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Analysing the ethics of breast cancer overdiagnosis: a pathogenic vulnerability

Introduction

Breast cancer overdiagnosis refers to the identification of harmless or indolent cancers, largely through breast screening programs. Breast cancer overdiagnosis occurs because, at the time of histopathological confirmation of the diagnosis of breast cancer, there is no reliable way of differentiating harmless lesions from apparently identical lesions that, if left untreated, would follow the malignant trajectory usually associated with breast cancer.¹ Given this inability to distinguish malignant from indolent lesions, overdiagnosis seems to be an inevitable consequence of breast cancer screening programs. To date, responses to this problem largely focus on improving the consent process so that women can make informed choices about accepting or declining screening in full knowledge of the risk of overdiagnosis. In this paper, I argue that this normalisation of breast cancer overdiagnosis is ethically concerning, because it obscures the pathogenic nature of vulnerability to overdiagnosis (Rogers et al. 2012; Mackenzie et al. 2014). Women's vulnerability to the risk of overdiagnosis is not a matter of chance or brute bad luck (an "inevitable consequence"). Rather, it is a consequence of factors including deliberate policy decisions that, although motivated by a desire to ameliorate vulnerability to breast cancer, have in fact resulted in large numbers of women being exposed to increased susceptibility to harm. In the first sections of the paper, I briefly explain the nature of breast cancer overdiagnosis and explain pathogenic vulnerability. Then I specify the harms of breast cancer overdiagnosis and argue that these are the result of pathogenic

¹ Scholars differ in formal definitions of overdiagnosis (see e.g., Hofmann 2014; Carter et al 2016; Rogers and Mintzker 2016). However, all of these authors would include breast cancer overdiagnosis as described here within their definitions of overdiagnosis.

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vulnerability. My analysis provides an original way of conceptualising the harms of breast cancer overdiagnosis and shows why individualistic responses such as the informed choice model are ethically inadequate. Finally, I outline potential solutions that avoid pathogenic vulnerability.

1. Breast cancer overdiagnosis

Breast cancer screening is motivated by the idea that the early detection of breast cancers will save lives. The underlying premise is that pre-emptively identifying and removing small lesions will lead to better outcomes than if women are not treated until their cancers become symptomatic. Additionally, early detection may permit the use of less invasive therapies (for example, ‘lumpectomy’ instead of mastectomy), thus leading to lower morbidity for treated women. Early trials of breast cancer screening seemed to hold out the promise of a 30% reduction in the risk of dying from breast cancer in women aged 50 who were screened regularly, compared with women who did not receive screening (Brennan and Houssami 2016). However, the widespread introduction of breast cancer screening programs has not achieved these gains. Instead there has been a 30% increase in the incidence of breast cancer in women of screening age (Welch et al. 2016) but this has not been matched by a compensatory fall in the incidence of breast cancer in older women. If screening was identifying progressive cancers at earlier stages, there should be a fall in later incidence (Jorgensen et al. 2017). In addition, the incidence of metastatic breast cancer has not fallen (Welch et al. 2016). Taken together, these two findings indicate that many of the cancers detected by screening are overdiagnosed. That is, screening

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detects both ductal carcinoma in situ (DCIS) and invasive lesions, which left undetected would not have progressed to metastatic disease (Barratt 2015).²

Overdiagnosis of breast cancer is problematic because, at the time of diagnosis, there is no way of reliably differentiating between lesions that will behave indolently, and those that will exhibit the expected malignant behaviour. Therefore all women with screening-detected cancers are offered treatment for potentially invasive breast cancer. The women who are overdiagnosed not only receive no benefit (because their lesions would not have progressed on a malignant trajectory), but they are harmed because the diagnosis itself and any consequent treatment entail psychological, physical, social and economic burdens. Many women treated for screening detected breast cancer would never develop clinically apparent disease, but it is not possible to identify which specific individuals are overdiagnosed.

The existence of breast cancer overdiagnosis is widely acknowledged (Elmore 2016), but there is little consensus as to how frequently it occurs or even how to measure it.³ Estimates vary but it is possible that up to 50% of screening detected breast cancers are overdiagnoses (Barratt 2015; Welch and Passow 2014). If the upper estimates are correct, up to half of all women who receive a diagnosis of and treatment for screening detected breast cancer do not receive any benefit but are only harmed.

² Note that overdiagnoses differ from false positives which occur when an initial positive test is found to be incorrect on further testing.

³ The rate of overdiagnosis may be expressed in relation to numbers of women invited to be screened, women actually screened, or cancers detected by screening. The number of overdiagnosed cancers may be presented as a percentage of the cancers diagnosed in the screening group or as the percentage of excess cancers found in screened women versus the numbers of cancers in unscreened women (Marmot 2012, 41).

A 2017 overview of national breast cancer screening guidelines found widely differing estimates as to how many women are overdiagnosed per breast cancer death averted, with numbers ranging from 2 to 14 (Jorgensen et al. 2017).

Thus we have the situation in which a practice motivated by the desire to decrease deaths from breast cancer instead disrupts the lives of and causes harm to many women who do not have health-threatening disease. One possible response to this situation is simply to document the benefits and harms of breast cancer screening in order to assist individual women to make informed choices about screening (Hersch et al. 2011). However, the informed choice approach is problematic (Rogers et al. 2017). In contrast, analysing breast cancer overdiagnosis in terms of vulnerability offers a nuanced and comprehensive moral evaluation, and points to ethically justifiable responses.

2. Vulnerability

In what follows, I draw on a recently proposed taxonomy of vulnerability (Rogers et al. 2012; Mackenzie et al. 2014). On this account, human vulnerability refers to particular kinds of susceptibility to harm or suffering, often associated with powerlessness to avert the harm on the part of those affected. Vulnerability may arise from inherent or situational sources. Inherent vulnerability arises from biological, psychological and social features that are intrinsic to human embodiment. Human beings have bones that break, organs that fail and other fragilities linked to corporeal existence. They have psychological and social needs that if left unmet lead to various harms. Despite these shared inherent vulnerabilities, not all humans are equally likely

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to come to specific kinds of harm, because of differences in situational vulnerability.

Situational vulnerability refers to context-specific factors such as the personal, social, political, economic or environmental circumstances in which social groups or individuals exist. Thus individuals whose employment exposes them to asbestos are more vulnerable to the cancer mesothelioma than individuals working in asbestos-free environments; and communities living in coastal regions are more vulnerable to flooding from tsunamis than mountain dwellers. Inherent and situation vulnerabilities co-exist and may overlap.

Pathogenic vulnerability is a sub-type of situational vulnerability that arises in the context of significant power imbalances, in which the agency of vulnerable individuals is limited or undermined. Pathogenic vulnerability can be generated by a variety of sources including morally dysfunctional or abusive relationships and socio-political injustices. Additionally, pathogenic vulnerability arises when vulnerable individuals or groups are subject to an intervention aimed at remedying their situation, but instead the intervention exacerbates existing vulnerabilities or creates new ones. For example, at various times orphan children have been placed in institutions charged with their care and upbringing, to avoid the harms that might otherwise come to them living unprotected on the streets. But this response to the vulnerability arising from being without parents creates pathogenic vulnerability when those charged with their care instead mistreat or abuse the children. This not only harms the children directly, but also undermines, rather than supports opportunities for the children to develop and exercise their own agency. Paradoxically, the vulnerable become worse off as the result of actions ostensibly aimed at assisting them.

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Based on this account, I take vulnerability to screening-related breast cancer overdiagnosis to be a pathogenic vulnerability. Breast cancer screening programs are government-funded in many countries, motivated by the desire to avert deaths from breast cancer. All women, and to a lesser extent men, are inherently vulnerable to the development of breast cancer, by virtue of having breast tissue. Breast cancer can be a devastating disease. It is the commonest cancer to occur in women, with a lifetime cumulative risk of 12% (American Cancer Society 2011). While current five-year survival rates exceed 90%, the situation was far different when screening was first proposed in the 1950s, at which time 40% of women died of their disease by 5 years (Ban and Godellas 2014). Despite improvements in treatment, breast cancer is the second leading cause of cancer death (after lung cancer) in women. Given this context, breast cancer screening programs are an attempt by governments to ameliorate the harms caused by women's inherent vulnerability to breast cancer. Yet in the attempt, these programs create pathogenic vulnerability to overdiagnosis, thereby undermining women's agency and causing harm. Labelling it as such permits the identification and grouping of multiple factors contributing to vulnerability to breast cancer ODx and simultaneously mandates broad-ranging responses grounded in decreasing vulnerability by supporting women's agency.

3. The harms of breast cancer overdiagnosis

Breast cancer screening is associated with various harms including false positives and their psychological sequelae, pain during mammography, and screening-related

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deaths from radiation-induced cancer (Nelson et al. 2016).⁴ However, my focus here is on the harms of overdiagnosis.

Breast cancer overdiagnosis (ODx) occurs as a direct result of screening. Despite disagreements about the magnitude of the problem, there is general agreement that breast cancer ODx exists and is harmful, and that the proximate cause lies in the inability of current diagnostic technologies to distinguish between lesions with malignant versus indolent trajectories. As ODx cannot be identified in individual women, the response is to treat each woman as if she has malignant disease, triggering what Marmot (2012) characterises as “the cascade of harm”.

Most women (more than 99%) with histopathologically confirmed screening-detected cancers undergo surgery. 25-30% of women have mastectomies. The remainder have local excision known as lumpectomy or breast conserving surgery (BCS), including the 20% of women diagnosed with ductal carcinoma in situ (DCIS), which many consider to be a benign lesion or precursor rather than cancer per se. Of women with non-DCIS breast cancer who have BCS, 96% have radiotherapy and 21% receive chemotherapy. Women with non-DCIS breast cancer treated by mastectomy have higher rates of chemotherapy (42%) and lower rates of radiotherapy (34%) than those treated with BCS. Nearly 90% of all women with non-DCIS breast cancer receive endocrine therapy (Marmot 2012). These invasive and extensive interventions are aimed at curing breast cancer, but for those women who are overdiagnosed, the interventions are not beneficial, as they did not have disease requiring treatment.

⁴ I thank an anonymous reviewer for noting that all of these are iatrogenic harms. The harms of ODx are a subset of these.

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In addition to these interventions aimed at cure, prophylactic contralateral mastectomy (i.e., amputation of the non-affected breast) is becoming commoner in women with screening detected cancer. In 1998, 1.9% of women eligible for BCS had bilateral mastectomy for unilateral disease; by 2011 this had risen to 11.2% (Kummerow et al. 2015). A recent US study found that 35% of patients with early stage disease (that could be safely treated with BCS) had mastectomies, and nearly one fifth of these had bilateral mastectomies (Kummerow et al. 2015). That is, some women have bilateral amputation of their breasts for an overdiagnosed screening-detected cancer that would not have damaged their health if left undiagnosed.

As well as the harms of initial but unnecessary treatment, women who are treated for overdiagnosed breast cancers are susceptible to the long-term consequences of breast cancer treatment. Physical effects include fatigue, lymphedema and sexual dysfunction (Beckjord et al. 2014); increased risk of cardiovascular disease (Gernaat et al. 2017); and adverse cosmetic outcomes (Agrawal 2014). The psychological sequelae of breast cancer diagnosis include anxiety, depression, existential uncertainty and fear of recurrence (Drageset et al. 2016). Many of these emotions dissipate with time, but fear of recurrence is both the most frequent emotional concern in women who have been diagnosed with breast cancer and the most long-lasting (Ozakinci et al. 2014; Vickberg 2003). Breast cancer diagnosis affects women's employment and hence financial status. On average, nearly two thirds of women return to paid employment following breast cancer treatment (Mehnert 2011), but this varies depending upon the educational status of the woman, the nature of the employer, type of employment (Blinder et al. 2017; Sun et al. 2017), and presence of long term side effects such as lymphedema (Boyages et al. 2016). There is evidence from the US that

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low income minority women are more likely to lose their employment following breast cancer treatment (Blinder et al. 2017).

Women who are overdiagnosed have the best prognoses (because they did not have invasive disease in the first place), therefore do not suffer harms related to disease progression (Yin et al. 2017). Nonetheless, they are susceptible to the physical and psychological consequences of treatment, while at the same time, overdiagnosed women believe that they are cancer survivors whose lives have been saved by screening (Welch et al. 2011). Finally, in addition to the effects on individual women, following overdiagnosis women's relatives may consider themselves to be at increased risk of breast cancer (Hersch et al. 2013), leading to greater surveillance, and potentially lowered thresholds for intervention should any abnormality be found.

As no individual overdiagnosed women can be identified, women's own views of the potential harms of ODX can only be explored hypothetically using scenarios (Hersch et al. 2013):

“So you have to go through all the rigmarole of chemotherapy, radiation, all that sort of thing, and it may not have been necessary, and those in themselves are hard to go through.” (Participant 09, age 45, 0 screens). (Hersch et al. 2013, 5/13)

Women can imagine themselves in that situation:

“That 50% [rate of ODX] is not good information ... because if I was told ... I've got cancer, I won't want to have in the back of my mind, 'Oh well, it

might not be, and I'm going through all this and my family's all going bananas for nothing.'" (Participant 42, age 72, 3 screens). (Hersch et al. 2013, 6/13)

In summary, screening for breast cancer is justified on the basis that it decreases harm to women through minimizing avoidable breast cancer deaths. Yet it leads to considerable numbers of women being overdiagnosed, the vast majority of whom accept invasive treatment with long lasting physical, psychological and social sequelae.

4. Pathogenic vulnerabilities in breast cancer overdiagnosis

On the typology of vulnerability discussed earlier, susceptibility to breast cancer overdiagnosis is a pathogenic vulnerability because it arises as the result of an ostensibly benevolent intervention aimed at ameliorating women's vulnerability to breast cancer but which instead results in reduced agency and harm. Importantly, the context in which women are offered screening is pathogenic as it undermines agency in three ways: there are significant pressures, both implicit and explicit, to accept invitations to screening; ongoing controversies over the effectiveness of screening seriously impede women's informed decision making; and there are practical barriers to women's informed decision making.

Pressures to be screened

The pressure to be screened arises from a number of sources. Specific fears about breast cancer develop in the context of widely shared cultural phobias about cancer in general. Cancer is known as "the most feared disease", portrayed in the media as silent, deadly, ubiquitous and almost inevitable (Clarke and Everest 2006, 2591). Fear

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of cancer is coupled with beliefs about the value of early detection, attributed, at least in part, to a “lay logic” that early detection of cancer may be beneficial (Waller et al. 2015, 565). This general attitude to cancer and positive appraisal of screening provides fertile ground for breast cancer awareness campaigns, with their oft-repeated statistic that women have a “lifetime risk of 1 in 8” of contracting breast cancer (BreastScreen NSW 2017). These campaigns reinforce and amplify the message that cancer is an ever present possibility, simultaneously stoking women’s fears and offering an apparent solution (Bayer and Fairchild 2016). This leads to women believing that their risk of cancer is much higher than it really is, and that screening is far more effective at saving lives than is the case. For example, US women greatly overestimate the 10 year risk of dying of breast cancer, believing that without screening, 160 women out of every thousand will succumb, and that this number will be halved by screening. The actual figure is 5 breast cancer deaths per 1000 without screening, which reduces by one death to 4 per 1000 with screening (Biller-Andorno and Jüni 2014). Breast cancer screening is promoted as the way to avoid this perceived risk, constituting just one part of the routine surveillance to which women are well habituated (Howson 1998). Breasts, cervixes, bones, fertility, weight, and so forth are all subject to the medical gaze, contributing to the impression that left to their own devices, women’s bodies would be disease-riddled and headed for an early grave.

This view that health can only be achieved or maintained through active medical surveillance is pervasive in wealthy industrialised economies. Participating in screening is not only welcomed (Schwartz et al. 2004; Waller et al. 2015); it is seen as part of responsible citizenship (Lupton 1995). Breast cancer screening is described by

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at least some women as a personal and a social responsibility (Willis 2004). Women both see themselves and are seen by others as under a “moral obligation” to participate in breast screening (Parker and Carter 2016, 282).

Invitations to attend screening add to the pressure created by fear of breast cancer. For example, in Australia, once women turn 50, they are inundated with ‘invitations’ to attend screening, phrased in terms such as:

“Its free. It saves lives.

- 1 in 8 women in NSW will develop breast cancer in their lifetime.
- 9 out of 10 women who develop breast cancer do **not** have a family history of breast cancer.
- Breast screening can find cancers before they can be felt or noticed - you have a better chance of survival when breast cancer is found early.
- 20 minutes every two years can offer peace of mind” (Breastscreen NSW 2017).

The Breastscreen NSW (2017) website contains testimonials from women who believe their lives have been saved by screening. The invitation or reminder letters are described as “a life-saving spark into action,” which triggered attendance at screening where cancers were detected and successfully treated. The implication is that it would be perverse to the point of stupidity not to invest 20 minutes of your time in avoiding death from breast cancer.

Screening invitations suggest that breast cancer is common but can be evaded. The promise is that screening will detect early cancers “before they can be felt or noticed”

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(BreastScreen NSW 2017), leading to better outcomes (if cancer is detected) or peace of mind (if no cancer is found). Screening is presented as the sensible option: “it is better to be safe than sorry” (Lindberg et al. 2013; Silverman et al. 2001). As Hersch et al found: “the opportunity for early detection through breast screening is perceived as a way of minimizing potential regret, whereas failure to be screened puts one at risk of a preventable death” (2011, 145).

However, it is worth putting into perspective the risk of dying from breast cancer. In Australia, for example, women are more likely to die from coronary heart disease, cerebrovascular disease, dementia and Alzheimers, or lung cancer, than from breast cancer. Internationally, in high income countries, breast cancer is the sixth commonest cause of death for women (WHO 2013).

This is not to trivialise breast cancer as a cause of premature death for women. But the successful awareness-raising campaigns (that it affects 1 in 8 women and is the second leading cause of cancer death in women) rarely contextualise the disease.

Women in high-income countries are six times more likely to die of cardiovascular disease than breast cancer: heart attacks and strokes cause 189 deaths per 100,000 women compared with 31 deaths per 100,000 from breast cancer (WHO 2013).

Sustained public discourse about the dangers of breast cancer (Clarke and Everest 2006) contributes to women’s unrealistic view of the likelihood that they will die of this disease (and the corollary view that screening will be life-saving). As mentioned above, women do believe they are much more likely to die of breast cancer than is actually the case, while a multi-country survey of over 4000 women found that the majority of women surveyed held various incorrect beliefs about the benefits of breast

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cancer screening (Domenighetti et al. 2003).⁵ In the drive to save lives by screening, women's inherent vulnerability to breast cancer is exaggerated.

The “mammography wars”

These pressures to be screened, which in and of themselves undermine women's agency, are exacerbated by the lack of reliable information about the harms and benefits of screening. Perhaps a degree of exaggeration or even fear-mongering would be justified if the promise held true, if screening mammography did save women's lives (Bayer and Fairchild 2016). This after all is the rationale of nudging: raising awareness and propelling women to “choose” screening (Ploug et al. 2012). But as the “mammography wars” demonstrate, the claim that breast cancer screening saves lives is contestable and bitterly contested, as are claims about rates of overdiagnosis (Quanstrum and Hayward 2010). Welch and Passow attempt to provide credible upper and lower limits to estimates of the benefits of breast cancer screening. On their analysis, the relative risk reduction (RRR) is between 5 % and 36%. This means that if a 50 year old woman undergoes annual screening for 10 years, her relative risk of dying of breast cancer will be reduced by between 5 and 36% compared with no

⁵ These incorrect beliefs about screening included:

- screening prevents or reduces the risk of contracting breast cancer (68% believed this but screening has no effect on this risk);
- screening at least halves breast cancer mortality (62% believed this but even the most optimistic estimates are a reduction of no more than 31% rather than 50% [Paci et al. 2012]);
- 10 years of regular screening will prevent 10 or more breast cancer deaths per 1000 women (75% of women believed this, whereas the real figure is thought to be between 0.3- 3.2 per 1000 [Welch and Passow 2014]).

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screening. There is modest consensus that screening leads to around a 20% relative risk reduction (Keen and Jorgensen 2015; Myers et al. 2015).

A 20% relative risk reduction may sound quite worthwhile, but its value depends on the level of baseline risk – how likely a woman is to die of breast cancer in a given time period. If the baseline risk is small, even a 20% relative reduction in risk will make little difference. This reduction in the baseline risk is known as absolute risk reduction (ARR). Estimates of the ARR conferred by screening range from 0.3%-3.2% (Keen and Jorgensen 2015; Myers et al. 2015; Welch and Passow 2014). Put another way, to prevent one breast cancer death in women aged 50-59, at least 351 women need to be screened annually, and the number may be in the thousands (Welch and Passow 2014). The ARR takes into account only the reduction in women's chances of dying of breast cancer. When all cause mortality is considered, screening mammography offers no reduction in the risk of dying from any cause. That is, women who undergo screening are just as likely to die at the same rate as women who are not screened, when all causes of death are taken into account (Biller-Andorno and Jüni 2014). Finally, for every one woman who avoids breast cancer death through screening, approximately four women will be overdiagnosed and treated needlessly (Welch and Passow 2014).

The lack of clarity about the exact benefits of breast cancer screening is somewhat surprising. After all, the first randomised controlled trials of breast cancer screening were over 50 years ago. But instead of an unequivocal answer about the effectiveness of this intervention, women are caught in the cross fire of bitter disputes over the research evidence and what it means (Quanstrum and Hayward 2010). These

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arguments rapidly become unintelligible to most people as epidemiologists and biostatisticians thrash out the finer points of trial design, bias, reporting and meta-analysis (Jorgensen et al. 2017).

There are some valid reasons as to why the jury is still out on the effectiveness of screening.⁶ Some of these issues are straightforwardly epistemic, such as the best treatment for DCIS (Marmot 2012, 56). Others reflect not so much a knowledge gap per se as a lack of agreement as to what constitutes the ‘best’ evidence. This is undoubtedly a thorny question over which reasonable people may disagree (Walker and Rogers 2017a). But sometimes it seems that there is more at stake than reasonable disagreement. Some of the confusion about the effectiveness of breast cancer screening seems to reflect personal biases, rigid methodological commitments, academic rivalries and so forth, rather than an insurmountable incapacity to discover whether or not breast cancer screening saves lives, and at what cost in terms of overdiagnoses.

Irrespective of the reasons for the confusion over the benefits and harms of breast cancer screening, the lack of information contributes to women’s pathogenic vulnerability regarding decisions about screening. Women are affected by the consequences of research agendas over which they have little to no power, while those charged with performing relevant research fail to provide results that can

⁶ These include methodological and contextual features that preclude meaningful comparisons of trials, ever-evolving diagnostic technologies, improvements in breast cancer treatment outcomes that change the baseline by reducing the anticipated benefit conferred by early diagnosis, and uncertainty about the most effective treatment for DCIS, which is detected almost exclusively through screening (Carter et al. 2015).

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meaningfully inform women's decisions. Given that publicly funded researchers have a responsibility to perform research with merit and integrity (NHMRC 2007), it seems ethically inadequate for breast cancer screening researchers to continue to argue past each other by producing contradictory reviews based upon different trials and using different assumptions. In the absence of any international consensus, women are left with conflicting and disputed evidence that, were they informed of it, might undermine their apparent confidence in the benefits of screening.

Barriers to informed decision making

The lack of professional consensus about the reduction in risk conferred by screening contributes to the poor quality of the information offered to women who are considering screening, undermining their agency and potentially invalidating consent. To make an informed choice about screening, women require unbiased information presented in accessible ways. However, such information is lacking in the public domain, such as on relevant website, where women might look for it. A recent examination of the websites of charities, health service providers, government agencies and independent health organisations found variable information about overdiagnosis (Ghanouni et al 2016) (see Table 1).

Insert Table 1 around here

Taken as a whole, the information on these websites provides a reasonably accurate snapshot of the state of uncertainty in the professional literature. But as information to help women make informed decisions, it is deeply unsatisfactory as it is contradictory and confusing. Only one Australian site presented statistical information explaining

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that estimates about overdiagnosis have changed over time and that different reports give different estimates. As the authors of the study note, there is clearly a tension between providing consistent information, and doing justice to the uncertainty of and range in expert estimates (Ghanouni et al. 2016). Meanwhile, women are left with high levels of uncertainty about overdiagnosis and its harms if they actively seek information.

What of professionals as sources of information about ODx? A recent Australian study found that around two thirds of breast cancer experts support providing women with full information about overdiagnosis (Parker et al. 2015). But in practice, the proportion of health professionals providing information may be far lower. A US study asked 300 citizens who had been invited by their physician to undergo routine cancer screening whether their physician had mentioned the possibility of overdiagnosis or overtreatment. Only 8.4% of the women who had been invited to screening (the majority of these for mammography) reported that their physician had done so. In contrast, 80% of all participants stated that they would want information about potential harms before undergoing any testing (Wegwarth and Gigerenzer 2013). If representative, these findings indicate that there is a long way to go to fill the gap between those who would like to receive information about ODx and those who actually do receive it.

Research on the extent to which women are informed of the benefits and harms of screening is fairly meagre, but it does suggest that women are agreeing to be screened without a full understanding of the implications, in particular the fact that screening exposes them to the risk of overdiagnosis and consequent unnecessary treatment (see

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also Hersch et al. 2013). The likely impact of receiving such information on decision making is unclear. Qualitative research with women found that the majority of respondents are tolerant of overdiagnosis, preferring “to be overdiagnosed [rather] than underdiagnosed” (Waller et al. 2015, 7).⁷

All of the factors discussed above, exaggerated beliefs about the risks of breast cancer, heavy-handed nudging in the form of breast cancer screening campaigns and invitations to screening, the normalisation of surveillance as the duty of responsible citizens, and the widely accepted view that it is better to be safe than sorry, create a strong and pervasive social imperative to accept the invitation to be screened. In this context, it is not plausible that individual women might insulate themselves from the social zeitgeist; any decision an individual might make about breast cancer screening is subject to these pressures well before she reaches the clinic. If she seeks publicly available information about the potential harms of screening, such as ODx, she is faced with conflicting and confusing information on relevant websites. Once she reaches the clinic she may or may not be offered information about ODx, and this information may be influenced by her clinician’s own (lack of) understanding of ODx, their degree of commitment to screening as an essential part of women’s healthcare services, and their selection of ‘favourable’ statistics from the literature. This nexus of factors creates pathogenic vulnerability by undermining women’s

⁷ This is not a carte blanche for any level of ODx: Australian women’s stated willingness to be screened is sensitive to potential rates of overdiagnosis. Rates of up to 30% ODx had little impact on intentions and attitudes to screening. Rates of 50% prompted some women to decline screening altogether although others retained an unchanged commitment to participate (Hersch et al. 2013).

agency while simultaneously exposing them to the considerable harms of overdiagnosis.

5. The informed choice response: an ethical solution?

In situations of pathogenic vulnerability, any initial vulnerability is exacerbated by misguided or unjust actions that undermine agency and precipitate harm. Therefore, as well as ameliorating harm, morally adequate responses must seek to restore and support the agency of those affected to the extent possible (Rogers et al. 2012; Mackenzie et al. 2014). Whilst not framed in these terms, most commentators responding to overdiagnosis concur, emphasising women's right to know and the importance of informed decision making (Welch and Passow 2014, 448).

In support of this goal, there have been moves to develop and deliver decision aids that facilitate informed choice (van Agt et al. 2012; Hersch et al. 2015). An Australian study found that 29% of women given a decision aid met the threshold for adequate overall knowledge of the benefits of screening, overdiagnosis and false positives compared with 17% of the control group.⁸ Overall, 24% of the intervention group and 15% of the control group made an informed decision⁹, leading the study authors to deem the intervention successful (Hersch et al. 2015).

Assessing the adequacy of informed choice is challenging, but it seems likely that tools such as decision aids may help to improve women's awareness of the risks of

⁸ The percentages rose to 50% and 19% respectively regarding 'conceptual information' only (i.e., general understanding of the issues rather than recall of specific numerical information).

⁹ These authors defined informed choice in terms of adequate knowledge about the benefits and harms of screening including overdiagnosis and intentions consistent with attitudes.

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overdiagnosis and false positives. Prima facie, this goes some way towards meeting the ethical obligation to seek informed consent and is consistent with changing norms in screening away from a focus on ensuring maximum uptake and towards decisions based upon an informed choice by individuals to accept or decline the screening service offered (Entwistle et al. 2008; Gigerenzer 2015).

And yet, this seems an ethically inadequate response to the pathogenic vulnerability engendered by breast cancer fear-mongering, social pressure to be screened, the exaggerated benefits and minimised or ignored harms, and generally poor communication about these matters. Relying solely upon informed choice might be a reasonable ethical response if the information was more definitive and the background milieu far less coercive. But in the current context, women's agency will not be supported given unresolved and bitter disputations about the benefits and the harms of screening, and providing information alone will not address the other sources of pathogenic vulnerability identified above.

One reason why informed choice seems ethically inadequate in this situation is because it places all of the responsibility onto individual women who have to make a decision, while absolving those whose professional responsibility it is to make sense of complex medical and epidemiological data. Rather than shouldering the epistemic burden¹⁰ by developing consistent information, or by making policy level decisions

¹⁰ I am indebted to my colleagues Stacy Carter, Bjorn Hofmann and Lynette Reid for this term, 'epistemic burden'.

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about whether or not screening mammography should be offered at all¹¹, the burden is shifted onto individual women, using the ethical fig leaf of informed choice. The choice that women are offered is likely to exacerbate rather than reduce vulnerability, because the apparent choice is to be screened, or risk dying of cancer. If they opt for screening, there is a risk (of unknown magnitude) that they will be diagnosed with a harmless cancer and receive invasive treatment with serious long term psychological, personal, economic and physical consequences. There are no risk-free alternatives in this situation, whereas prior to the implicitly or explicitly coercive invitation to screening, the woman was living in apparent good health with no life or death decision to make.

A second reason as to why offering informed choice is ethically inadequate as the major response to overdiagnosis lies in the multiple sources of vulnerability leading up to the decision to be screened. As described above, there are many pressures on women to be screened. By the time an individual woman reaches the point of being asked to consent to the intervention, it seems unlikely that even very high quality information (should it become available) will be adequate to counterbalance the pressures to which she has already been exposed, and which will continue relentlessly if she declines screening on this occasion. While lack of information is one source of pathogenic vulnerability, it is only one of many, making it disingenuous to imagine that improving the processes of informed choice will compensate for all of them.

¹¹ The Swiss Medical Board is notable here for shouldering the epistemic burden. After 12 months of deliberation, the Board decided to time limit existing screening mammography programs and not introduce any new ones (Biller-Adorno and Juni 2014).

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Rather than meeting ethical obligations, it seems irresponsible to offer a choice like this, to a woman who is well. In order to justify interrupting people's lives ("Only 20 minutes!") for the alleged purpose of benefitting them, the intervention on offer ought to be of a higher standard, with more accurate estimates of benefits and a clearer account of the harms. Information should be provided about the consequences of not being screened, should they later develop symptomatic breast cancer. The responsibility rests with the whole complex conglomeration that lies behind breast cancer screening to develop better answers to these questions in order to avoid offering women a choice that exacerbates, rather than reduces vulnerability.

Accepting informed choice as the panacea for the pathogenic vulnerability created by breast cancer screening deflects attention away from other sources of vulnerability, risks accepting the status quo in a relatively uncritical manner, and leaves women with choices that carry a high potential for regret whichever way they decide.

6. Ethical responses to pathogenic vulnerability generated by breast cancer screening-related overdiagnosis

Given that breast cancer screening generates pathogenic vulnerability, not adequately ameliorated by attempts to offer women informed choice, the question arises, what kind of responses might be justified, and on what grounds? Here there is space only to sketch out some possible directions, taking account of the imperative to seek responses to pathogenic vulnerability that foster and support autonomy and avoid paternalism and stereotyping (Rogers et al. 2012; Mackenzie et al. 2014).

First, pressure on women to be screened for breast cancer may be decreased by challenging the general notion that screening is essential for health. This notion that

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screening is (always) beneficial is taken for granted in public health and medical care in many countries. Some screening does lead to improved health.¹² Nonetheless, there is something impoverished about accepting the view that individuals' health can be measured by and known through an ever-expanding range of screening tests, with little reference to how people actually feel or function in the world. This is a broad criticism of public health more generally – that it has become synonymous with medicalised interventions performed on individuals rather than an approach to creating the conditions in which people might live healthy lives.

Regarding breast cancer specifically, we should debunk the notion that women's bodies are cancer time bombs waiting to explode, such that the only way women can reach a ripe old age is to continuously be monitored for signs of malignancy. The aim of screening is to 'catch' disease at an earlier stage when there is a better prognosis and scope for less invasive treatment. However, even the least aggressive forms of screening detected breast cancer are subject to invasive interventions including double mastectomies, thereby undermining the claim that early detection leads to less extensive treatment. It is entirely possible that women who wait until they find a lump in their breast may do as well as women who have early intervention for screening detected disease, due to developments in breast cancer treatment (Early Breast Cancer Trialists' Collaborative Group 2015). At the very least, women should be provided with information about their prognosis should they develop symptomatic breast cancer compared with treatment for a screening-detected cancer. Limiting treatment to clinically detected cancers significantly reduces the possibility of overdiagnosis

¹² For example, screening for cervical cancer is generally accepted to have made a major contribution to the decrease in deaths from this disease, although this belief has never been tested in a randomized controlled trial.

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and eliminates the pathogenic offer of screening in which women have to balance their fear of getting breast cancer (which may or may not be realistic) against the harms and disputed benefits of screening. Clearly there are significant political and other barriers to withdrawing breast cancer screening. Nonetheless, an effective communication campaign ought to be able to garner public support for a moratorium on breast cancer screening until there is more definitive evidence about its harms and benefits.

Next, the notion that when it comes to health, the medical profession knows best is problematic. This notion undermines women's confidence in their own bodily knowledge, as screening (performed and endorsed by experts) leads to the diagnosis of imperceptible disease that in many cases is harmless. The woman who felt well on her way to screening may indeed be well, but her confidence in that feeling of wellness is shattered by the discovery of an occult lesion, overdiagnosed as cancer, with long lasting consequences, including on her identity (Walker and Rogers 2017b). This claim needs further unpacking to do justice to the nuances and complexity of the situation, but at the very least, some skepticism is warranted regarding the advice of experts in this context.

Third, the rhetoric in support of screening ought to be modulated and instead, information provided that places the risk of breast cancer in perspective. Women may add more years to their lives by taking care of their cardiovascular health than by attending breast screening, but this is not widely promoted through public campaigns, nor understood by the public. This point is linked to the earlier one about the medicalised nature of public health. Creating and supporting the conditions in which

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women can live free from violence, with access to affordable high quality foods, in secure housing with opportunities for exercise built into their environments are measures far more likely to increase healthy longevity than the provision of breast cancer screening.

Next, a shift from secondary to primary prevention of breast cancer would decrease the opportunities for pathogenic vulnerability and give women more options for agency regarding their health. Primary breast cancer prevention can avoid the harms of screening (secondary prevention) and lead to potentially better outcomes. There are modifiable risk factors for breast cancer. These include use of oral contraceptives or hormone replacement therapy [HRT], alcohol consumption, low physical activity, and high body mass index (Nomura et al. 2016; Dartois et al. 2016; Sisti et al. 2016).

However, these risk factors are not well known. A significant proportion (53.5% [12.8 to 78.7%]) of post-menopausal breast cancer is attributable to modifiable risk factors (Dartois et al. 2016, 2422). That is, women can halve their risk of breast cancer by not taking HRT, by limiting alcohol intake and by maintaining a healthy weight; and the reduced risk occurs regardless of the presence of non-modifiable risk factors (Nomura et al. 2016, 2603). This is critical information for making meaningful choices, but women are not asked whether they would prefer to reduce their risk of getting breast cancer by living a healthy life style, instead of by having screening mammography with all of its attendant harms.

These are just some of the ways to address women's inherent vulnerability to breast cancer. These options have the potential to offer solutions that avoid pathogenic vulnerability, by creating meaningful choices, by supporting agency, by developing

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and reinforcing the conditions in which women might lead long and healthy lives.

Compared to these, screening mammography falls far short; it is the offer of a malign choice, presented in the context of exaggerated accounts of danger and benefits, and understated harms.

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