared knowledge and experience, for instance understanding the end- to-end practical process within BreastScreen, methods for objectively gaining information through focus groups and surveys, and understanding the importance of research and research methodologies. The Advisory Group gave additional insights and feedback.

The Working Group and Advisory Group met regularly. This model was very successful and will be retained for future pilot study implementation.



## 7. CONCLUSION

We have developed a detailed protocol to pilot routine risk assessment and advice in the BreastScreen Victoria program. This is a critical step towards implementing more personalised, tailored breast screening in the future.

## 8. PROJECT TEAM

### Working Group

A/Prof Carolyn Nickson – University of Melbourne and Cancer Council NSW

Doris Whitmore – BreastScreen Victoria

Lisa Devereux – Peter MacCallum Cancer Centre

Dr Prabhathi Basnayake – University of Melbourne

Dr Sabine Deij – University of Melbourne and Cancer Council NSW

Tori Cresswell – BreastScreen Victoria

### Advisory Group

Terri Smith – BreastScreen Victoria (replacing Vicki Pridmore in early 2020)

Prof Jon Emery – University of Melbourne

A/Prof Paul James – Peter MacCallum Cancer Centre

Dr Holly Keane – Peter MacCallum Cancer Centre and Royal Women's Hospital

A/Prof Louise Keogh – University of Melbourne

Dr Jocelyn Lippey – Victorian Breast and Oncology Care and University of Melbourne

Prof Bruce Mann – Peter MacCallum Cancer Centre, University of Melbourne, Royal Women's Hospital and Royal Melbourne Hospital