The future of breast screening

Implementing emerging technologies to detect breast cancer: findings from key stakeholder interviews

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ALLEN+CLARKE

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1. INTRODUCTION

1.1. Purpose of this report

This report presents summarised findings from interviews with stakeholders involved in delivering BreastScreen Australia (BSA) screening services, undertaking breast cancer research, or providing consumer/patient support. It discusses potential implementation issues associated with automated whole breast ultrasound (ABUS), computer-aided detection (CADe) and artificial intelligence (AI), and digital breast tomosynthesis (DBT), and two hypothetical (but unlikely scenarios) based on radical changes to breast screening (i.e., biomarker-based tests or population-based breast screening being no longer considered appropriate).

1.2. Background

Population-based approaches to breast cancer screening are evolving. Researchers and developers are innovating new breast imaging technologies and continue to work on improving the application of AI to existing technologies. Other research is exploring tools that may not involve breast imaging (such as biomarker-based testing). In 2017, the Australian Department of Health engaged *Allen + Clarke* to undertake a qualitative horizon scan (comprising a literature review supplemented by key informant interviews) to identify new and emerging technologies likely to impact on population-based screening of asymptomatic women and the BSA program.

1.3. Methodology

Allen + Clarke invited stakeholders to participate in an interview. The stakeholders invited to interview had expertise in fields relevant to breast cancer screening, including delivery of BSA screening services, undertaking research and providing consumer/patient support. We provided information about the purpose, background and intended output of the interview, anticipated time commitment, preferred method of engagement (face-to-face or tele-interview), consent requirements, and confidentiality. Semi-structured interviews were held between September and November 2018. Two *Allen + Clarke* interviewers were present at each interview. Detailed written notes were taken. Qualitative data from the interviews was analysed using thematic analysis.

2. COMMON THEMES EMERGED FROM ALL THE INTERVIEWS

2.1. BSA is trusted and is an integral part of Australian women's health culture

BSA was regarded as a '*women's thing*' and part of Australian culture. Interview participants thought that women, GPs and the public have trust in and are loyal to the BSA program. This is underpinned by the BSA program being rigorous, having strong governance, quality data and stringent performance measurements, and raising awareness about breast cancer and overall breast health. Women like to be part of a caring and friendly service, appreciate the support and how they are treated.

2.2. Confidence in the BSA program could be shaped by media reports on innovation

Interview participants noted that women go to BSA believing they are having the best screening. Confidence in BSA could be undermined if media reports do not balance exciting research findings with advice on research limitations or applications. For example, media reports that promote an under-tested R+D development as a gold standard could lead to questioning about BSA. There was concern that some women may choose to leave BSA because of this, even if the new technology is relatively untested or inappropriate for primary screening. This is a difficult area to respond to.

2.3. Imaging is here to stay

Interview participants were mindful that stakeholders need to see BSA as a modern screening program. They thought that mammography is likely to stay as the primary screening test for breast cancer because other interventions are not sufficiently developed or have not been proven to reduce deaths from breast cancer through early detection. Some noted that BSA offers one test based on one risk factor when breast cancer is a highly heterogeneous disease with a wide range of risk factors that can interact.

2.4. Caution is needed when making assumptions about whether technology motivates women to participate in breast-screening

There were mixed views about whether the screening test used is a motivator for participation in screening. A knowledge gap in understanding participation motivators was raised.

2.5. Any change to BSA services must be evidence-based and planned

Maintaining confidence in the BSA program requires quality decisions based on robust evidence. Interview participants thought that evidence of reduced mortality must underpin any major changes to the BSA program. Developing a robust evidence base takes time, with the time requirements often under-estimated or unrealistic. Robust evidence pointing to a reduction in morbidity was also considered important and interview participants noted that any changes must also meet the World Health Organization's screening criteria.

Interview participants advised that the first requirement is a clearly articulated and stable intervention. Following that, consistent, integrated evidence from multiple systematic reviews, meta studies and randomised controlled trials reporting consistent results is needed. Results need to demonstrate superior sensitivity and specificity rates, reduced interval cancers, increased morbidity and mortality benefit, acceptability, impact on workflow and treatment or clinical management pathways, and cost-effectiveness. A clear roadmap of downstream management pathways including screening interval, age of eligibility, and clinical management pathways is needed.

2.6. BSA may evolve

Interview participants noted that breast cancer risk factors and screening is complex. Many interview participants thought that BSA should continue to be women-centred and holistic but with knowledge advances, it could potentially become more personalised.

2.7. The role of general practitioners in advising women about breast cancer and participation in screening was widely acknowledged

Interview participants acknowledged the role of the GP in providing information to women on breast cancer, breast cancer risk and participation in breast screening. Greater interaction between primary care and BSA was recommended, to assist GPs' understanding of who is screened and who is under-screened, and to ensure GPs have appropriate information and resources to assist them in their conversations with women.

2.8. Nationally consistent, unified advice on screening is critical

Interview participants were clear that the BSA program needs to deliver consistent advice and recommendations including a nationally consistent campaign and communications strategy. There were strong views that this needs to be driven by the Commonwealth. With no single site for GPs to go to about breast screening, some felt that this may account for the variability in advice from GPs about participation and technology.

2.9. Equity in access to screening, assessment and diagnostic services is a major consideration when considering change

Interview participants were clear about the need to ensure access to screening services is equal for all women. If any change to the primary screening test is considered, its impact on equity must be a major consideration. Modelling could help with equity considerations.

2.10. BSA programs may be impacted differently by change depending on service configuration

Individual state/territory BSA programs are configured differently. Determining the impact of certain innovations involves implementation considerations that apply nationally, and those that respond to the individual differences between BSA programs. It is likely that any change would result in some different impacts for each BSA program. A nationally consistent set of implementation considerations cannot be assumed.

2.11. Communication with women must be honest about the limitations of mammography and must focus on the benefits if there is change

Interview participants commented on the need to be honest about the limitations of mammography to enable informed decision-making. This included providing further information on age and breast cancer risk, the limitations of two-view mammography's sensitivity including for women with dense breasts, overdiagnosis and morbidity associated with mammography screening and safety (radiation exposure).

Communication with women about change was noted. Women expect health technology to change and for programs to keep pace with innovation. Communication is therefore straightforward if evidence indicates that the proposed change provides clear benefit compared to what is currently offered. Appropriate messaging about effectiveness is needed, and a clear description about how funding will be used to support early detection of breast cancer. Change messages must be consistent, delivered by critical influencers, focus on the benefit that the change accrues to women (particularly in terms of reduced mortality and morbidity), and maximise the effectiveness message for BSA to counter misconceptions or misunderstandings about the change. Additionally, interview participants noted that any messaging regarding change needs to be communicated with extreme caution if a new approach may lead to the perception of an increase in harm or a perception that changes are due to cost savings. Communications should be provided well in advance of any proposed change coming into effect.

2.12. Change is complex: skilful preparation involves all stakeholders and requires a clearly articulated framework

Interview participants commented that any change to a complex, existing screening program will be challenging. Proposed changes must be effective and be of significant benefit to women. Communications to women and clinicians must be nationally consistent, clear, be delivered well ahead of time, and involve all stakeholders in terms of preparation and delivery. A coalition of stakeholders and champions is needed to develop a clear framework for change, drive change management and provide clear guidance that everyone adheres to including professional colleges and peak bodies. Some interview participants noted that incremental improvements to the BSA program should not be forgone in favour of more dramatic changes.

2.13. BSA has already managed a large-scale transition

While noted by only one interview participant, the BSA's preparedness for change has already been tested through the analogue to digital transition. The range of issues that would need to be considered in a new change scenario would be similar to the planning and preparation required to manage the previous transition.

3. AUTOMATED WHOLE BREAST ULTRASOUND

Ultrasound uses high-frequency soundwaves that 'echo' as they pass through tissue. These echoes are used to create an image called a sonogram, which depicts the internal structures inside the body. Automated whole breast ultrasound (ABUS) is completed using an automated process rather than a clinician with a held-held transducer. There are currently two types of ABUS systems available. The first uses an automated arm to move a handheld transducer, creating 2D images of the breast; a technician guides this automated arm throughout the examination to ensure sufficient contact between the transducer and the breast. The second ABUS system uses a high-frequency, large-format transducer to obtain 3D volumetric images of the breast.

3.1. Insights from the participant interviews

Interview participants generally had limited experience using ABUS as an adjunct screening tool in clinical or research settings.

The potential benefits of implementing ABUS as a screening tool described by interview participants mirrored those articulated in the published literature (in particular, increased detection of some types of cancers, lower safety risk compared to mammography, etc.).

There was limited support for implementation of ABUS. Interview participants noted that:

- there is no evidence that ABUS saves lives and reduces mortality from breast cancer
- the benefits of ABUS need to outweigh any harms (that is, higher false positive recall rates, potential to increase overdiagnosis, confirming acceptability to women and clinicians), and
- workforce and workflow implementation challenges need to be managed including considering the availability of an appropriately trained sonography workforce who can correctly position women to ensure optimal imaging, ensuring ABUS includes axilla in imaging, equipping fixed or mobile units with ABUS workstations when there is already limited space, reading time, image file size and storage and transmission of images between mobile units, clinics and reading, assessment and surgical centres.

Interview participants thought that adding ABUS as a supplemental test would increase appointment times, with a significant impact on clinic workflow and women's time, effectively doubling the appointment time for fixed clinics. Fewer women would be screened in a day.

There was no suggestion that ABUS is ready for implementation. If ABUS develops to a sufficiently robust technology with a clear application to screening, consideration would also need to be given to clinical pathway planning.

4. COMPUTER-AIDED DETECTION (CADe)/ARTIFICIAL INTELLIGENCE (AI)

CADe/AI are sophisticated computerised methods to detect lesions suspicious for breast cancer. The programs used in CADe separate suspicious regions that may contain masses from background breast tissue. They then identify and mark areas that the software identifies as abnormal breast tissue. CADe is not intended to be the sole method for analysing images. Rather, it is designed to alert the radiologist to possible suspicious areas. A radiologist (or other reader) must interpret and decide to accept or dismiss each mark. With recent advances in computer processing capabilities, the rapid growth of digital capture and storage of health data, and cloud-

based storage capabilities, researchers have identified the potential of AI to perform image interpretation on its own (without the need for a human interpreter).

4.1. Insights from the participant interviews

Interview participants had limited or no experience using either CADe or AI in clinical settings although some had some experience in research settings, including in ongoing projects.

AI is in its infancy (but is growing quickly). It is not clear when AI could be considered ready for use in a screening program. Interview participants noted that no specific algorithms are sufficiently advanced for clinical trials yet and noted that it is likely that there will always be a role for human readers. Implementing an effective CADe/AI could reduce reading errors and inter-reader variability or alter reading and reporting protocols. Development of an effective AI could also overcome reading issues associated with tests like digital breast tomosynthesis (DBT).

Before implementation of CADe/AI, gaps in the evidence base need to be addressed and technological refinements are needed (including developing an effective intervention). Other advances needed include determining the intervention's contribution to a reduction in interval cancers and mortality from breast cancer, its cost-effectiveness, as well as addressing clinical challenges raised by pseudo-lesions marked on images, clarification of where best to set detection thresholds, and quality assurance processes that build and maintain trust.

Supporting the development of AI is a challenge for the BSA program: access to sufficiently large datasets to support deep learning is a particular issue, especially for rare cancers or those with unusual mammographic presentations. International collaboration is likely to be required. BSA is in a prime position to be actively involved in the process and development of this AI technology.

Interview participants noted that administrative applications of AI to the BSA program may be closer (such as booking women in for screening, checking consent, data integrity, other call centre tasks, data management, hanging images, etc.).

5. DIGITAL BREAST TOMOSYNTHESIS

DBT is an imaging technology that records between 11 and 25 low-dose images of a compressed breast (depending on the imaging system used). These images are reconstructed in 1mm (or more) parallel slices (or stacks) to form a three-dimensional image of the breast. Radiologists (or other readers) then analyse these images to determine the presence of suspected abnormalities or to further investigate an area identified as suspicious on FFDM or, in some cases, ultrasound.

In Australia, private radiology providers and some (but not all) BSA assessment centres use DBT to obtain additional information about suspicious areas on a screening mammogram or for women presenting with symptoms. DBT may also be used as part of a work-up to confirm breast cancer. An interim Medicare rebate for DBT is now available and can be claimed for women with a past occurrence of breast cancer, a family history of breast cancer, or who have symptoms or indications of cancer, including from a positive FFDM screening mammogram.

5.1. Insights from the participant interviews

The potential benefits of implementing DBT as a screening tool described by interview participants mirrored those articulated in the published literature, but most interview participants agreed that there is not enough evidence to suggest its use as a primary screening test at this time.

Before using DBT as a screening test, we need to know that:

- using DBT saves lives and reduces mortality from breast cancer
- additional cancers detected by DBT are clinically significant and interval cancers reduce, and
- false positive recalls are reduced compared to two-view mammography.

We also need to understand the best ways of integrating DBT as a screening test. A number of different ways that DBT could have a role in primary screening (not assessment) were identified but no single preference emerged. Interview participants advised that implementation of DBT would vary depending on the level of effort required by services with different service configurations.

Interview participants noted that the capital costs of upgrading to DBT would be significant (but usually manageable) but that ongoing operational costs associated with the increased workforce needed to read the larger volume of images would be prohibitive. Training in reading DBT is important, and most radiologists can read DBT; however, there may not be sufficient radiologist capacity available to read DBT images but advances in other technologies (such as AI) may lessen this impact. DBT takes slightly longer to perform that two-view mammography, potentially adversely impacting on the number of women who can be screened during set clinic times. DBT files are large and data transmission and storage will be problematic, especially for mobile units and BSA programs operating in rural/remote areas, which already struggle to transmit images to reading and assessment clinics.

There were mixed views on whether DBT (where it is promoted as a screening test available in private practice) would reduce participation in BSA if it is not the primary screening test. Interview participants noted that addressing marketing of DBT by private providers is difficult, but important. Actively promoting the BSA program's quality was proposed as a way forward.

6. HYPOTHETICAL SCENARIOS

Emerging screening technologies include tests that do not involve breast imaging. The two hypothetical scenarios were selected for their potential to generate insights and represent the extreme of possible change to BSA and are not considered likely. The two scenarios were:

1. Digital mammography is superseded by a completely different type of screening test (for example, a biomarker(s) detected in blood or saliva), or
2. Population-based breast screening is no longer required or considered appropriate.

6.1. Insights from the participant interviews: a different screening test

The concept of a biomarker-based test was supported by interview participants if it was safer and more comfortable for women. The likelihood of developing a sufficiently sensitive and specific

biomarker-based test in the near future was doubted given the heterogeneity of breast cancer. A breakthrough could result in a rapid change.

Before implementation, the superiority and acceptability of a biomarker-based test (compared to mammography) would need to be demonstrated. The test would need to be able to detect breast cancer at a very early stage. If the test modality changed, clarity would also be needed about the safe screening interval (which would depend on the reliability of the test), and recall would be dependent on the sensitivity and specificity of the test (depending on what it is). Regardless, imaging is still likely to be needed to determine the cancer's location and characteristics.

Shifting to a biomarker-based test would involve a significant shift in society's view of breast cancer screening and women's health. The BSA program would look radically different, essentially ceasing to exist and becoming a confirmation and diagnostic imaging service. Most interview participants noted that there would be significant workforce implications, with many being philosophical about the changing workforce dynamics.

There is an assumption that a biomarker-based test would be performed in primary care (or possibly a community-setting like a pharmacy). Quality considerations would need to be very high if other providers offered the test. A biomarker-based test may increase screening participation rates but would have implications for primary care workforce, workflow and training and, potentially, for genetic counselling services. Pathology and laboratory services may need support to cope with potential increased demand for screening.

Interview participants were unanimous in that managing a change to a biomarker-based test would require a considered, consistent and prolonged communications strategy, especially focused on managing consumer expectations during a change-over to a 'better' technology.

6.2. Insights from the participant interviews: evidence no longer supports population-based breast screening

Interview participants thought that it would be extremely difficult to wind-up the BSA program. Removing screening would need international consensus founded on a very rigorous evidence review. There would still be a need for services to examine women who presented with symptoms requiring investigation or pathology. Closing a population-based screening program may increase health and social inequality: a common theme was that while the health literate will find a way to access care if they wanted it, women with lower literacy would be disadvantaged.

If evidence suggested that closure was appropriate, there are options to alter the scope of the BSA program. Screening cycles could be increased while reducing the prompt cycle or population-based screening could be replaced with individualised approaches to identifying breast cancer early. A very effective pilot would be needed before introducing tailored screening.

While overall survival for screen-detected cancers is high, interview participants thought that there is limited evidence that treatment for breast cancer will become so effective in the future that time of diagnosis does not impact on mortality. Additionally, participants thought that a vaccine to prevent breast cancer is unlikely at this time.

Regardless of the preferred option, extensive workforce planning will be needed if any significant changes to the BSA program are proposed.

7. OTHER EMERGING TECHNOLOGIES AND CONSIDERATIONS

Interview participants told us about other emerging technologies. In particular, some thought that FAST/abbreviated MRI looks promising. Other promising technologies included molecular breast imaging and contrast-enhanced subtraction mammography. There is also a need for research on early detection of aggressive cancers, and treatment decision-making of low risk pre-cancers.