



**Australian Government**

**Department of Health**

Department Reference: FOI 226-1718

Mr Michael Shephard

Via email: [foi+request-4394-3ef1177e@righttoknow.org.au](mailto:foi+request-4394-3ef1177e@righttoknow.org.au)

Dear Mr Shephard,

**NOTICE OF DECISION**

I refer to your request of 25 February 2018 to the Department of Health (Department) seeking access under the *Freedom of Information Act 1982* (FOI Act) to:

- " 1. A copy of the official Terms of Reference for that review.*
- 2. The name(s) of the organisation and/or person(s) who is/are conducting that review for the Standing Committee.*
- 3. The date by which the review team is planned to present the draft revision of the Position Statement to the Standing Committee for its consideration.*
- 4. Contact details for members of the community to provide input to that review in accordance with BreastScreen Australia's stated policy 'BreastScreen Australia supports greater discussion, public awareness and research into breast density.' By 'community' I mean individuals such as myself and organisations that are not reliant on government funding and support (i.e. independent)."*

**Scope of request**

On 7 March 2018, the Department wrote to you advising that the right of access under the FOI Act is to existing documents of an agency, not information. Dot points 2-4 of your request, is for information and not documents.

The Department advised the information that you are seeking in dot points 2-4 of your request, would be able to be provided in the Department's response to your letter to the Department.

On 9 March 2018, you advised the Department that you agree for dot points 2-4 to be answered in the Department's letter, which is outside of the FOI process. Therefore, only dot point one of your request has been processed in accordance with the FOI Act.

I am writing to advise you of my decision.

## Decision

I am authorised under section 23(1) of the FOI Act to make decisions in relation to Freedom of Information requests. I am writing to notify you of my decision on your request.

I have identified one document falling within the terms of your request. The document is set out in the schedule at Attachment A.

I have decided to give access to all documents in their entirety.

## Third Party Consultation

As you were informed on 7 March 2018, it was necessary for me to undertake consultation with a third party as part of my decision making function. There were no objections from the third party to the release of the document.

## Review rights

If you are dissatisfied with my decision, you may apply for an internal review or Australian Information Commissioner (Information Commissioner) review of the decision.

### Internal review

Under section 54 of the FOI Act, you may apply in writing to the Department for an internal review of my decision. The internal review application must be made within 30 days of the date of this notice (or such further period as the Department allows). Where possible please provide reasons why you consider review of the decision is necessary. The internal review will be carried out by another officer of this Department within 30 days. An application for an internal review should be addressed to:

Email: [FOI@health.gov.au](mailto:FOI@health.gov.au)

OR

Mail: FOI Unit (MDP 41)  
Department of Health  
GPO Box 9848  
CANBERRA ACT 2601

### Information Commissioner Review

Under section 54L of the FOI Act, you may apply to the Information Commissioner to review my decision. An application for review must be made in writing within 60 days of this notice (if you do not request an internal review).

The Australian Information Commissioner can be contacted by:

Email: [enquiries@oaic.gov.au](mailto:enquiries@oaic.gov.au)

Phone: 1300 363 992

More about the Information Commissioner review is available on the Office of the Australian Information Commissioner (OAIC) website at <http://www.oaic.gov.au/freedom-of-information/requesting-a-review>

You may also make a complaint to the Information Commissioner about action taken by the Department in relation to your application. Further information can be obtained from the OAIC website.

### **Relevant provisions**

The FOI Act, including the provisions referred to in this letter, can be accessed from the Federal Register of Legislation website:

<https://www.legislation.gov.au/Details/C2018C00016>

### **Publication**

You should be aware that where I have decided to release documents to you, the Department may also publish the released material on its Disclosure Log. The Department will however, not publish information (such as personal or business information) where it would be unreasonable to do so.

For your reference the Department's Disclosure Log can be found at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/foi-disc-log-2017-18>

### **Contacts**

If you require clarification of any of the matters discussed in this letter you should contact the FOI Unit on (02) 6289 1666 or via email at [FOI@health.gov.au](mailto:FOI@health.gov.au).

Yours sincerely



Alice Creelman

Assistant Secretary

Cancer Policy & Services Branch

21 March 2018

ATTACHMENT A

SCHEDULE OF DOCUMENTS - FOI 226-1718

Doc. No.	No. of Pages	Date	Author	Addressee	Description of Document	Decision <sup>1</sup>	Portion Exempt
1	6	13.12.2017	Department of Health	N/A	Literature Review on the Management and Reporting of Breast Density	R	

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<sup>1</sup> R= Release

## LITERATURE REVIEW ON THE MANAGEMENT AND REPORTING OF BREAST DENSITY

### Background

Breasts are made up of fat and fibroglandular (non-fatty) tissue with the composition of breast tissue varying between women. On a mammogram, fatty tissue appears black while the remaining breast tissue appears white or 'dense', with the relative amount of fibroglandular tissue areas on a mammogram referred to as breast (or mammographic) density. The amount of breast density ranges from negligible through to a majority of the breast area. Breast density can be measured on mammography; however, there is no consensus about the most effective way to measure or manage breast density. A woman may get different results depending on how her mammogram is analysed or who analyses it. Breast density values are a continuous range. Breast density declines with age, with international research indicating more than half of women under the age of 50 years have dense breasts; for women over 50 years of age about one third have dense breasts.

Higher breast density is associated with a higher risk of breast cancer, with the risk of breast cancer and the risk of masking increasing incrementally with increasing breast density. Breast density has an impact on screening mammography with lower sensitivity and specificity for cancer detection. As cancers appear as white areas on mammograms, high breast density can potentially mask some cancers and interfere with the interpretation of mammograms.

In the United States, successful lobbying by advocacy groups has seen changes in the law, with the Breast Density and Reporting Act 2015 requiring facilities to include up-to-date information about breast density in the written report of the results of a mammography examination to the patient's physician and in the summary report given to the patient. The summary report needs to convey:

1. the effect of breast density in masking the presence of breast cancer on a mammogram, and
2. that individuals with dense breasts should talk with their physicians about any questions or concerns regarding the summary and whether they would benefit from any additional tests.

As at June 2017, breast density notification laws have been put into effect in 31 US States. However, concerns are being raised in the literature about breast density notification laws limiting a broader understanding and discussion of personal risk, the legislation bringing the probability of greater clinical uncertainty and increased liability for radiologists and primary care physicians, and for women additional tests leading to an increased likelihood of false-positive results, unnecessary biopsies and over-diagnosis.

BSA, based on the current Standing Committee recommendations, does not routinely record breast density or provide supplemental screening using other technologies for women with dense breasts but notes that breast density may have a role in determining the frequency and method of an individual's breast screening in the future, and that further research is required. In New Zealand, Breast Screen Aotearoa does not currently measure breast density within the national breast screening programme, based on its 2016 review of the evidence on breast

density. Western Australia does however provide information about an individual's breast density as part of its mammography process for some women participating in its screening programme.

With interest heightened through the media and online about breast density and how it relates to mammographic screening, the Department has received consumer interest from women who would like to hear whether they have dense/fatty breasts when they have a mammogram.

The Department of Health has engaged *Allen + Clarke* to undertake a literature review on the reporting and management of breast density. This review will help decide if an update to the 2016 position statement is required. Following this review and advice from stakeholders, *Allen + Clarke* will prepare an interim update to the position statement (if this is needed).

## Purpose of this document

Annex B sets out the terms of reference for the search strategy to identify published literature to inform the literature review on the reporting of breast density and mammography. We will use this information to conduct the search of published literature. Annex A contains GRADE which *Allen + Clarke* will use to rate the level of evidence for identified outcomes presented across the included research. A range of guidelines (including AMSTAR and SIGN will be used to assess the quality of individual studies).

## Scope and topics

This literature review focuses on breast density and how it relates to mammography and breast screening. We want to know:

- the established increase in risk of breast cancer for women with dense breasts
- to what degree breast density masks breast cancer in modern digital mammograms
- the relative risk of breast cancer by age and by breast density
- how the association between breast density and risk changes with adjustment for age, and
- whether there is any evidence available from jurisdictions where women have received information about their breast density and that information has been used to inform changes in screening participation (including invitation to participate and/or differential screening or management) or health and psychosocial outcomes.

This includes considering from the available published evidence whether legislation and mandatory reporting of breast density is warranted, the advantages and disadvantages of providing breast density information to women, and research and evaluation on consumer views and satisfaction with information and resources. The literature review may also include grey literature, including publications and position statements about breast density and mammography from professional bodies and organisations to understand the level of information and support currently available to consumers in Australia and internationally.

The literature search will not explore:

- the assessment and diagnosis of breast cancer

- literature about breast cancer that does not relate to breast density, or
- other technologies that may have a population screening application for determining breast density/identifying breast cancer (i.e., ultrasound, magnetic resonance imaging, computed tomography).

Different levels of evidence will be required to provide satisfactory answers to the research questions. These are described in the following tables.

### Research questions

- QUESTION 1** In asymptomatic women aged over 40 years, what is the reported increase in risk of breast cancer for women diagnosed by mammography to have higher breast density compared with women diagnosed to have lower breast density?
- Is there a method that is the best for measuring breast density?
  - Is there a measure that is the best measure of risk?
- QUESTION 2** In asymptomatic women aged over 40 years, what is the level of reported masking of breast cancer in mammograms for women diagnosed with higher breast density compared with women with lower breast density?
- Is there a measure that is the best measure of masking?
- QUESTION 3:** In asymptomatic women aged over 40 years, what is the relative risk of breast cancer by age for women diagnosed by mammography to have higher density breasts compared with women with lower breast density?
- Taking breast density in account, does age mitigate or exaggerate the risk of breast cancer?

Criterion	Description
<b>Population</b>	Women aged over 40 years (inclusive) with no symptoms of breast cancer and screened by mammography <i>Sub-population of interest: Women aged 40-50 years (inclusive) with no symptoms of breast cancer and screened by mammography</i>
<b>Intervention</b>	2-view digital mammography
<b>Comparators</b>	Women with 'dense breasts' or higher breast density Women with 'non-dense breasts' or lower breast density
<b>Outcomes</b>	Risk of breast cancer by breast density Risk of breast cancer by breast density and age Role of masking in detecting breast cancer in women with dense breasts Relative risk; odds ratios; risk difference Specificity (recall rates and over-diagnosis for specific types of breast lesions) Interval cancer rates

Criterion	Description
Study types	Systematic reviews and randomised controlled trials

QUESTION 4 In asymptomatic women aged over 40 years (inclusive) who have received information about their validated breast density compared with women who have not received information on validated breast density:

- What is the evidence on changes in clinical health outcomes with differential management?
- What are the psychosocial outcomes for women, in jurisdictions where breast density is reported?
- Are there any lessons from jurisdictions where breast density information is reported to women, including acceptability of reporting (or not) and reporting protocols?
- What advice and support do women want and need if breast density is reported?

Criterion	Description
Population	Women aged over 40 years (inclusive) with no symptoms of breast cancer and screened by mammography and who have received information on validated breast density <i>Sub-population of interest: Women aged 40-50 years (inclusive) with no symptoms of breast cancer and screened by mammography</i>
Intervention	Validated breast density reported to screened woman
Comparator	Women who have not received information on validated breast density
Outcomes	Additional diagnostic tests undertaken and outcomes Choice of adjunct screening (ultrasound, DBT, MRI) Breast cancer diagnosis and stage at detection Ongoing participation in breast screening Frequency of breast screening Mortality from breast cancer Interval cancer rates Seeking of support from primary care, counsellors, mental health services Anxiety, depression Additional costs incurred Acceptability of reporting protocol by GP



Criterion	Description
Study types	Systematic reviews, randomized controlled trials, cohort, longitudinal, observational, grey literature

## Terms of reference for literature search

### Breadth of search

- OVID Medline
- The Cochrane Library database
- Scopus
- Embase, and
- National Institute for Health and Clinical Excellence
- Sources of grey literature like the Australian Clinical Trials Registry, Breast Cancer Research Institute of Australia, Breast Cancer Network Australia, Clinical Trials Registry, Current Controlled Trials metaRegister, Health Technology Assessment International, International Network for Agencies for Health Technology Assessment, Medicines and Healthcare Products Regulatory Agency (UK), National Library of Medicine Locator Plus database, National Institute for Health Research UK HTA programme, New York Academy of Medicine Grey Literature Report, TRIP database, U.K. National Research Register, US Food and Drug Administration, Center for Devices and Radiological Health, and National Breast Cancer Foundation.

### Inclusions

From the results of the search, literature will be prioritised according to the following criteria:

- Currency (published between 1 January 2010 and 30 November 2017)
- Relevance to primary research questions
- English language
- Material that exhibits methodological rigour (eg, the AMSTAR 2 tool/SIGN level of evidence), and
- Grey literature from reputable sources.

### Exclusions

The literature review will exclude published literature that does not relate to breast density and mammography. Non-English language sources will also be excluded. Grey literature like media releases/statements will generally be excluded except where these link to reputable grey literature. False drops and duplicates will be removed our library services.

## Search terms

Where possible (subject to the flexibility of database search functions), the keywords included in the search strategy are outlined below.

- Breast density; dense breasts; dense breast tissue; volumetric mammographic breast density; fibroglandular density; mammographic density
- Breast density grading; measuring breast density; BI-RADS
- Breast cancer; breast cancer risk; interval breast cancer; interval breast cancer risk; screen-detected breast cancer
- Population-based screening; screening; screening for breast cancer
- Meta-analysis; systematic review; randomised control trial; cohort; longitudinal; observational
- Mammogram; mammography; digital mammography
- Reporting; accuracy Outcome; survival; survival rate; interval cancer rate; long-term
- Risk; relative risk; odds ratio
- Over diagnosis; over detection
- Masking
- Anxiety; psychosocial; depression; mental health; distress
- Management pathway; clinical pathway; quality; quality guidelines
- Acceptable; Ethnicity; minority group; Aboriginal; Torres Strait Islander
- Breast density legislation; breast density mandatory reporting; breast density information
- Acceptable; women; consumer; support; acceptability

## Provision of materials

Massey University will provide a list of returns that includes citations and abstracts. *Allen + Clarke* will review this list of returns and identify the documents for which we require full-text. The University library will provide access to these full-text articles through a Mendeley group.