Don't Ask, Don't Tell: the breast density secret that changed our lives (but not in a good way)

Jean and I appreciate the opportunity we have today to share our experience and views with you.

Diagnosis

Five months after Jean received her May 2017 screening report from BreastScreen Australia advising that her mammogram result was all clear she felt a lump in her right breast. Although a little apprehensive we thought it couldn't be cancer. If it was cancer then the mammogram would surely have shown a lump of that size, wouldn't it? Fast forward a few days and we received the diagnosis: Jean had a cluster of three tumours: the largest being an invasive ductal carcinoma of nearly three centimetres. The pathologist defined Jean's cancer as Stage 2A, Grade 2, estrogen-receptor positive and HER2 negative.

Treatment

In November 2017 Jean had a lumpectomy operation comprising the removal of 128 grams of breast tissue and eleven lymph nodes. She endured four courses of strong chemotherapy drugs and six weeks of daily radiation therapy. Daily treatment with an aromatase inhibitor will continue for several years, as may some of the side effects.

Late Detection

Based on Jean's pathology report that her cancer had a moderate (intermediate) rate of growth, her surgeon estimated that it would've taken at least three years to grow to three centimetres. But three years growing from what? In an article[1] following on from his book *Breast Imaging*, Daniel B Kopans estimates that a cancer with an average intermediate growth rate takes about six years (approximately) to become invasive. After another fourteen years (approximately) as an invasive ductal carcinoma it will be two centimetres in size. Jean's tumour was nearly three centimetres.

Kopans also explains that growth is not linear - the number of cancerous cells of an intermediate grade tumour will double (and hence the tumour size will double) every 120 days (on average).

Assuming all this is true and applicable to Jean's condition, then Jean's cancer would've been less than two centimetres when Jean received her

2017 all clear (false-negative) report. Jean's *EndoPredict*[2] genomic test score has tumour size as one of it's parameters and a size of less than two centimeters would've placed Jean into the low risk category and she wouldn't have required chemotherapy and so wouldn't have had to suffer its side effects.

Betrayal

Naturally, we were shocked and apprehensive when Jean was diagnosed with cancer. But imagine how we felt when it was revealed that BreastScreen failed to detect the cancer because she has breasts in the density range 50 to 75% on the BI-RADS scale; that women with dense breasts are at an increased risk of cancer and, more alarmingly, there is a substantially lower probability that cancer will be detected where 2D mammography is used as the only screening method.

Worst of all, radiologists would've noticed that Jean's breasts are dense but BreastScreen Australia has a policy of *not recording* breast density and *not advising* women that they have dense breasts. We felt betrayed by our government health service provider.

One may well ask what right our health service and the medical profession generally have to withhold details of a patient's body and health from her. Insofar as *our* health is concerned, Jean and I are risk averse. We have periodic checks for several potential conditions. If we'd known that breast density was a thing and that Jean has dense breasts we would've self-funded supplemental screening such as ultrasound or MRI at a private clinic and detected the offending tumour at least five, if not twenty-nine or more, months earlier.

There's a time for tears: there's a time for anger. Then there's a time for turning anger into action: turning negativity into positive energy. In parallel with supporting Jean through her treatment I started seeking answers - researching, reading and documenting - engaging with the Department of Health, NSW Health, the RANZCR, the American College of Radiology, the Human Rights Commission and various advocacy groups within Australia and overseas.

We also attempted to engage with ministers. Greg Hunt's office passed our letter to his department whilst the Minister for Women (then Michaelia Cash) failed to respond.

Don't Tell

Whilst visiting an office of BreastScreen NSW to discuss Jean's false-negative reports, I collected copies of all of the brochures in the rack. Only one brochure provides information on breast density – a brochure targeting women under forty years of age. It states that *'Breast screening is not as effective in younger women due to denser breast tissue, which makes it harder to see small cancers on a mammogram.'* Jean was by no means under forty and her cancer was by no means small. Why can't BreastScreen provide breast density information to women in its target group - ages forty to seventy-three? For sure, people can do some data mining on the subject of breast density on BreastScreen Australia's website. However it may be that only patients and others who've already been impacted by interval breast cancer and have been told they have dense breasts would bother to do that. By then, of course, it's too late.

The current (2016) position statements on breast density issued by both Breastscreen and the RANZCR are remarkably similar and, in the main, reference the same body of literature. They highlight a laundry list of reasons why a woman *shouldn't* be told that her breasts are dense; reasons such as existing methods of measuring breast density are imprecise, women might become distressed when told that their breasts are dense and women might expect and demand supplemental screening such as ultrasound or MRI. This additional screening might lead to over-diagnosis, more intrusive procedures, a risk of false positive diagnosis, an impact on the valuable time of hard-working clinicians and (worst of all) higher costs for government.

Health told us that in preparing its position statement it considered both the benefits and harms of supplementary screening. We responded that nowhere in the position statement or references is there a discussion of the *benefits* of breast density reporting and supplemental screening. *No* discussion of the harms of false-negative screening reports. *No* discussion of benefits such as earlier diagnosis (which logic would suggest would save lives, even if there hasn't yet been a randomized trial showing survival benefit). *No* discussion of the ethical responsibility for disclosure and informed choice. Putting it simply - *no* balance.

However, our main concern is not about the benefits or otherwise of supplemental screening: it's about breast density non-reporting - medical ethics and the rights of patients. Whether it's ethical to withhold

information from patients and thus deny them the opportunity to participate in decision-making on the subject of their own screening.

Paternalism

BreastScreen and the RANZCR are acting paternalistically: they are deliberately, as a matter of policy, disempowering women. As we pointed out to Health, this attitude is anachronistic, a throw-back to the days when doctors were mainly men and more condescending to *all* patients – but especially to women.

Concatenating two clichés, we would describe this attitude as: *they can't handle the truth so let's not bother their pretty little heads about it*. We are surprised that so many women in the health industry seem to either support this policy or are prepared to go along with it rather than speak truth to power. Perhaps many are somewhat conflicted in their views.

Everyone agrees that existing methods of measuring breast density are imprecise, but that doesn't mean that gauging and recording meaningful data on density is impossible. Three BreastScreen NSW radiologists retrospectively examined Jean's most recent three screening mammograms produced using both analogue and digital technologies and had no problem placing Jean's breast density into the BI-RADS Breast Composition Category C for all three.

So given that screening mammograms are read by at least two radiologists why can't each radiologist separately or jointly rate breast density and discuss and/or get a third opinion if ratings differ? BreastScreen's written reports to GPs and their patients could be appropriately qualified. Thirty-five USA states have already mandated breast density reporting despite measurement not always being easy. So, in our view, measurement difficulty is not an adequate excuse for non-reporting.

Ethics

Refusal to report breast density is, in our view, a flagrant denial of a human right. Women should have the right to know and the right to choose - the right to converse with specialists and GPs on matters that may be critical to their health. We took this up with the Human Rights Commission who politely advised that it's not their problem and referred us to the NSW Health Care Complaints Commission, the Australian

Health Minister's Advisory Council (AHMAC) and organizations that provide legal advice.

Health has a New Zealand based consultancy firm reviewing recent literature that it considers relevant to its breast density position statement and, based on the outcome, *may* issue an update to its position statement sometime this year.

Unfortunately, nothing of substance will change. We reviewed the terms of reference for the literature review that we acquired via a Freedom of Information Act request and noticed that there are no terms of reference related to medical ethics. No review of the ethical question of disclosure v non-disclosure.

We contacted Health's consultants and suggested that they try for a scope change to their contract - that is, ask Health whether it's prepared to add literature on medical ethics to the terms of reference. After all, what consultant doesn't like an increase in the scope of the brief? Well, the consultants advised that they *did* pass our suggestion to Health which presumably said *no* because in response to a subsequent question from us Health confirmed that the terms of reference *don't* contain a review of the practice ethics of withholding information about a woman's breast density. It said that its focus is on the evidence base to support decision-making about screening participation rather than the ethics of reporting breast density.

So, clearly, Health refuses to consider a review of literature that doesn't play in to its existing narrative. The status quo will be maintained. The can will be kicked down the road for another couple of years. The stakeholders that really matter, the counters of the beans, will be well satisfied with the outcome.

Breastscreen's FAQs

In answer to several of our questions, Health re-states the Frequently Asked Questions (FAQs) attached to BreastScreen Australia's position statement. In one FAQ, BreastScreen asks whether there's value in a woman knowing her own breast density. In an indirect way BreastScreen concludes that there *is no* value. We disagree; it would've been of immense value to Jean.

The FAQs further state that BreastScreen *'... respects a client's right of access to their personal medical information....'.* We are unsure how a client could know that there are questions to ask when BreastScreen hasn't told her that breast density is a thing. And even if she *does* know what to ask, BreastScreen doesn't record her breast density anyway. It's a catch-22.

BreastScreen also claims that it '… *encourages the involvement of clients in developing evidence-based approaches to breast cancer risk assessment, prevention and early diagnosis.'* We are unsure as to how 99.99% of clients would have the knowledge and skills to do that. Nevertheless, as Jean is a client and we'd love to help, we've asked Health how we can become involved in that development. We breathlessly await the response.

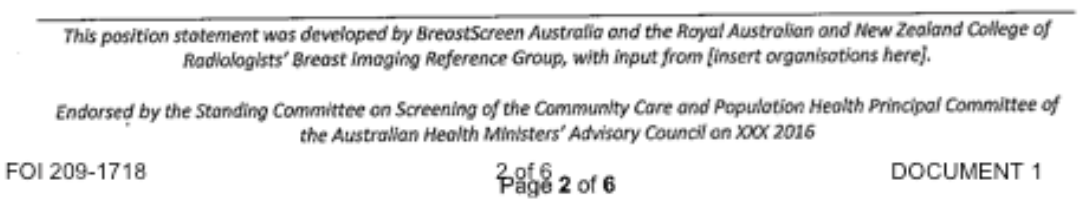
The FAQs also state that the *'... benefits and drawbacks of routine reporting of breast density are a complex issue that needs to be evaluated, in discussion with the consumers.'* Given that we have offered more than once to go to Canberra to meet them and discuss these matters face-to-face, only to be told recently by Health that it will not meet with individual consumers, this statement seems somewhat mendacious.

Health appears to have two preferred methods of engaging customers. The ongoing method is via a public email address that is answered anonymously. A recent invitation to the public to anonymously submit evidence-based (only) views via a *Survey Monkey* account managed by a consultancy firm was another recent initiative. Neither method is adequate for a '… discussion with the consumers.'

The RANZCR

Our first letter to Health was copied, with our permission, to the RANZCR by supportive employees of BreastScreen NSW. The RANZCR responded to our observation that both theirs and Health's position statements look remarkably similar. The heads of two committees at the RANZCR advised that the College wrote its own position statement independently of BreastScreen Australia and that the '… reasoning for this similarity is that the position statements are evidence-based and so a similar stance and practice is typical. In effect, they're implying there was no collusion.

We told the RANZCR that its explanation is inconsistent with two unreleased drafts of Health's 2016 position statement that we obtained via the Freedom of Information Act[3]. The footers on the drafts have the RANZCR as a co-author. Here is one of them:



This position statement was developed by BreastScreen Australia and the Royal Australian and New Zealand College of Radiologists' Breast Imaging Reference Group, with input from [insert organisations here].

Endorsed by the Standing Committee on Screening of the Community Care and Population Health Principal Committee of the Australian Health Ministers' Advisory Council on XXX 2016

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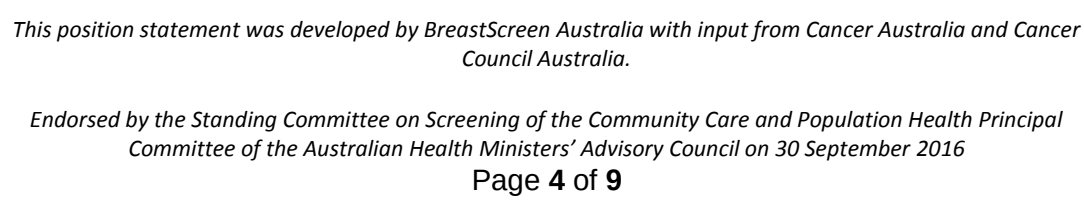
Here is the final version that does not have the RANZCR as a co-author or even as a contributor in the footer:



This position statement was developed by BreastScreen Australia with input from Cancer Australia and Cancer Council Australia.

Endorsed by the Standing Committee on Screening of the Community Care and Population Health Principal Committee of the Australian Health Ministers' Advisory Council on 30 September 2016

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We don't know the reason for this change of heart, nor why the RANZCR was less than candid with us. We've asked the RANZCR whether the change has anything to do with the fact that the letters NZ appear in the centre of the acronym RANZCR. Authoring a position statement jointly with the Australian government when the New Zealand government has produced a completely different series of position papers - how would that work for trans-Tasman harmony? The RANZCR hasn't responded and so I assume we are free to speculate.

We made the point to the RANZCR that each organization *ought to* have separate objectives and *ought* to derive its own separate position. The government has a concern with funding and so it should. The RANZCR should be concerned with the rights of patients and what's best for them whilst at the same time representing and supporting the interests of its members.

We offered to discuss these matters on the phone or in person. We received no response to our letter; nor to several emails we subsequently sent on related topics to the RANZCR. Like trying to find a tumour in a dense breast mammogram, seeking truth can be like looking for a snowball in a snowstorm.

Via an email account set up for public queries, the RANZCR advised that it has completed a literature review and is in the process of updating its position statement. The release date depends on how long the various approval processes will take. It's targeting sometime this year. Seemingly, the RANZCR is now showing signs of independence.

The motto of the RANZCR is *Lumen Afferimus Morbis* which translates to *We Shed Light on Disease*. If its breast screening radiologists were allowed to shed light for patients on their breast densities – wouldn't *that* be a good thing?

In Closing

In closing we note that the demand for change in breast density reporting is gathering momentum around the world with advocates in the USA having considerable success with legislature at the state level.

We are encouraged that several employees of BreastScreen with whom we have spoken also side with our cause - how could they not? They don't enjoy having patients present with interval cancer for *any* reason including dense breasts.

We look forward to discussing these and other issues during this workshop.

Happy for questions, comments and suggestions to Mike Shephard, winewort@yahoo.com.au.

References

[1] KOPANS, Daniel B et al: *A Simple Method of Breast Carcinoma Growth May Provide Explanations of Observations of Apparently Complex Phenomena*
https://onlinelibrary.wiley.com/doi/pdf/10.1002/cncr.11434

[2] EndoPredict: *website*
https://endopredict.com/overview/

[3] Freedom of Information: *3rd party access link*
https://www.righttoknow.org.au/user/michael_shephard