

Ethical and Legal considerations in Breast Density, Adelaide August 2018

Clinical and Public Health Perspectives on Breast Density

Prof Nehmat Houssami

Sydney School of Public Health, Faculty of Medicine & Health

University of Sydney

Interests & Conflicts of Interests

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Research interests: adjunct screening trials in dense breasts; DBT screening studies BreastScreen (& several European screening programs); Wisser Healthcare



THE UNIVERSITY OF SYDNEY

Professional Roles

- Clinician (breast services since 1991), private and public sector
- *I collaborate with* but not employed by BreastScreen (limited advisory/ committee roles breast screening program)
- Current clinical work: public breast services (RHW)
- Co-editor (Breast)
- Breast Research program: evidence on impact of new technologies; population breast screening outcomes; screening trials; clinical guidelines

Clinician perspective

- As a clinician: factor density into clinical decision-making, when deciding and discussing breast imaging/testing however:
 - Patient in context of **overall risk factors** & why she is presenting/ seeking consult
 - Reduced mammographic sensitivity from higher BD (vs risk factor)
 - Referred patients ***do not represent population screening***: BRCA mutations carriers; women with personal history BC; breast symptoms; findings from elsewhere imaging (eg. US-detected false positives post-screen dense breasts)
- I factor density into clinical decision-makingbut not necessarily informing all women of density status ... **the extent that I discuss BD depends on the woman's other risk factors and concerns (individualised)**
- Radiologists routinely include density in report

BD is one of many risk factors, age, gene mutations, family history, **BD, BMI**, ...

Table 1	
Relative risks of developing breast cancer for women aged 40 to 49 years	
Risk Factor	Breast Cancer Risk Ratio (95% CI)
Two first-degree relatives with breast cancer	3.84 (2.37–6.22)
First-degree relative with breast cancer at age <40 y	3.0 (1.8–4.9)
First-degree relative with breast cancer at age <50 y	2.17 (1.86–2.53)
One first-degree relative with breast cancer	2.14 (1.92–2.38)
Extremely dense breasts on mammography	2.04 (1.84–2.26)
Prior benign breast biopsy	1.87 (1.64–2.13)
Second-degree relative with breast cancer	1.7 (1.4–2.0)
Heterogeneously dense breasts on mammography	1.62 (1.51–1.75)
Current oral contraceptive use	1.30 (1.13–1.49)
Nulliparity	1.25 (1.08–1.46)
Age at first birth ≥ 30 y	1.20 (1.02–1.42)

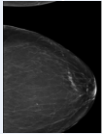
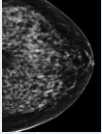
From Lee et al ; Med Clin N Am 2017

Public Health perspective on BD notification

- Clinical perspective vs Public Health perspective (divergent on BD??)
- *Communicating BD information: there are pros & cons (in context BS program)*
- Public health perspective: change to screening program should be based on evidence that *the change will improve health outcomes for women*
- Facts: adjunct imaging detects *more cancer* in women with high BD after negative screening mammogram *but*
 - Majority of women with dense breasts and *no additional risk factors/ no symptoms*, are likely to experience more harms than benefits by adding more screening (US, MRI)
 - RCTS of population screening (mammography only, all breasts)
 - No consensus about what to offer women with high BD

Note also that adjunct imaging detects cancer in *less dense* breasts (RCT example)

RCT population screening, Italy: mammography (2D) vs Tomosynthesis (3D with 2D): number of *breast cancers detected at screen across all density categories*
Reggio Emilia RCT, Radiology 2018.

Breast Density	Digital Breast Tomosynthesis (DBT) with 2D (9777)	Digital Mammography (2D) (9783)	Relative risk of cancer detection
A - almost entirely fatty 	4	2	2
B - scattered areas of fibroglandular density	25	12	2.1
C – heterogeneously dense 	27	18	1.5
D - extremely dense	16	7	2.3

No consensus on which adjunct imaging modalities benefit women with **dense breasts**

Modality	Detects more cancer after negative mammograms	False positives	Other pros/ cons	Availability & costs	Evidence of mortality benefit (above mammography)
Tomosynthesis (DBT/3D)	Yes +	No (+/-)	Radiation (can replace mammogram)	Progressively more available Low cost	Not established *modelling suggests some benefit
Ultrasound	Yes ++	++	No radiation Operator dependent	Widely available Moderate cost	Not established *modelling suggests <i>little benefit</i>
MRI	Yes +++	+++	IV contrast	Moderate/limited availability High cost	Not established <i>*references available</i>

Some concerns: BD notification

- No framework to support notification in a broad-reach population program
- Unknowns: who informs the woman; how/where? What to offer to manage risk?
- What are **ethical issues** of **notifying/not notifying** BD without proof of additional health benefit *but given evidence of additional cancer* detection (vs mammography)?
- **Not established:** information material that present accurate BD facts, and do not cause undue fear/anxiety; reliable, reproducible and feasible measure of BD (over repeated screens)
- **Opinion:** avoid passing on the 'BD issue' to woman & her GP without offering a pathway to deal with 'next step' and to collect outcomes/monitor effect of providing BD information
- Looking at USA: most frequent outcomes of (non-organised) adjunct testing: cost and FPs

BD notification – examples from surveys of women & doctors where legislated

1 - semi-structured telephone interviews of *women who received 'dense breasts' notification* (post negative screening mammography):

- Most women recalled receiving notification but most did not recall specific content or key messages
- More than half of women expressed initial concern and worry at receiving BD information; some considered the notification as a positive health message

2- Web-based survey of Massachusetts *primary care physicians & practitioners*:

- None of respondents could identify all 8 required components of notification under Massachusetts legislation
- 49% did not feel prepared to address patient questions about dense breasts
- 85% needed training to support discussing dense breast risks or supplemental screening

1- Gunn et al, Patient Education and Counseling 2018; 2- Gunn et al, Journal of Women's Health 2018

Adapted from Houssami & Lee (Review, 2018: under peer-review)

Other concerns, opinions and suggestions

- BS-embedded strategy to measure BD lacking (*essential first step!*)
- Collaboration needed between **all stakeholders to find a way forward** and address uncertainties around BD
- Informing women (without additional support/guidance, care pathway) may cause more harm than good, may also widen health disparities
- Clinical (individualised) care: BD factored in decisions /communicated
- Unsure if BD notification part of the role of a high-volume screening program that does not provide individual consultation??
- Screening policy: *lack of evidence of incremental mortality reduction* (from adjunct screen in women with dense breasts) is a key issue